Government of Pakistan
Ministry of National Health Services, Regulation & Coordination
Drug Regulatory Authority of Pakistan
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MINUTES OF THE 17TH MEETING OF THE MEDICAL DEVICE BOARD (MDB) HELD ON 13-07-2020

17th 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 13th July, 2020. 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 Prof. Dr. Syed Mohsin Naveed Abbas, Consultant Nephrologist & Transplant Physician, Head of Department of Nephrology & Dialysis, Cantt General Hospital, Rawalpindi/ Federal Administrator, Human Organ Transplant Authority (HOTA) to preside over the meeting as Chairman. Subsequently meeting was chaired by Dr. Syed Mohsin Naveed Abbas, Consultant Nephrologist & Transplant Physician, Head of Department of Nephrology & Dialysis, Cantt General Hospital, Rawalpindi/ Federal Administrator, Human Organ Transplant Authority (HOTA) and was attended by the following:-

S.No.	Name and Designation / Department	Position in the MDB
1.	Prof. Dr. Syed Mohsin Naveed Abbas, Consultant Nephrologist & Transplant Physician, Head of Department of Nephrology & Dialysis, Cantt General Hospital, Rawalpindi/ Federal Administrator, Human Organ Transplant Authority (HOTA)	Chairman
2.	Mr. Imranullah, Chief Drug Inspector, Abbottabad, KPK, (Nominee of Director General Health, Khyber Pukhtunkhwa).	Member
3.	Professor Sami Saeed, Professor of Chemical Pathology, Foundation University Medical College, Islamabad.	Member
4.	Mrs. Tazeen S. Bukhari, Biomedical Equipment Planner, Saleem Memorial Trust Hospital, Lahore.	Member
5.	Dr. Prof. Saqib Shafi Sheikh, Executive Director, Punjab Institute of Cardiology, Lahore.	Member
6.	Dr. Prof. Sajid Bashir, Professor of Pharmaceutics, University of Sargodha, Sargodha.	Member

7.	Dr. Abdul Haleem Khan, Associate Professor F.C University, Lahore	
8.	Dr. Muhammad Farid Khan,Director Emegency Services, District Kasur.	Member
9.	Dr. Ghazanfar Ali Khan, Additional Director (MDMC), DRAP, Islamabad.	Secretary / Member

Ch. Muhammad Naeem, Senior Vice Chairman, Healthcare Devices Association of Pakistan (HDAP) participated as observer on behalf of HDAP. 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 16TH MEDICAL DEVICE BOARD MEETING**

Decision: The Board confirmed the minutes of the 16th 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 SAA International, Suit No. 01, Farah Heights, Block-10, F.B Area, Karachi. **Godown Address:** House No.B-296, Block-10, F.B Area, Karachi.	Erum Ashraf	Mr. Sajjad Abbasi, FID, Quetta (Based at Karachi), DRAP, Karachi. Mrs. Hira Bhutto, Assistant Director, CDL, Karachi	No	**Approved** for storage of warm range medical devices without cold chain facility.
2.	M/s Standard Impex, 11-A,	Mr.Mansoor Iqbal	Mr. Shoaib Ahmed, FID, DRAP, Lahore.	No	**Approved** for storage of room

	Punjab Small Industrial Corporation Estate, District Kasur.		Mst. Uzma Barkat, AD, DRAP, Lahore.		temperature medical devices without cold chain facility.
3.	M/s Lab Links, 14-Khan Arcade, 16-Mouj Darya Road, Lahore.	Mr.Muhammad Tufail	-do-	Yes	**Approved** for storage of room temperature medical devices alongwith cold chain facility.
4.	M/s Muaaz Medical Traders, Office No.401-402, 6th Floor, Saith Center 10-Syed Moj Darya Road, Lahore.	Mr.Muhammed Ghulam Rasool	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility.
5.	M/s B.N.S Trading Est., Office No. 339, 3rd Floor, Land Mark Plaza, Jail Road, Lahore.	Mr.Muhammad Nadeem Aftab	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility.
6.	M/s Shawn Enterprises, Suit No. 521, 5th Floor, Land Mark Plaza, Jail Road, Gulberg, Lahore	Mr.Waqar Masih	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility.
7.	M/s Diagnostic Center, Fatima Mansion, 1st Floor Edward Road, Lahore.	Shaikh Hamid Ali	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility.
8.	M/s New Asia Dental Supply, 6-B, Mall View Plaza Bank Square The Mall, Lahore.	Mr.Ahmed Hassan Mr.Hassan Pervaiz	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility.
9.	M/s AGP Limited, B-23-C, S.I.T.E., Karachi.	Mr. Mahmud Yar Hiraj Mr. Tariz Moinuddin Khan Mr. Kamran Nishat Ms. Nusrat Munshi	Mr. Sajjad Abbasi, FID, DRAP, Karachi. Mrs. Hira Bhutto, Assistant Director, CDL, Karachi	No	**Approved** for storage of room temperature medical devices without cold chain facility.

		Mr. Naved Abid Khan Mr. Zafar Iqbal Sobani Mr. Muhammad Kamran Mirza			
10.	M/s Genix Pharma (Pvt) Ltd., 44-45 B, Korangi Creek Road, Karachi.	Ch. Muhammad Israr Sharif	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility.
11.	M/s Altimi Biosciences (Pvt) Ltd., Office No. 201, Located on Plot No. 43-C, Second Floor, Lane-10, Bukhari Commercial, Phase VI, D.H.A. Karachi. **Godown Address:** B-40, S.I.T.E, Karachi.	Dr.Fazlullah Pechuho Mr. Kahlil Memon	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility.
12.	M/s Taj Diagnostics, Shop No. G-166, Maryam Market, M.A. Jinnah Road, Saddar, Karachi.	Mr. Muhammad Farhan	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility.
13.	M/s Spero Enterprises, Office No. 301, 3rd Floor, Trade Arcade, 23/F, M.A.C.H.S. Karachi.	Mr. Usman Tanzeel	-do-	No	**Approved subject to compliance of following non-conformities / observations which are to be confirmed by the panel in 15 days:-** • Firm was advised to apply for change of address in DSL. • Prepare documents as per

					GDPMD checklist. • Imporve storage facility as store and office sitting area is under one room. • Firm asked one week time for the compliance, still no compliance received till 16-03-2020.
14.	M/s Pulse Surgicals, Suite No. 113, 1st Floor, Almas Heights 190/1 Block 2, P.E.C.H.S. Karachi.	Mr.Gulfam Haider	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility.
15.	M/s Al-Meraj Medical System, Suit No. 211, 2nd Floor, Al-Sehat Centre, 195 Rafiqui Shaheed Road, Karachi.	Mr. Muhammad Rafique	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility.
16.	M/s Kavi & Co., B-505, Clifton Belleview, Block-5, Clifton, Karachi.	Mr. Tikam Das Mr. Kavi Raj	-do-	No	**Approved subject to compliance of following non-conformities / observations which are to be confirmed by the panel in 15 days:-** • Firm was advised on 24-02-2020 to improve storage facility as per GDPMD checklist and improve documents as per

					GDPMD checlist. • Expired IOL were placed in normal stock. • No proper arrangements of stock were in place. Most of the stock are without labelling and in strips of IOL. • No description of device written.
17.	M/s Akash Traders, 07 Hina Place, Housing Road, Civil Line, Karachi.	Suresh Kumar Manjiani	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility.
18.	M/s Swift Cure Pharmaceuticals, 4th Floor, Commercial Plaza No. 164, Main Boulevard, D.H.A. Phase 6, Lahore Cantt.	Mr. Hadir Malik Mst.Hooria Malik	Dr. Akbar Ali, Assistant Director, DRAP, Lahore. Miss Maham Misbah, Assistant Director, DRAP, Lahore.	No	**Approved** for storage of room temperature medical devices without cold chain facility.
19.	M/s Jamsung (Pvt) Ltd, 211 Qayyum Block, Mustafa Town, Lahore.	Mr. Faiz Rasool Mst. Shabana Rasheed		No	**Approved** for storage of room temperature medical devices without cold chain facility.
20.	M/s M.A. Tech, 18-G, Upper Basement, Memona Centre, Mouj Darya Road, Fareed Court House, Lahore.	Mr. Muneeb-ur-Rehman		No	**Approved** for storage of room temperature medical devices without cold chain facility.
21.	M/s Khan Trading Agency, New Data Complex, 16-Syed Mouj Darya Rpoad, Lahore.	Mr. Muhammad Waqas Mr. Muhammad Waqar		No	**Approved** for storage of room temperature medical devices without cold chain facility.

22.	M/s Sonotech, Office No. C 938-C Block, FAisal Town, Near Ravi Restaurant, Maulana Shaukat Ali Road, Lahore.	Muhammad Sabir Siddiqui Muhammad Khawar Siddiqui	Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore. Dr. Akbar Ali, Assistant Director, DRAP, Lahore.	No	**Approved** for storage of room temperature medical devices without cold chain facility.
23.	M/s Subh-e-Noor, House 236, Badar Block, AllamaIqbal Town, 7-KM Multan road, Lahore.	Mr. Salah ud Din Gondal	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility.
24.	M/s Biomed International, House No. 348, Block-R, Model Town Lahore, Gulberg Town Lahore.	Mr. Javed Iqbal Muhammed Farooq Arshad	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility.
25.	M/s Al-Farman Trading, 74-C, Satellite Town, Sargodha	Muhammad Bilal Khan	Dr. Akbar Ali, Assistant Director, DRAP, Lahore. Miss Maham Misbah, Assistant Director, DRAP, Lahore.	No	**Approved** for storage of room temperature medical devices without cold chain facility.

Item No. III. CHANGE OF TECHNICAL/QUALIFIED PERSON OF M/S RHS INTERNATIONAL, LAHORE. (AD-I).

M/s RHS International, 1st Floor of Building, S60-R34-A, Opp. Total Petrol Pump, Mozang Road, Lahore has requested for approval of proposed change of their technical person in ELI-00354 as per detail given below:-

Existing Technical	**Proposed Technical Person**
Ms. Nida Habib CNIC No.35404-5367411-4	Ms. Sana Saeed, House No.259, Z Block, Farid Town, Sahiwal. CNIC No.36502-85024-7-8

The firm has submitted following documents:-

(i) Application on Form-2.

(ii) Copy of receipt in change on Drug Sale License.
(iii) Copy of appointment letter of new Technical/Qualified person.
(iv) Copy of resignation letter of previous Technical/Qualified person.
(v) Fee of Rs.10,000/-

Decision: The Board acceded to the request of the firm /company and approved the change of qualified /technical person from Ms. Nida Habib to Ms. Sana Saeed, House No.259, Z Block, Farid Town, Sahiwal, CNIC No.36502-85024-7-8.

Item No. IV. CHANGE OF TECHNICAL/QUALIFIED PERSON OF M/S PHARMEVO (PVT) LTD, KARACHI. (AD-I).

M/s PharmEvo (Pvt) Ltd., A-29, North Western Industrial Zone, Port Qasim, Karachi has requested for approval of proposed change of their technical person in ELI-00055 as per detail given below:-

Existing Technical	**Proposed Technical Person**
Mr. Ejaz Hussain, House A-79, Block 10-A, Gulshan-e-Iqbal, Karachi. CNIC No.42201-9438259-3	Mr. Junaid Sharif Choudhary, House No. A-22, Naseerabad Society, Shah Faisal Colony, Karachi. CNIC No.42201-0355875-1

The firm has submitted following documents:-

(i) Application on Form-2.
(ii) Copy of Drug Sale License mentioning the name of new technical person.
(iii) Credentials of new technical/qualified person.
(iv) Fee of Rs.10,000/-
(v) Copy of resignation letter of previous technical person.
(vi) Copy of appointment letter of new technical person.

Decision: The Board acceded to the request of the firm /company and approved the change of qualified /technical person from Mr. Ejaz Hussain to Mr. Junaid Sharif Choudhary, House No. A-22, Naseerabad Society, Shah Faisal Colony, Karachi; CNIC No.42201-0355875-1.

Item No. V. CHANGE OF QUALIFIED PERSON OF M/S FY DIAGNOSTIC & SURGICALS, KARACHI (AD-IV).

M/s FY Diagnostic & Surgicals, Suit No. 203. Anum Blessing, 2nd Floor, KCHSU, Shahrah-e-Faisal, Karachi has requested for approval of change of their qualified person in their Licence to Import Medical Devices (ELI-00323) as per details given below:-

Existing Qualified Person	Proposed Qualified Person
Mr. Raheel Saeed, CNIC No.42301-4411562-1	Dr. Noor-ul-Ain Zahra, CNIC No.54400-8500826-6 (Pharm D)

The firm has submitted following documents:-

(i) Application on Form-2.
(ii) Copy of Drug Sale License.
(iii) Credentials of qualified person
(iv) Copy of appointment letter of new qualified person.
(v) Requisite Fee of Rs.10,000/-

Decision: The Board acceded to the request of the firm /company and approved the change of qualified /technical person from Mr. Raheel Saeed, to Dr. Noor-ul-Ain Zahra, CNIC No. 54400-8500826-6.

Item No. VI. CHANGE OF QUALIFIED PERSON OF M/S GLOBAL MARKETING SERVICES, RAWALPINDI (AD-IV).

M/s Global Marketing Services, 111-B, Hali Road, Westridge-1, Rawalpindi has requested for approval of change of their qualified person in Licence to Import Medical Devices (ELI-00109) as per details given below:-

Existing Qualified Person	Proposed Qualified Person
Aqsa Ayaz, CNIC No.48403-9959352-0	Ms. Kaukab Mahnoor, CNIC No.42201-1312064-0 (Pharm D)

The firm has submitted following documents:-

(i) Application on Form-2.
(ii) Copy of receipt for change of qualified person on Drug Sale License.
(iii) Credentials of new qualified person.
(iv) Copy of Establishment Licence to Import medical devices.
(v) Requisite Fee of Rs.10,000/-

Decision: The Board acceded to the request of the firm /company and approved the change of qualified /technical person from Miss Aqsa Ayaz to Ms. Kaukab Mahnoor, CNIC No.42201-1312064-0.

Item No. VII. CHANGE OF QUALIFIED PERSON OF M/S GETZ PHARMA (PVT) LIMITED, KARACHI (AD-IV).

M/s Getz Pharma (Pvt) Limited, Plot No.29-30, Sector 27, Korangi Industrial Area, Karachi has requested for approval of change of their qualified person in ELI-00471 as per details given below:-

Existing Qualified Person	**Proposed Qualified Person**
Syed Zubair Hussain, CNIC No.42101-3886566-1	Mr. Abu Rehan Bari (B.Pharmacy) CNIC No.42501-6166759-9

The firm has submitted following documents:-

(i) Application on Form-2.
(ii) Copy of receipt for change on Drug Sale License.
(iii) Credentials of new qualified person.
(iv) Copy of Establishment Licence to Import medical devices.
(v) Requisite Fee of Rs.10,000/-

Decision: The Board acceded to the request of the firm /company and approved the change of qualified /technical person from Syed Zubair Hussain, to Mr. Abu Rehan Bari CNIC No.42501-6166759-9.

Item No. VIII. 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 Establishment**	**Address**	**Name of Qualified Person**	**Name of QC Incharge**	**Inspection panel & date of inspection**	**Recommenda-tions**
1.	M/s Kolachee International (Pvt) Limited.	Plot No.C-79 (Formal F-675) Unit No.2, Sourth Avenue, Opp Generation School,	Mr. Noor ul Amin BS (Bio Medical Engineering)	Mr. Hammad Hussain BS (Bio Medical Engineering)	Mr. Sajjad Ahmed Abbasi, FID, DRAP, Karachi.	Keeping in view the facts and the current scenario of demand of PPEs accross the country due to emergent conditions in the

		S.I.T.E, Karachi.	(Production Incharge)	(QC Incharge)	Mr. Awais Ahmad, AD/FID, DRAP, Karachi. Mrs. Hira Bhutto, Assistant Director, CDL, Karachi.	country after pandemic situation of Corona Virus (COVID) worldwide, the panel is in the opinion to recommend the grant of establishment license to manfuacture medical devices (Personal Protective Equipment) which come under the Class-A of the Medical Devices Rules, 2017.

It is submitted that due to the shortage of PPEs in country and encourage the local manufacturer in the country, the above firm was granted Establishment Licence on fast track basis vide ELM-0017 dated 18-03-2020 as per decision of the MDB.

Submitted for approval / ratification/endorsement of MDB.

Decision: The Board approved/endorsed/ratified the Establishment Licence to Manufacture Medical Devices issued to M/s Kolachee International (Pvt) Limited, Karachi by the MDMC Division vide ELI-0017 dated 18-03-2020.

Item No.IX. **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 Person	Name of QC Incharge	Inspection panel & date of inspection	Recommendations
1.	M/s Dr. Sethi Pharma Industries	3-Burewala Road, Chichawatni	Shahzada M. Durrani (Production Manager) (B.Pharmacy)	Hafiz Anwar-ul-Haq, QC Manager (MSC chemistry) NOTE: QUALIFICATION NOT IN ACCORDANCE WITH MDR, 2017)	Malik Irshad, Secretary Pharmacy Council, Punjab. Abdul Rashid Sheikh, FID, DRAP, Lahore. Ms. Maham Misbah, AD, DRAP, Lahore.	Keeping in view the manufacturing facilithy like building, HVAC system, sanitation, production macnhinery, equipment in quality control and microbiology laboratory, testing facilities, technical personnels met and documentation, the panel of inspectors recommends the renewal of DML (Establishment Licence) by way of formulation to M/s Sethi Pharma Industries, 3-Burewala Road, Chichawatni for the following five sections:- • Fine Tape Section. • Sufre Tule Section. • Cotton/Crepe Bandage Section. • First Aid Bandage Section. • Adhesive Plaster Section.

Decision: The Board approved M/s Dr. Sethi Pharma Industries, 3-Burewala Road, Chichawatni for grant of Renewal of Establishment Licence to Manufacture Medical Devices subject to change of quality control incharge in accordance with MDR, 2017.

Item No. X. <u>APPLICATIONS FOR GRANT OF ESTABLISHMENT LICENSE TO MANUFACTURE MEDICAL DEVICES.</u>

M/s Sorabjee Patel, Office No.45, Badri Building, I.I Chundrigarh Road, Saddar, Karachi has applied for grant of Establishment License to manufacture medical devices under MDR, 2017 for which inspection panel comprising Mr. Awais Ahmed, AD/FID-IX, DRAP, Karachi and Mrs. Hira Bhutto, Assistant Director, CDL, Karachi was constituted for inspection of their establishment. The panel conducted the inspection on 06-03-2020. The recommendations of the panel are reproduced as under:-

> "The panel visited the site of M/sorabjee Patel, situated as Office No.45, Badri Building, I.I Chundrigarh Road, Saddar, Karachi for the establishment of manufacturing unit for medical devices on 6th March, 2020. The copy of sketch of the site plot was not available. However, the said site was 2nd floor, Right side of the premises is the Central Police Office, on the left side National Bank of Pakistan, head offie and front side facing to wide commercial road. Manufacturing of Intraocular lenses was underway at the time of the inspection for which firm has established manufacturing assembly and testing facility for the manufacturing of intraocular lenses. As, the manufacturing facility is situated at busy comercial road**, site is not not suitable for manufacturing of medical devices.** Firm management informed that they have been manufacutirng intraocular lenses since 2010 and requested for 03 years to shift their manufacturing facility to any industrial area."

Decision: The Board rejected the site of M/s Sorabjee Patel, Office No.45, Badri Building, I.I Chundrigarh Road, Saddar, Karachi for establishment of manufacturing unit of medical devices in the light of above mentioned recommendations of the panel.

Item No. XI. <u>RENEWAL AND CONVERSION OF DML INTO ESTABLISHMENT LICENCE TO MANUFACTURE MEDICAL DEVICES (AD-III).</u>

M/s Finetex Cotton Industry, Gujranwala have applied for conversion/renewal of DML (Establishment License to Manufacture Medical Devices) under MDR, 2017 for which inspection panel were constituted by Licensing Division dated 22-09-2017 for inspection of their establishment. Since cotton bandage, crepe bandage and surgical guaze are defined as medical devices and with the promulgation of Medical Device Rules, 2017 vide S.R.O. 32(I)/2018, the mentioned therapeutic goods are dealt by MDMC Division. The inspection report from Area FID Lahore dated 03-02-2020 has been recieved containing 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 Person	Name of QC Incharge	Inspection panel & date of inspection	Recommendations

1.	M/s Finetex Cotton Industry	Near Dera Sahi Singh, 3-KM, G.T. Road, Kamoke, District Gujranwala.	Mr. Kamran Abid, Production Manager (B.Pharm)	Dr.Erum Shahzadi, QC Manager (Pharm-D)	Dr. Ikram Ul Haq, Member, CLB, DRAP. Dr. Zaka ur Rehman, Secretary, Pharmacy Council, Punjab. Mr. Ajmal Sohail Asif, FID, DRAP, Lahore.	The panel of inspectors **recommends** the renewal of Drug Manufacturing License by way of formulation bearing No. 000741 in favour of M/s Finetex Cotton Industry, situated at Near Dera Sahi Singh, 3-Km, G.T. Road Kamoke, Distt. Gujranwala in respect of following sections: *i.* Cotton Bandage *ii.* Cotton Crepe Bandage *iii.* Surgical Gauze (sterile/non-sterile).

Decision: The Board approved M/s Finetex Cotton Industry, Near Dera Sahi Singh, 3-KM, G.T. Road, Kamoke, District Gujranwala for grant of Renewal and conversion of DML into Establishment Licence to Manufacture Medical Devices.

Item No.XII. <u>CONVERSION OF DML INTO ESTABLISHMENT LICENCE TO MANUFACTURE MEDICAL DEVICES AND CHANGE OF TECHNICAL PERSONS.</u>

M/s 3N Lifemed Pharmaceuticals, 45-S.B, Abdullah Colony, Sargodha had surrendered their original Drug Manufacturing Licenses No.000831 (By Way of Formulation) issued on 03-12-2015 (valid till 02-12-2020) in lieu of fresh issuance of Establishment License to Manufacture Medical Devices under Medical Devices Rules, 2017.

Accordingly a panel comprising Additional Director (MDMC) and Federal Inspector of Drugs -IV, DRAP, Lahore was constituted for inspection of the firm. The recommendations of the panel are as under:-

"Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the insection M/s 3N-Lifemed Pharmaceuticals, Sargodha was considerd to be operating at Good level of compliance with guidelines as per DRAP Act, 2012 and rules framed thereunder. The panel was of the opinion that the DML of the firm may be converted to Establishment License under the Medical Devices Rules."

Meanwhile, the firm has applied for change of their Production Incharge and Quality Control Incharge and submitted the required documents. The detail of technical persons is given below:-

Existing Production Incharge	**Proposed Production Incharge**
Abdul Majid Malik (M.Phil Pharmaceutics)	Maria Fakhar (Pharm-D)
Existing Quality Control Incharge	**Proposed Quality Control Incharge**
Mr. Muhammad Azeem (B-Pharm)	Muhammad Bilal Dildar

Decision: The Board approved M/s 3N Lifemed Pharmaceuticals, 45-S.B, Abdullah Colony, Sargodha for conversion of DML into Establishment Licence to Manufacture Medical Devices under Medical Devices Rules, 2017 and approved the following technical persons of the firm:-

Maria Fakhar (Pharm-D), Production Incharge
Muhammad Bilal Dildar, Quality Control Incharge.

Item No. XIII. CHANGE OF TECHNICAL STAFF (PRODUCTION MANAGER) OF M/S UNISA (PVT) LIMITED, NOWSHERA, KPK (AD-I).

M/s Unisa (Pvt) Limited, Main GT Road, Adamzai, Akora Khattak, Nowshera has applied for change of their Production Manager. The firm has submitted all relevant documents alongwith fee of Rs.50,000/- and requested for approval of new Production Manager as detail given below:-

Existing Production Manager	**Proposed Production Manager**
Mr. Adil Ghaffar (Pharmacist)	Mr. Muhammad Zahid Khan (Pharm-D)

The firm has submitted following documents:

(i) Application of Form-1.
(ii) Requisite fee of PKR 50,000/-

Decision: The Board acceded to the request of the firm and approved Mr. Muhammad Zahid Khan, (Pharm-D) as QC Incharge for change in particular of the licence.

ITEM NO. XIV. CHANGE OF TECHNICAL STAFF OF M/S RENACON PHARMA LIMITED, LAHORE (AD-I).

M/s Renacon Pharma Limited, 18 KM, Ferozpur Road, Opp Nishtar Colony, Lahore has requested for approval of change of QC Incharge in their ELM-0007, dated 01-10-2019 as per details given below:-

Previously approved QC Incharge	**Proposed QC Incharge**
Mr. Mr. Adeel-ur-Rehman Qureshi (B-Pharmacy)	Ms. Meshal Shaukat (Pharm-D)

The firm has submitted following documents:

(i) Application of Form-1.
(ii) Requisite fee of PKR 50,000/-
(iii) Resignation letter of previously approved QC Incharge.
(iv) Appointment letter of proposed QC Incharge.
(v) Experience certificate of proposed QC Incharge.
(vi) Credentials of proposed QC Incharge.

Decision: The Board acceded to the request of the firm and approved Ms. Meshal Shaukat (Pharm-D) as QC Incharge for change in particular of the licence.

ITEM NO. XV. <u>SITE VERIFICATION OF M/S GREENECO LIMITED, KARACHI (AD-I).</u>

M/s GreenEco Limited, Karachi has informed that they are interested to install Manufacturing Unit for Medical Devices. The proposed plot for the construction of the Unit is located at Plot No.251-255, Deh Ibrahim Hyderi, Korangi Creek, Karachi. They have submitted all relevant documents and requested to depute a team for the verification of plot and for granting NOC to start construction on the proposed site.

Accordingly Mr. Sajjad Ahmed Abbasi, FID, DRAP, Karachi, Mr. Awais Ahmed Juno, AD/FID, DRAP, Karachi and Mrs. Hira Bhutto, AD, CDL, Karachi was nominated for verification of site and analyze their proposed lay out plan grant of establishment license to manufacture medical devices within 15 days. Accordingly inspection was conducted on 14th May, 2020. Recommendations/report of the panel is reproduced as under:-

"The management of the firm informed tha they are not ready to manufacture the medical devices at this time however the site has been reserved for future construction and the layout plan has also been presented to the panel members.

The said site is not open plot, there was some construction work already being in progress, the site is located at Plot No.251-255, Deh Ibrahim Hyderi, Korangi Creek, Karachi and the location/surroundings are suitable to establish the manufacturing unit for manufacture of medical devices. The layout plan has been analyzed by panel and some improvements advised to firm, the firm submitted the revised layout plan. The copy of sketch of the site plot and surrounding areas with the proposed layout plan is enclosed with this lettter for further necssary action.

The panel recommends the site for establishment of manufacturing facility within stipulated time period to manufacture medical devices as per Medical Devices Rules, 2017."

Decision: The Board approved the site of M/s GreenEco Limited, located at Plot No.251-255, Deh Ibrahim Hyderi, Korangi Creek, Karachi for establishment of manufacturing unit of medical devices.

Item No. XVI. <u>SITE VERIFICATIONM/S CASTLE PHARMA INDUSTRY, OKARA.</u>

M/s Castle Pharma Industry, 82/2L Road, 49/2L, Okara has informed that they are interested to install Manufacturing Unit for Medical Devices. The proposed plot for the construction of the Unit is located at 82/2L Road, 49/2L, Okara. They have submitted all relevant documents and requested to depute a team for the verification of plot and for granting NOC to start construction on the proposed site.

Accordingly Mr. Ajmal Sohail Asif, FID, DRAP, Lahore was nominated for inspection of site verification. Accordingly inspection was conducted on 3rd March, 2020. Recommendations/ report is reproduced as under:-

1.	Location	The plot is located 82/2L Road, 49/2L, Okara. The plot was located in agricultural area. Location map of the proposed site is attached, taken from the google maps at the time of visit, showing geographical coordinates (30.785397, 73.513454) for future reference.
2.	Surrounding	On the east side of the plot was agricultural land. On the west side of the plot was road. On the south side of the plot was agricultural land. On the north side of the plot was agricultural land.
3.	Size	The size of the plot was 08 Kanals approx. as per documents provided.

4.	Recommendations	In the light of the physical verification of the site and scrutiny of documents provided by the applicant, the proposed site is suitable for establishment of medical device manufacturing unit.

Decision: The Board approved the site of M/s Castle Pharma Industry, located at 82/2L Road, 49/2L, Okara for establishment of manufacturing unit of medical devices.

Item No. XVII. EXEMPTION FROM INSPECTION OF MANUFACTURER ABROAD.

The following product of M/s Pharma Supply Corporation, Karachi was approved in 13th Meeting of MDB subject to inpection of manufacturer abroad: -

1.	M/s Pharma Supply Corporation. 49-J, Block-6, PECHS, Nursery Karachi. (ELI-00092) **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** Shantou Wealy Medical Instument Co., Ltd. North Jinhuan Road (Near Qishan Mid-School) Shantou. China (FSC Issuance 11-06-2019)	Wealy Saftey Syringe Automatically Retractable 3ml, 5ml, 10ml Class B Shelf Life: 3 Years Fee submitted: Rs. 50,000/-	Disposable automatically retractable safety syringe with needle	**Approved** subject to Inspection abroad by the panel of inspectors. The board also authorized the secretary MDB to issue registration certificate if recommended by the panel of inspectors and provision ofStability data and EPSP

The MDB may consider the above product for registration on the basis of CE Mark documents.

Submitted for consideration of MDB please.

Decision: The Board approved the product subject to verification of CE marked documents by Prof. Dr. Saqib Shafi Sheikh, member MDB.

Item No.XVIII. EXEMPTION FROM INSPECTION OF MANUFACTURER ABROAD (AD-IV).

The MDB in its 11th meeting held on 01-02-2019 considered and approved the following medical device of M/s A.S Enterprices, Lahore subject to foreign inspection of manufacturer:-

Sr No.	Name of Importer	Name of Manufacturer	Name of Medical Device	Brief Description	Remarks
1.	M/s A.S. Enterprises. 03 Mozang Road, Lahore (ELI-00190)	**Legal Manufacturer/ Manufacturing Site:** M/s Suzhou Laishi Transfusion Equipment Co., Ltd., Changsheng Road, Tongli Town, Wujiang District, Suzhou City, Jiangsu Province, PR China FSC China Valid Till 10-09-2019)	Laishi Disposable Plastic Blood Bag Class D Shelf Life: 3 Years **Fee submitted:** Rs.50,000/-	Disposable Plastic Blood Bag with CPDA-1 for Whole Blood (Human). Single, 500 ml with 17 G needle for Single Use	**Approved** subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017 and the MDB authorized Secretary, MDB to issue Registration Certificate if recommended by panel of inspectors.

Meanwhile, the firm has provided the Embassy attested Free Sale Certificate of Germany issued on 02-04-2020 for the above mentioned medical device which is a reference country reference country as per Medical Devices Rules, 2017.

Decision: The Board approved the above mentioned medical device on basis of Free Sale Certificate of Germany.

Item No. XIX. EXEMPTION FROM INSPECTION OF MANUFACTURER ABROAD (AD-IV).

The following product of M/s Leven Medical Care, Lahore was approved in 14th Meeting of MDB subject to inspection of manufacturer abroad and provision of notarized credentials of manufacturer abroad: -

Name and Addresses of Establishment	Manufacture Details	Name of Medical Device with sizes/ Class/Shelf Life	Brief Description
M/s Leven Medical Care, 8-C, Ground Floor, Street No. 3 Near LGS School Shah, Jamal, Lahore. (ELI-00387)	**Legal Manufacturer:** ALmediko saglik urunleri Turizm Gida Sanayl ve Ticaret limited	**Meme Thol Barrier Spray** Barrier Spray Class B	Meme Thol Barrier Spray is an anal barrier spray which is intended to be used to reduce and eliminate the symptomatic complaints of

Evaluator: **Ms. Hira Bhutto**	Sirketi (Mimar Sinan Mah. 1420 Soak Ak No:108/203 Konak/ Izmir/ Turkiye. (FSC Issue 07-12-2017)	Shelf Life: 24 Months Meme Thol Barrier Spray Code: 8680782940026	hemorrhoids and anal fissures. It is intended for external use Only.

Meanwhile, the firm has provided the Notarized credentials of manufacturer abroad and CE mark documents. The MDB may consider the above product for registration on the basis of CE Mark documents

Decision: The Board approved the product subject to verification of CE marked documents by Prof. Dr. Saqib Shafi Sheikh, member MDB.

Item No. XX. **TRANSFER OF REGISTRATION (AD-IV).**

M/s IBL Health Care, Karachi has requested for transfer of following registered imported Medical Devices (registered as drug) from the name of M/s Genome Pharma, Hattar, Haripur to their name:-

S.#	Regn.No.	Brand Name of Medical Device	Packing	Shelf Life	Name of Manufacturer
(i)	062271	WEGO Insulin Syringe	1 ml	2 years	M/s Shandong Weigao Group Medical Polymer Co., Ltd, China
(ii)	079218	WEGO Disposable Burette Infusion Set (with needle)	1's	5 years	-do-

The firm has submitted following documents:-

(i) Application dossier alongwith Form 7-A for the above product.

(ii) Fee of Rs.25,000/- for above products.

(iii) Copy of registration letter.

(iv) Letter of Authorization regarding above product to M/s IBL Healthcare Limited, Karachi from the foreign manufacturer, namely, Shandong Weigao Group Medical Polymer Co., Ltd., China.

(v) Copy of Letter of Termination of Authorization of M/s Genome Pharmaceuticals (Pvt) Ltd, Rawalpindi from the foreign manufacturer.

(vi) Copy of NOC from M/s Genome Pharmaceuticals (Pv) Ltd., Rawalpindi regarding transfer of registration of above products to M/s IBL Healthcre Limited, Karachi.

Sr No.	Name of Importer	Name of Manufacturer	Name of Medical Device	Brief Description	Remarks
1.	M/s IBL Health Care First floor, N.I.C.L Building Abbasi Shaheed Road, Karachi (ELI-00119)	**Manufacturer:** M/s Shandong Weigao Group Medical Polymer Co., Ltd, China. No 18 Xingshan Road, Weihai Torch Hi-tech Science Park, Shandong Province, China FSC China issued by China chamber of commerce for import and exportof medicines & Health Products valid till 19-08-2020)	WEGO Insulin Syringe Class B Size: 1ml, U-100, 0.3mm Shelf Life: 5 Years Fee submitted:Rs.25,000/-	Sterile, single-use insulin syringe	Real time stability studies not provided. Full QA expired FSC issued from China chamber of commerce and not from Chinese FDA MRP not provided
2.	M/s IBL Health Care First floor, N.I.C.L Building Abbasi Shaheed Road, Karachi (ELI-00119)	**Manufacturer:** M/s Shandong Weigao Group Medical Polymer Co., Ltd, China. No 18 Xingshan Road, Weihai Torch Hi-tech Science Park, Shandong Province, China FSC China issued by China chamber of commerce for import and exportof medicines & Health Products valid till 19-08-2020)	WEGO Disposable Burette Infusion Set Class B Size: 100ml 150ml Shelf Life: 3Years Fee submitted:Rs.25,000/-	Sterile, single-use burette infusion set	Real time stability studies not provided. Full QA expired FSC issued from China chamber of commerce and not from Chinese FDA MRP not provided

It is submitted that M/s IBL Healthcare Limited, Karachi has been issued Establishment Licence to Import Medical Devices under MDR, 2017 vide Licence No. ELI-00119, dated 3rd August, 2018.

Decision: The Board cancelled the registration of WEGO Insulin Syringe and WEGO Disposable Burette Infusion Set (with needle) in the name of /s Genome Pharma, Hattar, Haripur and approved the registration of the said products in the name of M/s IBL Health Care, First floor, N.I.C.L Building Abbasi Shaheed Road, Karachi subject to provision of deficient documents and CE-marked documents or inspection of the manufacturer abroad under Rule 71 of Medical Device Rules,

2017. The Board also authorized the Secretary, MDB to issue registration of the product if the manufacturing plant is approved by the panel of experts or provision of defiencient documents and CE marked documents.

Item No.XXI. **SEIZURE OF UN-REGISTERED PRODUCT - GRANT OF PERMISSION FOR SAFE CUSTODY TILL THE DECISION OF THE CASE (AD-III).**

FID-IV Islamabad visited the premises of Malik Pharmacy and Mart, main Murree road, Athal Chowk, Opposite Summit Bank, Barakahu Islamabad on 17-04-2019 and seized the following stock of products:-

Sr. No.	Name of Device	Batch No.	Mfg Date	Exp Date	Manufacturer	Quantity
1	Spine LP18×3.5	20161120	11-2018	10-2021	M/s SHI International Holding CalpGMbH (EII) Effosharss 80 20537, Hanburg, Germany	06
2	Spine LP23×3.5	20160125	01-2018	12-2020	Same as above	06

The above mentioned medical devices fall under the category of Class-D medical device for which the exemption period according to Rule 52 of MDR 2017, has been expired on 15-10-2018. Area FID mentioned the reason of seizure as "Un-registered product" and requested for grant of permission for safe custody till the decision of the case.

Decision: The Board considered and granted permission for safe custody of the above products till the decision of the case.

Item No.XXII. **SEIZURE OF REGISTERED PRODUCT - GRANT OF PERMISSION FOR SAFE CUSTODY TILL THE DECISION OF THE CASE (AD-III).**

FID-IV Islamabad visited the premises of Malik Pharmacy and Mart, main Murree road, Athalchowk, opposite Summit Bank, Barakahu Islamabad, dated 17-04-2019 and seized following stock:-

Sr. No	Name of Device	Batch No.	Mfg Date	Exp Date	Manufacturer	Quantity
1	BD Ultra-fine II Reg. No: 059212	7338769-D	01-2018	12-2022	M/s Becton Dickinson and Company, USA	40 syringes
2	BD Ultra-fine II Reg. No: 059212	7338769-A	01-2018	12-2022	Same as above	40 syringes
3	BD Ultra-fine II Reg. No: 059212	7338769-B	01-2018	12-2022	Same as above	40 syringes

Area FID mentioned the reason of seizure as over pricing since "**MRP on internal pack of 10 syringes is Rs: 250/- printed on sticker while actually price on outer carton is 1900/100 syringes**" and requested grant of permission for safe custody till the decision of the case.

Decision: The Board considered and granted permission for safe custody of the above products till the decision of the case.

Item No. XXIII. STOCK OF PARTICULATE RESPIRATOR N95 3M "NOT TO DISPOSE OF" M/S SAFETY EQUIPMENT EXPERIENCE (SEE) 12-S-18 BAHAWALPUR HOUSE GOR-III, NEAR SDO OFFICE, LAHORE (AD-IV).

Mr. Abdul Rashid Shaikh, FID, DRAP, Lahore has informed that he alongwith Mr. Ajmal Sohail Asif, FID, DRAP, Lahore visited the premises of Safety Equipment Experience (SEE) 12-S-18 Bahawalpur House GOR-II, Near SDO Office, Lahore. At the time of visit, Mr. Bilal Hussain, Chief Executive alongwith others were present. The quantity of particulate Respirator N85 3M were present in the store as described in letter of M/s 3M No.SIBG/2020 March/072 dated 30-03-2020. The following item Particulate Respirator N95 3M were orders "Not to dispose of" on Form-1, under Section 18(1) (i) of Drugs Act, 1976/DRAP Act, 2012 with reference to epidemic situation of corona virus emergency in the presence of Mr. Bilal Hussain, Chief Executive:-

Sr. S.#	Name of Device	Batch No.	Mfg Date	Exp Date	Manufacturer	Quantity
1	Particulate Respirator N95 3M	-	-	-	M/s 3M Personal Safety Division made in UK	125 boxes x 160 masks = 20,000 masks.

FID, DRAP, Lahore has requested to grant extension in Orders "**Not To Dispose Of**" Period for further **three months** or till the emergency situation of this epidemic.

Decision: The Board considered and granted extension in order "Not to Dispose Of" for a period ot three months for above product.

Item No. XXIV. REGISTRATION OF MEDICAL DEVICES OF M/S TREU-DYNAMIC INTERNATIONAL, LAHORE FOR IMPORT (DEFERRED CASE).

The following medical devices of M/s Treu-Dynamic International, Lahore were placed before the MDB in its 12th meeting for consideration. **The MDB referred the case to Dr. Khalid S. Aslam, Orthopaedic Surgeon, Quaid-e-Azam International Hospital for opinion whether in international practice the product under consideration is supplied sterile or are sterilized in the hospital before surgery. Secondly the components mentioned can be grouped together as one system to be used in surgery:-**

S.#	Name of Importer	Name of Manufacturer	Name of Medical Devices	Brief description
1.	**M/s. Treu-Dynamic International,** C-206, 2nd Floor city Towers, Main Boulevard, Gulberg, Lahore. (ELI-00175) Evaluator: Muhammad Ayub Naveed	**Legal manufacturer** M/s. SURGIVAL Co. S.A.U C/Leonardo da Vinci 12-14 46980 Paterna (Valencia) Spain. FSC Spain Issued on March 14, 2018 Rs. 50,000	**Genutech Total Knee Replacement system** Class C Shelf Life : 05 years **Components of system: Codes & Sizes as per FSC No. 16/2018 of Spain** • PS Cemented Femoral Component • NPS Cemented Femoral Component • Revision Cemented Femoral Component • PS Cementless Femoral Component • NPS Cementless Femoral Component • PS Tibial insert • NPS Tibial insert • Revision Tibial insert • Tibial Tray • Revision Tibial Tray. • Patellar Component • Offset Revision Stem. • Straight Revision Stem. • Posterior Femoral supplement • Distal Femoral supplement • Tibial supplement	Total Knee Prosthesis.
2.	**-do-** Evaluator: Muhammad Ayub Naveed	**Legal manufacturer** **M/s. SURGIVAL Co. S.A.U**	**Total Hip Replacement System.** Class C Shelf Life: 05 years	The total hip replacement System is Group of Medical

		Leonardo da Vinci 12-14 46980 Paterna (Valencia) Spain. FSC Spain Issued on March 14, 2018 Rs. 50,000	**Consist on the following components :-** **1. SELF-LOCKING STEM.** Nitrogen S.S SELF-LOCKING STEM 12/14 6.25 mm (A1501009E) Nitrogen S.S SELF-LOCKING STEM 12/14 7.5 mm (A1501010E) Nitrogen S.S SELF-LOCKING STEM 12/14 10.0 mm (A1501020E) Nitrogen S.S SELF-LOCKING STEM 12/14 11.25 mm (A1501021E) Nitrogen S.S SELF-LOCKING STEM 12/14 12.50 mm (A1501030E) Nitrogen S.S SELF-LOCKING STEM 12/14 13.75 mm (A1501031E) Nitrogen S.S SELF-LOCKING STEM 12/14 15.00 mm (A1501040E) 17.50 mm (A1500014E) Titanium SELF-LOCKING STEM 12/14 6.25 mm , TPS Cementless (A1502010E) Titanium SELF-LOCKING STEM 12/14 7. 50 mm , TPS Cementless (A1502011E) Titanium SELF-LOCKING STEM 12/14 10. 00 mm , TPS Cementless (A1502012E) Titanium SELF-LOCKING STEM 12/14 11. 25 mm , TPS Cementless (A1502112E) Titanium SELF-LOCKING STEM 12/14 12. 50 mm ,	Devices used as System under the name of the total Hip replacement system.

			TPS Cementless (A1502013E) TitaniumSELF-LOCKING STEM 12/14 13.75 mm TPS Cementless (A1502113E) TitaniumSELF-LOCKING STEM12/14 15.00 mm TPS Cementless (A1502014E) Titanium SELF-LOCKING STEM 12/14 17.50 mm TPS Cementless (A1502015E) Titanium SELF-LOCKING STEM 12/14 6.25 mm , HA Cementless (A1504010E) Titanium SELF-LOCKING STEM 12/14 7. 50 mm , HA Cementless (A1504011E) Titanium SELF-LOCKING STEM 12/14 10. 00 mm , HA Cementless (A1504012E) Titanium SELF-LOCKING STEM 12/14 11. 25 mm , HA Cementless (A1504112E) Titanium SELF-LOCKING STEM 12/14 12. 50 mm , HA Cementless (A1504013E) TitaniumSELF-LOCKING STEM12/14 13.75 mm HA Cementless (A1504113E) TitaniumSELF-LOCKING STEM 12/14 15.00 mm HA Cementless (A1504014E) Titanium SELF-LOCKING STEM 12/14 17.50 mm HA Cementless (A1504015E) Titanium Karey-C Femoral Stem Cemented 12/14No. 9 (F0005109E) Titanium Karey-C Femoral Stem Cemented 12/14 No. 10 (F0005110E)	

			Titanium Karey-C Femoral Stem Cemented 12/14 No. 11 (F0005111E) Titanium Karey-C Femoral Stem Cemented 12/14 No. 12 (F0005112E) Titanium Karey-C Femoral Stem Cemented 12/14 No. 13 (F0005113E) Titanium Karey-C Femoral Stem Cemented 12/14 No. 14 (F0005114E) Titanium Karey-C Femoral Stem Cemented 12/14 No. 15 (F0005115E) Titanium Karey-C Femoral Stem Cemented 12/14 No. 16 (F0005116E) High Nitrogen S.S Karey-C Femoral Stem Cemented 12/14 No. 8 (F0005158E) High Nitrogen S.S Karey-C Femoral Stem Cemented 12/14 No. 9 (F0005159E) High Nitrogen S.S Karey-C Femoral Stem Cemented 12/14 No. 10 (F0005160E) High Nitrogen S.S Karey-C Femoral Stem Cemented 12/14 No. 11 (F0005161E) High Nitrogen S.S Karey-C Femoral Stem Cemented 12/14 No. 12 (F0005162E) High Nitrogen S.S Karey-C Femoral Stem Cemented 12/14 No. 13 (F0005163E) High Nitrogen S.S Karey-C Femoral Stem Cemented 12/14 No. 14 (F0005164E)	

			High Nitrogen S.S Karey-C Femoral Stem Cemented 12/14 No. 15 (F0005165E) High Nitrogen S.S Karey-C Femoral Stem Cemented 12/14 No. 16 (F0005166E) Titanium Karey-HA Femoral Stem Cementless 12/14 No. 8 (F0005008E) Titanium Karey-HA Femoral Stem Cementless 12/14 No. 9 (F0005009E) Titanium Karey-HA Femoral Stem Cementless 12/14 No. 10 (F0005010E) Titanium Karey-HA Femoral Stem Cementless 12/14 No. 11 (F0005011E) Titanium Karey-HA Femoral Stem Cementless 12/14 No. 12 (F0005012E) Titanium Karey-HA Femoral Stem Cementless 12/14 No. 13 (F0005013E) Titanium Karey-HA Femoral Stem Cementless 12/14 No. 14 (F0005014E) Titanium Karey-HA Femoral Stem Cementless 12/14 No. 15 (F0005015E) Titanium Karey-HA Femoral Stem Cementless 12/14 No. 16 (F0005016E) Titanium Karey-Revision HA Femoral Stem Cementless 12/14 No.12 (F0005412E) Titanium Karey-Revision HA Femoral Stem Cementless 12/14 No.14 (F0005414E) Titanium Karey-Revision	

			HA Femoral Stem Cementless 12/14 No.16 (F0005416E) Titanium Karey-Revision HA Femoral Stem Cementless 12/14 No.18 (F0005418E) Titanium Karey-Revision C Femoral Stem Cemented 12/14 No. 12 (F0005452E) Titanium Karey-Revision C Femoral Stem Cemented 12/14 No. 14 (F0005454E) Titanium Karey-Revision C Femoral Stem Cemented 12/14 No. 16 (F0005456E) Titanium Karey-Revision C Femoral Stem Cemented 12/14 No. 18 (F0005458E) Titanium Karey-Revision C Femoral Stem Cemented 12/14 No. 20 (F0005460E) Nitrogen S.S Shine-C Femoral Stem Cemented 12/14 No. 0 (A2700000E) Nitrogen S.S Shine-C Femoral Stem Cemented 12/14 No. 1 (A2700001E) Nitrogen S.S Shine-C Femoral Stem Cemented 12/14 No. 2 (A2700002E) Nitrogen S.S Shine-C Femoral Stem Cemented 12/14 No. 3 (A2700003E) Nitrogen S.S Shine-C Femoral Stem Cemented 12/14 No. 4 (A2700004E) 2. **Femoral Head** Stainless Steel Endocephalic Femoral Head, 12/14 38 mm (A1513238E) Stainless Steel Endocephalic Femoral Head, 12/14 39 mm (A1513239E) Stainless Steel Endocephalic Femoral Head, 12/14 40 mm	

			(A1513240E) Stainless Steel Endocephalic Femoral Head, 12/14 41 mm (A1513241E) Stainless Steel Endocephalic Femoral Head, 12/14 42 mm (A1513242E) Stainless Steel Endocephalic Femoral Head, 12/14 43 mm (A1513243E) Stainless Steel Endocephalic Femoral Head, 12/14 44 mm (A1513244E) Stainless Steel Endocephalic Femoral Head, 12/14 45 mm (A1513245E) Stainless Steel Endocephalic Femoral Head, 12/14 46 mm (A1513246E) Stainless Steel Endocephalic Femoral Head, 12/14 47 mm (A1513247E) Stainless Steel Endocephalic Femoral Head, 12/14 48 mm (A1513248E) Stainless Steel Endocephalic Femoral Head, 12/14 49 mm (A1513249E) Stainless Steel Endocephalic Femoral Head, 12/14 50 mm (A1513250E) Stainless Steel Endocephalic Femoral Head, 12/14 51 mm (A1513251E) Stainless Steel Endocephalic Femoral Head, 12/14 52 mm (A1513252E) Stainless Steel Endocephalic Femoral Head, 12/14 53 mm (A1513253E) Stainless Steel Endocephalic Femoral Head, 12/14 54 mm (A1513254E) Stainless Steel Endocephalic Femoral Head, 12/14 55 mm (A1513255E) Stainless Steel Endocephalic Femoral Head, 12/14 56 mm (A1513256E) Stainless Steel Endocephalic Femoral Head, Neck-5 38 mm	

			(A1513338E) Stainless Steel Endocephalic Femoral Head, Neck-5 39 mm (A1513339E) Stainless Steel Endocephalic Femoral Head, Neck-5 40 mm (A1513340E) Stainless Steel Endocephalic Femoral Head, Neck-5 41 mm (A1513341E) Stainless Steel Endocephalic Femoral Head, Neck-5 42 mm (A1513342E) Stainless Steel Endocephalic Femoral Head, Neck-5 43 mm (A1513343E) Stainless Steel Endocephalic Femoral Head, Neck-5 44 mm (A1513344E) Stainless Steel Endocephalic Femoral Head, Neck-5 45 mm (A1513345E) Stainless Steel Endocephalic Femoral Head, Neck-5 46 mm (A1513346E) Stainless Steel Endocephalic Femoral Head, Neck-5 47 mm (A1513347E) Stainless Steel Endocephalic Femoral Head, Neck-5 48 mm (A1513348E) Stainless Steel Endocephalic Femoral Head, Neck-5 49 mm (A1513349E) Stainless Steel Endocephalic Femoral Head, Neck-5 50 mm (A1513350E) Stainless Steel Endocephalic Femoral Head, Neck-5 51 mm (A1513351E)	

			Stainless Steel Endocephalic Femoral Head, Neck-5 52 mm (A1513352E) Stainless Steel Endocephalic Femoral Head, Neck-5 53 mm (A1513353E) Stainless Steel Endocephalic Femoral Head, Neck-5 54 mm (A1513354E) Stainless Steel Endocephalic Femoral Head, Neck-5 55 mm (A1513355E) Stainless Steel Femoral Head 12/14, Short Neck 22 mm (A1509060E) Stainless Steel Femoral Head 12/14, Short Neck 26 mm (A1509050E) Stainless Steel Femoral Head 12/14, Short Neck 28 mm (A1509040E) Stainless Steel Femoral Head 12/14, Short Neck 32 mm (A1509013E) Stainless Steel Femoral Head 12/14, Medium Neck 22 mm (A1509061E) Stainless Steel Femoral Head 12/14, Medium Neck 26 mm (A1509051E) Stainless Steel Femoral Head 12/14, Medium Neck 28 mm (A1509041E) Stainless Steel Femoral Head 12/14, Medium Neck 32 mm (A1509014E) Stainless Steel Femoral Head 12/14, Long Neck 22 mm (A1509062E) Stainless Steel Femoral Head 12/14, Long Neck 26 mm (A1509052E) Stainless Steel Femoral Head 12/14, Long Neck 28 mm (A1509042E)	

			Stainless Steel Femoral Head 12/14, Long Neck 32 mm (A1509015E) Stainless Steel Femoral Head 12/14, Extra Long Neck 26 mm (A1509053E) Stainless Steel Femoral Head 12/14, Extra Long Neck 28 mm (A1509043E) Alumina Ceramic Femoral Head 12/14, Short Neck 26 mm (A1507050E) Alumina Ceramic Femoral Head 12/14, Short Neck 28 mm (A1507040E) Alumina Ceramic Femoral Head 12/14, Medium Neck 26 mm (A1507051E) Alumina Ceramic Femoral Head 12/14, Medium Neck 28 mm (A1507041E) Alumina Ceramic Femoral Head 12/14, Long Neck 26 mm (A1507052E) Alumina Ceramic Femoral Head 12/14, Long Neck 28 mm (A1507042E) CrCoMo Femoral Head 12/14, Short Neck 22 mm (A1506060E) CrCoMo Femoral Head 12/14, Short Neck 26 mm (A1506050E) CrCoMo Femoral Head 12/14, Short Neck 28 mm (A1506040E) CrCoMo Femoral Head 12/14,Medium Neck 22 mm (A1506061E) CrCoMo Femoral Head 12/14, Medium Neck 26 mm (A1506051E) CrCoMo Femoral Head	

			12/14, Medium Neck 28 mm (A1506041E) CrCoMo Femoral Head 12/14,Long Neck 22 mm (A1506062E) CrCoMo Femoral Head 12/14, Long Neck 26 mm (A1506052E) CrCoMo Femoral Head 12/14, Long Neck 28 mm (A1506042E) CrCoMo Femoral Head 12/14, Extra Long Neck 26 mm (A1506053E) CrCoMo Femoral Head 12/14, Extra Long Neck 28 mm (A1506043E) Stainless Steel Biarticular Head 41 mm (A1519041E) Stainless Steel Biarticular Head 42 mm (A1519042E) Stainless Steel Biarticular Head 43 mm (A1519043E) Stainless Steel Biarticular Head 44 mm (A1519044E) Stainless Steel Biarticular Head 45 mm (A1519045E) Stainless Steel Biarticular Head 46 mm (A1519046E) Stainless Steel Biarticular Head 47 mm (A1519047E) Stainless Steel Biarticular Head 48 mm (A1519048E) Stainless Steel Biarticular Head 49 mm (A1519049E) Stainless Steel Biarticular Head 50 mm (A1519050E) Stainless Steel Biarticular Head 51 mm	

			(A1519051E) Stainless Steel Biarticular Head 52 mm (A1519052E) Stainless Steel Biarticular Head 53 mm (A1519053E) Stainless Steel Biarticular Head 54 mm (A1519054E) Stainless Steel Biarticular Head 55 mm (A1519055E) Biarticular Head Polyethylene (UHMWPE) Insert 28 mm A (41,42,43 mm) (A1519141E) Biarticular Head Polyethylene (UHMWPE) Insert 28 mm B (44,45,46 mm) (A1519144E) Biarticular Head Polyethylene (UHMWPE) Insert 28 mm C (47,48,49,50 mm) (A1519147E) Biarticular Head Polyethylene (UHMWPE) Insert 28 mm D (51,52,53,54,55 mm) (A1519151E) Biarticular Head Polyethylene (UHMWPE) Insert 22 mm A (41,42,43 mm) (A1519241E) Biarticular Head Polyethylene (UHMWPE) Insert 22 mm B (44,45,46 mm) (A1519244E) Biarticular Head Polyethylene (UHMWPE) Insert 22 mm C (47,48,49,50 mm) (A1519247E) Biarticular Head Polyethylene (UHMWPE) Insert 22 mm D (51,52,53,54,55 mm) (A1519251E)	

			3. **Acetabular Cup** Polyethylene (UHMWPE) Antiluxation Acetabular Cup Type Muller Cemented 40 x 28 mm (A1512240E) Polyethylene (UHMWPE) Antiluxation Acetabular Cup Type Muller Cemented 42 x 28 mm (A1512242E) Polyethylene (UHMWPE) Antiluxation Acetabular Cup Type Muller Cemented 44 x 28 mm (A1512244E) Polyethylene (UHMWPE) Antiluxation Acetabular Cup Type Muller Cemented 46 x 28 mm (A1512246E) Polyethylene (UHMWPE) Antiluxation Acetabular Cup Type Muller Cemented 48 x 28 mm (A1512248E) Polyethylene (UHMWPE) Antiluxation Acetabular Cup Type Muller Cemented 50 x 28 mm (A1512250E) Polyethylene (UHMWPE) Antiluxation Acetabular Cup Type Muller Cemented 52 x 28 mm (A1512252E) Polyethylene (UHMWPE) Antiluxation Acetabular Cup Type Muller Cemented 54 x 28 mm (A1512254E) Polyethylene (UHMWPE) Antiluxation Acetabular Cup Type	

			Muller Cemented 56 x 28 mm (A1512256E) Polyethylene (UHMWPE) Antiluxation Acetabular Cup Type Muller Cemented 58 x 28 mm (A1512258E) Titanium S.H.Y+ TI Plasma Spray (TPS) +Hidroxiapatite (HA)Cementless 46 mm (A2400646E) Titanium S.H.Y+ TI Plasma Spray (TPS) +Hidroxiapatite (HA) Cementless 48 mm (A2400648E) Titanium S.H.Y+ TI Plasma Spray (TPS) +Hidroxiapatite (HA) Cementless 50 mm (A2400650E) Titanium S.H.Y+ TI Plasma Spray (TPS) +Hidroxiapatite (HA) Cementless 52 mm (A2400652E) Titanium S.H.Y+ TI Plasma Spray (TPS) +H hidroxiapatite (HA) Cementless 54 mm (A2400654E) Titanium S.H.Y+ TI Plasma Spray (TPS) +Hidroxiapatite (HA) Cementless 56 mm (A2400656E) Titanium S.H.Y+ TI Plasma Spray (TPS) +Hidroxiapatite (HA) Cementless 58 mm (A2400658E) Titanium S.H.Y+ TI Plasma Spray (TPS) +Hidroxiapatite (HA) Cementless 60 mm (A2400660E) Titanium S.H.Y+ TI Plasma Spray (TPS) +Hidroxiapatite (HA) Cementless 62 mm (A2400662E) S.H.Y Cup Polyethylene Insert (UHMWPE) 46 x 26 mm (A2400746E) S.H.Y Cup Polyethylene Insert (UHMWPE) 48 x 26	

			mm (A2400748E) S.H.Y Cup Polyethylene Insert (UHMWPE) 46 x 26 mm (A2400746E) S.H.Y Cup Polyethylene Insert (UHMWPE) 50 x 28 mm (A2400750E) S.H.Y Cup Polyethylene Insert (UHMWPE) 52 x 28 mm (A2400752E) S.H.Y Cup Polyethylene Insert (UHMWPE) 54 x 28 mm (A2400754E) S.H.Y Cup Polyethylene Insert (UHMWPE) 56 x 28 mm (A2400756E) S.H.Y Cup Polyethylene Insert (UHMWPE) 58 x 28 mm (A2400758E) S.H.Y Cup Polyethylene Insert (UHMWPE) 60 x 28 mm (A2400760E) S.H.Y Cup Polyethylene Insert (UHMWPE) 62 x 28 mm (A2400762E) Cementless Quarter Cup Titanium 40 mm (A2401640E) Cementless Quarter Cup Titanium 42 mm (A2401642E) Cementless Quarter Cup Titanium 44 mm (A2401644E) Cementless Quarter Cup Titanium 46 mm (A2401646E) Cementless Quarter Cup Titanium 48 mm (A2401648E) Cementless Quarter Cup Titanium 50 mm (A2401650E) Cementless Quarter Cup	

			Titanium 52 mm (A2401652E) Cementless Quarter Cup Titanium 54 mm (A2401654E) Cementless Quarter Cup Titanium 56 mm (A2401656E) Cementless Quarter Cup Titanium 58 mm (A2401658E) Cementless Quarter Cup Titanium 60 mm (A2401660E) Cementless Quarter Cup Titanium 62 mm (A2401662E) Cementless Quarter Cup Titanium 64 mm (A2401664E) Cementless Quarter Cup Titanium 66 mm (A2401666E) Cementless Quarter Cup Titanium 68 mm (A2401668E) Quarter InsertAntiluxation 40 x22 mm (A2412240E) Quarter Insert Antiluxation 42 x22 mm (A2412242E) Quarter Insert Antiluxation 44x22 mm (A2412244E) Quarter Insert Antiluxation 46x22 mm (A2412246E) Quarter Insert Antiluxation 44x28 mm (A2412844E) Quarter Insert Antiluxation 46x28 mm (A2412846E) Quarter Insert Antiluxation 48x28 mm (A2412848E) Quarter Insert Antiluxation 50x28 mm (A2412850E) Quarter Insert Antiluxation 52x28 mm (A2412852E) Quarter Insert Antiluxation 54x28 mm (A2412854E)	

			Quarter Insert Antiluxation 56x28 mm (A2412856E) Quarter Insert Antiluxation 58x28 mm (A2412858E) Quarter Insert Antiluxation 60x28 mm (A2412860E) Quarter Insert Antiluxation 62x28 mm (A2412862E) Quarter Insert Antiluxation 64x28 mm (A2412864E) Quarter Insert Antiluxation 66x28 mm (A2412866E) Quarter Insert Antiluxation 68x28 mm (A2412868E) Quarter Insert Antiluxation 48x32 mm (A2413248E) Quarter Insert Antiluxation 50x32 mm (A2413250E) Quarter Insert Antiluxation 52x32 mm (A2413252E) Quarter Insert Antiluxation 54x32 mm (A2413254E) Quarter Insert Antiluxation 56x32 mm (A2413256E) Quarter Insert Antiluxation 58x32 mm (A2413258E) Quarter Insert Antiluxation 60x32 mm (A2413260E) Quarter Insert Antiluxation 62x32 mm (A2413262E) Quarter Insert Antiluxation 64x32 mm (A2413264E) Quarter Insert Antiluxation 66x32 mm (A2413266E) Quarter Insert Antiluxation 68x32 mm	

			(A2413268E) Quarter Insert Antiluxation 52x36 mm (A2413652E) Quarter Insert Antiluxation 54x36 mm (A2413654E) Quarter Insert Antiluxation 56x36 mm (A2413656E) Quarter Insert Antiluxation 58x36 mm (A2413658E) Quarter Insert Antiluxation 60x36 mm (A2413660E) Quarter Insert Antiluxation 62x36 mm (A2413662E) Quarter Insert Antiluxation 64x36 mm (A2413664E) Quarter Insert Antiluxation 66x36 mm (A2413666E) Quarter Insert Antiluxation 68x36 mm (A2413668E) Quarter Insert Neutral 44x28 mm (A2402844E) Quarter Insert Neutral 46x28 mm (A2402846E) Quarter Insert Neutral 48x28 mm (A2402848E) Quarter Insert Neutral 50x28 mm (A2402850E) Quarter Insert Neutral 52x28 mm (A2402852E) Quarter Insert Neutral 54x28 mm (A2402854E) Quarter Insert Neutral 56x28 mm (A2402856E) Quarter Insert Neutral 58x28 mm (A2402858E) Quarter Insert Neutral 60x28 mm (A2402860E) Quarter Insert Neutral 62x28 mm (A2402862E) Quarter Insert Neutral 64x28 mm (A2402864E) Quarter Insert Neutral 66x28 mm (A2402866E)	

			Quarter Insert Neutral 68x28 mm (A2402868E) Quarter Insert Neutral 48x32 mm (A2403248E) Quarter Insert Neutral 50x32 mm (A2403250E) Quarter Insert Neutral 52x32 mm (A2403252E) Quarter Insert Neutral 54x32 mm (A2403254E) Quarter Insert Neutral 56x32 mm (A2403256E) Quarter Insert Neutral 58x32 mm (A2403258E) Quarter Insert Neutral 60x32 mm (A2403260E) Quarter Insert Neutral 62x32 mm (A2403262E) Quarter Insert Neutral 64x32 mm (A2403264E) Quarter Insert Neutral 66x32 mm (A2403266E) Quarter Insert Neutral68x32 mm (A2403268E) Quarter Insert Neutral 52x36 mm (A2403652E) Quarter Insert Neutral 54x36 mm (A2403654E) Quarter Insert Neutral 56x36 mm (A2403656E) Quarter Insert Neutral 58x36 mm (A2403658E) Quarter Insert Neutral 60x36 mm (A2403660E) Quarter Insert Neutral 62x36 mm (A2403662E) Quarter Insert Neutral 64x36 mm (A2403664E) Quarter Insert Neutral 66x36 mm (A2403666E) Quarter Insert Neutral 68x36 mm (A2403668E) Quarter Insert Neutral 56x40 mm	

			(A2404056E) Quarter Insert Neutral 58x40 mm (A2404058E) Quarter Insert Neutral 60x40 mm (A2404060E) Quarter Insert Neutral 62x40 mm (A2404062E) Quarter Insert Neutral 64x40 mm (A2404064E) Quarter Insert Neutral 66x40 mm (A2404066E) Quarter Insert Neutral 68x40 mm (A2404068E) **4. Screw for Cup** SHY Screw for Cup L= 20 mm (A2400520) SHY Screw for Cup L= 25 mm (A2400525) SHY Screw for Cup L= 30 mm (A2400530) SHY Screw for Cup L= 35 mm (A2400535) SHY Screw for Cup L= 40 mm (A2400540) SHY Screw for Cup L= 45 mm (A2400545)	
3.	-do-	**Legal manufacturer** M/s. Wuxi BoTEC Medical Innovation Co., Ltd. No. 8-9 Jingrui Rd, Zhangjing, Xibei Town, Xishan Area, Wuxi, Jiangsu Province, 214194 P.R. China FSC Germany Issued on 01.10.2018 Fee Submitted Rs.50,000/-	**Anterior Spinal fixation System** OSTEOSYNTHESİS SYSTEM.having following parts PINE ROD PINE FIXED AXIAL SCREW PINE MULTI AXIAL SCREW PINE MULTI AXIAL Reduction SCREW PINE SET SCREWw PINE CROSS LINK Hopper Plates, Screw set Eagle Plates, screw set Octopus plates, screw set	Botec Osteosynthesis System Description of Device, Presentation form and List of Instruments used to implant the Device. The Botec Osteosynthesis Implants Group of Medical Devices used as System.

			Leopard Plates, Screw set Rhino Plates, Screw set Double thread Screws Hummer Screws DORADO Wire. Class D Shelf Life : 05 years	The Botec Spinal System consists mainly of three key elements: the Spinal Screw (Fixed Head, Multiaxial, and Reduction), Titanium Rod, and Cross Link.

Dr. Khalid S. Aslam, Senior Consultant Orthpedic Surgeon, Quaid-e-Azam International Hospital, Islamabad has given following views/comments/opinion on the above mentioned medical devices:-

> *"I have reviewed the literature and all the other standards and it appears that they are following the European Union Standards and both the hip and knee are coming in the standard way, that is pre-sterilized and they are opened in the operating room. As far as the hip and knee are concerned, they are pretty much standard and I do not think there is any harm in registratering them (product at Sr.No.1&2 above). I must point out that I do have any personal information about them because I have not used this particular system.I cannot comment* on *Osteosynthesis system for the spine (product at Sr.No.3 above)"*

Decision: The Board approved the above mentioned medical devices at Sl. No.1 & 2 keeping in view the recommendations mentioned above. The Board referred the product at Sl. No.3 to Orthopaedic Surgeon for opinion whether in international practice the product under consideration is supplied sterile or are sterilized in the hospital before surgery. Secondly, keeping in view their usage, can the components/parts mentioned with the product be grouped together as one System or not for the purpose of registration under MDR, 2017?

Item No. XXV. REGISTRATION OF MEDICAL DEVICES OF M/S LIFE-TEC, ISLAMABAD FOR IMPORT (DEFERRED CASE) (AD-IV).

The following medical devices of M/s Life-Tec, Islamabad were placed before the MDB in its 15th meeting for consideration. The case was Deferred in 15th MDB meeting. The decision is as follows:

Deferred subject to foreign inspection of manufacturer and provision of Original notarized ISO 13485 and full quality assurance certificate. The Board also authorized the Secretary MDB to issue registration of the product, if the panel of experts approves the manufacturing plant**:-**

S.#	Name of Importer	Name of Manufacturer	Name of Medical Devices	Brief description
1.	M/s Life-Tec Unit B, 1st Floor, Block 20-D, G-8, Markaz, Islamabad. ELI-00155	**Manufacturer:** M/s Sichuan Nigale Biotechnology Co, Ltd, No.28, Kuixing Road, Dongxi town, 641400, Jianyang, Sichuan, People's Republic of China FSC China valid till 3rd July, 2020	Nigale Plasma Separator(Model: NGL XJC 2000) Class: C Service life: 5 years Fee submitted: Rs 25,000/-	The Plasma Separator takes advantages of density difference of blood components of finish the process of centrifugation, separation, collection as well as returning rest components to blood donor. This equipment is indicated in collecting material plasma and preparing clinically fresh frozen plasma.
2.	M/s Life-Tec Unit B, 1st Floor, Block 20-D, G-8, Markaz, Islamabad. ELI-00155	**Manufacturer:** M/s Sichuan Nigale Biotechnology Co, Ltd, No.28, Kuixing Road, Dongxi town, 641400, Jianyang, Sichuan, People's Republic of China FSC China valid till 8-5-2020	Nigale Disposable Blood Components Apheresis Set (Model: P-2000IA) Class: C Shelf Life: 4 years Fee submitted: Rs 50,000/-	Intended to be used with blood component separating machine or blood cell separating machine for collection of blood platelet, collection of plasma, collection of red cell. Sterile, single-use

3.	M/s Life-Tec Unit B, 1st Floor, Block 20-D, G-8, Markaz, Islamabad. ELI-00155	**Manufacturer:** M/s Sichuan Nigale Biotechnology Co, Ltd, No.28, Kuixing Road, Dongxi town, 641400, Jianyang, Sichuan, People's Republic of China FSC China valid till 3rd July, 2020	Nigale Blood Component Separator (NGL XCF-3000) Class: C Service life: 5 years Fee submitted: Rs 50,000/-	Medical equipment that takes advantage of density difference of blood components to perform function of pheresis platelet or pheresis plasma through process of centrifugation, separation, collection as well as returning rest components to blood donor. This equipment is indicated in collecting and supplying blood sections or medical units which collect platelet and/or plasma

For product at serial no. 1, the firm has provided above mentioned documents. In this process, Free Sale certificate has expired and differential fee of Rs. 25,000/- is also required. For products at Serial no.2 and serial no. 3 the firm has provided above mentioned documents. In this process, Free Sale certificate has expired.

Decision: Approved subject to provision of valid Free Sale Certificates of above mentioned medical devices and submission of differential fee of Rs.25000/- for the product at Sl . No.1.

Item No.XXVI. REGISTRATION OF MEDICAL DEVICES FOR EXPORT.

M/s Herbion Pakistan (Pvt) Ltd., Plot 30, Sector 28, Korangi Industrial Area, Karachi has applied on Form-7 for registration of following medical devices for export purpose only:-

Sl.No.	Name of medical device or accessory or component	Brief description	Class	Shelf life
1.	Neemplast Kids Tape Acrinol 19mm x 72mm (20 Packs)	Neemplast kids tape is a first aid plaster that provides ultra-protection against microbes and water. Acrinol is used as an antiseptic and anti-infective in first aid bandages.	B	4 Years
2.	Neemplast Non Elastic Fabric Tape 19mm x 72mm (20 Packs)	It is used for preventing damaged skin from external effects and infections. Acrinol is used as an antiseptic and anti-infective in first aid bandages	B	4 Years
3.	Neemplast Transparent Tape 19mm x 72mm (20 Packs)	It is used to heals, protect & Prevents skin damages (Cuts, Scratches, ulcer and insect bites) from germs, water and dust. Neem and black pepper distillates have anti-infective properties and also promotes rapid healing.	B	4 Years

The Authority has already approved Form-8C for issuance of registration/enlistment of medical devices for export only.

To facilitate the export of medical devices, registration letters for the above mentioned medical devices were issued.

Submitted for endorsement/ratification of MDB please.

Decision: The Board approved/endorsed/ratified the issuance of registration letters of above mentioned medical devices for export.

Item No. XXVII. <u>EXEMPTION FROM LABELING REQUIREMENTS UNDER MDR, 2017 (AD-IV).</u>

M/s Roche Pakistan Limited, Karachi have stated that their company is law abiding entity and intends to import and distribute/market medical devices strictly in accordance with law. By way of this instant letter the company requests for expeditious grant of approval for the use of its licensed

premises for the purpose of labeling as per the Medical Devices Rules (MDR), 2017. Previously, company requested that DRAP to grant the same approval for labeling of medical devices within its licensed premises. However, the matter was never taken up in the proceeding meeting of the MDB. Company intends to start labeling medical devices imported by the same in accordance with Rules 38 (2), 39 (a) and (b) of the MDR.

They have further stated that under the rules the labeling of medical devices is only permissible within the vicinity of a licensed premises and after seeking formal approval from DRAP. In this regard, it is essential to note that the company is an importer of medical devices and by virtue of stay order dated 13-09-2019 passed in W.P. No.50812 of 2019 before the Hon'ble Lahore high Court, Lahore the DRAP has been restrained from requiring the company to be registered as an importer of medical devices pursuant to the Rules. Therefore, the company is only liable to comply with the labeling requirements provided under the Rules in relation to those products which are already registered with DRAP. Since the company's application for approval is pending at DRAP's end it is against the principles of justice to make the labeling requirements prescribed under Chapter IV of the Rules applicable upon the same.

M/s Roche Pakistan Limited, Karachi has requested to decide the matter pertaining to the grant of approval to Roche Pakistan Limited vis-a-vis labeling of medical devices as per Chapter VI of MDR, 2017 at the earliest preferably in the next meeting of MDB and in the mean while no coercive or adverse action may be taken against Roche Pakistan Limited pursuant to the MDR, 2017.

In this regard, it is submitted that Rule 38 of the MDR, 2017 is 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.*

It is submitted that the firm has not submitted fee for the said purpose.

Decision: The Board discussed the matter at length and decided to allow M/s Roche Pakistan Limited, Karachi to print the required information i.e. Establishment License Number, Registration Number and MRP at their licensed premises (warehouse) with inkjet printing on both inner and outer pack of their registered medical devices for a period of one year.

Item No. XXVIII. <u>EXEMPTION FROM LABELING REQUIREMENTS UNDER MDR, 2017(AD-IV).</u>

M/s Medtronic Pakistan (Private) Limited, Karachi have stated that they are registered importer of medical devices under DRAP Medical Devices Rules, 2017 with Establishment License No. ELI-00273. Medtronics is operating from more than 350 locations in more than 150 countries worldwide and has a product/patents range of about 46000 products. Operation on such a vast scale makes labelling of commercial products a very complex and time consuming process. Products are manufactured and packed for global sales so it is practically impossible to print Pakistan's local regulatory requirments such as Establishment Licence Number, Registration Number, Local Importers Address and MRP on each pack specifically for Pakistan market. The demand/use of various devices imported to Pakistan varies both in terms of sizes and quantities hence making Pakistan specific printing difficult at the scattered manufacturing sites.

They have requested to grant them permission for local inkjet printing as per Medical Devies Rules, 2017 on their registered medical devices at their licenced premises (Warehouse approved by DRAP in Establishment Licence) under the supervision of qualified person. This would enable

them to make sure that there are no supply disruption of life saving medical devices to the Pakistan market.

In this regard, it is submitted that Rule 38 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.*

The firm has submitted fee of Rs.10,000/-.

Decision: The Board discussed the matter at length and decided to allow M/s Medtronic Pakistan (Private) Limited, Karachi to print the required information i.e. Establishment License Number, Registration Number and MRP at their licensed premises (warehouse) with inkjet printing on both inner and outer pack of their registered medical devices for a period of one year.

Item No. XXIX. <u>EXEMPTION FROM LABELING REQUIREMENTS UNDER MDR, 2017 (AD-IV).</u>

M/s Johnson & Johnson Pakistan (Pvt) Limited, Karachi has requested for exemption of country specific labeling information and to grant them permission to affix printed labels on the external package (secondary package) of their registered products with following information after importation:-

(i) Establishment License No.,
(ii) Registration/Enlistment No.,
(iii) MRP, and
(iv) Name and address of authorized representative.

This is being requested to the following constraints:-

(i) In our case the multiple manufacturing sources, supplies the products globally in uniform packaging/standard export packs therefore, it is not possible to meet country specific requirements on the outer package due to complex nature of medical devices and huge number of products SKUs.
(ii) The implementation of country specific labeling information by multiple manufacturing sites before import, will cause delay in the availability of products to the health care professional & patients.
(iii) The products are packed in carton boxes & then wrapped with transparent cellophane film by the manufacturers. The sterility and safety of the medical devices are being further ensure through cellophane wrapping hence cellophane cannot be removed furing the process of over-pritning locally.

In this regard, it is submitted that Rule 38 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.

It is submitted that the firm has not submitted fee for the said purpose.

Decision: The Board discussed the matter at length and decided to allow M/s Johnson & Johnson Pakistan (Pvt) Limited, Karachi to print the required information i.e. Establishment License Number, Registration Number and MRP at their licensed premises (warehouse) with inkjet printing on both inner and outer pack of their registered medical devices for a period of one year.

ITEM NO.XXX: LEGAL MATTER

ITEM NO.XXXI: ISSUANCE OF FREE SALE CERTIFICATES OF ALREADY REGISTERED MEDICAL DEVICES FOR LOCAL MANUFACTURE (AD-I).

M/s Uniferoz (Pvt) Limited, Karachi has stated that they are engaged in manufacturing of First Aid Bandages and Surgical Tapes for export and local markets. They have requested for issuance of Free Sale Certificates of their following registered product for the countries mentioned against each:-

S.No.	Enlistment No.	Name of Medical Device (s)	Date of Initial Registration	Date of Validation	Name of Country for which FSC required
1.	MDME-0000013	Saniplast First Aid Bandages	07-07-2003	23-09-2023	Russia

2.	MDME-0000013	Saniplast First Aid Bandages	07-07-2003	23-09-2023	Uzbekistan
3.	MDME-0000015	Saniplast Aqua Bandage	12-03-2013	01-01-2025	Kazakhstan

The firm has provided following documents for the purpose:-

(i) Fee of Rs.5000/- for each product.

(ii) Copy of registration letter.

(iii) Copy of Establishment License to manufacture medical devices.

(iv) Copy of last inspection report conducted on 10-01-2020.

It is submitted that the firm was also issued GMP Certificate on 15th April, 2020. DRAP has also approved the format of Free Sale Certificate (FSC) for medical devices.

Decision: The Board approved the issuance of Free Sale Certificate for the above mentioned medical devices

Item No. XXXII. NOMINATIONS FOR MDB AS CO-OPT EXPERT

It is submitted that under rule 59 (3) of MDR, 2017, the MDB may co-opt any other person who is expert or any specialty for the disposal of relevant cases.

1. Pakistan Engineering Council (PEC), Islamabad has requested for nomination of following experts as Co-Opt expert of MDB as representative of PEC:-

S.#	Name of Expert	Qualifications
1.	Dr. Mohsin Tiwana, CTO of Tech Valley, Pakistan **Nominee of PEC.**	Ph.D in Biomedical Engineering.
2.	Engr. Dr. Zia Mohy-ud-Din, Head of Biomedical Engineering Department, Associate Professor, Air University, Islamabad. **Nominee of PEC.**	Ph.D in Biomedical Engineering.

2. Furthermore, following two nominations of Co-opt Expert are proposed by Division of MDMC:-

1.	Dr. Muhammad Shafique, Head of Biomedical Engineering Department, Associate Professor, Riphah International University, Islamabad.	Ph.D in Biomedical Engineering.

2.	Dr. Muhammad Zaman, Professor of Biomedical Engineering, Boston University, USA	Ph.D in Chemistry

Decision: The Board approved the above mentioned nominations as Co-Opt members of MDB.

ITEM NO. XXXIII. ADDITIONAL SIZES OF ALREADY REGISTERED MEDICAL DEVICES OF M/S MULLER & PHIPPS PAKISTAN (PVT) LIMITED, KARACHI (AD-IV).

M/s Muller & Phipps Pakistan (Pvt) Limited, Uzma Court, Main Clifton Road, Karachi has requested to grant them additional sizes of their following registered imported medical device as mentioned below:-

S.No	Regn.No.	Name of Medical Device	Name of Manufacturer	Existing Approved Sizes/Codes	Demanded Additional Sizes/ Codes.
1.	MDIR-0000299	DuoDERM Extra Thin Dressing.	**Manufacturer:** M/s Conva Tec Limited, First Avenue, Deeside Industrial Park, Deeside, Flintshire, CH5 2NU, UK	7.5 x 7.5 cm (1x5 PK) GB187951.	187955------10x10 cm (1x10 PK) 187957-------15x15 cm (1x10 PK) 187959--------5x10 cm (1x10 PK) 187961--------5x20 cm (1x10 PK) As per Free Sale Certificate of MHRA.

The firm has deposited fee of Rs.25,000/- for above product and has given application on Form 7-A. Firm has already submitted valid and original and Embassy attested Free Sale Certificates of MHRA mentioning the requested additional codes.

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

ITEM NO.XXXIV: APPROVAL OF ADDITIONAL SIZES OF ALREADY REGISTERED MEDICAL DEVICES (AD-I).

M/s Uniferoz (Pvt) Limited, 32/8 & 33/2, Sector-15, Korangi Industrial Area, Karachi has requested for approval of additional sizes of their following already registered/Enlisted medical devices for local manufacture as per detail mentioned below:-

S.No	Regn.No	Name of Product	Existing Approved Sizes	Demanded Additional Sizes.
1.	MDMR-000055	Dermapore Surgical Wound Dreswsing.	6 cm x 7 cm (10 Sheet/Box) 9 cm x 10 cm (25heet/Box)	6 cm x 10 cm 9 cm x 15 cm 9 cm x 25 cm 10 cm x 20 cm
2.	MDME-00000007	Sanyplast Fabric Bandage.	20 mm x 70 mm = 20 strips 20 mm x 70 mm = 100 strips	**Kunckle**: 38 mm x 76mm **Fingertip**: 45mm x 50mm. **Assorted 3 in 1 20's** **10 Strips** medium 20mm x70mm **05 strips** Kunckle 38mm x 76 mm **05 Strips** Fingertip 45mm x 50mm

The firm has submitted following documents:-

(i) Application form on Form 7 and Form 6.
(ii) Fee challan of Rs.5000/- for each product.
(iii) Copy of registration letter of above mentioned products.
(iv) Copy of Establishment Licence to manufacture medical devices.
(v) Packaging Artworks.

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

Item No.XXXV. <u>DELEGATION OF POWERS REGARDING EXPORT OF MEDICAL DEVICES.</u>

It is submitted that as per MDB in its 8th meeting delegated the powers under rule 27 (1) of Medical Devices Rules, 2017 to Additional Directors of Field Offices of DRAP. The powers under rule 27 (3) & (4) were inadvertently missed in the agenda as well as in minutes of the meeting. Rule 27 (3) & (4) of Medical Device Rules, 2017states as under:-

"(3) For obtaining an export permit under sub-ruel (2) an application on the format as set out in form-12 for an export permit shall be mae to the MDB or an officer Authorized in this behalf and accompanied with the application fee as specified in rule 63.

(4) The MDB or the oficer authorized by its may reject an application made under sub-rule (3) if the applicant fails to deposit the requisite fee or to submit the required information, particulars or documents."

Submitted for deliberation and consideration of MDB for authorization on its behalf in aforesaid cases for smooth functioning and to facilite the exports of the country.

Decision: The Board delegated the powers for performance of above functions under the relevant rules to Additional Directors of DRAP's field offices.

Item No.XXXVI. CANCELLATION OF SOLE AGENCY AGREEMENT.

The termination letter of exclusive sole agency distribution agreement (original notarized) received from M/s. Yangzhou Medline Industry Co., Ltd, China wherein they have informed that due to certain reasons they have terminated M/s. Zenith International, Karachi and M/s. Sultan Sons, Karachi and their register products may be de-registered. They further confirmed that M/s Platinum Corporation has been appointed as exclusive agent for future registration of related products in Pakistan.

It is submitted that following devices of M/s. Yangzhou Medline Industry Co., Ltd, China have been registered/enlisted in favour of M/s. Zenith International, Karachi. Details are as under:-

S.#	Name of Importer	Name of Manufacturer	Name of Medical Device
1.	M/s Zenith International Room No 104, Tahir Plaza, A/20, Block 7 & 8, KCHSU, Karachi.	M/s Yangzhou Medline Industry Co., Ltd. No. 108, Jinshan Road, Economic Development Zone, 225009 Yangzhou Jiangsu. P.R China	Perfect Fine A.D. Disposable Auto Disable Syringe,Sterile with needle [1ml, 2ml, 3ml, 5ml, 10ml, 20ml] Regn.No.MDIR-0001530 Date: 10-06-2020
	-do-	-do-	PERFECT FINE Disposable Syringe Sterile, Without Needle (60ml) Enl.No.MDIE-0000048 Date: 24-12-2019
	-do-	-do-	PERFECT + Disposable Urine Bag, Sterile (2000ml) Enl.No.MDIE-0000049 Date: 24-12-2019

Moreover, the following medical devices have already approved by the MDB in its 14th meeting (subject to inspection of manufacturer abroad) in the name of M/s Zenith International, Karachi from the same manufacturer i.e. M/s. Yangzhou Medline Industry Co., Ltd, No. 108, Jinshan Road, Economic Development Zone, 225009 Yangzhou Jiangsu, P.R. China. Details are as under:-

Name & Address of establishment	Product Name

M/s. Zenith International, Room No. 104, Tahir Plaza, A/20, Block 7&8, KCHSU, Karachi (ELI-00090)	PERFECT FINE Disposable Scalp Vein Set, Sterile Sizes: 19G, 21G, 22G, 23G, 24G, 25G, 26G, 27G
-do-	PERFECT FINE Disposable Infusion Set, Sterile, With Needle. Disposable Infusion Set, Sterile, with Needle, with Burrette (100ml, 150ml)
-do-	PERFECT FINE Disposable Syringe, Sterile with needle (Sizes: 1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml)
-do-	PERFECT Disposable Insulin Syringe, Sterile (U-100) (29G, 30G, 31G) (0.5ml, 1 ml)
-do-	PERFECT Disposable Surgical Hypodermic Needle, Sterile (Sizes: 18G, 19G, 21G, 22G, 23g, 24G, 25G, 26G, 27G)

Decision: Keeping in view the termination of sole agency distribution agreement of above mentioned products by the principal abroad, the Board decided to issue show cause notice to M/s. Zenith International, Karachi to explain their position before the Board.

Item No.XXXVII: MATTERS RELATING TO PAKISTAN ENGINEERING COUNCIL (PEC).

F.R received from Advisor on Innovation-PEC, Pakistan Engineering Council wherein he has enclosed an application of Umbulizer (having US FDA Emergency Use authorization) developed by M/s Umbulizer Inc duly vetted and approved for engineering design and technical performance parameters by PEC to be processed for registration by DRAP. He has enclosed an application on Form-2 (Application for grant of an Establishment License to Import Medical Devices) and Form-7A (Application for registration of a medical device for import).

2. It is submitted that there are some ambiguities related to this case. It is not clear if the product in question i.e. Umbulizer (Breathing device) is to be manufactured in Pakistan or will be imported in finished form from manufacturer abroad and therefore the purpose of application cannot be comprehended. If the product is to be locally manufactured then after confirmation of clinical safety and performance by the competent forum, the application is to be made on Form-1 for grant of Establishment Licence to manfacture

medical devices and subsequently on Form-7 for registration of that locally manufactured device. If the product is imported in finished form then the application for Establishment Licence to import medical device on Form 2 must be submitted by the local sole authorized representative determined by the manufacturer abroad and subsequent application on Form 7-A for registration of the imported medical device. Whereas in this application, the request is made directly from the manufacturer through PEC.

3. It is, therefore, proposed that we may ask PEC to clarify the purpose of application and direct the applicant to apply on the relevant Forms as mentioned above directly to DRAP for further processing of their case. We may also ask them to provide the details of the standards adopted by PEC, the Acceptance test procedure (ATP), the composition and findings of the committee which vetted and approved the engineering design and technical performance parameters of the said device.

In the instant case:-

- it is not clear who is the applicant for the grant of establishment License
- clarification also required whether the proct will be imported or manufacture locally
- the Umbulizer has been granted Emergency Use Authorization for use in USA and the said authorization will cease to exist once the emergency is over

MDB may consider the application for the grant of establishment licese and registration of the product once all the ambiguities are removed and the report of Clinical Study Committee (CSC) is available.

Decision: The Board gave the decision on subject matter while discussing the Case No. 1 of the Additional agenda.

Item No.XXXVIII. 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 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	Decision
1.	M/s. Siemens Healthcare Pvt Ltd., 4th Floor, State Life Building 15-A, Sir Agha Khan Road, Lahore.	**Legal manufacturer** M/s. Siemens Healthcare GmbH, Henkestr. 127, 91052 Erlangen, Germany. **Manufacturing site:**	Cios Family • Cios Alpha Part No:10308191 • Cios connect Part No: 10308193 • Cios Fusion Part No: 10308192	Mobile x-ray c-arm unit for fluoroscopy	**Deferred** The board deferred the case to Prof. Dr. Muhammad Nadeem Ahmad, Department of Radiology, Aga

	ELI-00146 **Evaluator**: AD-IV	M/s. Siemens Healthcare GmbH, Advanced Therapies, Siemensstr. 1, 91301 Forchheim, Germany. **Manufacturing site:** Jabil Inc. 3800 Giddings Road, Auburn Hills, MI 48326, USA FSC Germany Issue Date 11th January, 2017	Class C Service life: 10 years Fee submitted: Rs. 50,000/-		Khan University Hospital, Karachi, Member MDB for his expert opioion whether the applied models can be grouped as family in the light of MDR, 2017 or not ?
2.	M/s Johnson & Johnson Pakistan (Pvt) Ltd., Office No.806, 8th Floor, Horizon Towers, Block 3, Scheme 5, Clifton, Karachi (ELI-00154) **Evaluator**: AD-IV	**Legal Manufacturer:** Ethicon Endo-Surgery, LLC 475 Calle C Guaynabo PR USA 00969. (FSC USFDA valid till 30-10-2020)	Generator G11 (GEN11) Class C Shelf Life: N/A Fee submitted: Rs. 50,000/-	Provides radiofrequency power to drive ENSEAL electrosurgical instruments that are used during open or laproscopic general and gynaecological surgery to cut and seal vessels and to cut, grasp and dissect tissues. Provides power to drive HARMONIC ultrasonic surgical instruments indicated for soft tissue incisions when bleeding control and minimal themal injury are desired	**Approved**
3.	-do- **Evaluator**: AD-IV	**Legal Manufacturer/ Manufacturing site:** Depuy International Limited T/A Depuy CMW, Cornford Road, Blackpool, FY4 4QQ, United Kingdom.	Depuy CMW 3 Gentamicin Bone Cement, 40g (Code: 3335040) Class D Shelf Life: 3 years	A self-curing, radiopaque polymethyl methacrylate based cement containing antibiotic used for securing a	**Approved**

		(FSC UK MHRA issued on 03-04-2019)	Fee submitted: Rs. 50,000/-	metal or polymeric prosthesis to living bone in arthoplasty procedures of joints in which infection by gentamicin sensitive organisms is a potential risk	
4.	-do- **Evaluator**: AD-IV	**Legal Manufacturer/ Manufacturing site:** Ethicon, LLC. Highway 183 Km. 8.3 San Lorenzo, PR USA 00754 (FSC US FDA valid till 10-04-2020)	Ethicon® Temporary Cardiac Pacing Wire (Ref: TPW42) Class D Shelf Life: 5 years Fee submitted: Rs. 50,000/-	Intended for use in temporary epicardiac pacing or monitoring and should be removed after temporary pacing has been discontinued. Sterile, single-use, MR conditional	**Approved** subject to provision of valid Free Sale Certificate.
5.	-do- **Evaluator**: AD-IV	**Legal Manufacturer ;** Ethicon, LLC 475 C Street Los Frailes Industrial Park, Suite 401 Guaynabo, PR USA 00969. **Manufacturing Site:** Ethicon, INC. Calle Durango No. 2751, Lote Bravo, Ciudad Juarez, Chihuahua Mexico C.P 32575. (FSC US FDA valid till 08-04-2021)	Ethicon SECURESTRAP™ Absorbable Strap Fixation Device Class D Codes: STRAP25 STRAP12 Shelf Life: 24 Months Fee submitted: Rs. 50,000/-	Intended for fixation of prosthetic material to soft tissues in various minimally invasive and open surgical rpocedures such as hernia repairs	**Approved**
6.	-do- **Evaluator**: AD-IV	**Legal Manufacturer:** Biosense Webster, Inc. 33 Technology Drive Irvine, CA USA 92618 **Manufacturing sites:** 1. Biosense Webster, Inc, 15715 Arrow Hwy, Irwindale, CA USA. 91706	Webster® CS Catheter with EZ Steer™ Technology Class D Codes: 36D5JR, 36D35R Shelf Life: 36 Months	Deflectable Tip Electrophysiology Catheters indicated for electrophysiological mapping of cardiac structures; i.e stimulation	**Approved**

		2. Biosense Webster, Inc, Circuito Interior Norte, No. 1820 Parque Industrial Salvarcar Juarez, Chihuahua Mexico 32574 (FSC USFDA valid till 21-02-2021)	Fee submitted: Rs. 50,000/-	and recording only. The catheter is designed for use in the coronary sinus. Sterile, single-use	
7.	-do- **Evaluator**: AD-IV	**Legal Manufacturer:** Ethicon LLC, 475 C, Street, Los Frailes Industrial Park, Suite 401 Guaynabo PR. USA 00969 **Manufacturing site:** Ethicon INC. Calle Durango No 2751, Lote Bravo, Ciudad Juarez Chihuahua Mexico C.P 32575. (FSC US FDA valid till 08-04-2021)	Ethicon® Nylon Tape (Code: W277) Size: 6mm x70 cm Pack size: 12/box Class B Shelf Life: 5 years Fee submitted: Rs. 25,000/-	Sterile, single-use, non-absorbable, non-needled, white nylon tape indicated for temporary ligation or retraction of tissues, organs or other anatomical structures during surgical procedures. Not intended to be implanted in the body	**Approved**
8.	-do- **Evaluator**: AD-IV	**Legal Manufacturer:** Ethicon Inc. Route 22 West, P.O. Box 151, Somerville, New Jersey USA, 08876. **Manufacturing Site:** Ethicon, Inc. 3348 Pulliam St. San Angelo, TX USA, 76905 (FSC US FDA valid till 26-05-2022)	Vicryl™ (Polyglactin 910) Mesh Class D Code: 1. VKMMC Size: 15cm x 15cm Pack size: 3 units/box 2. VKMLC Size: 30cm x 30cm Pack size: 3 units/box (Codes not in FSC, codes present in DOC) Shelf Life: 60 Months Fee submitted: Rs. 50,000/-	Undyed knitted absorbable mesh used for temporary wound or organ support. Sterile, single-use	**Approved** subject to provision of original and legalized Free Sale Certificate.
9.	-do- **Evaluator**:	**Legal Manufacturer:** Biosense Webster, Inc,	Celsius® FTLR™ Catheter (uni-directional)	Indicated for cardiac electrophysiolo	**Approved.**

	AD-IV	33 Technology Drive Irvine, CA USA. **Manufacturing sites:** 1. Biosense Webster, Inc, 15715 Arrow Hwy, Irwindale, CA USA. 91706 2. Biosense Webster, Inc, Circuito Interior Norte, No. 1820 Parque Industrial Salvarcar Juarez, Chihuahua Mexico 32574 (FSC USFDA valid till 21-02-2021)	Class D Codes: D135501 D135502 Shelf Life: 3 Years Fee submitted: 50,000/-	gical mapping (stimulation and recording) and, when used in conjunction with a radiofrequency generator, for cardiac ablation. Sterile, single-use	
10.	-do- **Evaluator**: AD-IV	**Legal Manufacturer:** Biosense Webster, Inc, 33 Technology Drive Irvine, CA USA. **Manufacturing sites:** 1. Biosense Webster, Inc, 15715 Arrow Hwy, Irwindale, CA USA. 91706. 2. Biosense Webster, Inc, Circuito Interior Norte, No. 1820 Parque Industrial Salvarcar Juarex, Chihuahua Mexico 32574 (FSC US FDA valid till 21-02-2021)	EZ Steer Thermocool Catheter (Non-Nav catheter) Class D Codes: 36Q35M 36Q5JM 36Q33M 36Q55M 36QJJM Shelf Life: 3 Years Fee submitted: Rs 50,000/-	Indicated for use in catheter based cardiac electrophysiological mapping (stimulating and recording) and when used in conjunction with a radiofrequency generator, for cardiac ablation.	**Approved**
11.	-do- **Evaluator**: AD-IV	**Legal Manufacturer:** Biosense Webster, Inc, 15715 Arrow Hwy, Irwindale, CA USA. 91706. **Contract Manufacturer:** Siemens Healthineers Ltd, 2nd& 3rd Venture Building, Pohang Technopark, 394, Jigok-	Soundstar 3D Diagnostic Ultrasound Catheter Class D Codes: SNDSTR10 SNDSTR10G Shelf Life: 2 Years	Indicated for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices	**Approved** subject to provision of valid Free Sale Certificate.

		ro, Nam-gu, Pohang-si, Gyeongsangbugdo, republic of Korea. (FSC US FDA valid till 23-05-2020)	Fee submitted: Rs. 50,000/-	in the heart. Sterile, single-use	
12.	-do- **Evaluator**: AD-IV	**Legal manufacturer:** DePuy orthopaedics, Inc. 700 orthopaedic Dr. Warsaw, In USA. **Manufacturing Site:** Johnson & Johnson Medical (DEPUY – Suzhou) Ltd, No.299, Changyang street Suzhou industrial Park Suzhou, Jiangsu China. **Manufacturing Site:** DePuy Intl., Ltd St. Anthonys Rd. Leeds, Leeds United Kingdowm LS11 8DT (FSC Valid till 16-07-2020) DePUY (Ireland) Loughbeg Ringaskiddy Co. Cork Ireland. (FSC Valid till 21-09-2022) DePuy Intl., Ltd St. Anthonys Rd. Leeds, Leeds United Kingdowm LS11 8DT (FSC Issuance 26-07-2018)	Cemented Cups Sizes & Codes: 1. Elite Plus Cup OGEE Cemented LPW 28mmIDX40mmOD (965328040) 2. Elite Plus cup OGEE Cemented LPW 28mmIDX40mmOD (965328043) 3. Marathon XLPE Cemented Cup 36IDX53OD (965513653) Class D Shelf life: 5 Years Fee submitted: Rs. 50,000/-	Generally accepted indications for joint replacement include: Severearthropathy due to advance rheumatoid or osteo-arthritis where sonservative therapy or alternative treaments have failed or are considered unsuitable.	**Deferred** for clarification/ provision of following documents:- i) The device namely **cemented cup** is not found on Free Sale certificate. ii) Multiple Free Sale Certificates submitted. iii) Clearly state the Brand Name required and the product codes relating to the brand name. iv) the legal manufacturer and manufacturing sites of the product and highlight it on Free Sale Certificates, as well as provide all the relevant technical documents (stability studies, EPSP, DOC, manufacturing and quality control processes etc) as per the type required.

					v) Multiple systems cannot be applied on one application. vi) Provide labels for the required codes and IFU vii) Justify the grouping as per grouping criteria in MDR, 2017 supported by brochure, labels, Free Sale Certificate, Design-Examination Certificate and Declaration of Conformity etc viii) Provide MRP for the required codes ix) Letter of Authorization from the manufacturer abroad does not indicate Exclusive/ Sole authorization to the importer, validity not mentioned, list of products authorized not mentioned and complete address of importer not mentioned. (This shortcoming is applicable to all DePuy Orthopaedics, Inc products)

13.	-do- **Evaluator**: AD-IV	**Legal Manufacturer:** DePuy Orthopaedic, Inc., 700 Orthopaedic Drive Warsaw, Indiana, 46582, DePuy International Ltd. St Anthony's Road, Leeds LS11 8DT, United Kingdom. (FSC UK 19-05-2019)	C-Stem C-Stem Class B Shelf Life: Non-sterile instruments (Sizes & Codes as Per FSC) 235410000 Muller awl reamer w/Hudson 257004100 Summit Calcar Planer-small 257004200 Summit Calcar Planer – Large Fee submitted: Rs. 25,000/-	An orthopaedic surgical instrument designed to open and enlarge medullary canal (e.g. in the femur, humerus, tibia, ulna) for the insertion of various devices during prosthesis implanatation or fracture fixation procedures.	**Deferred** for clarification/ provision of following documents:- i) The device namely **C-stem** is not found on Free Sale certificate. ii) Multiple Free Sale Certificates submitted and multiple legal manufacturers mentioned. iii) Clearly state the Brand Name required and the product codes relating to the brand name, the legal manufacturer and manufacturing sites of the product and highlight it on Free Sale Certificates, as well as provide all the relevant technical documents (stability studies, EPSP, DOC, manufacturing and quality control processes etc) as per the type required. iv) Multiple legal manufacturers cannot be applied on one application.

					v) Provide labels for the required codes, IFU and brochure vi) Justify the grouping as per grouping criteria in MDR, 2017 supported by brochure, labels, Free Sale Certificate, Declaration of Conformity etc vii) Provide MRP for the required codes viii) Letter of Authorization from the manufacturer abroad does not indicate Exclusive/ Sole authorization to the importer, validity not mentioned, list of products authorized not mentioned and complete address of importer not mentioned. ix) (This shortcoming is applicable to all DePuy Orthopaedics, Inc products)
14.	M/s Roche Pakistan Limited, 1st floor, 37-B, Block-6, P.E.C.H.S, Karachi. (ELI-00009)	**Manufacturer:** Roche Diagnostics GmbH, Sandhofer Str. 116, 68305 Mannheim, Germany. (FSC Germany issued on 15-03-2017) (FSC Germany issued on 22-08-2018)	Diabetes Assay CPS (Centralized and Point of Care Testing Solutions) Cluster Class B 1. Elecsys C-Peptide Shelf life: 19 months Size:100 Tests	1- Immunoassay for the in vitro quantitative determination of C-peptide in human serum, plasma and urine. The assay is	**Approved subject to differential fee**

	Evaluator: AD-IV	(FSC Germany issued on 19-09-2016) (FSC Germany issued on 09-01-2019) (FSC Germany issued on 09-07-2019-Not Embassy attested)	Code: 03184897 2. Elecsys C-Peptide Shelf life: 19 months Size:100 Tests Code: 07027168190 3. C-Peptide CalSet Shelf life: 18 months Code:03184919 4. Elecsys Insulin Shelf life: 19 months Size: 100 Tests Code: 12017547 5. Elecsys Insulin Shelf life: 19 months Size:100 Tests Code: 07027559190 6. Insulin CalSet Shelf life: 18 months Code:12017504 7. cobas HbA1c (Hemoglobin A1c) Test Shelf life: 22 months Size:10 Tests Code:06378676 8. A1C-3 Tina-quant Hemoglobin A1c Gen.3 Shelf life: 22 months Size: 150 Tests. Code: 05336163190 9. A1C-3 cobas c111 Tina-quant Hemoglobin A1c Gen.3 Shelf life: 18 months Size: 2 x 100 Tests. Code: 05336180190 10. A1CX3 Tina-quant Hemoglobin A1cDx Gen.3. Shelf life: 18 months Size: 200 Tests Code:08445699190 11. A1CX3 Tina-quant Hemoglobin A1cDx Gen.3	intended for use as an aid in the diagnosis and treatment of patients with abnormal insulin secretion 2- Immunoassay for the in vitro quantitative determination of C-peptide in human serum, plasma and urine. The assay is intended for use as an aid in the diagnosis and treatment of patients with abnormal insulin secretion. 3- C-Peptide CalSet is used for calibrating the quantitative Elecsys C-Peptide assay on the Elecsys and cobas e immunoassay analyzers. 4- Immunoassay for the in vitro quantitative determination of human insulin in human serum and plasma. The determination of insulin is utilized in the diagnosis and therapy of various	

			Shelf life: 18 months Size: 500 Tests Code: 08056668190 12. A1CX3 Tina-quant Hemoglobin A1cDx Gen.3 Shelf life: 18 months Size: 500 Tests Code: 07559674190 13. cobas HbA1c Control. Shelf life: 18 months Code: 06380204 14. A1CD2 cobas c111 Hemolyzing Reagent Gen.2 Shelf life: 18 months Code:05007232 15. A1CD2 Hemolyzing Reagent Gen.2 Shelf life: 18 months Size:51 mL. Code: 04528182 16. A1CD Hemolyzing Reagent Shelf life: 18 months Size: 50 mL Code: 08463107190 17. A1CD Hemolyzing Reagent Shelf life: 18 months Size:98 mL. Code:07224648190 18. C.f.a.s. HbA1c Shelf life: 24 months Code: 04528417190 19. PreciControl HbA1c norm Shelf life: 19 months Code: 05479207190 20. PreciControl HbA1c path Shelf life: 19 months Code: 05912504190 21. Hemolyzing Reagent Roce/Hitchi	disorders of carbohydrate metabolism, including diabetes mellitus and hypoglycemia. 5-Immunoassay for the in vitro quantitative determination of human insulin in human serum and plasma. The determination of insulin is utilized in the diagnosis and therapy of various disorders of carbohydrate metabolism, including diabetes mellitus and hypoglycemia 6-Insulin CalSet is used for calibrating the quantitative Elecsys Insulin assay on the Elecsys and cobas e immunoassay analyzers. 7- The cobas b 101 is an in vitro diagnostic test system designed to quantitatively determine the % hemoglobin A1c (DCCT/NGSP) and mmol/mol hemoglobin A1c (I	

			Shelf life: 18 months Size: 1000 mL. Code: 11488457122	FCC) in human capillary and venous whole blood by photometric transmission measurement. An estimated average glucose level (eAG) is calculated by the cobas b 101 system. The system is intended for professional use in a clinical laboratory setting, or point of care (PoC) locations 8-In vitro test for the quantitative determination of mmol/mol hemoglobin A1c (IFCC) and % hemoglobin A1c (DCCT/NGSP) in whole blood or in hemolysate on Roche/Hitachi cobas c systems. 9-In vitro test for the quantitative determination of mmol/mol hemoglobin A 1c (IFCC) and % hemoglobin A1c (DCCT/NGSP	

				) in whole blood and hemolysates prepared from whole blood on the cobas c 111 system. HbA1c determinations are useful for monitoring of long-term blood glucose control in individuals with diabetes mellitus. Moreover, this test is to be used as an aid in diagnosis of diabetes and identifying patients who may be at risk for developing diabetes 10-In vitro test for the quantitative determination of mmol/mol hemoglobin A 1c (IFCC) and % hemoglobin A1c (DCCT/NGSP) in whole blood or hemolysate on Roche/Hitachi cobas c systems. HbA1c determinations are useful for monitoring of long-term blood glucose control in individuals with diabetes mellitus.	

				Moreover, this test is to be used as an aid in diagnosis of diabetes and identifying patients who may be at risk for developing diabetes. 11-In vitro test for the quantitative determination of mmol/mol hemoglobin A 1c (IFCC) and % hemoglobin A1c (DCCT/NGSP) in whole blood or hemolysate on Roche/Hitachi cobas c systems. HbA1c determinations are useful for monitoring of long-term blood glucose control in individuals with diabetes mellitus. Moreover, this test is to be used as an aid in diagnosis of diabetes and identifying patients who may be at risk for developing diabetes 12. In vitro test for the quantitative determination of mmol/mol hemoglobin A 1c (IFCC) and	

				% hemoglobin A1c (DCCT/NGSP) in whole blood or hemolysate on Roche/Hitachi cobas c systems. HbA1c determinations are useful for monitoring of long-term blood glucose control in individuals with diabetes mellitus. Moreover, this test is to be used as an aid in diagnosis of diabetes and identifying patients who may be at risk for developing diabetes. 13- cobas HbA1c Control solution is used for performing quality control of HbA1c with cobas HbA1c reagent discs on the cobas b 101 instrument 14-The hemolyzing reagent is used as diluent for the Tina-quant Hemoglobin A1c assays on the cobas c 111 system.	

				15 -The hemolyzing reagent is used as diluent for the Tina-quant Hemoglobin A1c Gen.3 assay on cobas c systems. 16-The hemolyzing reagent is used as diluent for the Tina-quant Hemoglobin A1c Gen.3 assay on cobas c systems. 17-The hemolyzing reagent is used as diluent for the Tina-quant Hemoglobin A1cDx Gen.3 assay on the cobas c 513 system. 18-C.f.a.s. (Calibrator for automated systems) HbA1c is for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the enclosed value sheets. 19-PreciControl HbA1c norm is for use in quality control	

				by monitoring accuracy and precision for the quantitative methods as specified in the value sheets. 20-PreciControl HbA1c path is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheets. 21-In vitro test for the quantitative determination of mmol/mol hemoglobin A1c (IFCC) and % hemoglobin A1c (DCCT/NGSP) in whole blood or in hemolysate on Roche/Hitachi cobas c systems.	
15.	M/s Intek Corporation Office No. 30, First Floor, Al-Amin Plaza, The Mall Rawalpindi. ELI- 00034 **Evaluator**: AD-IV	**Manufacturer:** NuMED Canada Inc. 45 Second Street West Cornwall ON, K6J IG3 FSC Canada Date of issue 6th Feb, 2019	Z-MED II-X™ PTV Catheter Class D Codes: PDZ700, PDZ701, PDZ702, PDZ703, PDZ704, PDZ705, PDZ706, PDZ707, PDZ708, PDZ709, PDZ710, PDZ711, PDZ712, PDZ713, PDZ714, PDZ715, PDZ716, PDZ717, PDZ718, PDZ719,	Sterile, single-use catheter recommended for Percutaneous Transluminal Valvuloplasty (PTV) of the pulmonary valve. • A patient with isolated pulmonary stenosis. • A patient with valvular	**Approved.**

			PDZ720, PDZ721, PDZ722, PDZ723, PDZ724, PDZ725, PDZ726, PDZ727, PDZ728, PDZ729, PDZ730, PDZ731, PDZ732, PDZ733, PDZ734, PDZ735, PDZ736, PDZ737, PDZ738, PDZ739, PDZ740, PDZ741, PDZ742, PDZ743, PDZ744, PDZ745, PDZ746, PDZ747, PDZ748, PDZ749, PDZ750, PDZ751, PDZ752, PDZ753 Shelf life: 05 years Fee submitted: Rs. 50,000/-	pulmonary stenosis with other minor congenital heart disease that does not require surgical intervention.	
16.	-do- **Evaluator**: AD-IV	**Manufacturer:** NuMED Canada Inc. 45 Second Street West Cornwall ON, K6J IG3 FSC Canada Date of issue 7-12-2018	Z-5™ Atrioseptostomy Catheter Class D Codes: SPT002, SPT003 Shelf life: 05 years Fee submitted: Rs. 50,000/-	Sterile, single-use catheter recommended for balloon atrioseptostomy for the palliation of several congenital cardiac defects.	**Approved.**
17.	-do- **Evaluator**: AD-IV	**Legal Manufacturer/Manufacturing site:** Terumo Europe N.V., Interleuvenlaan 40, 3001 Leuven, Belgium FSC Belgium Date of issue 20th June,2019	Radifocus® Glidecath™ (Angiographic Catheter) Class D Codes: RF-ZB34108M RF-ZV1410GM RF-ZB44108M RF-ZV14110M RF-ZB4410GM RF-ZV9410GM RF-ZB54108M RF-ZV94110M RF-ZB5410GM RF-ZVZ410GM RF-ZB54110M RF-ZW3410GM RF-ZB64108M	Intended for use in angiographic procedures in peripheral and neural vasculature. It delivers radiopaque media and therapeutic agents to selected sites in the vascular system. It is also used to lead a guidewire or a	**Approved.**

			RF-ZW34110M RF-ZB6410GM RF-ZWC4108M RF-ZBV4110M RF-ZWD4108M RF-ZD4410GM RF-YA15108M RF-ZDJ4108M RF-YA15110M RF-ZFC410GM RF-YA25108M RF-ZM74108M RF-YA25110M RF-ZM7410GM RF-YB15110M RF-ZM74110M RF-YE15110M RF-YE25110M RF-XB55108M RF-YG15110M RF-XB5510GM RF-YH15110M RF-XB55110M RF-WA14107M RF-XB65108M RF-WA14110M RF-XB6510GM RF-WA24110M RF-XD4510GM RF-WB14110M RF-XFB5109M RF-WE14110M RF-XIR510GM RF-WE24110M RF-XIR5110M RF-WG14110M RF-XM75104M RF-WH14108M RF-XVZ510GM RF-WH14110M RF-XW35110M RF-XB15108M RF-XWC5108M RF-XB45108M RF-XB4510GM Shelf life: 36 months Fee submitted: Rs. 50,000/-	catheter into the target site.	
18.	-do-	**Manufacturer:** NuMED Canada Inc.	Tyshak-X™ PTV Catheter	Sterile, single-use catheter	**Approved.**

	Evaluator: AD-IV	45 Second Street West Cornwall ON, K6J IG3 FSC Canada Date of issue 6th Feb, 2019	Class D Codes: PDC300, PDC301, PDC302, PDC303, PDC304, PDC305, PDC306, PDC307, PDC308, PDC309, PDC310, PDC311, PDC312, PDC313, PDC314, PDC315, PDC316, PDC317, PDC318, PDC319, PDC320, PDC321, PDC322, PDC323, PDC324, PDC325, PDC326, PDC327, PDC328, PDC329, PDC330, PDC331, PDC332, PDC333, PDC334, PDC335, PDC336, PDC337, PDC338, PDC339, PDC340, PDC341, PDC342, PDC343, PDC344, PDC345, PDC346, PDC347 Shelf life 05 years Fee submitted: Rs. 50,000/-	recommended for Percutaneous Transluminal Valvuloplasty (PTV) of the pulmonary valve. • A patient with isolated pulmonary stenosis. • A patient with valvular pulmonary stenosis with other minor congenital heart disease that does not require surgical	
19.	-do- **Evaluator**: AD-IV	**Manufacturer:** Terumo Medical Corporation 950 Elkton Boulevard, Elkton, Maryland USA, 21921, FSC US FDA valid till 07.04.2021	Destination® Carotid Guiding Sheath Class: D Sizes and codes as per US FDA CFG No. 7777-4-2019 Shelf Life: 30 months Fee submitted: Rs.50,000/-	Designed to be used for the introduction of interventional and diagnostic devices into the human vasculature, including but not limited to the carotid arteries. Sterile, single-use.	**Approved.**
20.	-do- **Evaluator**: AD-IV	**Manufacturer:** Terumo Europe N.V., Interleuvenlaan 40, 3001 Leuven, Belgium	Radifocus® Introducer II (Trans-radial Kit) Class- B Codes:	Intended for percutaneous insertion into the radial artery in order to facilitate the	**Approved.**

		FSC Belgium Date of issue 20th June, 2019	RT-R40A07PQ RT-R50G07PQ RT-R40A10PQ RT-R50G10PQ RT-R40D07PQ RT-R60A07PQ RT-R40D10PQ RT-R60A10PQ RT-R40G07PQ RT-R60D10PQ RT-R40G10PQ RT-R60G07PQ RT-R50A07PQ RT-R60G10PQ RT-R50A10PQ RT-R70D10PQ RT-R50D10PQ Shelf Life: 30 Months Fee submitted: Rs. 25,000/-	introduction of angiographic electrode, balloon or similar catheters Sterile, single-use	
21.	-do- **Evaluator**: AD-III	**Legal manufacturer** NuMED, Inc. 2880 Main Street Hopkinton, NY 12965 USA FSC USA Valid till 20.05.2021	D'VILL Introducer (Introducer) DV1230, DV1265, DV1285 DV1430, DV1465, DV1485 Class B Shelf life 05 years Rs. 25,000/-	The D'VILL Introducer is indicated for introduction of balloons, catheters and other diagnostic and interventional devices	**Approved.**
22.	M/s. Optisurg 17- C1, Valencia Town, Lahore. ELI-00305 **Evaluator**: AD-IV	**Manufacturer:** M/s. MORIA S.A., 15 Rue George Besse F92160 Antony, France FSC France valid till 3-7-2020	Evolution 3e Control Unit Ref No. 19380 Class B Life time: 5 years Fee submitted: Rs. 25,000/-	Control unit of the microkeratome system which is used on two kinds of surgeries, Refractive Surgery and Corneal Graft Surgery.	**Approved** subject to provision of valid Free Sale Certificate and notarized Letter of Authorization.
23.	M/s. Optisurg 17- C1, Valencia Town, Lahore.	**Manufacturer:** M/s. MORIA S.A., 15 Rue George Besse F92160 Antony, France	ONE® Vacuum Trephine Adjustable CLASS: B	Designed for performing corneal grafts (lamellar or	**Approved** subject to provision valid Free Sale

	ELI-00305 **Evaluator**: AD-IV	FSC France valid till 3-7-2020	Code: 17202D600 17202D650 17202D675 17202D700 17202D725 17202D750 17202D775 17202D800 17202D825 17202D850 17202D875 17202D900 17202D950 17202D1000 Shelf life: 59 months Fee submitted: Rs. 25,000/-	penetrating keratoplasty. Sterile, single-use	Certificate and notarized Letter of Authorization .
24.	-do- **Evaluator**: AD-IV	**Manufacturer:** M/s. MORIA S.A., 15 Rue George Besse F92160 Antony, France FSC France valid till 3-7-2020	ONE® Vacuum Trephine Class B Code: 17201D700 17201D725 17201D750 17201D775 17201D800 17201D825 17201D850 17201D875 17201D900 17201D950 Shelf Life: 59 months Fee submitted: Rs. 25,000/-	Designed for performing penetrating keratoplasty. Sterile, single-use	**Approved** subject to provision of valid Free Sale Certificate and notarized Letter of Authorization
25.	-do- **Evaluator**: AD-IV	**Manufacturer:** M/S LENSTEC (BARBADOS) INC. Airport Commercial Centre, Pilgrim Road, Christ Church, BB17092, Barbados FSC Barbados, West Indies (copy provided, not embassy attested):	Softec HP1™ (hydrophobic posterior chamber intraocular lens) Class: C Shelf Life: 5 Years Fee submitted: Rs. 50,000/-	Sterile, single-use, single piece, biconvex, ultraviolet absorbing intraocular lens designed for insertion into the posterior chamber of the	**Approved.**

		Date of Issue: May 22, 2018 FSC UK MHRA Date of Issue: 12-04-2019		human eye for visual correction of aphakia and as a replacement of damaged (cataract) natural lens	
26.	-do- **Evaluator**: AD-IV	**Manufacturer:** M/S LENSTEC (BARBADOS) INC. Airport Commercial Centre. Pilgrim Road. Christ Church, BB17092, Barbados FSC Barbados, West Indies (copy provided, not embassy attested): Date of Issue: May 22, 2018 FSC US FDA valid till 13-02-2021	Softec HDM™ (Posterior Chamber Intraocular Lens) Class: C Shelf Life: 5 Years Fee submitted: Rs. 50,000/-	Sterile, single-use, single-piece intraocular lens with "modified C loop" haptics designed for insertion in the posterior chamber of the eye for visual correction of aphakia	**Approved.**
27.	-do- **Evaluator**: AD-IV	**Manufacturer:** M/S LENSTEC (BARBADOS) INC. Airport Commercial Centre. Pilgrim Road. Christ Church, BB17092, Barbados FSC Barbados, West Indies (copy provided, not embassy attested): Date of Issue: May 22, 2018 FSC US FDA valid till 13-02-2021	Softec I™ (Posterior chamber intraocular lens Class: C Shelf Life: 5 Years Fee submitted: Rs. 50,000/-	Sterile, single-use, single-piece intraocular lens with "modified C loop" haptics designed for insertion in the posterior chamber of the eye for visual correction of aphakia.	**Approved.**
28.	M/s Schazoo, SPL, Consumer Health care 71 B/C2, Gulberg 3, Lahore ELI-00095 **Evaluator**:	**Manufacturer:** Bio Science GmbH, Walshmuhler Street 18 19073, Dummer Germany FSC Germany Date of issue 21.05.2019	Hyacorp Lips (Hylan Gel) Class D Ref: BS070 Hyaluronic Acid Gel Crosslinked: 16 mg Hyaluronic Acid 2mg Volume: 1ml Shelf life: 3 years	Sterile, single-use gel implant produced from hyaluronic acid intended for the restoration of volume and contour of the lips supplied in a pre filled	**Approved.**

	AD-IV		Fee submitted: Rs. 50,000/-	syringe. Dermal filler	
29.	-do- **Evaluator**: AD-IV	**Manufacturer:** Bio Science GmbH, Walshmuhler Street 18 19073, Dummer Germany FSC Germany Date of issue 21.05.2019	Hyacorp Face (Hylan Gel) Class D 1. Ref: BS069 Hyaluronic Acid Gel Crosslinked: 20 mg Hyaluronic Acid 2mg Volume: 1ml 2. Ref: BS087 Hyaluronic Acid Gel Crosslinked: 20 mg/ml Hyaluronic Acid 2mg/ml Volume: 2x2ml Shelf life 36 months Fee submitted: Rs. 50,000/-	Sterile, single-use gel implant produced from hyaluronic acid indicated for the restoration of the facial volume and contour: replaces lost hyaluronic acid in the skin, is used for volume replacement (filling of folds), medium to deep folds, nasolabial folds, check area, glabella folds supplied in a pre filled syringe. Dermal filler	**Approved.**
30.	-do- **Evaluator**: AD-IV	**Manufacturer:** Bio Science GmbH, Walshmuhler Street 18 19073, Dummer Germany FSC Germany Date of issue 21.05.2019	Hyacorp Body Contouring MLF2 (Hylan Gel Contour) Class D Ref. BS088 Hyaluronic Acid crosslinked: 20 mg Hyaluronic Acid: 2 mg Volume: 10ml Shelf life 3 years Fee submitted: Rs. 50,000/-	Sterile, single-use gel implant produced from hyaluronic acid intended for volume replacement and contouring of body surfaces sch as buttocks, calves, correction of concave deformities, supplement after plastic surgery processes such as liposuction, supplied in a pre filled syringe. Not intended for	**Approved.**

				use in facial region	
31.	-do- **Evaluator**: AD-IV	**Manufacturer:** Bio Science GmbH, Walshmuhler Street 18 19073, Dummer Germany FSC Germany Date of issue 21.05.2019	Hyacorp Fine (Hylan Solution) Class D Ref. BS074 Hyaluronic acid: 14mg Volume: 1ml Shelf life 3 years Fee submitted: Rs. 50,000/-	Sterile, single-use gel implant produced from hyaluronic acid intended to replace lost hyaluronic acid in the skin, increases elasticity, improves skin hydration, provides skin with a fresh look through its lifting effect and restores lost anatomical structures of the skin, supplied in a pre filled syringe.	**Approved.**
32.	-do- **Evaluator**: AD-IV	**Manufacturer:** Bio Science GmbH, Walshmuhler Street 18 19073, Dummer Germany FSC Germany Date of issue 21.05.2019	Hyacorp Body Contouring MLF1 (Hylan Gel Contour) Class D Ref. BS089 Hyaluronic Acid crosslinked: 20 mg Hyaluronic Acid: 2 mg Volume: 10ml Shelf life 3 years Fee submitted: Rs. 50,000/-	Sterile, single-use gel implant produced from hyaluronic acid intended for volume replacement and contouring of body surfaces sch as buttocks, calves, correction of concave deformities, supplement after plastic surgery processes such as liposuction, supplied in a pre filled syringe. Not intended for use in facial region	**Approved.**

33.	M/s. Cardiac Care, 848-C Shadman-I, Lahore. ELI-00070 **Evaluator**: AD-IV	**Manufacturer:** VYGON, 5 rue Adeline, 95440 Ecouen. France. FSC France valid till 9th May. 2021	EASY DRAIN **(**Percutaneous thoracic drain) Class: B Codes: 681.06 681.08 681.082 681.10 Shelf Life: 5 years Fee submitted: Rs. 25,000/-	Sterile, single-use catheter for pleural/thoracic drainage in case of pleural effusions, hemothorax and pneumothorax	**Approved.**
34.	-do- **Evaluator**: AD-IV	**Manufacturer:** Pacific Hospital Supply Co, Ltd. 4F, No. 160, Daye Road, Beitou District, 122 Taipei, Taiwan (ROC) FSC Germany issued on 05.06.2018	PAHSCO® FEEDING TUBE (Pediatric) Class: B Codes: I05105----5FR I05106----6FR I05108----8FR I05110----10FR Shelf Life: 3 years Fee submitted: Rs. 25,000/-	Designed to provide nutrition to patients who cannot obtain nutrition by swallowing or aspiration. Sterile, single-use	**Approved.**
35.	-do- **Evaluator**: AD-IV	**Manufacturer:** Pacific Hospital Supply Co, Ltd. 4F, No. 160 Daye Road, Beitou District, 12268 Taipei, Taiwan FSC Germany issued on 05.06.2018	PAHSCO® Stomach Tube Class: B Codes: I02112-----12FR I02114-----14FR I02116-----16FR I02118-----18FR I02726-----20FR I02316-----16FR I02712-----12FR Shelf Life: 3 years Fee submitted: Rs. 25,000/-	Designed for nasogastric introduction for nutritional purposes and aspiration of intestinal secretions. Sterile, single-use	**Approved.**
36.	-do- **Evaluator**: AD-IV	**Manufacturer:** M/s. PRO-ACTIVE S.r.l. Via del	Pro-Active Pro-Long Tube Class: B	Extension lines for fluid canalization and optionally,	**Approved** subject to provision of details of manufacturing

		Commercio 12, 45100 Rovigo (RO) Italy FSC Italy Date of Issue: 12.03.2018	Codes: E38LL/120 E38LL/150 Shelf life: 5 years Fee submitted: Rs. 25,000/-	with flow controller to be connected to an administration device. Sterile, single-use	and QC tests/certificate of analysis.
37.	-do- **Evaluator**: AD-IV	**Legal manufacturer** VYGON, 5 RULE Adeline- 95440 Ecouen France. FSC FRANCE Issued on 04.05.2018	**(Octopus)** (Octopus) Code: ARE 841.264 , 841.364 Class: B Self Life 3 years	Add-on device for intravenous..	**Deferred** for clarification/ provision of following documents:- i) Multiple brand names applied on one application. ii) Clearly state the brand name required on this application along with codes/ref no. required for that brand name supported by labels and brochures. iii) Multiple products cannot be applied on one application. iv) Free Sale Certificate is not clear and different products are mentioned with same brand name. v) Provide valid Embassy Attested Free Sale Certificate from country of origin clearly differentiating among different products i.e

					octopus 1, 2, 3 etc and their corresponding codes against each type. vi) Letter of Authorization expired. Provide valid and notarized Letter of Authorization/ Agency agreement giving sole authorization to the importer clearly mentioning the products for which sole authority is given vii) ISO 13485 and Full Quality Assurance not notarized. Provide notarized certificates viii) Provide MRP of the applied product ix) Provide real-time aging studies (detailed) clearly mentioning the claimed shelf life, signed by responsible personnel of manufacturer abroad
38.	-do- **Evaluator**: AD-III	Legal Manufacturer: M/s Vygon, 5 rule Adeline (95440) Ecouen, France	**V-Green extension** Lectrocath **Code:71100.**	This estension tube is recommended for the administration of solutions or drugs which	**Approved** subject to provision of following documents:-

		FSC France Issued Date 12.10.2016	**Class B** **Shelf Life 05 years**	give rise to interactions with (absorption, migtaion of plasticzers).	i) Proposed MRP on Form. ii) Provide required codes and clarification regarding grouping of medical device. iii) Provide labels of applied product and brochers. iv) Provide agency agreement.
39.	M/s. ASTO Life Sciences (Pvt) Ltd Plaza No. 1 Block Orchard 1, Paragon City, Barki Road, Lahore ELI-00103 **Evaluator**: AD-IV	**Legal manufacturer:** Becton Dickinson Infusion Therapy Systems Inc. 9450 South State Street Sandy, Utah 84070., United States **Manufacturing site:** Becton Dickinson Medical (s) Pte Ltd 30 Tuas Avenue 2 Singapore, 693461 FSC Singapore date of issue 28 February, 2019	BD Angiocath Plus ™ I.V. catheters Class B Sizes and Codes: 382412------24GA 382423------22GA 382434------20GA 382444------18GA Shelf Life: 05 years Fee submitted: Rs. 25,000/-	Sterile, single-use conventional (non safety) over-the-needle intravascular catheter inserted into a patient's vascular system to administer fluids, medications or blood products, to obtain blood samples and to monitor blood pressure.	**Approved** subject to inspection of manufacturer aboard under rule 71 of MDR, 2017 or provision of CE mark documents. and provision of following documents:- i) Stability studies supporting the claimed shelf life of 5 years ii) Original and notarized Letter of Authorization .
40.	-do- **Evaluator**: AD-IV	**Manufacturer:** BECON, DICKINSON & CO. 7 Loveton CIR Sparks, MD USA 21152	BD DIFCO ™ Neisseria Meningitidis Antiserum Class B Codes:	Recommended for use in slide agglutination tests for serotyping	**Approved** subject to provision of Valid and Embassy attested Free Sale Certificate.

		FSC US FDA valid till 25-03-2020	222321 222531 Shelf Life: 32 months Fee submitted: Rs. 25,000/-	*Neisseria Meningitidis*	
41.	M/s. Digital Imaging Systems, 121-Habitat Apartments, Shadman II, Ghaus -ul-Azam Road, Lahore. ELI-00094 **Evaluator**: AD-IV	**Legal Manufacturer:** Volcano Corporation, 2870 Kilgore Rd, Rancho, Cordova, CA 95670 **Manufacturing site:** Volcano Corporation by Volcarica S.R.L Coyol Free Zone and Business Park Building B37, Coyol, Alajuela Costa Rica FSC USA valid till 5th September 2021	Verrata PLUS Pressure Guide Wire Class D Code: 10185P 10185JP Shelf Life: 3 years Fee submitted: Rs. 50,000/-	Indicated for use to measure pressure in blood vessels, including both coronary and peripheral vessels, during diagnostic angiography and /or any interventional procedures. It can also be used to guide the positioning of a balloon dilatation catheter, as well as other interventonal devices. Blood pressure measurements provide hemodynamic information for the diagnosis and treatment of vascular disease. Sterile, single-use	**Approved.**
42.	-do- **Evaluator**: AD-IV	**Legal Manufacturer:** Volcano Corporation, 2870 Kilgore Rd, Rancho, Cordova, CA 95670 **Manufacturing site:** Volcano Corporation by Volcarica S.R.L Coyol Free Zone and Business Park Building B37, Coyol, Alajuela Costa Rica	Verrata Pressure Guide Wire Class D Code: 10185 10185J Shelf Life: 3 years	Indicated for use to measure pressure in blood vessels, including both coronary and peripheral vessels, during diagnostic angiography and /or any interventional procedures.	**Approved.**

		FSC USA valid till 5th September 2021	Fee submitted: Rs. 50,000/-	Blood pressure measurements provide hemodynamic information for the diagnosis and treatment of vascular disease. Sterile, single-use	
43.	M/s. Ferozsons Laboratories Limited, P.O Ferozsons, Amangarh, Nowshera (KPK)-Pakistan. ELI-00120 **Evaluator**: AD-IV	**Legal Manufacturer:** Cardiac Pacemarkers Incorporated, a wholly owned subsidiary of Guidant Corporation, a wholly owned subsidiary of Boston Scientific Corporation, 4100 Hamline Avenue North, St. Paul, Minnesota 55112, USA. **Manufacturing Site:** Boston Scientific Limited Cashel Road Clonmel Co. Tipperary Ireland. (FSC Ireland Valid till 14-03-2022)	VIGILANT X4 CRT-D (Model: G237 and G247) Class D Models: G237:MR conditional G247:MR conditional Shelf Life: 2 Years Fee submitted: Rs. 50,000/-	Cardiac Re-Synchronization Therapy Device (CRT-D). Indicated for patients who are at risk of sudden cardiac death caused by ventricular arrhythmias and who have heart failure with ventricular dys synchrony Active implantable medical device. Sterile, single-use	**Approved.**
44.	-do- **Evaluator**: AD-IV	Manufacturer Address: Symetis SA Chemin de la Venoge 11, CH-1024 Ecublens, Switzerland FSC Switzerland valid till 16.01.2021	ACURATE neo™ Aortic Bioprosthesis Class: D Codes: SYM-SV23-002 -- ACURATE neo™ Aortic Bioprosthesis size S SYM-SV25-002-- ACURATE neo™ Aortic Bioprosthesis size M SYM-SV27-002-- ACURATE neo™ Aortic Bioprosthesis size L Shelf Life: 1 year	Porcine heart valve. Sterile, single-use	**Approved.**

			Fee submitted: Rs. 50,000/-		
45.	-do- **Evaluator**: AD-IV	**Legal Manufacturer:** Cardiac Pacemarkers Incorporated, a wholly owned subsidiary of Guidant Corporation, a wholly owned subsidiary of Boston Scientific Corporation, 4100 Hamline Avenue North, St. Paul, Minnesota 55112, USA. **Manufacturing Site:** Boston Scientific Limited Cashel Road Clonmel Co. Tipperary Ireland. (FSC Ireland Valid till 14-03-2022)	VIGILANT™ EL ICD (Model: D233) Class D Model: D233- DR (dual-chamber: MR conditional) Shelf Life: 2 Years Fee submitted: Rs. 50,000/-	Implantable Cardioverter Defibrillator (ICD) intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. Sterile, single-use	**Approved.**
46.	-do- **Evaluator**: AD-IV	Manufacturer Address: Symetis SA Chemin de la Venoge 11, CH-1024 Ecublens, Switzerland FSC Switzerland valid till 16.01.2021	ACURATE TF™ Transfemoral Delivery System Class: D Code: SYM-DS-002 Shelf Life: 1 year Fee submitted: RS. 50,000/-	Designed to be used in combination with the ACURATE neoaortic bioprosthesis for the treatment of high-risk patients with severe aortic stenosis who are ineligible for conventional valve replacement via open heart surgery. Sterile, single-use	**Approved.**
47.	-do- **Evaluator**: AD-IV	**Legal Manufacturer:** Cardiac Pacemarkers Incorporated, a wholly owned subsidiary of Guidant Corporation, a wholly owned subsidiary of Boston Scientific Corporation,	VIGILANT™ EL ICD (Model: D232) Class D Model: D232 - VR (single-chamber: MR conditional)	Implantable Cardioverter Defibrillator (ICD) intended to provide ventricular antitachycardia pacing and	**Approved.**

		4100 Hamline Avenue North, St. Paul, Minnesota 55112, USA. **Manufacturing Site:** Boston Scientific Limited Cashel Road Clonmel Co. Tipperary Ireland. (FSC Ireland Valid till 14-03-2022)	Shelf Life: 2 Years Fee submitted: Rs. 50,000/-	ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. Sterile, single-use	
48.	-do- **Evaluator**: AD-IV	**Legal Manufacturer:** Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA. **Manufacturing Site:** Boston Scientific Limited Business and Technology Park, Model Farm Road, Cork, Ireland. FSC Ireland valid till 23.03.2022	Renegade ™ Hi-Flo™ Microcatheter Kit Class : C Codes: M001182980 M001182990 M001183000 M001183010 M001183020 M001183030 Shelf Life 3 years Fee submitted: Rs. 50,000/-	Intended for peripheral vascular use. The Microcatheter can be coaxially tracked over a steerable guidewire in order to access distal, tortuous vasculature. Once the subselective region has been accessed, the microcatheter can be used for the controlled and selective infusion of diagnostic, embolic, or therapeutic materials into vessel. Sterile, sinlge-use	**Approved.**
49.	M/s Cor-Med 2nd Floor 38/62 Rehman Plaza Bank Road, Saddar, Rawalpindi. ELI-00226 **Evaluator**: AD-IV	**Legal Manufacturer:** MERIT MEDICAL SYSTEMS, INC. 1600 West Merit Parkway, South Jordan UT USA, 84095 **Manufacturing Site:** Merit Maquiladora Mexico, S.DE R.L. DE C.V. Avenida Sor Juana Ines de la Cruz 19970 Interior B, Edificio 2,	One Step™ Centesis Catheter Class B Shelf Life: 3 years Code: OSC-4F-7 OSC-4F-10NH OSC-5F-7S OSC-5F-10LT OSC-4F-7L	Short term drainage catheter indicated for the percutaneous drainage of fluids. Sterile, single-use	**Approved** subject to provision of Labels of applied product codes.

		Parque Industrial Frontera Tijuana, Baja California, Mexico, 22630 FSC US FDA valid till 27th September, 2020	OSC-4F-10LNH OSC-5F-7T OSC-5F-15 OSC-4F-7LNH OSC-4F-10T OSC-5F-10 OSC-5F-15NH OSC-4F-7S OSC-4F-10LT OSC-5F-10L OSC-5F-15LNH OSC-4F-7T OSC-5F-7 OSC-5F-10NH OSC-5F-15S OSC-4F-7LT OSC-5F-7L OSC-5F-10LNH OSC-5F-15T OSC-4F-10 OSC-5F-7NH OSC-5F-10S OSC-5F-15LT OSC-4F-10L OSC-5F-7LNH OSC-5F-10T Fee submitted: Rs. 50,000/- dated 7-02-2017 submitted with Form- 5A out of which the firm claims Rs. 25,000/- were considered as acknowledgement fee and remaining Rs. 25,000/- they intend to cover in this product		
50.	-do- **Evaluator**: AD-IV	**Legal Manufacturer:** MERIT MEDICAL SYSTEMS, INC. 1600 West Merit Parkway, South Jordan UT USA, 84095 **Manufacturing Site:** MERIT MEDICAL IRELAND, LTD, Parkmore Business Park West, Galway, Ireland 0000 FSC US FDA valid till 27th February, 2021	Merit Laureate™ Hydrophilic Guidewire Class B Codes: Codes as per US FDA Free Sale Certificate No. 5485-2-2019 valid till 27th February, 2021 Shelf Life: 3 years Fee submitted: Rs. 50,000/- dated 7-02-2017 submitted with Form- 5A	Intended to be used in the peripheral vascular system to facilitate the placement of devices during diagnostic and interventional procedures. Sterile, single-use	**Approved** subjet to provision of Labels of applied product codes.

			out of which the firm claims Rs. 25,000/- were considered as acknowledgement fee and remaining Rs. 25,000/- they intend to cover in this product		
51.	-do- **Evaluator**: AD-IV	**Legal Manufacturer:** MERIT MEDICAL SYSTEMS, INC. 1600 West Merit Parkway, South Jordan UT 84095, USA **Manufacturing Site:** Merit Medical Systems, Inc. 14646 Kirby Drive, Houston, TX USA77047 FSC US FDA valid till 27th September, 2020	ReSolve™ Biliary Locking Drainage Catheter Class C Codes: RBC-8-038 RBC-8-SFX RBC-10-REV RBC-12-038 RBC-8-REV RBC-10-038 RBC-10-SFX RBC-12-REV RBDC-8-038 RBDC-10-038 RBDC-12-038 RBC-12-SFX RBDC-8-REV RBDC-10-REV RBDC-12-REV RBDC-14-REV RBDC-8-SFX RBDC-10-SFX RBDC-12-SFX RBDC-14-SFX RBC-14-038 RBC-14-REV RBDC-14-038 RBC-14-SFX RC-RTOOL Shelf Life: 3 years Fee submitted: **NOT SUBMITTED**	ReSolve Biliary Locking Drainage Catheter with locking pigtail and hydrophilic coating is used for drainage of bile within the biliary system. Sterile, single-use, MR conditional	**Approved** subject to submission of **Fee of Rs. 50,000/-** and provision of Labels of applied product codes.
52.	-do- **Evaluator**: AD-IV	**Manufacturer** MERIT MEDICAL, USA 1600 West Merit Parkway South Jordan UT 84095 , USA	**BasixCOMPAK™ Inflation Device** Class C Code: IN4130	The inflation device is used to inflate and deflate an angioplasty balloon or other interventinal	**Deferred** for clarification/ provision of following documents:- i) Letter of Authorization

		Manufacturing Site: MERIT MEDICAL IRELAND, LTD, Parkmore Business Park West, Galway, Ireland 0000 FSC US FDA valid till 27th February, 2020	Shelf Life: 3 years Fee submitted: Rs.	device and to measure the pressure within the balloon .	from the manufacturer abroad expired. Provide original, notarized Letter of Authorization. ii) The product has been applied as Class C medical device as stated on Form. Justify this classification and indicate relevant rule of Medical Device Rules, 2017. iii) On the Form the applied product is basixCompak inflation device whereas the fee, manufacturing details, stability studies, label, IFU etc provided are of basixTouch. Clarify? iv) Submit fee and provide the above stated information for basixCompak as well as provide detailed description of the device. v) On the Form manufacturing site indicated is Mexico whereas on Free Sale Certificate it indicates Ireland. Clarify? vi) Clearly state the legal manufacturer as well as manufacturing site of

					basixCompak. vii) Codes required on this application are not mentioned on Form. Clearly state the codes required on this application for basixCompak. viii) Multiple types of products cannot be applied on one application.
53.	-do- **Evaluator**: AD-IV	**Manufacturer** MERIT MEDICAL, USA 1600 West Merit Parkway South Jordan UT 84095 , USA **Manufacturer Site:** Merit Maquiladora Mexio, S.DE,R, L, DEe c.v avenida Sor Juana Ines de la Cruz 19970 Interior B, Edificio 2, Parque Industrial Frontera Tijuana,Baja California Mexico-22630 FSC : US. FDA Valid till: 27th September, 2020	**(ReSolve Drainage Catheter)** (ReSolve Drainage Catheter) RLC-NV-6- RLCMB-NV-6- RLC-NV-6-REV- RLC-NV-6-SFX RLC-NV-8- RLCMB-NV-8- RLC-NV-8-REV- RLC-NV-8-SFX RLC-NV-10- RLCMB-NV-10- RLC-NV-10-REV- RLC-NV-10-SFX RLC-NV-12- RLCMB-NV-12- RLC-NV-12-REV- RLC-NV-12-SFX RLC-NV-14- RLCMB-NV-14- RLC-NV-14-REV- RLC-NV-14-SFX RLCMB-NV-6-REV- RLC-NV-7 RLCMB-NV-6-SFX-RLCMB-NV-7 RLCMB-NV-8-REV-RLC-NV-7-REV-RLCMB-NV-8-SFX-RLCMB-NV-7-REV-RLCMB-NV-10-REV-RLC-NV-7-SFX-RLCMB-NV-10-SFX-RLCMB-NV-7-SFX-RLCMB-NV-12-REV-RLCMB-NV-14-REV-RLCMB-NV-12-SFX-RLCMB-NV-14-SFX Class C Shelf Life: 3 years	i) is intended for percutaneous drainage of fluid frombody cavities. .	**Deferred** for clarification/ provision of following documents:- i) Letter of Authorization from the manufacturer abroad expired. Provide original, notarized Letter of Authorization. ii) The product highlighted on the Free Sale Certificate is **Resolve Locking Drainage CatheterTRAY** whereas on Form the product name mentioned is **Resolve Drainage Catheter** and IFU provided is of **Resolve NON-Locking Drainage Catheter** and that highlighted on Declaration of Conformity (DOC) is **Resolve Locking Drainage**

					Catheter. Clarify? iii) Clearly state the name of the product required on this application alongwith codes and also highlight it and its codes on Free Sale Certificate and DOC and provide relevant IFU iv) Provide complete real time stability studies of the applied product signed and stamped by responsible personnel of manufacturer clearly stating the shelf life of the product. v) Flow chart of manufacturing is not readable. vi) Provide detailed description of the applied device . vii) On the Form manufacturing site indicated is Mexico whereas on Free Sale Certificate it indicates Houston, USA. Clarify? viii) Clearly state the legal manufacturer as well as manufacturing site of the applied product ix) Copy (not original) of fee challan of Rs.

					50,000/- submitted on 7-2-2017 is provided with application. Clarify the reason of this submission alongwith proof of submission of fee for provisional registration. x) Labels not provided. Provide labels for all codes required
54.	-do- **Evaluator**: AD-IV	**Legal Manufacturer** MERIT MEDICAL, USA 1600 West Merit Parkway South Jordan UT 84095 , USA **Manufacturer Site:** Merit Maquiladora Mexio, S.DE,R, L, DEe c.v avenida Sor Juana Ines de la Cruz 19970 Interior B, Edificio 2, Parque Industrial Frontera Tijuana,Baja California Mexico-22630 **FSC NOT PROVIDED**	**Bearing nsPVA® Embolization Particles** Class-C Sizes: Shelf Life 3 years **Fee submitted: Rs. 50,000/-**	Used for embolization of peripheral hypervascularized tumors including leiomyoma uteri and peripheral arteriovenous malformations (AVMs)	**Deferred** for clarification/ provision of following documents:- i) Letter of Authorization from the manufacturer abroad expired. Provide original, notarized Letter of Authorization. ii) Free Sale Certificate not provided. Provide Embassy attested Free Sale Certificate for the applied product iii) Particle size/ cat no required on this application are not mentioned on Form. Clearly state the Particle size/ cat no required. iv) Provide detailed description of the applied device v) Copy (not original) of fee challan of Rs. 50,000/-

					submitted on 7-2-2017 is provided with application. Clarify the reason of this submission alongwith proof of submission of fee for provisional registration. vi) Provide labels for all codes/cat no. required.
55.	M/s Med Lab Services. Office No.1, First Floor, ABC Plaza, Commercial Center, Satellite Town, Rawalpindi (ELI-00056) **Evaluator**: AD-IV	**Manufacturer:** M/s GeneProof a.s, Videnska 101/119 Dolni Herspice 619 00 Brno Czech Republic (FSC Czech Republic valid till 15-11-2020)	GeneProof Mycobacterium Tuberculosis PCR Kit Class C MT/ISEX/025 MT/ISEX/050 MT/ISEX/100 MT/ISIN/025 MT/ISIN/050 MT/ISIN/100 Shelf Life: 26Months Fee submitted: Rs. 50,000/-	Designed for *Mycobacterium tuberculosis* detection by the real-time Polymerase Chain Reaction (PCR) method Mycobacterium tuberculosis Nucleic acid IVD, Kit, Nucleic acid Technique (NAT)	**Approved** subject to inspection of manufacturer aboard under rule 71 of MDR, 2017 or provision of CE mark documents.
56.	M/s. Sadqain Health Care (Pvt) Ltd., Safari Villas II, Commercial Complex, 3rd Floor, Bahria Town, Phase 7, Rawalpindi. ELI-00020 **Evaluator**: AD-IV	**Manufacturer:** M/s. Intersurgical Limited, Crane House, Molly Millars Lane, Wokingham, Berkshire, United Kingdom. FSC U.K issued on 01.03.2016	SILVER KNIGHT ANAESTHETIC BREATHING SYSTEM, MAPLESON D DELUXE BAIN COAXIAL 1.6m (22mm Anti-microbial coaxial breathing system with 2L bag) Class B Ref No: 2115100 Shelf Life: 3 years Fee submitted: Rs. 25,000/-	Coaxial systems where the fresh gas is delivered directly to the patient. Can be used for both spontaneously breathing patitents and for controlled ventilation. Non-sterile, single-use	**Approved** subject to provision of valid Full QA Certificate.
57.	-do- **Evaluator**: AD-IV	**Manufacturer:** M/s. Intersurgical Limited, Crane House, Molly Millars Lane,	Cirrus™ 2 Nebuliser Breathing System, T-Kit 22mm	To convert a liquid drug into a mist to enable a patient to inhale and	**Approved.**

		Wokingham, Berkshire, United Kingdom. FSC U.K issued on 01.03.2016	Class B Ref No: 2605000 Shelf Life: 3 years Fee submitted: Rs. 25,000/-	deposit the drug in the lungs. Non-sterile, Single-use	
58.	-do- **Evaluator**: AD-V	Legal Manufacturer M/s. Intersurgical Limited, Crane House, MollyMillars Lane, Wokingha, Berkshire, United Kingdom. FSC U.K Issuedon 01.03.2016	*10mm Flextube Single heated wire breathing system.* (Breathing System) 4509810-4509850—4609850 Class-B Shelf Life: 5 years Rs 25,000	To deliver and remove respiratory gases from a patient via s system of tubing and connectors and to maintain the patient temperature and humidify within the inspiratory limb and expiratory gases so as to minimize "rain-out).	**Approved.**
59.	M/s FY Diagnostic & Surgicals Suit No. 203. Anum Blessing, 2nd Floor, KCHSU, Shahrah-e-Faisal, Karachi (ELI-00323) **Evaluator**: AD-IV	**Manufacturer:** DxGen Corp. Rm. 303-1 and Rm. 604, 172, LS-ro, Gunpo-si, Gyeonggi-do, 15807, Republic of Korea. (FSC Korea issued on 20-02-2019)	Epithod®616 HbA1c Measuring System Class B 1. Epithod® 616 Hb1Ac Test Kit (Ep616H) Shelf Life: 12 Months 2. Epithod®616 Analyzer (Ep.616) Shelf life: N/A Fee submitted: Rs. 25,000/-	Intended for in vitro diagnostic (IVD) use to determine glycated hemoglobin (HbA1c) quantitively from human blood for point-of-care testing. The system is useful to diagnose diabetes and monitor glycemic Control. Use only for professional in clinic or laboratory.	**Approved** subject to inspection of manufacturer abroad under rule 71 of MDR, 2017 or provision of CE mark documents and original notarized Letter of Authorization

60.	M/s. Tek Enterprises, Office No. MZ-9, Mezzanine Floor, Al Hafeez Heights, 65-D, Sir Syed Road, Gulberg III, Lahore ELI- 00189 **Evaluator**: AD-IV	**Legal Manufacturer:** ASAHI INTECC CO., LTD, 3-100, Akatsuki-cho, Seto, Aichi 489-0071, Japan **Manufactuing Sites:** 1. ASAHI INTECC CO., LTD, 3-100, Akatsuki-cho, Seto, Aichi 489-0071, Japan 2. ASAHI INTECC (Thailand) CO, LTD 158/1 Moo 5 Bangkadi Industrial Park, Tiwanon Road, Tambol Bangkadi, Amphur Muang Pathumthani 12000, Thailand. FSC Japan Date of issue 29.08.2019	ASAHI FUBUKI Neurovascular Guide Catheter Class D Codes: Codes as per Free Sale Certificate of Japan KYS.01.B dated 29th Aug, 2019 Shelf Life: 3 years Fee submitted: **NOT SUBMITTED**	Intended to be used to guide a therapeutic catheter or the like for Neurovascular therapy to a lesion or a procedural site for a percutaneous intravascular procedure in the neurovasculature. Sterile, single-use	**Approved** subject to provision of Labels and IFU and **Fee of Rs.50,000/.**
61.	M/s. Global Healthcare, Midway Commercial Plaza No 20, Back Side of Prism Arcade 2, Phase 7, Bahria Town Rawalpindi ELI-00086 **Evaluator**: AD-IV	**Manufacturer:** Xuzhou Yongkang Electronic Science Technology Co., Ltd. 4F Building C8, 40 Jingshan Road, Economic and Technological Development Zone, 221000 Xuzhou, People's Republic of China FSC China valid till 5-3-2021	Multi Parameter Patient Monitor Class C Model: E8 E10 E12 E15 Service Life: 5 years Fee submitted: **NOT SUBMITTED**	Plug-in type patient monitor. Portable multiple-parameter patient monitor which may be used to monitor and measure patients' vital signs of heart rate/pulse rate, non-invasive blood pressure, invasive blood pressure, respiration rate, electrocardiogram, blood oxygen saturation and temperature in hospital	**Approved** subject to inspection of manufacturer abroad under rule 71 of MDR, 2017 and provision of Labels and **Fee of Rs.50,000/.**

62.	M/s Medtronic Pakistan (Private) Limited, Office No.1301, 13th Floor Dilkusha Forum Tariq Road, Karachi (ELI-00273) **Evaluator**: AD-IV	Owner Operator: Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA, 55432. Manufacturing site: Medtronic Europe Sarl route Du Molliau 31 Case Postale Tolchenaz Vaud Switzerland 1131 (FSC USA valid till 15-08-2021)	Visia AF MRI™ S VR SureScan™ (implantable cardioverter defibrillator) Class D Models: DVFC3D1 DVFC3D4 Shelf Life: 18 Months Fee submitted: Rs. 50,000/-	MR conditional, digital single chamber implantable cardioverter defibrillator (ICD) with SureScan™ technology. It is multi-programmable cardiac device that monitors and regulates the patient's heart rate by providing chamber, rate-responsive bradycardia pacing and ventricular tachyarrhythmia therapies. Sterile, single-use.	**Approved** subject to provision of label of Model DVFC3D1.
63.	-do- **Evaluator**: AD-IV	**Name of Owner Operator:** Medtronic Inc., 710 Medtronic Pkwy, Minneapolis, MN USA 55432. **Manufacturing site**: Medtronic Heart Valves Division 1851 East Deere Ave. Santa Ana, CA USA 92705. (FSC USFDA valid till 05-12-2020)	Hancock™ Valved Conduit, Model 105 (Low Porosity) Class D Codes: HC105-12-size 12mm HC105-14-size 14mm HC105-16-size 16mm HC105-18-size 18mm HC105-20-size 20mm HC105-22-size 22mm HC105-26-size 26mm Shelf Life: 5 Years Fee submitted: Rs. 50,000/-	It consists of a **PORCINE** valve sutured into the centre of a woven fabric conduit. Indicated for use in right heart reconstructive procedures for the repair of congenital or acquired cardiac and great vessels malformations or pathology. MR Conditional. Sterile, single-use	**Approved** subject to provision of Manufacturing process and COA / design verification, EPSP, labels and stability studies.
64.	-do- **Evaluator**: AD-IV	Legal Manufacturer: Invatec S.p.A." Via Martiri della Liberta 7,	Pacific Xtreme PTA Catheter Class D	Over the Wire (OTW) peripheral balloon	**Approved.**

		Roncadelle, 25030 (BS), Italy Manufacturing Site: Medtronic Mexico S. de R.L. de C.V. Av. Paseo Cucapah, 10510 El Lago, C.P. 22210 Tijuana, Baja California, Mexico. (FSC Italy issue date 22-03-2017)	Codes: Codes as per FSC Italy dated 25-05-2018 Shelf Life: 3 Years Fee submitted: Rs. 50,000/-	catheter indicated for percutaneous transluminal angioplasty (PTA) in patients with obstructive disease of peripheral arteries.i.e ileo-femoral-, femoral-, popliteal-, infra-popliteal- and renal arteries. Only catheters with diameters from 2mm to 7 mm and lengths from 20mm to 40 mm are indicated for carotid and supra-aortic applications with the exception of catheters with a usable length of 180 cm. Sterile, single-use.	
65.	-do- **Evaluator**: AD-IV	Manufacturer: Medtronic CryoCath LP 9000 Autoroute Transcanadienne Pointe-Claire, Quebec H9R 5Z8 Canada. (FSC Netherlands valid till 31-03-2021)	Coaxial Umbilical Cable Class B Codes: 203CX 203CXC Shelf Life: 2 Years Fee submitted: Rs. 25,000/-	Designed for use with CryoConsole in cryoablation therapy. It transports liquid refrigerant to the catheter and returns waste refrigerant to the console for disposal. Sterile, single-use	**Approved.**
66.	-do- **Evaluator**:	Legal Manufacturer: Invatec S.p.A." Via Martiri della Liberta 7,	Admiral™ Xtreme PTA Catheter	Over the Wire (OTW) peripheral	**Approved.**

	AD-IV	Roncadelle, 25030 (BS), Italy Manufacturing Site: Medtronic Mexico S. de R.L. de C.V. Av. Paseo Cucapah, 10510 El Lago, C.P. 22210 Tinjuana, Baja California, Mexico. (FSC Italy issue 25-05-2018)	Class B Codes: Codes as per FSC Italy dated 25-05-2018 Shelf Life: 3 years Fee submitted: Rs. 25,000/-	balloon catheter indicated for percutaneous transluminal angioplasty (PTA) in patients with obstructive disease of peripheral arteries. Sterile, single-use. Not for use in coronary and cerebral vasculature	
67.	-do- **Evaluator**: AD-IV	Owner operator: Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA, 55432. Manufacturing site: Medtronic Europe Sarl, Route Du Molliau 31, Case Postale, Tolochenaz, Vaud Switzerland 1131 (FSC USA valid till 15-08-2021)	Primo MRI™ DR SureScan™ (implantable cardioverter defibrillator)[Model: DDMD3D1] Class D Shelf Life: 18 Months Fee submitted: Rs. 50,000/-	MR conditional, digital dual chamber implantable cardioverter defibrillator (ICD) with SureScan technology. It is multi-programmable cardiac device that monitors and regulates the patient's heart rate by providing single or dual chamber, rate-responsive bradycardia pacing; ventricular tachyarrhythmia therapies and atrial tachyarrhythmia therapies. Sterile, single-use	**Approved.**
68.	-do- **Evaluator**: AD-IV	Legal Manufacturer: Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN 55432 USA	Attain Select II + Sure Valve Delivery Catheter Class D	Indicated for the delivery of contrast medium and transvenous	**Approved.**

		Manufacturing site: Medtronic Ireland, Parkmore Business Park West, Galway, Ireland. (FSC Ireland valid till 05-12-2023)	Codes: Codes as per FSC Ireland issued on 5-12-2018. CFS009707 Shelf Life: 24 Months Fee submitted: Rs. 50,000/-	devices to the coronary sinus and left-heart venous anatomy. Sterile, single-use	
69.	-do- **Evaluator**: AD-IV	Legal Manufacturer: Medtronic Inc. 710 Medtronic Pkwy, Minneapolis, MN 55432 USA Manufacturing site: Medtronic Ireland, Parkmore Business Park West, Galway, Ireland. (FSC Ireland valid till 07-11-2022)	Attain Clarity™ 6225I Venogram Balloon Catheter Class D Ref No: 6225I Shelf Life: 2 Years Fee submitted: Rs. 50,000/-	Indicated for use within the coronary sinus. It is intended for infusing contrast solutions into the coronary vasculature for occlusive venogram imaging	**Approved** subject to provision of valid Full QA and Manufacturing details.
70.	-do- **Evaluator**: AD-IV	Owner Operator: Medtronic Inc. 710 Medtronic Pkwy, Minneapolis, MN USA, 55432. Manufacturing site: Medtronic Europe Sarl ROUTE DU MOLLIAU 31 Case Postale, TOLOCHENAZ, Vaud Switzerland 1131 (FSC USA valid till 15-08-2021)	Mirro MRI™ DR SureScan™ (implantable cardioverter defibrillator) Class D Model: 1. DDME3D1 2. DDME3D4 Shelf Life: 18 Months Fee submitted: Rs. 50,000/-	MR conditional, digital dual chamber implantable cardioverter defibrillator (ICD) with SureScan technology. It is multi-programmable cardiac device that monitors and regulates the patient's heart rate by providing single or dual chamber, rate-responsive bradycardia pacing; and ventricular tachyarrhythmia therapies. Sterile, single-use	**Approved.**
71.	-do-	Owner Operator:	Primo MRI™ DR SureScan™ (implantable	MR conditional,	**Approved.**

	Evaluator: AD-IV	Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA, 55432. Manufacturing site: Medtronic Europe Sarl, Route Du Molliau 31, Case Postale, Tolochenaz, Vaud Switzerland 1131 (FSC USA valid till 15-08-2021)	cardioverter defibrillator) [Model: DDMD3D4] Class D Shelf Life: 18 Months Fee submitted: Rs. 50,000/-	digital dual chamber implantable cardioverter defibrillator (ICD) with SureScan technology. It is multi-programmable cardiac device that monitors and regulates the patient's heart rate by providing single or dual chamber, rate-responsive bradycardia pacing; ventricular tachyarrhythmia therapies and atrial tachyarrhythmia therapies. Sterile, single-use	
72.	-do- **Evaluator**: AD-IV	Owner Operator: Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA, 55432. Manufacturing site: Medtronic Europe Sarl ROUTE DU MOLLIAU 31 Case Postale, TOLOCHENAZ, Vaud Switzerland 1131 (FSC USA valid till 15-08-2021)	Azure™ S SR MRI SureScan™ (pacemaker) [Model W3SR01] Class D Shelf Life: 18 Months Fee submitted: Rs. 50,000/-	MR conditional, single chamber pacemaker with SureScan technology and Bluetooth wireless telemetry. Implantable pulse generator is a multi-programmable cardiac device that monitors and regulates the patient's heart rate by providing single chamber rate-responsive bradycardia pacing. Sterile, single-use.	**Approved.**

73.	-do- **Evaluator**: AD-IV	**Owner Operator:** Medtronic Inc. 710 Medtronic Pkwy, Minneapolis, MN USA 55432 **Manufacturing site:** Plexus Manufacturing Sdn. Bhd. Bayan Lepas Free Industrial Zone, Phase II, Bayan Lepas, Pulau Pinang Malaysia. (FSC USA valid till 31-01-2020)	Dual Chamber Temporary Pacemaker (Model: 5392) Class C Shelf Life: Not applicable Fee submitted: Rs. 50,000/-	Battery powered, dual chamber, temporary external pacemaker designed primarily for temporary antibradycardia pacing therapy	**Approved** subject to provision of valid FSC, ISO 13485, Full QA, and manufacturing site and Labels.
74.	-do- **Evaluator**: AD-IV	Owner Operator: Medtronic Inc. 710 Medtronic Pkwy, Minneapolis, MN USA, 55432. Manufacturing site: Medtronic Europe Sarl ROUTE DU MOLLIAU 31 Case Postale, TOLOCHENAZ, Vaud Switzerland 1131 (FSC USA valid till 15-08-2021)	Mirro MRI™ VR SureScan™ Class D Models: 1. DVME3D1 2. DVME3D4 Shelf Life: 18 Months Fee submitted: Rs. 50,000/-	MR conditional, digital single chamber implantable cardioverter defibrillator with Sure Scan Technology, multiprogrammable cardiac device that monitors and regulates the patient's heart rate by providing single chamber rate-responsive bradycardia pacing and ventricular tachyarrythmias. Sterile, single-use.	**Approved.**
75.	-do- **Evaluator**: AD-IV	Legal Manufacturer: Medtronic Inc. 710 Medtronic Pkwy, Minneapolis, MN USA, 55432. Manufacturing site: Medtronic Ireland, Parkmore Business Park West, Galway, Ireland. (FSC Ireland valid till 20-08-2024)	Telescope™ Guide Extension Catheter Class D Codes: TELE6F Telescope™ Guide Extension Catheter -6F TELE7F Telescope™ Guide Extension Catheter -7F Shelf Life: Not mentioned	Intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature and to facilitate placement of	**Approved** subject to provision of Shelf life and stability studies.

			Fee submitted: Rs. 50,000/-	interventional devices. Sterile, single-use	
76.	-do- **Evaluator**: AD-IV	Legal Manufacturer**:** ev3 Inc., 4600 Nathan Lane North, Plymouth MN, 55442, USA Manufacturing site: ev3 Inc., 4600 Nathan Lane North Plymouth MN, 55442, USA (FSC Ireland valid till 13-06-2023)	Protégé™ GPS™ Self-expanding Peripheral Stent System Class D Codes as per FSC Ireland CFS009318 dated 13-06-2018 Shelf life: 3 years Fee submitted: Rs. 50,000/-	Peripheral use: Indicated for use in occlusions or lesions at high risk for abrupt close or threatened closure following PTA and lesions that appear to be at high risk for restenosis following PTA in the common iliac, external iliac or sub-clavian arteries. Biliary: intended as a palliative treatment of malignant neoplasms in the biliary tree. Sterile, single-use	**Approved.**
77.	-do- **Evaluator**: AD-IV	Legal Manufacturer: Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA, 55432. Manufacturing site: Medtronic Perfusion Systems 7611 Northland Dr Minneapolis, MN USA 55428 (FSC US FDA valid till 11-02-2021)	MC2X® Three Stage Venous Cannulae Class D Codes: 91429 91429C 91437 91437C Shelf life: 3 Years Fee submitted: Rs. 50,000/-	Sterile, single use. Intended for use in venous drainage via the right atrium and inferior vena cava simultaneously during cardiopulmonary bypass surgery upto six hours or less	**Approved** subject to provision of Embassy attested FSC.
78.	-do-	Name of Owner Operator:	Mosaic™ Bioprosthesis Model 310 (mitral)	**PORCINE** valve indicated	**Approved** subject to

	Evaluator: AD-IV	Medtronic Inc., 710 Medtronic Pkwy, Minneapolis, MN USA 55432. Manufacturing site: Medtronic Heart Valves Division 1851 East Deere Ave. Santa Ana, CA USA 92705. (FSC USFDA valid till 05-12-2020)	Class D Codes: 310C25-size 25mm 310C27-size 27mm 310C29-size 29mm 310C31-size 31mm 310C33-size 33mm Shelf Life: 5 Years Fee submitted: Rs. 50,000/-	for the replacement of pathologic or prosthetic mitral valve. Sterile, single-use	provision of valid Full QA, Design Examination, COA/design verification and labels.
79.	-do- **Evaluator**: AD-IV	Legal Manufacturer**:** ev3 Inc., 4600 Nathan Lane North, Plymouth MN, 55442, USA Manufacturing site: ev3 Inc., 4600 Nathan Lane North Plymouth MN, 55442, USA (FSC Ireland valid till 13-06-2023)	Visi-Pro™ Balloon-Expandable Peripheral Stent System Class D Codes as per FSC Ireland issued on 13-06-2018 CFS009319 Shelf Life: 3 Years Fee submitted: Rs. 50,000/-	Indicated for use in occlusions, lesions at high risk for abrupt closure or threatened closure following PTA or lesion believed to be at high risk of stenosis following PTA in common and external iliac, subclavian and renal arteries. Also indicated for use as a palliative treatment of malignant neoplasms in the biliary tree. Sterile, single-use	**Approved** subject to provision of details of manufacturing and quality control.
80.	-do- **Evaluator**: AD-IV	**Name of Owner Operator**: Medtronic Inc., 710 Medtronic Pkwy, Minneapolis, MN USA 55432. **Manufacturing site**: Medtronic Heart Valves Division 1851 East	Hancock™ Valved Conduit, Model 150 (Modified Orifice) Class D Codes: HC150-12-size 12mm HC150-14-size 14mm HC150-16-size 16mm	It consists of a **PORCINE** valve sutured into the centre of a woven fabric conduit. Indicated for use in right heart	**Approved** subject to provision of Manufacturing process, COA / design verification , EPSP, labels and stability studies.

		Deere Ave. Santa Ana, CA USA 92705. (FSC USFDA valid till 05-12-2020)	HC150-18-size 18mm HC150-20-size 20mm HC150-22-size 22mm HC150-25-size 25mm Shelf Life: 5 Years Fee submitted: Rs. 50,000/-	reconstructive procedures for the repair of congenital or acquired cardiac and great vessels malformations or pathology. MR Conditional. Sterile, single-use	
81.	-do- **Evaluator**: AD-IV	**Legal Manufacturer**: Medtronic Inc., 710 Medtronic Parkway N.E., Minnepolis MN 55432, USA **Manufacturing Site:** Medtronic Europe S.a.r.l., Route du Molliau 31, Case Postale, 1131 Tolochenaz, Switzerland. (FSC Switzerland issue 06-03-2021)	Evera™ XT VR (implantable cardioverter defibrillator) Class D Model: DVBB2D1 DVBB2D4 Shelf Life: 18 Months Fee submitted: Rs. 50,000/-	Digital single chamber implantable cardioverter defibrillator is a multi-programmable cardiac device that monitors and regulates the patient's heart rate by providing single chamber rate-responsive bradycardia pacing and ventricular tachyarrhythmia therapies. Sterile, single-use.	**Approved.**
82.	-do- **Evaluator**: AD-IV	Legal Manufacturer: Medtronic Inc., 710 Medtronic Parkway N.E., Minnepolis MN 55432, USA Manufacturing Site: Medtronic Europe S.a.r.l., Route du Molliau 31, Case Postale, 1131 Tolochenaz, Switzerland. (FSC Switzerland valid till 06-03-2021)	Sensia DDDR (implantable pulse generator) [Model: SEDR01] Class D Shelf Life: 18 Months Fee submitted: Rs. 50,000/-	Dual chamber, multiprogrammable, rate-responsive implantable pulse generator (IPG) indicated for use to improve cardiac output, prevent symptoms, or protect against arrhythmias related to cardiac impulse formation or	**Approved.**

				conduction disorders. Sterile, single-use	
83.	-do- **Evaluator**: AD-IV	Legal Manufacturer: Medtronic Inc., 710 Medtronic Parkway N.E., Minnepolis MN 55432, USA Manufacturing Sites: 1. Medtronic Perfusion Systems 7611 Northland Dr Minneapolis, MN USA 55428 2. Medtronic Mexico S. de R.L. de C.V. Av. Paseo Cucapah, 10510 El Lago, C.P. 22210 Tijuana, Baja California, Mexico. (FSC US FDA valid till 27-02-2020)	Affinity® NT Integrated CVR Oxygenator with Trillium® Biosurface (Model: 541T) Class D Shelf Life: 2 Years Fee submitted: Rs. 50,000/-	Intended to be used in an extra corporeal perfusion circuit to collect venous and cardiotomy suctioned blood, cool or warm the blood and oxygenate and remove carbon dioxide from the blood during routine cardiopulmonary bypass procedures up to 6 hours duration. Sterile, single-use only	**Approved** subject to provision Stability study and valid Embassy attested Free Sale Certificate.
84.	-do- **Evaluator**: AD-V [1342]	**Legal Manufacturer**: Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA **Manufacturing Site**: Medtronic Ireland Parkmore Business Park West Galway Ireland. (FSC Ireland valid 20-01-2020)	Valiant Thoracic Stent Graft with Captiviat™ System Synthetic Vascular Graft Class D, Shelf Life: 2 Years (Sizes & Codes as Per FSC) Rs.50,000/-	The Valiant Thoracic stent graft with the Captivia delivery system is indicated for treatment of diseases of the descending thoracic aorta including but not limited to aneurysms and dissections.	**Approved** subject to provision of valid Embassy attested Free Sale Certificate.
85.	-do- **Evaluator**: AD-V [1361]	Legal Manufacturer: Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA Manufacturer: M/s Medtronic Mexico S.de R.L. de CV Av.	Bio-Medicus Pediatric Arterial Cannulae and Introducer (Cardiopulmonary Bypass cannulal, arterial) Class D	Pediatric Cannula and Introducers are used to cannulate vessels, perfuse vessels or organs, and/	**Approved** subject to provision of valid Embassy attested Free Sale Certificate.

		PaseoCucapah 10510 El Lago Tijuana, Baja California CP 22210, Mexico (FSC USA Valid 08-03-2020)	Shelf Life: 4 Years (Sizes & Codes as Per FSC) Rs.50,000/-	or connect with accessory extracorporeal equipment. The cannula introducer is intended to facilitate proper insertion and placement of appropriately-sized cannula within the vessel for cardiopulmonary by pass. Thes products are intended for use up to 6 hours.	
86.	-do- **Evaluator**: AD-V [1339]	Legal Manufacturer: ev3, Inc 4600 Nathan LN. North Plymouth, MN USA 55442 (FSC USA valid 27-01-2021)	Evercross™ 0.035 Over-the-wire PTA Dilatation Catheter (Peripheral Angioplasty Balloon Catheter) Class B Shelf Life: 3 Years (Sizes & Codes as Per FSC) Rs.25,000/-	Peripheral angioplasty baloon catheter. The PTA Balloon Dilatation Catheter is intended to dilate stenosis in the iliac, femoral, ilio-femoral, popliteal, infrapopliteal and renal arteries, and for the treatment of obstructive lesion of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for stent post-dilatation in the peripheral vasculature.	**Approved.**
87.	-do-	Legal Manufacturer: Medtronic Inc.	Endurant II Bifurcated Stent Graft System	The Endurant II/ II stent graft	**Approved** subject to

	Evaluator: AD-V [1341]	710 Medtronic Pkwy. Minneapolis, MN USA Manufacturing Site: Medtronic Ireland Parkmore Business Park West Galway Ireland. (FSC Ireland valid 20-01-2020)	(Abdominal Aorta endovascular stent graft. Class D. Shelf Life: 2 Years (Sizes & Codes as Per FSC) Rs.50,000/-	system is indicated for the endovascular treatment of infrarenal or juxtarenal abdominal aortic or aortoiliac aneurysms in patients with the following characteristics:	provision of valid Embassy attested Free Sale Certificate.
88.	-do- **Evaluator**: AD-V [1358]	Legal Manufacturer: Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN 55432 USA Manufacturer: Manufacturer: M/s Medtronic Mexico S.de R.L. de CV Av. PaseoCucapah 10510 El Lago Tijuana, Baja California CP 22210, Mexico (FSC USA Valid till 08-03-2020)	Bio-Medicus™ Arterial insertion Kit (insertion Kit for arterial cannula) Class D Shelf Life: 3 Years Sizes & Code: 96552 Rs.50,000/-	This product contains the necessary components to achieve insertion of a Bio-Medicus™ Cannula and introducer. The Included items are: Sledinger needle, a guidewire, a scalpel blade, stepped dilators and a catheter tip syringe. Intended use: This kit is intended for use by a trained physician only, to assist in vessel cannulation for cardiopulmonary bypass circulation. Standard surgical or percutaneous insertion techniques can be employed. This kit is intended for	**Approved** subject to provision of valid Embassy attested Free Sale Certificate.

				use for upto 6 hours.	
89.	-do- **Evaluator**: AD-V [1359]	Legal Manufacturer: Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN 55432 USA Manufacturer: Manufacturer: M/s Medtronic Mexico S.de R.L. de CV Av. PaseoCucapah 10510 El Lago Tijuana, Baja California CP 22210, Mexico (FSC USA Valid till 08-03-2020)	Bio-Medicus™ Venous Insertion Kit. (insertion Kit for venous cannula) Class D Shelf Life: 3 Years Sizes & Code: 96551 Rs.50,000/-	This product contains the necessary components to achieve insertion of a Bio-Medicus™ Cannula and introducer. The Included items are: Sledinger needle, a guidewire, a scalpel blade, stepped dilators and a catheter tip syringe. Intended use: This kit is intended for use by a trained physician only, to assist in vessel cannulation for cardiopulmonary bypass circulation. Standard surgical or percutaneous insertion techniques can be employed. This kit is intended for use for upto 6 hours.	**Approved** subject to provision of valid Embassy attested Free Sale Certificate.
90.	-do- **Evaluator**: AD-V [1357]	Legal Manufacturer: Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN 55432 USA Manufacturer: Manufacturer:	Bio-Medics™ Pediatric insertion Kit (insertion Kit for Pediatric cannula) Class D	This product contains the necessary components to achieve insertion of a Bio-Medicus™	**Approved** subject to provision of valid Embassy attested Free Sale Certificate.

		M/s Medtronic Mexico S.de R.L. de CV Av. PaseoCucapah 10510 El Lago Tijuana, Baja California CP 22210, Mexico (FSC USA Valid till 08-03-2020)	Shelf Life: 3 Years Sizes & Code: 96553 Rs.50,000/-	Cannula and introducer. The Included items are: Sledinger needle, a guidewire, a scalpel blade, stepped dilators and a catheter tip syringe. Intended use: This kit is intended for use by a trained physician only, to assist in vessel cannulation for cardiopulmonary bypass circulation. Standard surgical or percutaneous insertion techniques can be employed. This kit is intended for use for upto 6 hours.	
91.	-do- **Evaluator**: AD-V [1356]	Legal Manufacturer: Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN55432 USA Manufacturing Site: Teleflex Medical, Annacotty Business Park, Annacotty, Co. Limerick, Ireland. (FSC Ireland Valid 06-02-2023)	Sentrant Sheath with hydrophilic Coating (introducer sheath) Class D Shelf Life: 1 Years (Sizes & Codes as Per FSC) Rs.50,000/-	The Sentrat introducer sheath with hydrophilic coating is intended to provide a conduit for the insertion of diagnostic or endovascular and to minimize blood loss associated with such insertions.	**Approved.**
92.	-do-	Legal Manufacturer:	Protégé™ Everflex Self-Expanding Peripheral Stent	In patients undergoing	**Approved** in Class C medical

	Evaluator: AD-V [1344]	ev3, Inc 4600 Nathan LN. North Plymouth, MN USA 55442 (FSC USA valid 27-01-2021) (FSC USA valid 07-01-2020)	(Multiple peripheral artery stent, Baremetal) Class D Shelf Life: 3 Years (Sizes & Codes as Per FSC) Rs.50,000/-	Percutaneous Transluminal Angioplasty (PTA) of the vascular system, stenting is intended to improve and maintain artery luminal diameter.	devices subject to provision of valid Embassy attested Free Sale Certificate.
93.	-do- **Evaluator**: AD-V [1343]	Legal Manufacturer: Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN, 55432 USA Manufacturing Site: Medtronic Ireland Parkmore Business Park West Galway Ireland. (FSC Ireland valid 24-05-2022)	IN. PACT Admiral (Paclitaxel-coated PTA Balloon Dilatation Catheter) (Peripheral Angioplasty Balloon Catheter, drug Coated) Class D Shelf Life: 3 Years (Sizes & Codes as Per FSC) Rs.50,000/-	IN. PACT Admiral is indicated for percutaneous transluminal angioplasty PTA in patients with obstructive disease of peripheral arteries, including in stent restenosis, and with obstructive lesion of native or synthetic aretiovenous dialysis fistulae.	**Approved.**
94.	-do- **Evaluator**: AD-V	Legal Manufacturer: Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN, 55432 USA Manufacturer: Medtronic Perfusion Systems 7611 Northland Dr Minneapolis, MN, 55428 USA Contractor Manufacturer: Medplast Medical Inc, 620 Watson SW GR, MI USA 49504	DLP® Torniquet Sets (Intravascular catheter-Snare) Class: D Shelf Life: 3 Years (Sizes & Codes as Per FSC) Rs. 50,000/-	A sterile, Flexible, end- and /or side-hole tube with a long snaring deice (e.g., a wire loop or noose) inserted through its lumen, designed to be introduced into a blood vessels or similar structure to manually retrieve or manipulate a	**Approved** subject to provision of valid Embassy attested Free Sale Certificate.

		(FSC USA Valid 08-03-2020)		foreign body. It is typically available in two form: 1 the loop emerges from the distal tip of the catheter while both free end of the wire emerges from the distal tip of the catheter while the free end is passed through the lumen to emerge at the proximal end. The wire is usually mad of high strength, stiff metal [e.g., nickel-titanium alloy (Nitinol)]	
95.	M/s Universal Enterprises, 29, Block-3, Overseas Co-operative Housing Society, Stadium Road, Karachi. (ELI-00079) **Evaluator**: AD-IV	**Manufacturer:** Swann-Morton Limited, Penn Works, Owlerton Green, Sheffield, S6 2BJ, United Kingdom. FSC UK issue date 12-04-2018	Carbon Sterile Surgical Blades Class B Codes: As per DOC (codes not on FSC) Shelf Life: 5 years Fee submitted: Rs. 25,000/-	Sterile surgical blades	**Approved** subject to provision of Stability studies supporting claimed shelf life of 5 years.
96.	M/s EngItech, C-59/1, Block-B, Gulshan-e-Jamal, Karachi. (ELI-00341) **Evaluator**: AD-IV	**Legal Manufacturer:** Hitachi Ltd. 2-16-1, Higashi-Ueno, Taito-ku, Tokyo, 110-0015 **Manufacturing site:** Hitachi, Ltd. Medical System Operations Group, Kashiwa 2-1, Shinotoyofuta, Kashiwa-shi, Chiba, 277-0804, Japan.	Hitachi Whole Body X-ray CT System SCENARIA VIEW Class C Shelf Life: N/A Fee submitted: Rs. 50,000/-	Whole body X-ray Computed Tomography system	**Deferred** for provision of Embassy attested Free Sale Certificate and Valid and Notarized Full QA Certificate , User manual, Original Notarized Letter of Authorization .

		(FSC Japan issued on 11-09-2018)			
97.	M/s. Global Marketing Services, 111-B, Hali Road, Westridge 1, Rawalpindi. ELI-00109 **Evaluator**: AD-IV	**Manufacturer:** UAB VILTECHMEDA Mokslininku Street. 6, LT-08412 Vilnius, Lithuania FSC Lithuania valid till 30.09.2019	Syringe Infusion Pump SP-12S Pro Class C Shelf Life: N/A Fee submitted: 50,000/- (0530783 dated 7-3-2017, submitted prev. on Form 6-A)	Indicated for infusion via intravenous (IV) intra-arterial (IA), epidural, or subcutaneous routes of administration. Infusion rates are programmable from 0.1 to 1500 ml/h	**Deferred** for provision of valid FSC, ISO 13485, Full QA, DOC and LOA from manufacturer does not indicate Exclusive/ Sole authorization to the importer and list of products for which importer is authorized.
98.	-do- **Evaluator**: AD-IV	**Manufacturer:** UAB VILTECHMEDA Mokslininku Street. 6, LT-08412 Vilnius, Lithuania FSC Lithuania valid till 30.09.2019	Syringe Infusion Pump SP-12S Pro Class C Shelf Life: N/A Fee submitted: 50,000/- (0530783 dated 7-3-2017, submitted prev. on Form 6-A)	Indicated for infusion via intravenous (IV) intra-arterial (IA), epidural, or subcutaneous routes of administration. Infusion rates are programmable from 0.1 to 1500 ml/h	**Deferred** for provision of valid FSC, ISO 13485, Full QA, DOC and LOA from manufacturer does not indicate Exclusive/ Sole authorization to the importer and list of products for which importer is authorized. Communicated
99.	-do- **Evaluator**: AD-V	Legal manufacturer EKF-diagnostic GmbH Ebendorfer Chaussee 3, 39179 Berleben, Germany FSC Germany Date of issue 9th November, 2018	Que-Lab Analyzer System (HbAIC Measuring System) Model: 0110-0000 Class B • Shelf Life: N/A Rs.25,000/-	Que-Lab Analyser is a point of care system intended for the in-vitro determination of glycated haemoglobin (HbA1c) in whole blood obtain from finger prick or venous whole blood sample collected into EDTA tubes.	**Approved.**
100.	-do-	Legal manufacturer	Hemo Control	The Hemo Control	**Approved.**

	Evaluator: AD-V	EKF-diagnostic GmbH Ebendorfer Chaussee 3, 39179 Berleben, Germany FSC Germany Date of issue 26.04.2019	Haemoglobin Measuring System Ref: 3040-0010-0218 Class B • Shelf Life: N/A Rs.25,000/-	Haemoglobin Measurement System is intended to be used for the quantitative determination of haemoglobin (Hb) concentrations in human blood.	
101.	M/s Innovate Medical Techonologies (Pvt) Ltd , House No. A-7, Baloch Goth, , Block No 13/D-3 Gulshan-e-Iqbal, Karachi. (ELI-00352) **Evaluator**: AD-IV	Manufacturer: Coloplast A/S Holtedam 1 3050 Humlebaek Denmark (FSC Denmark valid 14-11-2020, copy provided)	Purilon Gel Class: C Code: 3900----15gm 3903----25gm Shelf Life: 3 Years Fee submitted: 50,000/-	Autolytic debridement of tissue in both dry and moist necrotic wounds, when used in combination with a secondary dressing. Sterile, single-use	**Deferred** for provision of original valid Embassy attested FSC, Stability studies supporting claimed shelf life, EPSP and manufacturing details.
102.	-do- **Evaluator**: AD-IV	Manufacturer: DeRoyal Industries Inc. 200 DeBusk Lane Powell. TN 37849 USA. (FSC US FDA valid till 9-1-2021)	Multidex Gel Class: C Code: 46-710 ----- ½ Oz (15 g) 46-711 ----- ¼ Oz (7 g) 46-712 ----- 3 Oz (85g) Shelf Life: 5 Years Fee submitted: 50,000/-	Indicated for all types of wounds, including dermal ulcers, diabetic ulcers, abdominal wounds, superficial wounds, lacerations, cuts, abrasions, donor sites, and second degree burns. Indicated for moist to dry wounds. Sterile	**Deferred** for provision of original valid FSC, original LOA , EPSP, manufacturing and QC details.
103.	M/s Combined Engineers, House # 246, Street # 17 Off . Jamaluddine Afghani Road,	**Legal Manufacturer:** Nobel Biocare AB, Box 5190, SE-402 26 Goteborg, Sweden, **Manufacturer:**	Abutments, Clinical Screws Class C	Abutments, Clinical Screws	**Deferred** for clarification/ provision of following documents:-

	BMCHSk Sharafabad, Karachi. (ELI-00377) **Evaluator**: AD-IV	M/s Nobel Biocare, Dimbovagen 2, SE-691 51 Karlskoga Sweden. **Manufacturer:** Nobel Biocare USA LLC, 22715, Savi Ranch Parkway, Yorba Linda, CA 92887. (FSC Valid 04-12-2019)	Shelf Life: Not mentioned Clearly Size & Codes as per FSC Fee submitted: Rs. 50,000/-		i) Multiple types and their further sub-types are applied on the application. In order to clarify grouping of the applied medical devices, you are advised to send qualified person or person well conversant in the subject alongwith technical details, brochure and actual product labels of all the types and codes required. ii) Provide accelerated and real-time stability studies for the applied product duly signed and stamped by a responsible person from manufacturer iii) Original documents (Free Sale Certificate, Letter of Authorization, ISO 13485, Full Quality Assurance, Credentials of manufacturer abroad iv) Provide MRP of the medical device

104.	-do- **Evaluator**: AD-IV	**Legal Manufacturer:** Nobel Biocare AB, Box 5190, SE-402 26 Goteborg, Sweden, **Manufacturer:** M/s Nobel Biocare, Dimbovagen 2, SE-691 51 Karlskoga Sweden. **Manufacturer:** Nobel Biocare USA LLC, 22715, Savi Ranch Parkway, Yorba Linda, CA 92887. (FSC Valid 04-12-2019)	NobelReplace® Conical Connection PMC Dental Implants Class C Shelf Life: 5 Years Size & Codes as per FSC Fee submitted: Rs. 50,000/-	Dental Implants	**Deferred** for clarification/ provision of following documents:- i) Clearly state the product codes required under this application and provide the labels and brochure of those codes. ii) Provide accelerated and real-time stability studies for the applied product duly signed and stamped by a responsible person from manufacturer. iii) Provide MRP of the medical device
105.	M/s. Total Technologies (Pvt) Ltd., 696, J-2, Johar Town, Lahore. ELI-00129 **Evaluator**: AD-IV	**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** (Pressure Regulators) Pressure Regulator FM Pressure Regulator MU Pressure Regulator Easycare Pressure Regulator Easycare Plus Class C Shelf Life: Not defined Fee submitted: Rs. 50,000/-	Pressure Regulators	**Deferred** for clarification/ provision of following documents:- i) Multiple models and their further sub-types (not mentioned on Free Sale Certificate) are applied on the application. ii) In order to clarify grouping of the applied medical

					devices, you are advised to send qualified person or person well conversant in the subject alongwith brochure and actual product labels of the types and codes required. iii) Provide Notarized Full Quality Assurance Certificate iv) Provide Statement on shelf life from the manufacturer v) Provide MRP of the medical device vi) Provide details of quality control processes/tests/certificate of analysis for the applied products
106.	-do- **Evaluator**: AD-IV	**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** (Flow Meter Devices for Medical Gases) Flowmeter RS Flowmeter Selector Type DF Flowmeter easymed Flowmeter Easymed Plus Flowmeter QMED Flowmeter SF Flowmeter Easyflow Flowmeter Easymix Class B Shelf Life: Not defined	Flow Meter Devices for Medical Gases	**Deferred** for clarification/ provision of following documents:- i) Multiple models on one application. ii) codes not mentioned on FSC iii) Provide brochures and actual product labels

			Fee submitted: Rs. 25,000/-		iv) Provide Statement on shelf life from the manufacturer v) Provide MRP of the medical device vi) Provide details of quality control processes/tests/ certificate of analysis for the applied products.
107.	M/s Kaf Surgical & Disposable Equipement, HM Disposable Office No. 24-25, Mezzanine Floor, Medicine Corner, KachiGali No.2, Marriot Road, Karachi. **Evaluator**: AD-IV	**Manufactured By:** Plasti Lab S.A.R.L. Roumeih, El Metn Industrial area, Main Raod El Khoury Building, P.O. Box 70407, Lebnon. (FSC Lebnon Valid Till 31-03-2024)	JRZ I.V Cannula with Wings with injection port Intravenous Cannula all Sizes Class B Shelf Life Not provided Sizes: G-14, G-16, G-18, G-20, G-22, G-24, G-26	J.R.Z. Intravenous cannula is a medical Device composed of multiple components in single device. Many devices can attach with this device for parental route administration of injectable medicines and fluid management.	**Deferred** for clarification/ provision of below mentioned documents:- Free Sale certificate statement from Lebanon is not from the health regulatory body of Lebanon. Provide Free Sale Certificate from the relevant regulatory body attested by Embassy of Pakistan in Lebanon The reference country Free Sale Certificate from Netherland is issued for Egypt. Submit original valid Embassy attested Free Sale Certificate for the applied product issued for Pakistan. Fee deposit slips mentioned on

					cover letter are not present in the submitted dossier. Submit original fee deposit slips Provide Essential Principles of Safety and Performance for the applied product Provide label for all sizes applied Clearly state the shelf life required
108.	M/s Zhangjiakou Dongfang Pharmaceuticals Pakistan (Pvt) Ltd. D-2, 2nd Floor Westland Trade Centre, Plot No. C-5, Block 7/8 KCHSU, Shaheed-e-Millat Road, Karachi. (ELI-00079) **Evaluator**: AD-IV	**Legal Manufacture:** Shenzhen Yingchi Techonology Co., Ltd. B30, Digital Building, 1079 Nanhai Rd, Nanshan District, Shenzhen, China. FSC not provided	Brain Ultimate Pulse Magnetic Stimulation Device Class B Shelf Life:5 years	The application field include Electro-physiological examination of nervous system, nerve function evaluation in rehabilitation department, motor nerve evalutioan and inspecting intefrity of motor nerve pathways in neurology department.	**Deferred** for clarification/ provision of below mentioned documents:- Provide original Embassy attested Free Sale Certificate in the country of origin. Provide Credentials of Manufacturer abroad duly notarized in country of origin. Provide original Letter of Authorization or Agency agreement duly notarized in the country of origin (iv) Provide details of manufacturing and quality control processes for the applied product.

					(v) Provide ISO13485 and Full Quality Assurance certificate duly notarized in the country of origin (vi) Provide Declaration of Conformity printed on the manufacturer letter head, filled and signed by the responsible person. (vii) Provide clinical studies of the product (viii) Clearly state the Model No. of the product required in this application
109.	M/s Pharmevo (Pvt) Ltd. A-29, North Western Industrial Zone, Port Qasim Karachi. (ELI-00055) **Evaluator**: AD-IV	**Manufacturer:** Bioelectronics Corporation 4539 Metropolitan Court Frederick, MD 21704, USA (FSC US FDA Valid till 20-02-2021)	PAIN GEAR® • Back Pain • Knee Pain • Muscle & Joint Pain Non Thermal Shortwave Therapy Class B Shelf Life: Document pending PAIN GEAR® Knee Pain Model No. 088 PAIN GEAR® Back Pain Model No. 088 PAIN GEAR® Muscle & Joint Pain Model No. 088	The Pain Gear® is a drug free micro medical device that provides advance long lasting chronic pain relief using Electromagnetic Pulse Therapy to reduce pain and inflammation. As it is a drug and ingredient-free so far for continuous use and can be used while taking any other medication.	**Deferred** for clarification/ provision of below mentioned documents:- Original Embassy attested Free Sale Certificate Original Notarized Letter of Authorization from the Manufacturer abroad Notarized ISO 13485 and Full Quality Assurance Certificate Essential Principles of Safety and Performance

					MRP not mentioned on form Multiple products applied on one application. Submit separate application for Knee pain and Muscle & Joint Pain Shelf life supported with stability studies
110.	M/s RECH International, Office No: 247-B, Block-6. P.E.C.H.S, Near Hotel Faran, Yaseen Suleman Street, Karachi. (ELI-00257) **Evaluator**: AD-IV	**Legal Manufacturer:** Zimmer Inc 1800 West Center Street Warsaw Indiana 46580 United States of America. Zimmer.Inc, 345 E Main St WARSAW, In USA 46580 Zimmer manufacturing B.V. Route 1, KM 123.4 Bldg 1 turpeaux industrial park mercedia , PR USA 00715 Zimmer Orthopaedic Mfg ltd Building no.2 East park Shannon, Clare Ireland 0000000 Zimmer orthopedics Manufacturing Limited-Galway Deerpark Industrial Estate Oranmore, Galway Ireland Galway.	Persona- The Personalized Knee System Knee Repalcement System Class C Shelf Life:10 years (Sizes & Codes as Per FSC)	The Persona Personalized Knee System (Persona) Is a modular Knee joint replacement system designed to resurface the articulating surfaces of the distal femur, proximal tibia, and patella bones in the knee joint. It is indicated for patients with severe knee pain and disability.	**Deferred** for clarification/ provision of below mentioned documents:- Provide complete, valid, original, embassy attested Free Sale Certificate and highlight the required product codes/reference numbers required in this application on Free Sale Certificate. The codes/ref nos. should also be present in Declaration of Conformity (highlight) and Design Examination Certificate (highlight). Only the components and codes/ref no. which are part of Persona Knee System will be accepted in this application

					Provide labels for all the required codes/ref nos. indicating they are part of persona knee system alongwith brochure Provide summary of statement of shelf life of the components of persona knee system from the manufacturer abroad signed and stamped by their responsible personel ISO 13485 expired. Provide valid notarized ISO13485 certificate Provide notarized Full Quality Assurance Certificate and notarized Design Examination certificate. Letter of Authorization from the manufacturer abroad does not indicate Exclusive/ Sole authorization to the importer, validity not mentioned, list of products authorized not mentioned. Provide original, notarized letter of Authorization having above

					mentioned information
111.	M/s Excel Corporation, 435 BYJ Society, Bahadurabad, Karachi. (ELI-00110) **Evaluator**: AD-IV	**Manufacturer:** Jiangxi Daysure Medical Technology Co., Ltd West of Jinchang Road, Jinxian County, Nanchang City, 331700, Jiangxi, China (FSC China valid till 07-03-2020)	Pigeon-Disposable Sterile Foley Catheter (Silicone) Class B Sizes: 6Fr, 8Fr, 10Fr, 12Fr, 14Fr, 16Fr, 18Fr, 20Fr, 22Fr, 24Fr, 26Fr, 28Fr, 30Fr Single way disposable sterile Foley Catheter (silicone) 2-way way disposable sterile Foley Catheter (silicone) 3-way disposable sterile Foley Catheter (silicone) Shelf Life: 5 Years Fee submitted: Rs. 25,000/-	It is a thin tube inserted into the bladder to drain urine. Sterile, single-use	**Deferred** for clarification/ provision of below mentioned documents:- Free sale certificate expired. Provide original, valid, Embassy attested Free sale certificate from country of origin Provide complete real time stability/aging studies of the applied product signed and stamped by responsible personnel of manufacturer clearly stating the shelf life of the product Provide details of quality control tests performed on the applied product and certificate of analysis of the product as well as provide biocompatibility studies Provide specimen labels of all codes required in this application as approved in country of origin. Provide pictures of the actual product

					Provide brochure of the applied product having all codes required in this application and clearly state the difference among different codes applied Provide the recent sterilization validation report of the manufacturer Provide "final inspection report" of the product as mentioned in Declaration of Conformity Provides details of raw materials used in the manufacturing and their grades used
112.	-do- **Evaluator**: AD-IV	**Manufacturer:** Jiangxi Daysure Medical Technology Co., Ltd West of Jinchang Road, Jinxian County, Nanchang City, 331700, Jiangxi, China (FSC China valid till 07-03-2020)	**Pigeon-Disposable Endotracheal Tube** Disposable Endotracheal Tube Class B Codes: Shelf Life: 5 Years	Endotracheal Tube is supplied sterile with connectors. The tube is inserted into a patient's trachea through th patients nose or mouth in order to ensure that the airway not closed off and that air is able to reach the lungs.	**Deferred** for clarification/ provision of below mentioned documents:- The product and models mentioned in Free sale certificate are of REINFORCED endotracheal tube whereas the Declaration of Conformity (DOC) and technical documents provided are of simple endotracheal tube. Clarify whether the product

					required is endotracheal tube or Reinforced endotracheal tube and provide the relevant Free Sale Certificate. Also the Free Sale Certificate in this dossier is expired. Provide original, valid, Embassy attested Free sale certificate from country of origin for the required product Provide complete real time stability/aging studies of the required product signed and stamped by responsible personnel of manufacturer clearly stating the shelf life of the product Provide details of quality control tests performed on the required product and certificate of analysis of the product as well as provide biocompatibility studies Provide specimen labels of all codes required in this application as approved in country of origin as well as for Pakistan. Provide pictures

					of the actual product Provide brochure of the required product having all codes required in this application which should also be in Free Sale Certificate and clearly state the difference among different codes applied. Provide the recent sterilization validation report of the manufacturer Provide "final inspection report" of the product as mentioned in Declaration of Conformity Provides details of raw materials used in the manufacturing and their grades used
113.	M/s Flowtronix Systems, Flat No. 02, 1st Floor, Al-Ashraf Plaza, Range Road, Rawalpindi. (ELI-00217) **Evaluator**: AD-IV	**Manufactuer:** Nipro Medical Ltda, Avenida NIpro, 451, Regiao Norte CEP, Sorocaba Sau Paolo, 18087-127, Brazil. FSC Brazil issued on 23-05-2017 FSC Australia issued on 31-01-2019	**Nipro BrizIo-BRZ+12345A** (Oxygenator) 269D-8AA8-333B-D190-IA71-9888-F716,EF5F,2D97,571F Class B Shelf Life: 3 years Fee submitted: Rs. 25,000/-	The BRIZIO – MEMBRANE OXYGENATOR AND VENOUS RESERVOIR with integrated cardiotomy filter Nipro was designed for single use. It is sterile (sterlizied by ethylene oxide) and nonpyrogenic. The BRIZIO	**Deferred** for clarification/ provision of below mentioned documents:- Certificate from country of origin (Brazil) is not translated in English so could not be established if its Free Sale Certificate or not. Provide valid translation. The

				consists of a chamber for gas exchange and an internal heat exchanger plus venous blood reservoir and integrated cardiotomy filter. The blood circulates externally to the capillary fibers arranged in the oxygenation chamber in the form a belt of parallel fibers. The internal heat exchanger carries out the cooling/heating during oxygenation of the blood. The Blood coming from the aspiration of the intra-thoracic cavity passess through the venous reservoir through an independent system: integrated cardiotomy filter, later mixing with the blood from the venous drainage. The BRIZIO is remcommended for exchanging gas and for adjusting temperature of	model number applied is not on Free Sale Certficate of Australia and could be read on Brazil Certificate. Provide evidence that the applied product number is registered in country of origin or any reference country ISO13485 not provided. Provide valid and notarized certificate EC Full QA certificate not provided. Provided valid and notarized certificate Provide details of manufacturing processes for the applied product Provide QC tests/certificate of analysis for the applied product Labels and brochure not provided. Provide Instruction for use not provided. Provide MRP not provided. Provide

				blood (heat exchangeing) through extracorporeal circulationand reservoir is used for reservingdrained and sucked blood and also for removing air or bubbles in it during open-heartsurgery under direct vision. The blood contacting surface of the oxygenator is coated E8polymer in order to inhibit platelet adhesion.	Provide complete real time stability studies of the applied product signed and stamped by responsible personnel of manufacturer clearly stating the shelf life of the product Letter of Authorization from the manufacturer abroad does not indicate Exclusive/ Sole authorization to the importer for the products mentioned. Also the letter is from Singapore whereas the manufacturer is Brazil. Clearly establish the link between the two (Singapore and brazil) from the manufacturer, otherwise submit valid, notarized Letter of Authorization/Agency agreement from the manufacturer
114.	M/s. Mian Scientific Corporation (Pvt) Ltd Office No. 534, Jinnah Colony Faisalabad ELI: 00442 **Evaluator**:	**Manufacturer;** i-SENS, INC. 94-1, BANPO-daero 28-gil, Seocho-gu, Seoul, 06646, republic of Korea. FSC Korea date of Issue 02.04.2018	**(Nipro Premier S Blood Clucose Monitoring System)** (Blood Glucose Monitoring System) *Code: Not mentoned* Class: C Self Life Not applicable	Blood Glucose Monitoring System.	**Defered** for submission of below mentioned documents:- Manufacturing site not provided on Form-7A and different sites mentioned in Free Sale Certificate of

	AD-IV		Fee submitted: Rs. 50,000/-		Korea and Germany. Clearly state the manufacturing site Certificate of GMP expired. Full Quality Assurance Certificate expired. Provide valid and notarized certificate Provide summary/statement of shelf life from the manufacturer abroad signed and stamped by their responsible personnel for the applied product. Free Sale Certificate Germany expired. Provide original, valid, Embassy attested Free Sale Certificate from the country of origin. Also the provided Free Sale Certificate Germany does not have the product applied namely Nipro Premier S Blood Glucose Monitoring System. Free Sale Certificate of Korea bears the name Nipro Premier S Blood Glucose Monitoring System (without test strips).

					Clearly state the product required jn this application an provide documents accordingly. The letter is from Singapore which is a subsidiary of a company in Japan whereas the manufacturer is i-SENS Korea. The connection among them cannot be established. Moreover the Letter of Authorization from Singapore is not Original and Notarized and does not indicate Exclusive/ Sole authorization to the importer. Provide link between the three companies and provide letter of Authorization from Manufacturer or Market Authorization holder which should be original, notarized and indicate Sole/Exclusive authorization to the importer for the name of products authorized
115.	M/s. Safeway Systems Pakistan, Flat No. 4, 2nd Floor, Amna	**Legal manufacturer** M/s. *CARDIOMED SUPPLIES INC*	**(Centralcard)** ***(Venous Cannula)***	Venous cannula is intended for collection of venous blood	**Deferred** for clarification/ provision of below mentioned documents:-

	Shopping centre, Misrial Road, Rawalpindi (ELI-00308) **Evaluator**: AD-IV	*Address: 199 ST.DAVID STREET, LINDSAY, ONTARIO, CANADA K9V5K7* FSC : Canada Date of issue: 17th october,2018	Code: CM-3652L, CM-365IL-CM-3751V2, CM-6720V, CM-6722V-CM-6724V, CM-6726V-CM-6728V- CM-6730V-CM-6732V, CM-6734V-CM-6736V, CM-6738V-CM-6852VC, CM-68926V-CM-693446, CM-6934LNN-CM-6934LW, CM-6934V2-CM-693651L,CM-6730VWL-CM-6934LV2, CM-6934V2NW-CM-7732V, CM-6718V-CM-6818V, -CM-6820V-CM-6822V, CM-6826V-CM-6828V, CM-6830V-CM-6832V, DCM-6834V-CM-6836V, CM-6838V CM-6928DW,CM-6928LNW-CM-6932DW,CM-6932LNW-CM-6934DW, CM-6934LNW-CM-6936DW,-CM-6936LNW-CM-8224V,-CM-6936D-CM-6728EV,- CM-6732EV-CM-6928D, CM-6932D-CM-6932D40, CM-6934D-CM-6936D46, CM-6716VWG-CM-6718VWG, CM-6720VWG-CM-6722VWG, CM-6732VWH-CM-6412V, CM-6712VWHG-CM-6714V, CM-6714VWHG-CM-6716V, CM-6716VWHG-CM-6718VWHG, CM-6720VWHG-CM-6722VWHG-CM-6724VWHG-CM-6726VWHG, CM-6812V CM-6814V, CM-6816V-CM-6934D40, Class : B (should be D) Shelf Life : 2 years **Fee submitted: Rs. 50,000/-**	from the right side of the heart via superior and inferior vena cava during cardiopulmonary bypass up to 6 hours or less	Provide complete accelerated and real time stability studies of the applied product signed and stamped by responsible personnel of manufacturer clearly stating the shelf life of the product Only Single Stage Venous Perfusion Cannula and its types will be considered on this application. Clearly state the product codes required for Single Stage Venous Perfusion Cannula and also highlight those codes on Product List provided by the manufacturer as well as on the Medical Device Licence of Health Canada and provide labels of all codes required and brochure. Submit separate application for Dual Stage Cannula IFU provided is of Venous Return Cannula whereas the product applied is Venous Perfusion Cannula. Clarify and provide the relevant IFU

					Distributor agreement is not signed by the importer. Provide Credentials are not complete and are not signed by the manufacturer and are not notarized. Provide Provide quality control tests/certificate of analysis for the applied product
116.	-do- **Evaluator**: AD-IV	**Legal manufacturer** M/s. *CARDIOMED SUPPLIES INC* *Address: 199 ST.DAVID STREET, LINDSAY, ONTARIO, CANADA K9V5K7* FSC : Canada Date of issue: 17th october,2018	**(** *Tube connectors)* Code: -656, C-657, C-658, C-659, C-660-C-661, C-662, C-663, C-664 C-665, C-666, C-667, C-668-C-669, C-670, C-671-C-672, C-673, C-674, C-675, C-676, C-677, C-678, C-679, C-680, C-680NS, C-681, C-682, C-683, C-683NS, C-684, C-685, C-686, C-687, C-688, C-689, C-690, C-691, C-692, C-693, C-694, C-695, C-696, C-697, 17-005, CM-5015, CM-35AV, CM-35NAV, CM-925, CM-D925, CM-TSB, 17-4600, 17005 Class : B Shelf Life :5 years **Fee submitted: Rs. 50,000/-**	Tube connectors are used for Pressure relief for the extracorporeal circulation circuit during cardiopulmonary bypass.	**Deferred** for clarification/ provision of below mentioned documents:- Only One-way Vent Valve (CM-35NAV) will be considered on this application. Submit separate application for other type of connectors Provide complete accelerated and real time stability studies of the One-way Vent Valve signed and stamped by responsible personnel of manufacturer clearly stating the shelf life of the product Provide Instruction for use (IFU) and brochure for

					One-way Vent Valve Clearly state the purpose of One-way Vent Valve alongwith its detailed description Provide the relevant rule of Medical Devices Rules, 2017 according to which the device has been classified as Class B medical device Distributor agreement is not signed by the importer. Provide Credentials are not complete and are not signed by the manufacturer and are not notarized. Provide Provide manufacturing processes and quality control tests/certificate of analysis for One-way Vent Valve
117.	M/s Eastern Medical Care (Pvt) Ltd, 7A Block N, Model Town Extension, Lahore ELI-00130 **Evaluator**: AD-IV	**Manufacturer:** THAI AMTEC CO., LTD. 88/6 Asia Industrial Estate Suvarnabhumi, Moo 4, Tambon Khlongsuan, Amphur Bangbo, Samutprakarn, Province 10560, Thailand	**Cirtrix-LA (organic acid-based disinfectant)** Class:C Model: 30H001 (5L) Shelf Life: 3 years Fee submitted: Rs. 50,000/-	Liquid disinfectant mainly composed of citric acid, malic acid and lactic acid used for heat disinfection of fluid pathways of	**Deferred** for clarification/ provision of below mentioned documents:- Free Sale Certificate provided is from Thailand but Embassy

		FSC Thailand valid till 30-10-2021		hemodialysis machines	attestation is from Japan. This Free Sale Certificate from Thailand cannot be considered as Free Sale Certificate from Japan merely on the grounds of Japanese Company Declaration. Agency agreement not signed and stamped by importer. Provide Provide complete accelerated and real time stability studies of the applied product signed and stamped by responsible personnel of manufacturer clearly stating the shelf life of the product Credentials of manufacturer abroad not signed and stamped by manufacturer and not notarized also. Provide
118.	M/s. Hashir Surgical Services, Office No.16, Street 1, F-2, Phase 6, Hayatabad, Peshawar. (ELI-00075) **Evaluator**:	**Manufacturer;** M/s. USM Healthcare Medical Devices Factory JSC Lot I-4b-1.3, N3 Street, Saigon Hi-tech Park, Long Thanh My Ward, District 9, Ho Chi Minh City, Vietnam. FSC Vietnam Date of Issue 25/03/2019	**Favocath™ I.V Catheter with Injection Valve** Class B Code:- Shelf Life: 5 years. Fee submitted: Rs. 25,000/-	I.V Catheter provides access to a vein of a patient in order to sample blood, administer fluids or nutrition, for the continuous use of not	**Deferred** for clarification/ provision of below mentioned documents:- The Product namely **Favocath IV catheter with Injection Stopper** is not present on Free Sale

	AD-IV			more than seven days.	Certificate and two Free Sale Certificates are provided with two different names and model numbers whereas the technical documents indicates them together. Clearly state the brand name required and its models supported by Free Sale Certificate and relevant technical documents Provide complete accelerated and real time stability study reports of the applied product signed and stamped by responsible personnel of manufacturer clearly stating the shelf life of the product Clearly state from manufacturer if the product is CE marked or WHO Prequalified or not? If yes, then provide CE marking certificates or WHO Prequalification documents from WHO itself for the applied product. Provide readable labels of all the product codes

					required in this application Credentials of manufacturer abroad not signed and stamped by manufacturer and not notarized also. Provide Provide evidence that the attached manufacturing chart represents the manufacturing process of the applied product Declaration of Conformity is not signed and stamped by manufacturer. Provide
119.	-do- **Evaluator**: AD-I	Legal Manufacturer Trinon Titanium CmbH, Augartenstr. 1, 76137 Germany FSC Germany Date of issue 04.06.2018	**Surgical Scalpel Blades Disposable** **Carbon Steel** Sizes No.10, 11,12,13,15,16,17,18,19,20 ,21,22,23,24,34,36 15c, 12d, 24d, 36d, Disposable Scalpel No.10 Sterile, Disposable Scalpel No. 11 Sterile, Disposable Scalpel No.12 Sterile, Disposable Scalpel No.13 Sterile, Disposable Scalpel No.15 Sterile, Disposable Scalpel No.18 Sterile, Disposable Scalpel No.19 Sterile, Disposable Scalpel No.20 Sterile, Disposable Scalpel No.21 Sterile, Disposable Scalpel No.22 Sterile, Disposable Scalpel No.23 Sterile, Disposable Scalpel No.24 Sterile, Disposable Scalpel No.15c Sterile, Disposable Scalpel No.12d Sterile. Disposable Scalpel No.24d Sterile	**Brief description of the device with its intended use:** The product are intended for the performance of surgical invasive procedure, especially on humans. They are used by medical specialists.	**Approved** subject to provision of original FSC.

			Disposable Scalpel No.36d Sterile Class: B Shelf Life: 5 years Rs.25,000/-		
120.	M/s Noor International Noor House, 29-D, Block 6, PECHS, Karachi (ELI-00061) **Evaluator**: AD-VII	**Manufacturer:** Medin Medical Innovations GmbH Adam-Geisler-Str.1 82140 Olching Deutschland/Germany (FSC Germany 13-09-2017)	Prong Mask nCPAP accessories Class B Shelf Life: 5 Years Rs: 25000/-	Miniflow® is a single use product for nCPAP therapy/ non invasive ventilation therapy in treating neonates and premature infants in intensive care units.	**Approved** subject to provision of below mentioned documents:- The application form (From 7-A) has not been stamped and is incomplete as certain rows are either missing or not been properly filled. Upon scrutiny of the dossier, it is revealed that 'prong' and 'masks' are two separate nCPAP accessories, however, the applicant has mentioned as "Prong-Mask" in the application form and has not clarified whether application submitted is for 'Prong' or 'Mask'. Manufacturing & Quality Control processes as given in Annexure 4 of the application form are incomplete. The firm has not provided stability

					data for the shelf life of the products.
121.	-do- **Evaluator**: AD-V	**Manufacturer:** M/s UNISIS Corp., 4-11-4 Taito, Taito-ku, Tokyo 110-0016, Japan (FSC Japan Issuance Date 18-07-2018)	Uniever Loss of resistance syringe Class B Shelf Life: 5 Years Sizes: 5ml, 10ml	The syringe is used with Epidural anesthesia needle	**Approved.**
122.	-do- **Evaluator**: AD-I	**Manufacturer:** Kossan International SDN BHD Wisma Kossan, Lot 782, Jalan Sungai Putus off Batu 3 ¾, Jalan Kapra 42100 Klang Selangor Malaysia. (FSC MALAYSIA valid 20-11-2020)	Intouch Spot InTouch Powder Free Latex Surgical Gloves Class B Fee submitted 25000 Shelf Life: 5 Years (Sizes & Codes as Per FSC) Intouch Spot Sterile Powder Free Latex Surgical Gloves GB87500479417 SIZE : 5 ½, 6, 6 ½,7 ,7 ½ ,8 ,8 ½ , 9. Rs.25,000/-	Surgical gloves are intended to be used once in an invasive procedure involing a single patient and permanently discarded after use. The glose are worn on the hands of healthcare personnel to provide barrier protection from cross contamination between a patient and the healthcare personnel.	**Approved** subject to inspection of manufacturer abroad or provision of CE mark documents.
123.	-do- **Evaluator**: AD-I	**Manufacturer:** Kossan International SDN BHD Wisma Kossan, Lot 782, Jalan Sungai Putus off Batu 3 ¾, Jalan Kapra 42100 Klang Selangor Malaysia. (FSC MALAYSIA valid 20-11-2020)	iNtouch Lite Sterile Powdered Latex Surgical Gloves Class B Shelf Life: 5 years Codes as Per FSC GB92394822618 SIZE. 5 ½, 6, 6 ½,7 ,7 ½ ,8 ,8 ½ , 9 Rs.25,000/-	Surgical gloves are intended to be used once in an invasive procedure involing a single patient and permanently discarded after use. The glose are worn on the hands of healthcare personnel to provide barrier protection	**Approved** subject to inspection of manufacturer abroad or provision of CE mark documents

				from cross contamination between a patient and the healthcare personnel.	
124.	M/s. Physiomed (Pvt) Ltd, 268/3, Kamal Road Saddar Rawalpindi. ELI-00199 [439-P] **Evaluator**: AD-V	Legal Manufacturer / Manufacturing Site i) M/s. St. Jude Medical Cardiac Rhythm Management Division, 15900 Valley View Court, Sylmar, CA 91342 USA ii)M/s. St. Jude Medical Puerto LLC, Lot A Interior #2 Rd km.67.5, Santana Industrial Park, Arecibo PR 00612, USA iii) M/s. St. Jude Medical Operations(M) sdn. Bhd Plot 102, Lebuhraya Kampung Jawa, Bayan Lepas Industrial Zone, 11900 Penang, Malaysia. FSC Belgium Issue date : 23-10-2018	Quadra Assura MP ™ (Cardiac resynchronization device, tiered-therapy cardioverter/ defibrillator)) Class D Shelf Life : 24 Months Codes & Sizes: CD3371-40, CD3371-40C Rs.50,000/-	The devices is intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.Also intended tom resynchronize the right and left ventricles in patients with CHF.	**Deferred for provision of** Link up letter of Abbot with St Jude Medical required and valid Letter of Authorization.
125.	-do- **Evaluator**: AD-I	**Legal Manufacturer:** M/s St Jude Medical 15900 Valley View Court, Sylmar, CA 91342 USA FSC BELGIUM ISSUED ON 23-10-2018.	CPS™ Implant Kit (Cardiac Positioning System Kit) MODEL NO 410190 Class D Fee submitted RS 50000 Shelf Life 1 years Rs.25,000/-	The lead delivery tools and accessories are used for delivering lead to the left side of the heart by cannulating the coronary sinus ostium.	**Approved.**

126.	-do- **Evaluator**: AD-III	Legal Manufacturer: St Jude Medical 14901 DEVEAU PL.MINNETONKA, MN USA FSC USA Valid till 8th October,2020	**FAST CATH TRANSEPTAL GUIDING INTRODUCER** (TRANSEPTAL GUIDING INTRODUCE) 406553-406800-406802-406804-406805-406806406807-406840-406841-406842-406843-406849-406850-406851406852-406878-406879-406901-406902-406927-406948-406949-407400-407401-407402-407436-407438 Class D Shelf life 3 years Rs.50,000/-	The EP Fast-Cath introducer is designed for providing percutaneous access for diagnostic and therapeutic catheters. Devics may be configured to provide access to specific locations or regions within the human anatomy, particularly within the heart.	**Approved.**
127.	M/s The Searle Company Limited, 1st Floor, NICL Building, Abbasi Shaheed Road, Karachi (ELI-00057) **[1488]** **Evaluator**: AD-V	**Legal Manufacturer:** TG Medical SDN BHD LOT 5091, JALAN TERATAI, BATU 5, OFF JALAN MERU 41050 KLANG, SELANGOR D.E. Malaysia. (FSC valid 08-01-2024)	Protiex Sterile Latex Surgical gloves (Powdered) Class B Shelf Life: 5 Years Sizes & Codes GB1361668916 Rs. 25,000/-	Protiex Sterile Latex Surgical gloves (Powdered)	**Approved** subject to provision of Stability data, DoC, Composition & EPSP of Powered gloves and CE mark documents.
128.	M/s Fresenius Kabi, Pakistan (Pvt) Ltd. First Floor,Tanwir Ahmad Medical Center(YAMC), MM Alam Road, 27-C/3, Gulberg III, Lahore (ELI- 00266) [571] **Evaluator**: AD-V	Legal Manufacturer: M/s Fresenius Kabi AG, 61346 Bad Homburg, Germany Physical Manufacture Fresenius Vial S.A.S Le Gand Chemin 38590 Breziniz France. FSC France Valid till 07-06-2022	Agilia SP TIVA IN (Infusion IV Pump) Class C Service Life 10 years Code: Reference: Z018897 Rs.50,000/-	Infusion IV Pump	**Approved** subject to provision of valid Letter of Authorization and ISO 13485.
129.	-do-	Manufacturer:	Agilia SP IN (Infusion IV Pump)	Infusion IV Pump	**Approved.**

	Evaluator: AD-I	M/s Fresenius Kabi AG, 61346 Bad Homburg, Germany Physical Manufacture Fresenius Vial S.A.S Le Gand Chemin 38590 Breziniz France. FSC FRANCE Issud Date 11th January,2019	Reference CODE :Z018597 **Class C** **FEE SUBMITTED RS 50000** **Shelf Life 10 years**		
130.	M/s Saru International, B-194/1 Block-12, Gulistan Johar Karachi. (ELI-00316) [1109] **Evaluator**: AD-V	**Legal Manufacturer:** Yucel medkal ve tekstil urunleri sany TIC LTD STI (Selahatin Eyyubi Mh. 1612 Sk. No:19 ESENYURT ISTANBUL TURKIYE. (FSC Turkey Valid till: 4 Dec. 2021)	**Clinisponge** Absorbable Haemostatic Gelatin Sponge Class D Shelf Life: 5 Years (Sizes & Codes as Per FSC) Rs.50,000/-	Clinisponge is a s sterile , absorbable, haemostatic effective, implantable sponge. which is used locally in capillary, venous or leakage bleeding, where traditional hemostasis is difficult or unsuitable.	**Deferred for opinion from Islami Nazriati Council.** * **PIG SKIN** is the Source of Gelatin. Shortcomings communicated on 5th Dec. 2019, reply received on 18-05-2010 but following deficiencies are still not fulfilled Valid ISO-13485 Stability Studies data. Essential Principles of Safety and Performance. Design Examination certificate also required as product fall in class D
131.	-do- **Evaluator**: AD-V [1110]	Legal Manufacturer: Yucel medkal ve tekstil urunleri sany tic ltd sti (Selahatin Eyyubi Mh. 1612 Sk. No:19 ESENYURT	Cliniwax 2.5 g (Bone Wax) Class C Shelf Life: 5 Years	Cliniwax is a sterile hemostatic material to control of bleeding in bone injuries.	**Approved** subject to provision of below mentioned documents:- Valid ISO-13485

		ISTANBUL TURKIYE. (FSC Turkey Valid till: 22 Feb. 2021)	(Sizes & Codes as Per FSC) Rs.50,000/-	Cliniwax is produced from PH Eur bees wax. Bone wax-Cliniwax can be used in many surgical procedures such as orthopedic surgery and traumatolgoy in thoracic surgery (sternum and cost), in maxillofacial surgery. in general and plastic surgery and in neuro surgery.(trepanation)	Stability Studies data. Essential Principles of Safety and Performance.
132.	M/s. Future Scientific, FS House, Opposite Street No. 4, Main Road Shaheen Town, Gangal West, Post Office, Fazaia Colony, Rawalpindi. ELI-00209 **Evaluator**: AD-V	**Legal Manufacturer:** M/s. Immunodiagnostic Systems Limited, 10 Didcot Way, Boldon Business Park, Boldon Tyne & Wear, NE35 9PD, United Kingdom. FSC U.K Valid till 23.04.2024	**Product names** **IDS-iSYS CTX-1 (Cross Laps Â®),** Code **IS-3000** Class **B** Shelf Life: **12 months** **IDS-iSYS CTX-1 (Cross Laps Â®) control set,** Code **IS-3030** Class **B** Shelf Life: **15 months** **IDS-iSYS 25-Hydroxy Vitamin DS,** Code……**IS-2500**…… Class ……**B**……	IDS-iSYS CTX-I (CrossLaps®) assay is used for the quantitative determination of degradation products of C-terminal telopeptides of Type I collagen (CTX-I) released during bone resorption in human serum or plasma on the IDS-iSYS Multi-Discipline Automated System. IDS-iSYS CTX-I	Approved.

			Shelf Life: …….**21 months** **IDS-iSYS 25-Hydroxy Vitamin DS control set,** Code……**IS-2530**…… Class ……**B**…… Shelf Life: …….**24 months** **IDS-iSYS 1,25 Dihydroxy Vitamin DXP,** Code……**IS-2000**…… Class ……**B**…… Shelf Life: …….**06 months** **IDS-iSYS 1,25 Dihydroxy Vitamin DXP control set,** Code……**IS-2030**…… Class ……**B**…… Shelf Life: …….**18 months** **IDS-iSYS Intact PTH,** Code……**IS-3200**…… Class ……**B**…… Shelf Life: …….**09 months**	(CrossLaps®) Control Set IDS-iSYS 25 Vit Ds assay is intended for the quantitative determination of total 25-hydroxyvitamin D [(25(OH)D] in human serum or plasma on the IDS-iSYS Multi-Discipline Automated System IDS-iSYS 25 VitDs Control Set The IDS-iSYS 1,25 VitDXp assay is an *in vitro* diagnostic device intended for the quantitative determination of 1,25-dihydroxyvitamin D [1,25(OH)2D] in human serum on the IDS-iSYS Multi-Discipline Automated System. Results are to be used as an aid in the assessment of	

			IDS-iSYS Intact PTH control set Code……**IS-3230**…… Class ……**B**…… Shelf Life: …….**18 months**	vitamin D sufficiency. IDS-iSYS 1,25 VitDXp Control Set The IDS-iSYS Intact PTH assay is intended for the quantitative determination of PTH in human serum or plasma on the IDS systems. Results are to be used in conjunction with other clinical and laboratory data to assist the clinician in the differential diagnosis of hypercalcemia and hypocalcemia resulting from	
133.	-do- **Evaluator**: AD-III	Legal Manufacturer: Immundiagnostik AG Studenwald-Allee 8a, D 64625 Bensheim, Germany. FSC Germany Date of Issue 22.03.2019	IDk ® aI-Antitrypsin ELISA, IDk ® Pancratice Elastase ELISA aI-Antitrypsin ELISA Article No: K6750 Pancreatic Elastase ELISA Article No: K6915 Class B Shelf life: 2 years (For both product Rs. 25,000/-	This immunodiagnostic assay is an enzyme immunoassay intended for the quantitative determination of a antitrypsin in stool. For in vitro diagnostic. Pancreatic Elastase ELISA is intended for quantitive determination	**Approved** subvject to provision of shelf life supported with stability Data.

				of human pancreatic elastase in stool	
134.	M/s Shamco Traders (Pvt) Ltd 174, Ahmad Block New Garden Town Lahore: (ELI:00102) [24A] **Evaluator**: AD-V	**Legal Manufacturer** MedXl 285 Labrosse, Pointe, Chlaire (Qc) Canadal H9R IA3 FSC: Health Canada Issue Date: 19-05-2020	Cirtrflow Plus Sodium Citrate 4% and 30% Ethanol Class: B Shelf Life: 30 Months (Sizes & Codes: 38443-1	Sodium Citrate 4% used as an anti-coaggulant for central venous catheter and 30% Ethanol used as disinfectant	**Approved subject to provision of** original Embassy attested Free Sale Certificate of Health Canada .
135.	M/s Zenith International, Room No. 104, Tahir Plaza, A/20, Block 7&8, KCHSU, Karachi (ELI-00090) **[1416]** **Evaluator**: AD-V	**Manufacturer:** TianJin HuaHong Technology Co., Ltd. A01, Plant B, No. 278, Hangkong Road, Tianjin Pilot Free Trade Zone (Airport Industrial Park) Tianjin, China, **Exported By:** Ningbo Greetmed medical Instruments Co., Ltd. Address: 18 F-3, No. 1 Building, Wante Business Centre , Hi-Tech Zone, 315042, Ningbo, People's Republic of China. (FSC China Valid Date 06-01-2020)	Perfect Fine Disposable Lancets, Sterile Class B Shelf Life: 5 Years	A Sterile, hand-held, sharply-pointed, non mechanical, scalpel-like instrument intended to be used by a healthcare provider to manually puncture the skin of a patient to obtain a small blood specimen. This is a single use device.	**Approved** subject to inspection of manufacturer abroad or provision of CE mark documents and submission of valid FSC.
136.	-do- **Evaluator**: AD-II [2554]	**Manufacturer:** M/s. Dongguan Topwell Medical Devices Company Limited, Room 501, Building 1, No.10, Makeng Jinma Road Dalang Town, Dongguan City,	Perfect Neb (Piston compressor Nebulizer) Class B (according to Rule 11 of MDR, 2017) Shelf life: NA Service life: 02 years Code/Model: TCN-01WC	Nebulizer is intended for use in the treatment of asthma, COPD and other respiratory ailments in which an	**Approved** subject to inspection of manufacturer abroad or provision of CE mark documents.

		Guangdong Province, China. **FSC:** China (Valid upto 09-03-2021	Rs.25000/-	aerosolized medication is required during therapy.	
137.	-do- **Evaluator**: AD-II [2555]	**Manufacturer:** M/s. Dongguan Topwell Medical Devices Company Limited, Room 501, Building 1, No.10, Makeng Jinma Road Dalang Town, Dongguan City, Guangdong Province, China. **FSC:** China (Valid upto 09-03-20210	NEBYFLO + (Piston Compressor Nebulizer) Class B (according to Rule 11 of MDR, 2017) Shelf life: NA Service life: 02 years Code/Model: TCN-01W Rs.25,000/-	Nebulizer is intended for use in the treatment of asthma, COPD and other respiratory ailments in which an aerosolized medication is required during therapy.	**Approved** subject to inspection of manufacturer abroad or provision of CE mark documents.
138.	M/s Hoora Pharma (Pvt) Ltd., WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi (ELI-00037) **Evaluator**: AD-I	**Legal Manufacturer:** M/s Siemens Healthcare Diagnostics Inc, 511 Benedict Avenue, Tarrytown, NY, 10591, USA **Authorized Representative:** M/s Siemens Healthcare Diagnostics Limited, Sir William Siemens Square, Frimley, Camberley, Surrey, GU16 8QD, UK (FSC UK Valid Till 31-12-2020)	Advia Centaur Herpes-I IgG Advia Centaur Herpes-1 IgG (HSV1) Quality Control Class: C Fee SUBMITTED RS 50000 Shelf Life: 15 Months Each Codes as Per FSC Advia Centaur Herpes-I IgG SMN 10720846 Advia Centaur HSV1 Quality Control SMN 10720847 Rs.50,000/-	The Advia Centaur® Herpes-1 IgG (HSV1) assay is for in vitro diagnostic use in the qualitative determination of IgG antibodies to herpes Simplex virus type 1 (HSV-1) in human serum and plasma (EDTA and lithium heparn) using the advia centaur xp and advia centaur xpt systems. This assay is intended for use as an aid in the determination of serological status to HSV-1 and in the diagnosis of	**Approved** subject to provision of full quality assurance certificate.

				herpes simplex virus infection.	
139.	-do- **Evaluator**: AD-I	**Legal Manufacturer:** M/s Siemens Healthcare Diagnostics Inc, 511 Benedict Avenue, Tarrytown, NY, 10591, USA **Authorized Representative:** M/s Siemens Healthcare Diagnostics Limited, Sir William Siemens Square, Frimley, Camberley, Surrey, GU16 8QD, UK (FSC UK Valid Till 31-12-2020)	ADVIA Centaur Herpes-2 IgG ADVIA Centaur Herpes-2 IgG (HSV2) Quality Control Class C FEE SUBMITTED RS 50000 Shelf Life: ADVIA Centaur Herpes-2 IgG Shelf 15 Months ADVIA Centaur Herpes-2 IgG (HSV2) Quality Control Shelf life 3 Months Codes as Per FSC ADVIA Centaur Herpes-2 IgG SMN 10720849 ADVIA Centaur Herpes-2 IgG (HSV2) Quality Control SMN10720850 Rs.50,000/-	The Advia Centaur® Herpes-1 IgG (HSV1) assay is for in vitro diagnostic use in the qualitative determination of IgG antibodies to herpes Simplex virus type 1 (HSV-2) in human serum and plasma (EDTA and lithium heparn) using the advia centaur xp and advia centaur xpt systems. This assay is intended for use as an aid in the determination of serological status to HSV-2s and in the diagnosis of herpes simplex virus infection.	**Approved** subject to provision of full quality assurance certificate.
140.	-do- **Evaluator**: AD-I	**Legal Manufacturer:** M/s Siemens Healthcare Diagnostics Inc, 511 Benedict Avenue, Tarrytown, NY, 10591, USA **Authorized Representative:** M/s Siemens Healthcare Diagnostics Limited, Sir William Siemens	ADVIA Centaur High-Sensitivity Troponin I ADVIA Centaur Multi-Diluent 11 Class: C Shelf Life: ADVIA Centaur High-Sensitivity Troponin I 15 Months	The ADVIA Centaur ® High Sensitivity I (TNIH) assay is for in vitro diagnostic use in the quantitative measurement of cardiac troponin I in human serum	**Approved** subject to provision of full quality assurance certificate.

		Square, Frimley, Camberley, Surrey, GU16 8QD, UK (FSC UK Valid Till 31-12-2020)	ADVIA Centaur Multi-Diluent 11 11 Months Codes as Per FSC ADVIA Centaur High-Sensitivity Troponin I SMN 10994775 SMN 10994774 ADVIA Centaur Multi-Diluent 11 REF 05699280 REF 03479704 Rs.50,000/-	or plasma (lithium heparin) using the ADVIA Centaur XP and ADVIA Centaur XPT Systems. The assay can be used to aid in the diagnosis of acute myocardial infarction.	
141.	-do- **Evaluator**: AD-I	**Legal Manufacturer:** M/s Siemens Healthcare Diagnostics Inc, 511 Benedict Avenue, Tarrytown, NY, 10591, USA **Authorized Representative:** M/s Siemens Healthcare Diagnostics Limited, Sir William Siemens Square, Frimley, Camberley, Surrey, GU16 8QD, UK (FSC UK Valid Till 31-12-2020)	Immulite / Immulite 1000 Herpes I & II IgG Class C fee Submitted Rs 50000 Shelf Life: 12 Months Codes as Per FSC Immulite / Immulite 1000 Herpes I & II IgG SMN 10381274 REFLKHS1 Rs.50,000/-	For in vitro diagnostic use with the Immulite 1000 Systems Analyzers-for the qualitative detection of IgG antibodies to herpes simplex virus (HSV) types I and II in human serum, as an aid in determination of serological status to HSV II & II	**Approved** subject to provision of full quality assurance certificate.
142.	Ms. Medequips SMC Pvt Ltd, 30 Shahrah-e-Quaid-e-Azam Lahore. ELI-00362 **Evaluator**: AD-I	Legal Manufacturer: Accuray Incorporated, 1310 Chesapeake TerraceSunnyvale, CA 94089 USA **Site:** Accuray Incorporated 1240 Deming Way Madison Wisconsin 53717, USA FSC OF USA	**Radixact ™** (Radixactth Treatment Delivery system) Not mentioned Class C EFF SUBMITTED RS 50000	The Radixact Treatment Delivery System is intended to be used for the delivery of radiation therapy, stereotactic radiotherapy or stereotactic radiosurgery to tumors or other targeted	**Approved** subject to provision of valid & original Embassy attested Free Sale certificate.

		Valid till 25-07- 2020	Shelf life 10 years Rs.50,000/-	tissues. The megavoltage x-ray radiation is delivered using rotational, non-rotational, intensity modulated (IMRT) or non-modulated (non-IMRT/three dimensional conformal) treatment techniques and using image-guided (IGRT) or non-image-guided workflows in accordance with the physician approved plan.	
143.	M/s. Maxims Medical, House No, 534 H Block Street No, 13, Phase V DHA,Lahore 2. 210 2nd Floor Land Mark Plaza Jail Road Lahore ELI-00369 **Evaluator**: AD-I	**Legal manufacturer** STENTYS INCORPORATING Minvasys 7, rue du Fosse Blanc Batiment C1-92230 Gennevilliers, France FSC France Date of Issue 03.01.2018	**Yangtze Non- Compliant PTCA Balloon Dilatation Catheter** (PTCA Balloon Catheter) Class D Shelf life: 2 years	Balloon Catheter is Type of Soft Catheter with an inflatable balloon at its tip which is used during a catheterization procedure to enlarge a narrow opening or passage within the body. The deflated balloon catheter is positioned, then inflated to perform the necessary procedure and deflated again in order to be removed.	**Deferred for** provision of below mentioned cocuments:- Valid ISO.13485 Valid QA certificate. Labels. DOC. Clearly mentioning the required produts codes.
144.	M/s Abbott Laboratories	**Legal Manufacturer:**	Amikacin (Reagent Kit) Class C	Amikacin assay is	**Approved** subject to

	(Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi (ELI-00019) [1373] **Evaluator**: AD-II	M/s. Mircogenics Corporation 46500 Kato Road, Fremont, CA 94538 USA **Distributor:** M/s. Abbott Laboratories, 100 Abbott park Rd, Abbott Park, IL 60064 USA (FSC USA Valid 06-11-2020)	Shelf Life: 12 months (2ºC -8ºC) Estimated tests per kit: 140 Code: 6L35-20 TDM Multiconstituent Calibrator: Shelf life: 18 months (2ºC -8ºC) Code: 5P04-01 Rs.50,000/-(copy of challan. Original not available)	intended for the quantitative determination of amikacin in human serum or plasma on the architect c system. The results obtained are used in diagnosis and treatment of amikacin overdose and in monitoring of amikacin to help ensure appropriate therapy.	clarification/ provision of below mentioned documents:- Complete stability studies not provided. Proposed MRP of medical device is not provided. Provision of detail quality control processes and manufacturing processes. Name of the responsible person(s). Grouping of the TDM multi-constituent calibrator with Amikacin (Test Kit) needs to be justified. Provision of yellow copy or depositor copy of fee challan.
145.	-do- **Evaluator**: AD-II [1365]	**Legal Manufacturer:** M/s. Mircogenics Corporation 46500 Kato Road, Fremont, CA 94538 USA **Distributor:** M/s. Abbott Laboratories, 100 Abbott park Rd, Abbott Park, IL 60064 USA (FSC USA Valid 06-11-2020)	Tobramycin (Reagent Kit) Class C Shelf Life:12 months (2ºC -8ºC) Code: 7F93-20 Estimated tests per kit: 140 Tobramycin (Calibrator Kit) Shelf Life:15 months (2ºC -8ºC) Code: 7F93-01 Rs.50,000/-(copy of challan. Original not available)	Tobramycin assay is intended for the quantitative determination of tobramycin in human serum or plasma on the architect c System. Tobramycin calibrator kits are intended for use in	**Approved** subject to clarification/ provision of below mentioned documents:- Provision of detail quality control processes and manufacturing processes both for *Tobramycin* reagent kit and calibrator kit.

				calibration of the Tobramycin assay on the architect c System.	Complete stability studies. Proposed MRP of medical device is not provided. Provision of yellow copy or depositor coy of fee challan. Name of the responsible person(s).
146.	-do- **Evaluator**: AD-II [1369]	**Legal Manufacturer:** M/s. Mircogenics Corporation 46500 Kato Road, Fremont, CA 94538 USA **Distributor:** M/s. Abbott Laboratories, 100 Abbott park Rd, Abbott Park, IL 60064 USA (FSC USA Valid 06-11-2020)	Valproic Acid (Reagent Kit) Class C Code: 1E13-20 Shelf Life: 12 months (2ºC -8ºC) Estimated tests per kit: 180 TDM Multiconstituent Calibrators: Shelf life: 18 months (2ºC -8ºC) Rs.50,000/-(copy of challan. Original not available)	Valproic Acid assay is used for the quantitative in vitro measurement of valproic acid in human serum or plasma on the architect c System.	**Approved** subject to clarification/ provision of below mentioned documents:- Name of the responsible person(s). Provision of detail quality control processes and manufacturing processes. Two different types of calibrators are mentioned of the said IVD i.e 1E13-02 and TDM MCC (5P04-01) which needs clarification Provision of complete stability studies. Proposed MRP of medical device. Provision of yellow copy or

					depositor coy of fee challan.
147.	-do- **Evaluator**: AD-II [1371]	**Legal Manufacturer:** M/s. Mircogenics Corporation 46500 Kato Road, Fremont, CA 94538 USA **Distributor:** M/s. Abbott Laboratories, 100 Abbott park Rd, Abbott Park, IL 60064 USA (FSC USA Valid 06-11-2020)	Vancomycin (Reagent Kit) Code: 6E44-21 Class C Shelf Life: 12 months (2ºC -8ºC) Estimated tests per kit: 300 TDM Multiconstituent Calibrators: 18 months(2ºC -8ºC) Code: 5P04-01 Rs.50,000/-(copy of challan. Original not available)	Vencomycin assay is intended for the quantitative determination of vancomycin in human serum or plasma on the architect c system.	**Approved** subject to clarification/ provision of below mentioned documents:- Name of the responsible person(s). Provision of detail quality control processes and manufacturing processes. Proposed MRP of medical device. Two different types of calibrators are mentioned of the said IVD i.e 6E44-01 and TDM MCC (5P04-01) which needs clarification. Complete stability studies. Provision of yellow copy or depositor coy of fee challan.
148.	-do- **Evaluator**: AD-II [1327]	**Legal Manufacturer:** M/s. Abbott GmbH & Co, KG Max-Planck-Ring 265205, Wiesbaden, Germany. (FSC Germany Issuance 22-06-2017)	Alinity I HE4 Reagent Kit Code: 08P5022 Class C No. of tests: 200 Alinity I HE4 Calibrators Code: 08P5001 Alinity I HE4 Controls Code: 08P5010 Shelf Life: 12 months (2ºC -8ºC) Rs.50,000/-	The Alinity I HE4 assay is a chemiluminescentmicroparticle immunoassay (CMIA) used for the quantitative determination of HE4 antigen in human serum on the	**Deferred** for provision of below mentioned documents:- Name of the responsible person(s). Provision of detail quality control processes.

				Alinity I analyzer.	Proposed MRP of medical device. The letter of authorization refers to application submission to "Health Sciences Authority-Singapore". ISO 13485 certification not provided. Package insert for Alinity I HE4 reagent kit. Full quality assurance certificate or equivalent is marked as "N/A".
149.	-do- **Evaluator**: AD-II [1329]	**Legal Manufacturer:** M/s. Abbott GmbH & Co. Kg Max-Planck-Ring 2 65205 Wiesbaden Germany. (FSC Germany Issuance 14-10-2016)	Architect Active-B12 (Holotranscobalamin)reagent kit (100 test) Code:3P24-25 Architect Active-B12 (Holotranscobalamin)reagent kit (500 test) Code:3P24-35 Architect Active-B12 (Holotranscobalamin)Calibrator kit Code:3P24-01 Architect Active-B12 (Holotranscobalamin)Control kit Code:3P24-10 Class B Shelf Life:18 months (2ºC -8ºC) Rs.25,000/-	The Architect Active-B12 (Holotranscobalamin) assay is a chemiluminescentmicroparticle immunoassay (CIMA) for the quantitative determination of Holotranscobalamin in human serum on the Architect iSystem and is used as an aid in the diagnosis and treatment of vitamin deficiency.	**Deferred** for provision of below mentioned documents:- Name of the responsible person(s). The letter of authorization refers to application submission to "Health Sciences Authority-Singapore". Proposed MRP of medical device. Provision of detail quality control processes.

					Complete stability studies. ISO 13485 certification. Full quality assurance certificate or equivalent is marked as "N/A".
150.	-do- **Evaluator**: AD-II [1613]	**Legal Manufacturer:** M/s. Abbott Laboratories 1921 Hurd Dr, Irving, Tx USA 75038 (Address also known as); Abbott Laboratories Diagnostics Division 100 Abbott Park, IL USA 6004. (FSC USA Valid from 04-03-2019 to 03-03-2021)	Urine/CSF Protein Reagent Kit Code: 7D79-21 No. of tests: 2244 Shelf Life: 24 months (2ºC -25ºC) Urine/CSF Protein Reagent Kit Code: 7D79-31 No. of tests: 209 Shelf Life: 24 months (2ºC -25ºC) Urine /CSF Protein Calibrator Code: 1E71-02 Shelf Life: 24 months(2ºC -8ºC) Class B Shelf Life: 24 months(2ºC -25ºC) Rs.25,000/-	The Urine/CSF protein (Upro) assay is used for the quantitation of protein in human urine or cerebrospinal fluid (CSF). CSF protein measurement is used in the diagnosis and treatment of conditions such as meningitis, brain tumors, and infections of the central nervous system.	**Deferred** for provision of below mentioned documents:- Name of the responsible person(s). Complete name and address of legal manufacturer is not mentioned in Form-7A. Provision of detail quality control processes for both reagent kit and calibrator. Storage condition for Urine/CSF Protein reagent kit as per Form-7A is 2 ºC to 8 ºC while as per stability studies the storage condition is (2ºC -25ºC) and on the label specimen the storage condition is mentioned as (15ºC -30ºC). Proposed MRP of medical device.
151.	-do-	**Abbott** Ireland Diagnostics Division,	ARCHITECT Urine NGAL	ARCHITECT Urine NGAL	**Approved** subject to

	Evaluator: AD-III	Lisnamuck, Longford, Co. Longford, Ireland. VALID FSC OF IRELAND EXPIRED ON 03rd SEPTEMBER 2023.	Calibrator 1P37-01 Controls 1P37-10 Reagent Kit 1P37-25 Reagent Kit 1P37-35 Class-B Shelf Life: 18 Months	consists of Calibrator, Controls, Reagent Kit and Reagent Kit. The device may be used for the in-vitro determination of human NGAL in urine as an indication of kidney injury.	clarification/ provision of below mentioned documents:- Clarification of responsible persons names as per Form-4. Stability studies are missing. MRP is missing QMS Certificate is missing Details of Quality controls testing process are missing.
152.	-do- **Evaluator**: AD-III	Abbott Park, Illinois 60064 VALID FSC OF USA VALID FROM 04thMARCH 2019 TO 03rd MARCH	Glucose 3L82-21 Glucose 3L82-41 Creatinine 3L81-22 Creatinine 3L81-32 Creatinine 3L81-41 Urea Nitrogen 7D75-21 Urea Nitrogen 7D75-31 Urea Nitrogen 7D75-31 Uric Acid 3P39-21 Uric Acid 3P39-41 Multiconstituent Calibrator 1E65-05	The Creatinine assay is used for quantitation of creatinine in human serum, plasma or urine. The Glucose assay is used for quantitation of glucose in human serum, plasma, urine or CSF. The Multiconstituent calibrator is used in calibration of Albumin, Calcium, Cholestrol, Creatinine, Glucose, Iron, Lactic acid, Megnesium, Phosphorus, Total Protein, Triglyceride, Urea Nitrogen	**Deferred** subject to clarification/ provision of below mentioned documents:- Clarification of responsible persons names as per Form-4. Stability studies are missing. MRP is missing QMS Certificate is missing Details of Quality controls testing process are missing. Label of Creatinine (3L81-41) is missing. Justification on grouping of

				and Uric acid assays. The Urea nitrogen assay is used for the quantitation of urea nitrogen in human serum, plasma or urine. The Uric Acid assay is used for the quantitation of uric acid in human serum, plasma or urine.	substrates in one application
153.	M/s. Shirazi Trading Company (Pvt) Ltd., 8th Floor Adamjee House I.I Chundrigarh Road, Karachi. (ELI-00263) **Evaluator**: AD-II [1663]	**Legal Manufacturer/ Manufacturer:** M/s. Datex-Ohmeda, Inc., 3030 Ohmeda Drive, Madison, WI-53718, USA **Manufacturer:** M/s.GE Medical Systems (China) Co., Ltd., No. 19, Changjiang Road, National HI- Tech Dev. Zone, Wuxi, 214028 Jiangsu, China. **FSC**: US-FDA (valid 12-08-2020) China (validity not mentioned)	Carestation 650 (Anaesthesia, Workstation, General-Purpose) Class C (according to rule 9(i) and 11 of MDR, 2017) Shelf Life: Not Applicable Rs.50,000/-	GE Carestation 650 is intended to provide general inhalation anesthesia and ventilatory support to a wide range of patients (Pediatric and adult). The anesthesia systems are suitable for use in a patient environment such as hospitals, surgical centers, or clinics.	**Approved** subject to provision of below mentioned documents:- • Service life of the device. • Label. • Ref.No.
154.	-do- **Evaluator**: AD-II [1664]	**Legal Manufacturer/ Manufacturer:** M/s. Datex-Ohmeda, Inc., 3030 Ohmeda Drive, Madison, WI-53718, USA **Manufacturer:** M/s.GE Medical Systems (China) Co., Ltd., No. 19, Changjiang Road,	Carestation 650c (Anaesthesia, Workstation, General-Purpose) Class C (according to rule 9(i) and 11 of MDR, 2017) Shelf Life: Not Applicable Rs.50,000/-	GE Carestation 650c is intended to provide general inhalation anesthesia and ventilatory support to a wide range of patients (Pediatric and	**Approved** subject to provision of below mentioned documents:- • Service life of the device. • Label not provided.

		National HI- Tech Dev. Zone, Wuxi, 214028 Jiangsu, China. **FSC**: US-FDA (valid 12-08-2020) China (validity not mentioned)		adult). The anesthesia systems are suitable for use in a patient environment such as hospitals, surgical centers, or clinics.	• Ref.No.
155.	-do- **Evaluator**: AD-II [1689]	**Legal Manufacturer/ Manufacturer:** M/s. Datex-Ohmeda, Inc., 3030 Ohmeda Drive, Madison, WI-53718, USA **Manufacturer:** M/s.GE Medical Systems (China) Co., Ltd., No. 19, Changjiang Road, National HI- Tech Dev. Zone, Wuxi, 214028 Jiangsu, China. **FSC**: US-FDA (valid 12-08-2020) China (validity not mentioned)	Carestation 620 (Anaesthesia, Workstation, General-Purpose) Class C (according to rule 9(i) and 11 of MDR, 2017) Shelf Life: Not Applicable Rs.50,000/-	GE Carestation 620 is intended to provide general inhalation anesthesia and ventilatory support to a wide range of patients (Pediatric and adult). The anesthesia systems are suitable for use in a patient environment such as hospitals, surgical centers, or clinics.	**Approved** subject to provision of below mentioned documents:- • Service life of the device. • Ref.No.
156.	-do- **Evaluator**: AD-II [1670]	**Legal Manufacturer/ Manufacturer:** M/s. Datex-Ohmeda, Inc., 3030 Ohmeda Drive, Madison, WI-53718, USA **FSC**: US-FDA (Valid 17-07-2020)	Carescape R860 (Neonatal/adult intensive-care ventilator) Class C (according to Rule 9(i) of the MDR, 2017) Ref.No.1506-8600-000 Shelf Life: N/A Rs.50,000/-	The Carescape R860 ventilator is designed to provide mechanical ventilation or support to neonatal, pediatric and adult patients weighing 0.25kg and above.	**Approved** subject to provision of valid Free Sale Certificate.
157.	M/s Mediland Office NO, B-09 2nd Floor, Masood Arcade IJP Road Near Saidpur Road Rawalpindi.	**Legal manufacturer** MAQUET GETINGE GROUP GERMANY Kehler Street No. 31, 76437 Rastatt, Germany	**Quadroxi Adult and Small Adult Oxygenator and Venous Hard shell Cardiotomy** **Combination of reservoir with (**Oxygenator**)**	The device is intended to be used in a clinical environment.	**Approved** subject to provision of below mentioned documents:-

	ELI-00202 **Evaluator**: AD-I	FSC Germany Date of issue 26.03.2019	Codes and Sizes as per FSC Class D Shelf life 2 Years Rs.50,000/-		MRP not mentioned on Form QMS Certificate / ISO 13485. Original Agency Agreement Required dully notarized from the country of origin
158.	M/s Imtiaz Brothrs Suite, 7B, 2nd Floor, Abrar Business Center, 25-Mian Wahat Road Lahore ELI- 00133 **Evaluator**: AD-III	Legal Manufacturer: M/s Changzhou Kangxin Medical Insturments Co., Ltd Qiuzhuang, Luoxi town Xinbei District , Changzhou, China FSC China Valid Upto 19-03-2020.	**Arterial Cannula** (Arterial Cannula Not mentoned Class B FEE SUBMITTED 25000 Shelf Life 03 years	Disposable Arterial cannula is designed to deliver oxygenated blood to the arterial vasculature. These cannula feature thin wall wire-wound or non-wire wound construction and a clear, flexible cannula body with a tip orientation line. Arterial cannulas are made in various models to meet specific needs.	**Approved** in Class-D medical device subjecdt inspection of manufacturer abroad or provision of CE mark documents and submission of below mentioned documents:- Differenctial fee of Rs.25000/- Provide label Original FSC Required dully notiraized by country of origin
159.	M/s. Al Waali Care Concept, 86-Allama Iqbal road Garhi Shahu, Lahore ELI 00386 **Evaluator**: AD-III	Legal Manufacturer: Curatia Medicl Limited 198 Xiangjiang Road New District, Suzhou (215011) China. FSC USA FDA FSC CHINA Valid till 22.05.2021	Auto Seal Hemostasis Valve Kit (Aut) Size Codes **20109500** Class D Shelf life 3 years Rs.25,000/-	Autoseal Hemostatis Valve used to maintain a seal around interventional device and also used to maintain the hemosatis during procedure. .	**Approved** subject to inspection of manufacturer abroad or provision of CE mark documents and submssion of below mentioned documents:-

					Provide sole/ exclusive agency agreement. Clearly mention the codes and size supported with label. Differncial fee is to be submitted Rs.25,000/-.
160.	M/s. Iqbal and Company Alfalah manzil Opp. National Police Foundation Street No. E-11/4, Islamabad. ELI-00117. **Evaluator**: AD-III	**Legal Manufacturer:** M/s MEDICAL COMPONENTS INC DBA-Medcomp 1499 DELP DRIVE HARLEYSVILLE, PA USA 19438 FSC GERMANY Issued date 28 June, 2019	Dura lock-C (CATHETR LOCK SOLUTION) PFDLC 504 PFDLC 530 PFDLC 546 Class B FEE SUBMITTED RS 25,000/- Shelf Life 2 years	Dura Lock-C™ is indicated for use in maintaining patency Of Hemodialysis Catheters	**Approved** subject to provision of Sole Agency Agreement,details of real time stability studies supported with claimed shelf life.
161.	M/s. Uniplan Trade International Pvt ltd. 132/2 Quadi-e-Azam Industrial Estate, Kot Lakhpt, Lahore. ELI-00132 **Evaluator**: AD-III	**Legal Manufacturer:** M/s. Perfect Medical Industry Co. Ltd., Block D7/1 No IB Road Vinh Loc Industrial Zone Veitnam. FSC Veitnam Valid till 12.11.2019	**Hemodialysis Blodd Tubing Sets** (Blood Tubing Line) E07023 E07023-TP E07507 Class B Shelf Life : Not mentioned Rs.25,000/-	The device is designed to be used to access a vein or artery and to be used as a conduit to connect toblod tubing lines for performing patient hemodialysis.	**Approved** subject to inspection of manufacturer abroad or provision of CE mark documents and submission of Shelf life Studies.
162.	-do- **Evaluator**: AD-III	**Legal Manufacturer:** M/s. Perfect Medical Industry Co. Ltd., Block D7/1 No IB Road Vinh Loc Industrial Zone Veitnam. FSC Veitnam Valid till 12.11.2019	**AV Fistula Needle Sets** (Fistula Needles) V0801000103002 (E09541) V0801053103001 (E09641A) V0801103103001 (E09741A) Class B Shelf Life : Not mentioned Rs.25,000/-	The device is designed to transfer blood from patient to the hemodialyzer by the arteriol blood tubing and from the hemodialyzer bag t the patient via the venous blood tubing.	**Approved** subject to inspection of manufacturer abroad or provision of CE mark documents and submission of Shelf life Studies

163.	M/s. Biocare Enterprises, Plot No. 64/2, Street No. 17, FECHS (Npf) 09, PWD Road, Islamabad. ELI-00220 **Evaluator**: AD-III	**Legal Manufacturer:** M/s. Edan Instrument Inc., #15, Jinhui Road, Jinsha Community, Kengzi Sub-district, Pingshan District, 518122, Shenzhen, P.R China. FSC China Issued on 28-06-2017 TWO YEARS VALIDITY. (Expired)	**Blood Gas and Chemistry Analyser** (Codes not mentioned) Class B Shelf Life: Not mentioned Rs.25,000/-	**Blood Gas and Chemistry Analyser**	**Deferred** for provision of below mentioned documents:- Provide valid free sale certificate in the country of origin duly attested by embassy of pakistan. Provide Shelf life Supported with stability studies. Provide the List of constituent-components along with codes
164.	M/s Medica, House No. 188-1-B (First Floor) near Nursery area, Block 2, PECHS Karachi. (ELI-00237) **Evaluator**: AD-III	**Legal Manufacturer:** SaSanSaglikMazemeler I uretimvePazarlamaa.s. (DagyakaMah. 2004 Cad. No: 6 Kahramankazan/ Ankara/ Turkiye. (FSC Turkey issued on 09-03-2017)	Sasan Medical Disposable products. S.A. Adult Tubing Set without filter Class B Fee submitted. RS 25000. Shelf Life: 3 Years. (Sizes & Codes as Per FSC) Tubing Set Adult Ref: (SD920001/B) Adult Tubing Set Without Filter (SD921001/A) (SD921301/B)	Extracorporeal tubing set is a medical device that is used with cardiopulmonary pump and oxygenator for oxygenation of blood In open heart surgeries and allows the blood to be sent to the oxygenator and then to the patient. It is disposable. The filter set used to hold particles and air bubbles in the set during circulation is an arterial filter set.	**Approved** subject to inspection of manufacturer abroad or provision of CE mark documents and submission of below mentioned documents:- Provide detail of manufacturing and quality control process. provide shelf life supported With stability data. Proposed MRP of medical device. Provide sole /exclusive original agency agreement from market authorization holder duly notarized from

					the country of origin. Tubing Set Adult Ref: (SD920001/B) Not available in FSC.
165.	M/s Ali Gohar& Company (Pvt) Ltd., State Life Building 1-B, I.I ChundrigarRoad, Karachi (ELI-00004) **Evaluator**: AD-III	**Legal Manufacturer:** Smith Medical ASD Inc 10 Bowman Drive Keene NH 03431 0724 USA **Manufacturing Site:** Smiths Medical International Ltd 52 Grayshill Road, Cumbernauld Glasgow g68 9hQ United Kingdom. (FSC UNITED KINGDOM VALID UPTO 15-06-2023)	Portex® Combined Spinal / Epidural Minipack with Lock Class D Codes: 1. 100/491/318 2.100/491/718 3.100/491/716 4.100/491/916 Shelf Life: 5 Years Rs.50,000/-	A range of Sterile , Single use spinal and epidural needles to perform a spinal (Subarachnoid) injection through an epidural tuohy needle placed in the epidural space, followed by the placement of an epidural catheter to allows modification of the spinal analgesia if necessary or bolus injections or continues infusion of local anesthetics or other drugs into the epidural space for subsequent pain relief if required.	**Approved** subject to provision of below mentioned documents:- Provide valid authorization letter and clearly mention the sole /exclusive distributor of relevent medical device. Proposed MRP of medical device. Applied separately for others.
166.	-do- **Evaluator**: AD-III	**Legal Manufacturer:** Smith Medical ASD Inc 10 Bowman Drive Keene NH 03431 0724 USA **Manufacturing Site:**	Portex® RapID® Spinal Needle Set Spinal Access Needles Class D Shelf Life: 5 Years (Codes as Per FSC)	A Range of Sterile, Single use packs to perform a single injection of local anesthetic or others drugs into the subarachnoid	**Approved** subject to provision of below mentioned documents:- Provide valid authorization letter and clearly mention the sole

		Smiths Medical International Ltd 52 Grayshill Road, Cumbernauld Glasgow g68 9hQ United Kingdom. (FSC UNITED KINGDOM Valid UPTO 15-06-2023)	Lancet point 100/496/022 100/494/024 100/496/025 100/496//026 100/496/027 Pencil point spinal Needle 100/496/122 100/496/124 100/496/125 100/496/126 100/496/127. Rs.50,000/-	space for pain relief.	/exclusive distributor of relevent medical device. Proposed MRP of medical device.
167.	M/s DKT Pakistan Pvt. Ltd, 37-C RJ Building, 2nd Stadium Lane, Phase V, Defence Housing Authority, 75500 Karachi Pakistan. (ELI-00515) **Evaluator**: AD-III	**Manufacturer:** M/s Pregna International limited Plot Number 219, Survey No. 168, Dabhel Co. op. Industrial Soc. Ltd, Dabhel Daman (U.T) 396 210 (FSC INDIA valid UPTO 22-01-2022)	Intrauterine Device Copper Y Cu 380 Intrauterine Contraceptive Device Class D Shelf Life: 10 Years Copper Y Cu 3820 (Copper 380) Rs.50,000/-	Intrauterine Conctraceptive Device), Long-acting non hormonal contraception that is placed inside the uterus.	**Deferred** for provision of below mentioned documents:- Differential fee is to be submitted (45000). Provide copy of Establishment license. Essential principle of safety and performance. Declaration of conformity (DOC).
168.	-do- **Evaluator**: AD-III	**Manufacturer:** M/s Qinhuangdoao Zizhu Pharmaceutical Co., Ltd. No.10, Longhai Road, Economic & Techonological Development Zone, Qinhuandao, Hebi. (FSC issuance 29-01-2015)	Levoplant Levonorgestrel Silastic Implants (II), 75 mg, ROD Class D Shelf Life: 60 Months Rs.50,00/-	Sino-Implant II/ Levoplant is a subdermal contraceptive implant composed of two thin, flexible, silicone rods, each containing 75 mg leorgestrel, the active ingredients, for a total of 150mg . The rods are	**Deferred** for submission of below mentioned documents:- provision of evidence that the Product is a Medical Device Differential fee is to be submitted (45000). Provide copy of Establishment license.

				inserted undr the skin of the woman's upper arm by a trained health care provider. After discontinuation , there is no delaty in woman's return to fertility compared to women who are not using a contraceptive method.	Essential principle of safety and performance. Declaration of conformity (DOC).
169.	-do- **Evaluator**: AD-III	**Manufacturer;** M/s Qinhuangdoao Zizhu Pharmaceutical Co., Ltd. No.10, Longhai Road, Economic & Techonological Development Zone, Qinhuandao, Hebi. (FSC INDIA ISSUED ON 23-03-2018)	Intrauterine Device copper T 380 A Intrauterine Contraceptive Device. Class D Shelf life: 7 Years Rs.50.00/-	Long-acting non hormonal contraception that is place inside the uterus.	**Approved** subject to inspection of manufacturer abroad or provision of CE mark documents and submission of below mentioned documents:- Differential fee is to be submitted (Rs. 45000). Provide copy of Establishment license. Essential principle of safety and performance. Declaration of conformity (DOC). Provide shelf life supported with stability studies. Provide specimen of label.

170.	-do- **Evaluator**: AD-III	**Manufacturer:** Pregna International Limited UNIT II, SITUATED AT Surey No. 342/3, Plot No. 29, Bharat Industrial Estate, Village Bhimpore, Daman (U.T) 396 210. . (FSC valid 26-01-2020) **(EXPIRED)**	Eloria Hormonal Intruterine System Eloria Hormonal Intruterine System Class D Shelf Life: 5 Years Rs.50.00/-	Eloria Hormonal Intruterine System Is not a combined medical device.	**Deferred** subject to inspection of manufacturer abroad or provision of CE mark documents and submission of below mentioned documents:- Differential fee is to be submitted (Rs. 45000). Provide copy of Establishment license. Provide Valid FSC. Provide sole agency agreement. Shelf life supported with stability data. Proposed mrp of medical devicve. All required documents according to form 7(A).
171.	-do- **Evaluator**: AD-III	**Manufacturer:** The Female Health Company (UK) Plc, 3 Mansfiled Road, Western Avenue Business Park, London W3 0BZ . Manufacutring Site: The Female Health Company (M) SdnBhd No. 1A, Jalan CJ ¼, KawasanPerindustrianCherasjaya 43200	FC2 Female Condom Intravaginal Barrier device; polyurethane Sheath. Class C Shelf Life: 60 Months Rs.50.00/-	The FC2 female condom is a nitrile sheath or pouch 17cm 6.7 in length. At each end there is a flexible ring. At the closed end of the sheath, the flexible ring is inserted into the vagina to hold the	**Approved** subject to inspection of manufacturer abroad or provision of CE mark documents and submission of below mentioned documents:- Differential fee is to be submitted (Rs. 45000). Provide copy of

		Balakong. Selangor Malaysia. (FSC valid 01-04-2019) **NOT MENTIONED.**		female condom in place. The other end of the sheath stays outside the vulva at entrance to the vagina.	Establishment license. Provide Fsc. Sole agency agreement Shelf life supported by stability data. All required documents according to form 7(A).
172.	M/s S. Ejazuddin& Co. PO Box 5629, Zia Plaza, Altaf Hussain Road, Karachi (ELI-00078) **Evaluator**: AD-III	**Manufacturer:** EKF-diagnostic GmbH EbendorferChaussee 3 39179 Barleben, Germany. (FSC Germany ISSUED ON 07-08-2018)	Pocket Chem A1C System A1C test system. Class B Shelf Life: not mentioned Sizes As per Fsc: PocketChem™ A1C Measuring System. Model: 0114-0000 Catalouge no. 3108-0011 VS PocketChem™ A1C Analyzer System. Model 0130 Catalouge no: 3108-3011 VS PocketChem™ A1C Test Kit Model 0135 Catalouge No. 3108-6011 VS PocketChem ™ A1C Control Kit.	The Quo-Lab Test System Consists of Quo-lab Analyzer, Quo-Lab A1C Test Kit and quo-lab A1C Control Kit. The quo-Lab Test System is intended for the invitro quantitative determination of glycated hemoglobin obtained from a finger prick or venous whole blood sample collection.	**Approved** subject to provision of Sole/Exclusive agency agreement and Clearly mention the shelf life supported by stability study.

			Rs.25,000/-		
173.	M/s Sky Traders, A-11, Ground Floor, Al-Hail Co-operative Housing Society, Block No. IV & V, Scheme No. 7 Karachi. (ELI- 00047) **[1426]** **Evaluator**: AD-V	**Manufacturer:`** Shangdong Yiguang Medical Instruments Co., Ltd Sanjiu Science-Technology Industrial Park, Chiping county, Shandong Province, China. (FSC China 25-08-2019)	Sky Plus Disposable Infusion Set (I-V set) with Y-Port Class B Shelf Life: 5 Years Infusion set for single use scalp vein set 0.45x15mm, 0.5x20mm, 0.55x20mm, 0.6x 23mm, 0.7x23mm, 0.8x23mm, 0.9x28mm	The Disposable Infusion sets with needle are mainly made of medical grade PVC Polystyrene Laminated by DEHP. The basic composition is closure-piercingdevice, air fileter, lock clamp, dropper flexible and so on. The disposable infusion set with needle is used for clinical intravenous infusion, gravity infusion.	**Approved** subject to inspection of manufacturer abroad or provision of CE mark documents and submission valid FSC and Stability study data.
174.	M/s. Mubarak Division 32-A Usman Center, Shah ALam Market, Lahore. (ELI-00045) 596-P **Evaluator**: AD-V	Legal Manufacturer: Al.CHI.MI.A.Sr.I.viale Austra 14, (35020 Ponte San Nicolo (PD) Italy FCS Italy Date of issue 06.03.2017	RS-BLUE (Dye for staining the eye capsule) (RS-Blue) Codes: RSB 001-00, RSB 002-00 Class B Shelf Life: 36 months	Dye for staining the capsule during Cataract surgery	**Approved** in class C medical devices subject to provision of DoC and submission of differential fee of Rs.25,000/-. Multiple products applied in one application, that need to be applied separately.
175.	-do- **Evaluator**: AD-V	Legal Manufacturer: Al.CHI.MI.A.Sr.I.viale Austra 14, (35020 Ponte San Nicolo (PD) Italy FCS Italy	HPF-10 (Perfluorocarbons for vitreoretinal surgery) Class B Shelf Life: 36 months Codes:	Intended for intraoperative tamponade in vitreoretinal surgery	**Approved** in class C medical devices subject to provision of DoC and submission of differential fee of Rs.25,000/-.

		Date of issue 06.03.2017	HPF 003-00 HPF 004-00		Multiple products applied in one application, that need to be applied separately.
176.	-do- **Evaluator**: AD-V	Legal Manufacturer: Al.CHI.MI.A.Sr.I.viale Austria 14, (35020 Ponte San Nicolo (PD) Italy FCS Italy Date of issue 06.03.2017	RS-OIL 1000 (Liquid intraocular tamponade for vitreo-retinalsurgery) Codes: RSO 001-00 RSO 002-00 RSO 003-00 Class C Shelf Life: 03 years	RS-OIL is intended for long-term intraocular tamponade in vitreoretinal surgery.	**Approved** in class C medical devices subject to provision of DoC and submission of differential fee of Rs.25,000/-. Multiple products applied in one application, that need to be applied separately. DoC not provided.
177.	M/s Usmanco International, 220, Block: 3, DMCHS, S. Abdul Tawwab Road, Karachi. (ELI-00121) **Evaluator**: AD-II	**Legal Manufacturer:** Jiangxi Sanxin Medtec Co., Ltd. No. 999 FushandRoad, Xiaolan Economic Development Zone Nanchang Jiagxi China. (FSC China 06-03-2020)	YI XIN Auto Disable Syringe YI XIN Auto Disable Syringes Class B Shelf Life: 5 Years Sizes & Codes as Per FSC Rs. 25,000/-	Auto Disable syringe are Syringe that cannot be reused. They incorporate a mechanism to break or lock the plunger when the injection is given to make the syringe inoperable for being used for second time.	**Approved** subject to inspection of manufacturer abroad or provision of CE mark documents and submission valid.

Item No.XXXIX. ENLISTMENT OF MEDICAL DEVICES FOR IMPORT.

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

Sr. No	Name and Addresses of Establishment	Manufacture Details	Name of Medical Device with sizes/Class/Shelf Life	Brief Description	Decision
1.	M/s. Optisurg 17- C1, Valencia Town, Lahore. ELI-00305 **Evaluator**: AD-IV	**Manufacturer:** M/s. MORIA S.A., 15 Rue George Besse F92160 Antony, France FSC France valid till 3-7-2020	ONE® Punch Class: A Code: 17200D700 17200D725 17200D750 17200D775 17200D800 17200D825 17200D850 17200D875 17200D900 17200D950 Shelf Life: 59 months Fee submitted: Rs. 5,000/-	Sterile, single-use corneal vacuum punch is designed for performing corneal grafts (lamellar or penetrating keratoplasty	**Approved** subject to provision of original and notarized Letter of Authorization and Valid Free Sale Certificate
2.	M/s. Sadqain Healthcare (Pvt) Ltd., Safari Villas 11, Commercial Complex, 3rd Floor, Bahria Town, Phase 7, Rawalpindi. ELI-00020 **Evaluator**: AD-IV	**Manufacturer:** M/s. Intersurgical Limited, Crane House, Molly Millars Lane, Wokingham, Berkshire, United Kingdom. FSC U.K issued on 25.03.2019	TrachSeal Adult Endotracheal closed suction system, 72 hour Class A Code: 3720000- size F12 3720001- size F14 3720002- size F16 3720003- size F10 Shelf Life: 5 years Fee submitted: Rs. 5,000/-	To remove fluids from the airway of an intubated patient by connection to a source of negative pressure. Sterile, single-use	**Approved as Class B medical device** subject to provision of valid Full QA and submission of differential fee of Rs. 20,000/- and Form-7A
3.	M/s Johnson & Johnson (Pvt) Ltd., Office No.806, 8th Floor, Horizon Towers, Block 3, Scheme 5, Clifton, Karachi (ELI-00154) **Evaluator**: AD-IV	**Legal Manufacturer:** Biosense Webster, Inc, 33 Technology Drive Irvine, CA USA. **Manufacturer:** Biosense Webster, Inc, 15715 Arrow Hwy, Irwindale, CA USA. 91706. Biosense Webster, Inc, Circuito Interior Norte,	Cables Electrophysiology Cables Class A Shelf Life: 3 Years Sizes & Codes as per FSC	Interface Cables are used to connect electrophysiology ablation catheters to the radiofrequency generators and Carto® XP EP Navigation System. These Cables are	**Deferred** for provision of below mentioned documents:- The device namely **cable** is not found on Free Sale certificate. Clearly state the type of cable and models required as per grouping criteria

		No. 1820 Parque Industrial Salvarcar Juarex, Chihuahua Mexico 32574 (FSC Valid 21-02-2021)	Fee submitted: Rs. 5,000/-	provided sterile with the capability to be re-sterilized via Eto for reuse up to 10 times.	mentioned in MDR, 2017 and highlight it on Free Sale Certificate as well as provide all the relevant technical documents (stability studies, EPSP, DOC, manufacturing and quality control processes etc) as per the type required. Cables used for different systems cannot be applied on one application. Clearly mention the legal manufacturer and the sites required supported by Free Sale Certificate and technical documents Provide labels and IFU for the required type of cables Provide MRP for the required type of cables Letter of Authorization from the manufacturer abroad does not indicate Exclusive/ Sole authorization to the importer, validity not mentioned, list of products authorized not mentioned and complete address of importer not mentioned. (This shortcoming is applicable to all Biosense Webster, Inc products)
4.	-do-	**Legal Manufacturer:**	Smartabalate ™ System Interface Cable Interface Cable	Smartabalate ™ System Interface Cable	**Deferred** for provision of below

	Evaluator: AD-IV	Biosense Webster, Inc, 33 Technology Drive Irvine, CA USA. **Manufacturer:** Biosense Webster, Inc, 15715 Arrow Hwy, Irwindale, CA USA. 91706. Biosense Webster, Inc, Circuito Interior Norte, No. 1820 Parque Industrial Salvarcar Juarex, Chihuahua Mexico 32574 (FSC Valid 26-07-2019)	Class A Shelf Life: 36 Months Sizes & Codes as per FSC Fee submitted: Rs. 5,000/-	provides a means to interface a Biosense Webster Electrophysiology Catheter to the appropriated equipment.	mentioned documents:- Free Sale certificate expired. Provide Valid Embassy attested Free Sale Certificate for the applied product submitted. Manufacturing sites not mentioned on Form. Clearly state the legal manufacturer and manufacturing sites supported by Free Sale Certificate and technical documents ISO 13485 of USA site expired. Provide valid and Notarized ISO13485 Provide label for the code D130302 Provide Essential Principles of safety and performance for the applied code Provide MRP for the applied codes Provide stability studies supporting claimed shelf life of 36 months for the applied product Clearly state the difference between 2 applied models i.e D130302 and D130303 supported by technical details

					Provide IFU and brochure for the applied products Provide details of manufacturing and quality control processes/tests/certificate of analysis for the applied products Letter of Authorization from the manufacturer abroad does not indicate Exclusive/ Sole authorization to the importer, validity not mentioned, list of products authorized not mentioned and complete address of importer not mentioned. (This shortcoming is applicable to all Biosense Webster, Inc products)
5.	-do- **Evaluator**: AD-IV	**Legal Manufacturer:** M/s Depuy Orthopaedics Inc., 700 Orthopaedic Drive Warsaw, Indiana, 46582, USA **Manufacturer:** M/s Depuy International Ltd., St Anthony's Road Leeds LS 11 8DT, UK (FSC USFDA Valid 21-05-2021)	Cemented Caps Class A Shelf Life: not mentioned in form Sizes & Codes as per FSC	Generally accepted indications for joint replacement include: Severe arthropathy due to advanced rheumatoid or osteo-arthritis where conservative therapy or alternative treatments have failed or are considered unsuitable. Arthropathy due to degenerative disease, acute trauma and a pervious failed	**Deferred** for provision of below mentioned documents:- The same product name i.e cemented cup has been applied earlier to this Division in Class-D. In this dossier the same name is applied as Class-A. Clarify? Multiple Free Sale Certificates submitted. Clearly state the Brand Name required and the product codes relating to the brand name, the legal manufacturer and manufacturing sites of the product and

				joint replacement.	highlight it on Free Sale Certificate. Multiple legal manufacturers cannot be applied on one application. As well as provide all the relevant technical documents (stability studies, EPSP, DOC, manufacturing and quality control processes etc) of that leganl manufacturer Clearly state the purpose of the applied product and justify the grouping as per grouping criteria in MDR, 2017 supported by brochure, labels, Free Sale Certificate, and Declaration of Conformity etc Provide labels for the required codes and IFU from the legal manufacturer required in this application Provide MRP for the required codes Provide summary/statement of shelf life from the manufacturer abroad signed and stamped by their responsible personnel. Letter of Authorization from the manufacturer abroad does not indicate Exclusive/ Sole authorization to the importer, validity not mentioned, list of

					products authorized not mentioned and complete address of importer not mentioned. (This shortcoming is applicable to all DePuy Orthopaedics, Inc products)
6.	-do- **Evaluator**: AD-IV	**Legal Manufacturer:** M/s Depuy Orthopaedics Inc., 700 Orthopaedic Drive Warsaw, Indiana, 46582, USA **Manufacturer:** M/s Depuy International Ltd., St Anthony's Road Leeds LS 11 8DT, UK (FSC USFDA Valid 21-05-2021)	Orthopedic Implants & Instruments LPS ™ (Limb Preservation System) Class A Shelf Life: not mentioned in form Sizes & Codes as per FSC	Limb Preserving Techniques, using modular segmental endoprostheses, provide a reliable, functional reconstruction for patients.	**Deferred** for provision of below mentioned documents:- The same product name i.e Limb Preservation System has also been applied to this Division in Class-B and Class-D. In this dossier the same name is applied as Class-A. In order to clarify grouping of the applied medical devices and to address this ambiguity as well as for other similar products of DePuy Orthopaedics, Inc such as Attune Knee System, C-stem, Cemented Cups and Corail hip system, you are advised to send qualified person or person well conversant in the subject alongwith brochure and actual product labels of the proving they are in one system Manufacturing site not provided on

					Form-7A and multiple sites mentioned in Free Sale Certificate which has numerous products. Clearly state the manufacturing site Full Quality Assurance Certificate expired. Provide valid and notarized certificate Provide MRP for the required system Provide summary/statement of shelf life from the manufacturer abroad signed and stamped by their responsible personnel for the applied product. Letter of Authorization from the manufacturer abroad does not indicate Exclusive/ Sole authorization to the importer, validity not mentioned, list of products authorized not mentioned and complete address of importer not mentioned. (This shortcoming is applicable to all DePuy Orthopaedics, Inc products)
7.	M/s Saru International,	**Legal Manufacturer:**	Healthicon 3L Surgical Drape	3L Surgical Drape	**Deferred** for provision of below

	B-194/1 Block-12, Gulistan Johar Karachi. (ELI-00316) **Evaluator**: AD-IV	Jiangxi 3L Medical Products Group Co., Ltd High tech zone, New Century Industry City, Gaon, Jiangxi China. (FSC Valid 22-06-2020)	3L Surgical Drape Class A Shelf Life: 2 Years Sizes & Codes as per FSC		mentioned documents:- Clearly mention if surgical drape is required on this application or sterile drape as some documents are for surgical drape and others for sterile drape. Surgical drape (non-medicated) is a class B medical device. Submit application on Form 7-A alongwith differential fee Clearly mention the types, sizes and pack size of drapes that are required in this application which should also be present on Free Sale Certificate Provide original Embassy attested Free Sale Certificate from the country of origin. Provide original Letter of Authorization or Agency agreement duly notarized in the country of origin Provide details of manufacturing and quality control

					processes for the applied product Provide ISO 13485 certificate duly notarized in the country of origin (original notarization) Provide Full Quality Assurance certificate duly notarized in the country of origin (original notarization) Provide stability studies supporting the claimed shelf life Provide labels of all types and sizes required Provide Essential Principles of Safety and Performance for the applied product
8.	-do- **Evaluator**: AD-IV	**Legal Manufacturer:** Jiangxi 3L Medical Products Group Co., Ltd High tech zone, New Century Industry City, Gaon, Jiangxi China. (FSC Valid 22-06-2020)	Healthicon 3L Incise Drape 3L Incise Drape PE/ PU Class A Shelf Life: 2 Years Paper film Package 5 years in aluminum foil package Sizes & Codes as per FSC	3L Incise Drape PE/ PU	**Deferred** for provision of below mentioned documents:- Incide drape is not present in the copy of Free Sale Certificate provided. Provide original Embassy attested Free Sale Certificate from the country of origin having the incise drape. Clearly mention

					which incise drape is required PE or PU? Drape (non-medicated) is a class B medical device. Submit application on Form 7-A alongwith differential fee Clealy mention the sizes and pack size of drapes that are required in this application which should also be present on Free Sale Certificate Provide original Letter of Authorization or Agency agreement duly notarized in the country of origin Provide details of manufacturing and quality control processes for the applied product Provide ISO 13485 certificate duly notarized in the country of origin (original notarization) Provide Full Quality Assurance certificate duly notarized in the country of origin original notarization) Provide stability

					studies supporting the claimed shelf life Provide labels of all types and sizes required Provide Essential Principles of Safety and Performance for the applied product
9.	-do- **Evaluator**: AD-IV	**Legal Manufacturer:** Jiangxi 3L Medical Products Group Co., Ltd High tech zone, New Century Industry City, Gaon, Jiangxi China. (FSC Valid 04-03-2021)	Healthicon (Paper Surgical Tape (Non woven Surgical tape)/ Transparent Tape Surgical Tape Class A Shelf Life: 2 Years Paper film Package 5 years in aluminum foil package Sizes & Codes as per FSC	Surgical Tape	**Deferred** for provision of below mentioned documents:- Only Surgical Tape (Non-woven) will be considered in this application. Submit separate application for PE surgical tape. Clearly mention if the product is sterile or not Clearly mention the size and pack size required Provide original Embassy attested Free Sale Certificate in the country of origin. Provide original Letter of Authorization or Agency agreement duly notarized in the country of origin Provide details of

					manufacturing and quality control processes for the Surgical Tape (Non-woven) Provide ISO 13485 certificate duly notarized in the country of origin (original notarization) Provide Full Quality Assurance certificate duly notarized in the country of origin (original notarization) Stability studies supporting claimed shelf life Provide Essential Principles of Safety and Performance for the applied product
10.	-do- **Evaluator**: AD-IV	**Legal Manufacturer:** Jiangxi 3L Medical Products Group Co., Ltd High tech zone, New Century Industry City, Gaon, Jiangxi China. (FSC Valid 22-06-2020)	Healthicon (Wound Dressing) Wound Dressing Class A Shelf Life: 2 Years Paper film Package 5 years in aluminum foil package Sizes & Codes as per FSC	3 L Wound Dressing is made of highly imbibe water material. Its soft , and can make air move freely and entirely. It can imbibe the secretion of wound and prevent it from seeping effectively.	**Deferred** for provision of below mentioned documents:- Only I.V dressing will be considered in this application. Submit separate application each for adhesive wound dressing and transparent wound dressing on Form 7-A as they are class B medical device Clearly state if I.V dressing is sterile or

					not? Clearly state the sizes/codes required for I.V dressing Provide original Embassy attested Free Sale Certificate in the country of origin. Provide original Letter of Authorization or Agency agreement duly notarized in the country of origin Provide details of manufacturing and quality control processes for I.V dressing Provide ISO 13485 certificate duly notarized in the country of origin Provide Full Quality Assurance certificate duly notarized in the country of origin original notarization) Provide stability studies supporting the claimed shelf life Provide labels of codes required for I.V dressing
11.	-do-	**Legal Manufacturer:**	Healthicon (3L Surgical Gown)	Surgical Gown	**Deferred** for provision of below

	Evaluator: AD-IV	Jiangxi 3L Medical Products Group Co., Ltd High tech zone, New Century Industry City, Gaon, Jiangxi China. (FSC Valid 22-06-2020)	Surgical Gown Class A Shelf Life: 2 Years Sizes & Codes as per FSC		mentioned documents:- Clearly mention if the product is sterile or not Clearly mention the sizes required Provide original Embassy attested Free Sale Certificate in the country of origin. Provide original Letter of Authorization or Agency agreement duly notarized in the country of origin Provide details of manufacturing and quality control processes for the applied product Provide ISO 13485 certificate duly notarized in the country of origin (original notarization) Provide Full Quality Assurance certificate duly notarized in the country of origin (original notarization) Stability studies supporting claimed shelf life

					Provide readable label for the applied surgical gown
12.	-do- **Evaluator**: AD-IV	**Legal Manufacturer:** Jiangxi 3L Medical Products Group Co., Ltd High tech zone, New Century Industry City, Gaon, Jiangxi China. (FSC Valid 22-06-2020)	Healthicon (3L Surgical Mask) Surgical Face Mask Class A Shelf Life: 3 Years Sizes & Codes as per FSC	Surgical Mask is protective three layers fabric construction for protection when exposure to blood. It can be used in surgical, procedure and cone styles designed for use in general patient care, contact isolation and care continum environment. Breathable, fluid-resistant fabrics make for excellent choices where comfort and protection are needed in a variety of task and procedures.	**Deferred** for provision of below mentioned documents:- Clearly mention which mask is required on this application? disposable mask or protective mask for medical use? Also clarify that the required product is sterile or not? Provide original Embassy attested Free Sale Certificate in the country of origin. Provide original Letter of Authorization or Agency agreement duly notarized in the country of origin Provide details of manufacturing and quality control processes for the applied product Provide ISO 13485 certificate duly notarized in the country of origin (original notarization)

					Provide Full Quality Assurance certificate duly notarized in the country of origin original notarization) Provide stability studies supporting the claimed shelf life Provide labels of all types and sizes required Provide Essential Principles of Safety and Performance for the applied product
13.	-do- **Evaluator**: AD-IV	**Legal Manufacturer:** Jiangxi 3L Medical Products Group Co., Ltd High tech zone, New Century Industry City, Gaon, Jiangxi China. (FSC Valid 22-06-2020)	Healthicon (3L Surgical Cap) Surgical Cap Class A Shelf Life: 3 Years Sizes & Codes as per FSC	Surgical Cap is protective three layers fabric construction for protection when exposure to blood. It can be used in surgical, procedure and cone styles designed for use in general patient care, contact isolation and care continum environment. Breathable, fluid-resistant fabrics make for excellent choices where comfort and protection are needed in a variety of task and procedures.	**Deferred** for provision of below mentioned documents:- The sizes and types mentioned on Free Sale Certificate doesnot correlate with the brochure provided. Provide labels and brochure for the caps mentioned on Free Sale Certificate State the pack size required Clearly state whether the product is sterile or not. Provide original Embassy attested Free Sale Certificate in the country of origin.

					Provide original Letter of Authorization or Agency agreement duly notarized in the country of origin Provide ISO 13485 certificate duly notarized in the country of origin (original notarization) Provide Full Quality Assurance certificate duly notarized in the country of origin original notarization) Provide stability studies supporting the claimed shelf life Provide Essential Principles of Safety and Performance for the applied product
14.	M/s United Healthcare, Plot No. 330/B, 2nd Floor, DMCH, Bahadurabad, Karachi (ELI-00293) **Evaluator**: AD-IV	**Manufacturer:** Intco Medical (HK) Co., Ltd. Unit 04, 7/F Bright Way Tower, No. 33 Mong Kok Road. KL, Hong Kong **Manufacturing site:** Shanghai Intco Electrode Manufacturing Co., Ltd No. 1358, Hubin Road, Zhelin Town, Fengxian District, Shanghai China. (FSC China valid till 14-06-2020)	Safety Disposable ECG Electrode Class A Shelf Life: 2 years CODES TO BE DECIDED ONCE THE DIFFERENCE IS CLEAR Fee submitted: Rs. 5,000/-	Intended for electrocardiographic monitoring and diagnosis. Used with the connected equipment as medical sensors to achieve the required utility. Single-use	**Deferred** for provision of below mentioned documents:- ISO 13485 expired. Provide notarized certificate Provide specimen labels of all codes required in this application as approved in country of origin. Provide pictures of the actual product Clarify if "Safety" is

					brand name for Pakistan or its brand of the manufacturer? Provide brochure of the applied product having all codes required in this application and clearly state the difference among different codes applied Clearly state if the product is sterile or not? If sterile, then provide sterilization validation report of the manufacturer
15.	M/s Medtronic Pakistan (Private) Limited, Office No.1301, 13th Floor Dilkusha Forum Tariq Road, Karachi (ELI-00273) **Evaluator**: AD-V [80]	**Legal Manufacturer:** Medtronic, Inc. 710 Medtronic Pkwy Minneapolis, MN USA **Manufacturer:** Availmed S.A. de C.V., Ave. Paseo Reforma No. 8950, interior B1, C1, E1, E2, G1, (Local A, B, C, G, H) La Mesa, Tijuana, C.P. 22116, Mexio. (FSC valid till: 30-03-2021)	Everest Disposable Inflation Device Heart Valve prosthesis sinzer handle Class A Shelf Life : 5 Years Sizes & Codes as per FSC AC2200 Everest Inflation Device AC2205P Everest Inflation Device kit AC3200 Everest Inflation Device AC3205P Everest Inflation Device	The Everest 20cc Inflation Device is to be used to facilitate the use of the catheters and guide wires during interventional procedures, The Everest inflation device is deigned to be used to inflate/deflate balloon catheters as well as a to monitor pressure within balloon. The Y/Tri-Adaptor with Hemostatis Valve is designed to be used on guiding catheter or dilatation catheter to	**Approved** subject to provision of Stability data.

				control back bleeding and to provide a port for introduction of fluids into the interventional system. The Guidewire insertion tool is designed to facilitate placement of a guidewire tip through the Y/Tri-adaptor and into the wire lumen of an interventional catheter. The guidewire and provide a handle for manipulating the wire.	
16.	M/s. F.W. Distributors. Opposite Poonch House, Adamjee Road Saddar, Rawalpindi. ELI-00221 **Evaluator**: AD-V	**Legal Manufacturer:** M/s. SCW Medicath Ltd., No.4, Baolong 6th Road, Baolong Industrial Town10-P, Longgang, District Shenzhen, China FSC Belgium Issued on 29.10.2018 FSC China Valid till 08.03.2020	**SCW Medicath Connecting Tubing** Class A Shelf Life: 03 years Codes & Sizes: Model: OD: 3.6mm Effective length: 30cm, 60cm, 90cm, 120cm, 150cm.	The Connecting Tubing used with angiographic syringes intended to provide channel for infusion.	**Approved.**
17.	M/s Hospicare Systems, Mezzanine Floor, Rabbiya Garden, Block 3, MCHS, Shaheed-e-Millat Road, Karachi (ELI-00274) [97]	**Legal Manufacturer:** CytoTherm L.P., 110 Sewell Avenue, Trenton, NJ 08610, USA (FSC valid 23-01-2020) Expired	CytoTherm Plasma Thawing System Plasma Thawer/ Plasma Defroster Class A Shelf Life: N/A Sizes & Codes :	Plasma Thawing System	**Approved** subject to provision of below mentioned documents:- Firm applied the product in class A but Product fall in class B. Required to be applied on Form 7A with differential fee.

	Evaluator: AD-V		CT-4S / CytoTherm Plasma Thawing System CT-4T / CytoTherm Plasma Thawing System CT-D4 / CytoTherm Plasma Thawing System CT-DR / CytoTherm Plasma Thawing System CT-4T.6C / CytoTherm Plasma Thawing System CT-D1 / CytoTherm Plasma Thawing System		ISO13485, Full Quality Assurance system certificate EPSP are not provided rather provided decleration from manufacturer stating that the US FDA'S periodic inspection report is equivalent to certifications required in Form 7A, but the said report is also not provided.
18.	M/s. FM Health Care, 203, Al-Rehman Centre Block 7/8 KCHS, Shaheed-e-Millat Road, Karachi. (ELI-00082) **Evaluator**: AD-II [281]	**Legal Manufacturer:** M/s. RI.MOS S.r.l, Viale Gramsci 29-41037 Mirandola (MO), Italy **FSC** Italy (issuance date not clear)	Specuvag-AS (Vaginal Speculum) Sterile-Single use Class-A (class-I sterile) Shelf life: Not mentioned 1.Specuvag, Vaginal Speculum with central key locking system **Codes**: 720101, small (20mm) 720098, small (24mm) 720102, medium (26mm) 720103, large (30mm) 2.Specuvag CS, Vaginal speculum with central-screw locking system "Cusco" model **Codes**: 720045/S, small (19mm) 720043/S, medium (27mm) 720044/S, large (31mm) 3.Specuvag AS, Vaginal Speculum with smoke evacuator adapter and central key locking **Codes**: 720227, large (30mm) Rs. 10,000/-	For dilation of the vaginal canal and cervix exposure. 720227: for dilation of vaginal canal and evacuation of smoke and vapors from the treated area during laser procedures.	**Deferred** for provision of below mentioned documents:- Translation of portion of FSC wherein description of codes is mentioned as it is Italian language. There is difference in address of manufacturer in between the one mentioned in FSC and Form-6A. Shelf life alongwith stability studies not provided. Sole agency agreement expired on 31-12-2019. Various types/codes of the said device are mentioned in FSC which differ from one another in terms of sizes, shapes/

					designs and intended use. Therefore, needs clarification regarding grant of them under same enlistment number.
19.	M/s. Essity Pakistan Limited, A/69, SITE Manghopir Road, Karachi. (ELI-00011) **Evaluator**: AD-II [284]	**Legal Manufacturer:** M/s. BSN Medical GmbH, Quickbornstrasse 24 20253 Hamburg, Germany. **FSC:** Germany (Issuance Date: 28-08-2019)	Leukomed IV Film-Sterile (Transparent film dressing) **Codes/reference number:** 72390-00, 6cm x 8cm, 50 dressings 72390-03, 8.5cm x 11.5cm, 50 dressings 72390-04, 4.5cm x 4.5cm, 50 dressings 72390-05, 7cm x 9cm, 50 dressings Shelf life: 05 years Class-A Rs.5,000/-	Leukomed IV film is intended for fixation of intravenous catheters for covering and protection of puncture sites. The film dressing can stay in place for one up to several days depending on the status of the wound and on the skin conditions.	**Approved** subject to provision of below mentioned documents:- Responsible person mentioned in Form-6A is not in accordance with Form-4. Original free sales certificate not provided. Copy of agency agreement is provided. Furthermore, agreement is in the name of M/s. BSN medical (Pvt) Ltd, Karachi. Copy of ISO-13485 certificate is provided which expired on 01-06-2020. Copy of quality assurance certificate provided which expired on 01-06-2020. Stability studies provided by the manufacturer mentions that stability at real time storage is still under investigation. If concluded, shall be provided. Codes of sizes mentioned in DOC is

					different from the one stated in FSC. DoC is expired.
20.	M/s. K.M. Enterprises, 605-D-Block, M.A. Johar Town, Lahore. ELI-00054 **Evaluator**: AD-V [19-P]	**Legal Manufacturer:** M/s. Supermax Glove Manufacturing SDN BHD LOT 38, Putra Industrial Park, Bukit rahman Putra, 47000 Sungai Buloh, Selangor, Malaysia. FSC Malaysia Valid upto 04.02.2020	**Maxpro** (Latex Examinatiom gloves) Class A Shelf Life: NA	Latex Examinatiom gloves	**Approved** subject to provision of valid and Embassy attested FSC.

Item No. XXXX: APPLICATIONFOR REGISTRATION/ENLISTMENT OF MEDICAL DEVICES FOR IMPORT ON FAST TRACK FOR COVID-19 EMERGENCY

Secretary MDB informed the Board that the following applications for grant of enlistment/registration of medical devices for import on prescribed form 6-A/7-A under Medical Devices Rules, 2017 were received in the Division. The MDB discussed and decided as mentioned against earch:-

S. No.	Name and Addresses of Establishment	Manufacture Details	Name of Medical Device with sizes/Class/Shelf Life	Decision
1.	M/s Noor International Noor House, 29- D, Block-6 PECHS Karachi. Godown: Same as above **Evaluator:** AD-V	M/s R-vent Medikal Uretim A.S 29 Ekim Mah. Balkan Cad. No. 33, Yazibasi Beldesi, Torbali, Izmir, Turkiye	Sterile and Non-Sterile Catheter mounts Class B Shelf Life: 5 Years **Rs. 25,000/-**	**Approved** subject to inspection of manufactuer abroad under rule 71 of MDR, 2017 or provision of CE mark documents.
2.	-do- **Evaluator:** AD-V	M/s R-vent Medikal Uretim A.S 29 Ekim Mah. Balkan Cad. No. 33, Yazibasi Beldesi, Torbali, Izmir, Turkiye	Sterile and Non-Sterile Breathing Circuit Systems Class B Shelf Life: 5 Years **Rs. 25,000/-**	**Approved** subject to inspection of manufactuer abroad under rule 71 of MDR, 2017 or provision of CE mark documents.
3.	-do-	M/s Hamilton Medical AG Via	Hamilton Medical AG Hamilton S-1 Ventilators	**Approved.**

	Evaluator: AD-V	Crusch 8, 7402 Bonaduz, Switzerland FSC Switzerland valid till 10-07-2021	Class C Shelf Life: 9 Years **Rs. 50,000/-**	
4.	-do- **Evaluator:** AD-V	M/s Hamilton Medical AG Via Crusch 8, 7402 Bonaduz, Switzerland FSC Switzerland valid till 10-07-2021	Hamilton Medical AG Flow Sensors Class B Shelf Life: 9 Years **Rs. 25,000/-**	**Approved**.
5.	-do- **Evaluator:** AD-V	M/s Hamilton Medical AG Via Crusch 8, 7402 Bonaduz, Switzerland FSC Switzerland valid till 10-07-2021	Hamilton Medical AG Expiratory Valve Set Class B 160176, 161186, 161189, 950158 Rs. 25,000/-	**Approved**.
6.	-do- **Evaluator:** AD-V	M/s Hamilton Medical AG Via Crusch 8, 7402 Bonaduz, Switzerland FSC Switzerland valid till 10-07-2021	Hamilton Medical AG Breathing Circuit Set Class B Shelf Life: 5 Years **Rs. 25,000/-**	**Approved**.
7.	-do- **Evaluator:** AD-V	M/s Hamilton Medical AG Via Crusch 8, 7402 Bonaduz, Switzerland FSC Switzerland valid till 10-07-2021	Hamilton Medical AG NIV Full Face Mask Class B Shelf Life: 5 Years **Rs. 25,000/-**	**Approved**.
8.	-do- **Evaluator:** AD-II	M/s Fisher & Paykel Healthcare Limited 15 Maurice Paykel Place, East Tamaki, Auckland, New Zealand	Fisher & Paykel Airvo 2 Humidifier (Model: PT 101)	**Approved**.
9.	M/s 3M Pakistan (Pvt) Ltd Islamic Chamber of Commerce Building, St-2/A, Block-9, KDA Scheme-5, Clifton, Karachi. Godown Address: Plot No. A-6, A-7, Qasim Logistics Center, North West Industrial Zone, Port Qasim, Karachi	M/s 3M Deutschland GmbH Health Care Business Carl-Schurz-Str.1, 41453 Neuss, Germany	3M Surgical Mask [1810F] Class A Shelf Life: 5 Years **Rs. 5,000/-**	**Approved** as the firm has given undertaking on stamp paper that they will submit the remaining documents as required for enlistment of the product as per form 6-A within three months

	Evaluator: AD-II			
10.	-do- **Evaluator:** AD-II	M/s 3M Deutschland GmbH Health Care Business Carl-Schurz-Str.1, 41453 Neuss, Germany	3M Surgical Mask [1810G] Class A Shelf Life: 5 Years **Rs. 5,000/-**	**Approved** as the firm has given undertaking on stamp paper that they will submit the remaining documents as required for enlistment of the product as per form 6-A within three months
11.	-do- **Evaluator:** AD-II	M/s 3M Deutschland GmbH Health Care Business Carl-Schurz-Str.1, 41453 Neuss, Germany	HP Disposable Surgical Gown (Sterile) [7691K (M) 7692K (L) 7693K (XL)7694K (XXL)] Class A Shelf Life: 2 Years **Rs. 5,000/-**	**Approved** as the firm has given undertaking on stamp paper that they will submit the remaining documents as required for enlistment of the product as per form 6-A within three months.
12.	M/s. Sadqain Health Care (Pvt) Ltd. Safari Villas 11, Commercial Complex, 3rd Floor, Bahria Town Phase 7, Rawalpindi. ELI-00020 **Evaluator**: AD-IV	**Manufacturer** M/s. Medi-Sept Sp.z.o.o. ul. Konopnica 159c, 21-030 Motycz Poland. FSC Poland Date of issue 20.03.2019	**VELODES SILK** (Disinfectant) Class: B Sizes: 15ml, 50ml, 250ml, 500ml, 1L, 5L, 200L, 1000L Shelf Life: 3 years Fee submitted: Rs. 25,000/- It is ready to use, alcohol-based product in the form of a gel, designed for disinfection of non-invasive medical devices and hygienic surgical hand disinfectiontc	**Approved** subject to inspection of manufactuer aborad under rule 71 of MDR, 2017 or provision of CE mark documents.
13.	M/s Intra Health, 56/A, Unit No.1, Justice Inamullah Road, Block 7/8, KCHS, Karachi **Evaluator:** AD-VI	M/s Adventa Health SDN BHD 1, Jalan 8 PengkalanChepa 2 Industrial Zone 16100 Kota Bharu Kelantan DarulNaim, Malaysia	Maxitex Neuro Surgical Gloves Powder Free Sterile Class B Shelf Life: 5 Years **Rs. 25,000/-**	**Approved** subject to inspection of manufactuer aborad under rule 71 of MDR, 2017 or provision of CE mark documents as the firm has given undertaking on stamp paper that they will submit the remaining documents as required for registration of the

				product as per form 7-A within three months
14.	-do- **Evaluator:** AD-VI	M/s Adventa Health SDN BHD 1, Jalan 8 PengkalanChepa 2 Industrial Zone 16100 Kota Bharu Kelantan DarulNaim, Malaysia	NUGARD Nitrile Examination Gloves Class A Shelf Life: 5 Years **Rs. 5,000/-**	**Approved** subject to inspection of manufactuer aborad under rule 71 of MDR, 2017 or provision of CE mark documents as the firm has given undertaking on stamp paper that they will submit the remaining documents as required for enlistment of the product as per form 6-A within three months.
15.	-do- **Evaluator:** AD-VI	M/s Adventa Health SDN BHD 1, Jalan 8 PengkalanChepa 2 Industrial Zone 16100 Kota Bharu Kelantan DarulNaim, Malaysia	Sensiflex Plus Surgical Gloves Powdered/Powder Free Sterile Class B Shelf Life: 5 Years **Rs. 25,000/-**	**Approved** subject to inspection of manufactuer aborad under rule 71 of MDR, 2017 or provision of CE mark documents as the firm has given undertaking on stamp paper that they will submit the remaining documents as required for registration of the product as per form 7-A within three months.
16.	-do- **Evaluator:** AD-VI	M/s Adventa Health SDN BHD 1, Jalan 8 PengkalanChepa 2 Industrial Zone 16100 Kota Bharu Kelantan DarulNaim, Malaysia	Maxitex Surgical Gloves Powder/Powder Free Sterile Class B Shelf Life: 5 Years **Rs. 25,000/-**	**Approved** subject to inspection of manufactuer aborad under rule 71 of MDR, 2017 or provision of CE mark documents as the firm has given undertaking on stamp paper that they will submit the remaining documents as required for registration of the product as per form 7-A within three months.
17.	-do- **Evaluator:** AD-VI	M/s Adventa Health SDN BHD 1, Jalan 8 PengkalanChepa 2 Industrial Zone 16100 Kota Bharu	Maxitex Duplex Surgical Gloves Powder/Powder Free Sterile Class B Shelf Life: 5 Years	**Approved** subject to inspection of manufactuer aborad under rule 71 of MDR, 2017 or provision of CE

		Kelantan DarulNaim, Malaysia	**Rs. 25,000/-**	mark documents as the firm has given undertaking on stamp paper that they will submit the remaining documents as required for registration of the product as per form 7-A within three months
18.	-do- **Evaluator:** AD-VI	M/s Adventa Health SDN BHD 1, Jalan 8 PengkalanChepa 2 Industrial Zone 16100 Kota Bharu Kelantan DarulNaim, Malaysia	Nugard Latex Examination Gloves Class A Shelf Life: 5 Years **Rs. 5,000/-**	**Approved** subject to inspection of manufactuer aborad under rule 71 of MDR, 2017 or provision of CE mark documents as the firm has given undertaking on stamp paper that they will submit the remaining documents as required for enlistment of the product as per form 6-A within three months.
19.	-do- **Evaluator:** AD-II	M/s Antisptica Dr. Hans Joachim Molitor GmbH, Carl-Friedrich-Guab-Str.7, 50259, Pulheim, Germany	Manorapid Hand Disinfectant Class A Shelf Life: 5 Years **Rs. 5,000/-**	**Approved** subject to inspection of manufactuer aborad under rule 71 of MDR, 2017 or provision of CE mark documents as the firm has given undertaking on stamp paper that they will submit the remaining documents as required for enlistment of the product as per form 6-A within three months
20.	M/s Hashir Srugical Services, Office No.16, Street 1, F-2, Phase 6, Hayatabad, Peshawar,Godown Addresses: Office No.05, 2nd Floor, Syed's Tower, University Road, Peshawar and House No.2, Street No.1,	M/s Zhejiang Wellong Medical Technology Co. Ltd, Industrial Area, Lvshan Township, Changxing County, Huzhou City, Zhejiang Province, 313105, China	SOFTCARE Anti-Fog Face Shield Class A Shelf Life: 3 Years **Rs. 5,000/-**	**Approved** as the firm has given undertaking on stamp paper that they will submit the remaining documents as required for enlistment of the product as per form 6-A within three months.

	Gulshan Colony, GT Road, Peshawar **Evaluator:** AD-VI			
21.	-do- **Evaluator:** AD-VI	M/s Jiangsu WeikangJiejing Medical Apparatus Co., Ltd. 18 No. Wenzhou Road. Economical Development District, Shuyang, Jiangsu 223600, China	WERACON Disposable Medical Face Mask Class A Shelf Life: 3 Years **Rs. 5,000/-**	**Approved** as the firm has given undertaking on stamp paper that they will submit the remaining documents as required for enlistment of the product as per form 6-A within three months.
22.	-do- **Evaluator:** AD-VI	M/s N.A.Z. Medical Supplies SDN. BHD. No.4, Jalan BP 4/7, Bandar Bukit Puchong 47120 Puchong, Selangor, Malaysia	NazCare® Latex Examination Gloves Powder Free Class A Shelf Life: 3 Years **Rs. 5,000/-**	**Approved** as the firm has given undertaking on stamp paper that they will submit the remaining documents as required for enlistment of the product as per form 6-A within three months.
23.	-do- **Evaluator:** AD-VI	M/s N.A.Z. Medical Supplies SDN. BHD. No.4, Jalan BP 4/7, Bandar Bukit Puchong 47120 Puchong, Selangor, Malaysia	NazCare® Latex Examination Gloves Powdered Class A Shelf Life: 3 Years **Rs. 5,000/-**	**Approved** as the firm has given undertaking on stamp paper that they will submit the remaining documents as required for enlistment of the product as per form 6-A within three months.
24.	-do- **Evaluator:** AD-VI	M/s N.A.Z. Medical Supplies SDN. BHD. No.4, Jalan BP 4/7, Bandar Bukit Puchong 47120 Puchong, Selangor, Malaysia	NazCare® Latex Nitrile Gloves Powder Free Class A Shelf Life: 3 Years **Rs. 5,000/-**	**Approved** as the firm has given undertaking on stamp paper that they will submit the remaining documents as required for enlistment of the product as per form 6-A within three months.
25.	-do- **Evaluator:** AD-VI	M/s Shandong Steve Medical Science & Technology Co. Ltd. No.1 Zhenxing Road, Dewu New District, Wucheng, Dezhou, China	STEVE MEDICAL Disposable Surgical Masks Class A Shelf Life: 2 Years **Rs. 5,000/-**	**Approved** as the firm has given undertaking on stamp paper that they will submit the remaining documents as required for enlistment of the product as per

				form 6-A within three months.
26.	-do- **Evaluator:** AD-VI	M/s Shandong Steve Medical Science & Technology Co. Ltd. No.1 Zhenxing Road, Dewu New District, Wucheng, Dezhou, China	STEVE MEDICAL, Medical Face Mask Class A Shelf Life: 2 Years **Rs. 5,000/-**	**Approved** as the firm has given undertaking on stamp paper that they will submit the remaining documents as required for enlistment of the product as per form 6-A within three months. 6-A within three months.
27.	-do- **Evaluator:** AD-VI	M/s SHENGGUANG Medical Instrument Co. Ltd. No.1 Weiwu Road, Xincheng District, Pingdendshan, Henan Province, China	SHENGGUANG Disposable Surgical Masks Class A Shelf Life: 2 Years **Rs. 5,000/-**	**Approved** as the firm has given undertaking on stamp paper that they will submit the remaining documents as required for enlistment of the product as per form 6-A within three months.
28.	-do- **Evaluator:** AD-VI	M/s SHENGGUANG Medical Instrument Co. Ltd. No.1 Weiwu Road, Xincheng District, Pingdendshan, Henan Province, China	SHENGGUANG Medical Masks (KN-95) Class A Shelf Life: 2 Years **Rs. 5,000/-**	**Approved** as the firm has given undertaking on stamp paper that they will submit the remaining documents as required for enlistment of the product as per form 6-A within three months.
29.	M/s The Searle Company Limited, 1st Floor, NICL Building, Abbasi Shaheed Road, Karachi **Evaluator:** AD-V	M/s TG Medical SDN BHD Lot 5091, Jalan Teratai Batu 5, Off Jalan Meru 41050 Klang Selangor Darul Ehsan, Malaysia	Protiex Latex Examination Powder Free Gloves Class A Shelf Life: 5 Years **Rs. 5,000/-**	**Approved.**
30.	-do- **Evaluator:** AD-V	M/s TG Medical SDN BHD Lot 5091, Jalan Teratai Batu 5, Off Jalan Meru 41050 Klang Selangor Darul Ehsan, Malaysia	Protiex Nitrile Examination Powder Free Gloves Class A Shelf Life: 5 Years **Rs. 5,000/-**	**Approved.**
31.	-do- **Evaluator:** AD-V	M/s TG Medical SDN BHD Lot 5091, Jalan Teratai Batu 5, Off Jalan Meru	Protiex Latex Examination Powdered Gloves Class A Shelf Life: 5 Years	**Approved.**

		41050 Klang Selangor Darul Ehsan, Malaysia	**Rs. 5,000/-**	
32.	M/s Hamza Trading Co., Office No. 302, 3rd Floor, Makkah Market, Katchi Gali No.1, Marriot Road, Densohall, Karachi **Evaluator:** AD-V	M/s Xiantao Extripod Protective Products Co. Ltd, Yewang Minying Industrial Park, Xiantao City, Hubei Province, China	National Disposable Gown (Non-Woven, Non-Sterile) Class A Shelf Life: 5 Years **Rs. 5,000/-**	**Approved.**
33.	-do- **Evaluator:** AD-V	M/s Xiantao Extripod Protective Products Co. Ltd, Yewang Minying Industrial Park, Xiantao City, Hubei Province, China	National Surgical Non-Woven Surgeon Cap Class A Shelf Life: 5 Years **Rs. 5,000/-**	**Approved.**
34.	-do- **Evaluator:** AD-V	M/s Xiantao Extripod Protective Products Co. Ltd, Yewang Minying Industrial Park, Xiantao City, Hubei Province, China	National Disposable Beard Cover Class A Shelf Life: 5 Years **Rs. 5,000/-**	**Approved.**
35.	-do- **Evaluator:** AD-V	M/s Xiantao Extripod Protective Products Co. Ltd, Yewang Minying Industrial Park, Xiantao City, Hubei Province, China	National Disposable Non-Woven Face Mask (Ear Loop) Class A Shelf Life: 5 Years **Rs. 5,000/-**	**Approved** subject to provision of below mentioned documents:- LOA and FSC required. Firm has given undertaking on stamp paper that they will submit the remaining documents as required for enlistment of the product as per form 6-A within three months
36.	-do- **Evaluator:** AD-V	M/s Xiantao Extripod Protective Products Co. Ltd, Yewang Minying Industrial Park, Xiantao City, Hubei Province, China.	National Disposable Non-Woven Shoe Cover Class A Shelf Life: 5 Years **Rs. 5,000/-**	**Approved.**
37.	-do-	M/s Xiantao Extripod Protective Products	National Disposable PE Sleeve	**Approved.**

	Evaluator: AD-V	Co. Ltd, Yewang Minying Industrial Park, Xiantao City, Hubei Province, China.	Class A Shelf Life: 5 Years **Rs. 5,000/-**	
38.	-do- **Evaluator:** AD-V	M/s Xiantao Extripod Protective Products Co. Ltd, Yewang Minying Industrial Park, Xiantao City, Hubei Province, China	National Surgical Medical Disposable SMS Gown (Sterile) Class A Shelf Life: 5 Years **Rs. 5,000/-**	**Approved.**
39.	-do- **Evaluator:** AD-V	M/s Xiantao Extripod Protective Products Co. Ltd, Yewang Minying Industrial Park, Xiantao City, Hubei Province, China	National Disposable CPE Shoe Cover Class A Shelf Life: 5 Years **Rs. 5,000/-**	**Approved.**
40.	-do- **Evaluator:** AD-V	M/s Xiantao Extripod Protective Products Co. Ltd, Yewang Minying Industrial Park, Xiantao City, Hubei Province, China	National Disposable Tie-On Face Mask Class A Shelf Life: 5 Years **Rs. 5,000/-**	**Approved.**
41.	-do- **Evaluator:** AD-V	M/s Xiantao Extripod Protective Products Co. Ltd, Yewang Minying Industrial Park, Xiantao City, Hubei Province, China.	National Surgical Non-Woven Nurse Cap Class A Shelf Life: 5 Years **Rs. 5,000/-**	**Approved.**
42.	-do- **Evaluator:** AD-V	M/s Xiantao Extripod Protective Products Co. Ltd, Yewang Minying Industrial Park, Xiantao City, Hubei Province, China	National Disposable Dust Mask Class A Shelf Life: 5 Years **Rs. 5,000/-**	**Approved** subject to provision of below mentioned documents:- LOAand FSC Required. Firm has given undertaking on stamp paper that they will submit the remaining documents as required for enlistment of the product as per form 6-A within three months.
43.	M/s Organs Pharma, Office No.2, 2nd Floor, Plot No.50-D,	M/s Dongguan Wotushu Medical Technology Co., Ltd,	KN-95 Protective Mask	**Approved** subject to provision of below

	Khayaban-e-Ittehad, Muslim Comm Phase VI, DHA, Karachi (ELI-00403) **Evaluator:** AD-V	No.95, Ludong Road, Xixi Village, Liahou Town, Dongguang City, Guangdong Province, China		mentioned documents and lab testing reports:- Fee, Application on Form 6-A, Agency Agreement. Firm has given undertaking on stamp paper that they will submit the remaining documents as required for enlistment of the product as per form 6-A within three months
44.	M/s SY'AH Impex 1-6/15 Sector No. 5 Korangi Industrial Area Karachi-Pakistan ELI-00440 **Evaluator:** AD-III	Shanghai Motex Healthcare Co., Ltd No. 369, Jiasong Zhong Rd., Huaxin, Qingpu, Shanghai 201708, P. R. China. Valid FSC of China issued on 27th June 2020 valid till 27th June 2021	Shifa Surgical gloves Latex Powdered Surgical gloves (6.0 , 6.5, 7.0, 7.5. 8.0, 8.5) Class-B Sterile disposable device intended to be worn on hands, usually in surgical setting, to provide barrier against potentially infectious material and other contaminants.	**Approved** subject to CE marked documents or inspection of manufactur er abroad under rule 71 of the MDR, 2017
45.	-do- **Evaluator:** AD-III	Shanghai Motex Healthcare Co., Ltd No. 369, Jiasong Zhong Rd., Huaxin, Qingpu, Shanghai 201708, P. R. China. Valid FSC of China issued on 27th June 2020 valid till 27th June 2021	Shifa Examination Gloves Latex Examination Powdered gloves (S, M, L, XL)) Class-A Disposable device intended to be worn on hands or finger to prevent contamination between patient and examiner	**Approved.**

Item No. XXXXI: <u>APPLICATION FOR REGISTRATION OF MEDICAL DEVICES FOR LOCAL MANUFACTURER FORM 7.</u>

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

Sr. No	Name and Address of Establishment	Name of Medical Device	Brief Description	Remarks
1.	M/s Medical Devices Development Center (MDDC) National University of Sciences & Technology (NUST), Sector H-12, Islamabad. (ELM: 0018 issued on 19/03/2020) Scrutinized by: AD-IV	REJUVENATE Cobalt-Chromium Bare Metal Balloon Expandable Coronary Stent System Class: D Sizes (mm): 2.0 x 08 2.0 x 12 2.0 x 16 2.0 x 18 2.0 x 22 2.0 x 26 2.0 x 30 2.5 x 08 2.5 x 12 2.5 x 16 2.5 x 18 2.5 x 22 2.5 x 26 2.5 x 30 3.0 x 08 3.0 x 12 3.0 x 16 3.0 x 18 3.0 x 22 3.0 x 26 3.0 x 30 3.5 x 08 3.5 x 12 3.5 x 16 3.5 x 18 3.5 x 22 3.5 x 26 3.5 x 30 4.0 x 08 4.0 x 12 4.0 x 16 4.0 x 18 4.0 x 22 4.0 x 26 4.0 x 30 Shelf life: 3 years Fee submitted: Rs. 20,000/-	Indicated for used in coronary occlusive disease. Indicated to be implanted in a coronary artery to maintain luminal patency and improve luminal diameter in patients with symptomatic atherosclerotic heart disease. Sterile, single-use	The case has been scrutinized. Submitted for MDB for evaluation on design and clinical aspects. They have requested for 3 years shelf life. Accelerated aging provided

2.	-do- Scrutinized by: AD-IV	VASOGLIDE PTCA Balloon Dilatation Catheter (Rapid Exchange) Class: D Sizes (mm): 2.0 x 12 2.0 x 16 2.0 x 20 2.0 x 22 2.0 x 26 2.0 x 30 2.0 x 34 2.5 x 12 2.5 x 16 2.5 x 20 2.5 x 22 2.5 x 26 2.5 x 30 2.5 x 34 3.0 x 12 3.0 x 16 3.0 x 20 3.0 x 22 3.0 x 26 3.0 x 30 3.0 x 34 3.5 x 12 3.5 x 16 3.5 x 20 3.5 x 22 3.5 x 26 3.5 x 30 3.5 x 34 4.0 x 12 4.0 x 16 4.0 x 20 4.0 x 22 4.0 x 26 4.0 x 30 4.0 x 34 Shelf life: 3 years	Flexible tube designed to be used in percutaneous transluminal coronary angioplasty (PTCA) to dilate stenotic coronary artery by controlled inflation of a distensible balloon(s) at its distal tip. May also be intended for pre-or post-dilatation of a balloon-expandable stent in coronary arteries. Sterile, single-use	The case has been scrutinized. Submitted for MDB for evaluation on design and clinical aspects. They have requested for 3 years shelf life. Accelerated aging provided

		Fee submitted: Rs. 20,000/-		
Decision: The Representative from MDDC, NUST (Dr. Murtaza Najabat Ali) gave detailed presentation on the above mentioned products developed for the first time in the country. The Board discussed the matter at length and decided to refer the matter to National Interventional Cardiology Board (NICB) which has been constituted on the directions of Hon'able Supreme Court for its recommendations on the said products. The Board also authorized its Secreatary to issue registration certificate if the recommendations are received in favour of products.				
3.	M/s Finetex Cotton Industry, Singh 3-KM G.T Road, Kamoke Pakistan. Form 3 not issued Evaluated by: AD-I	Doctor's Gauze Swabs BPC (Non Sterile) Sizes: 5cm x 5cm 7.5 cm x 7.5cm 10cm x 10 cm 15cm x 15 cm	Gauze Swabs BPC Non Sterile is produced from bleached cotton fibre, woven in the amount of 17cm thread per cm2. The advantage is a good absorbency, breathability and softness. Class B Shelf Life: 2 Years	**Approved** subject to verification of fee.
4.	-do- Evaluated by: AD-I	Doctor's Cotton Bandage	Produced according to BPC specification. Adopt advance techniques for manufacturing and dried in dried chamber. Class B Shelf Life: 2 Years	**Approved** subject to verification of fee.
5.	-do- Evaluated by: AD-I	Doctor's Gauze Swabs BPC (Sterile) 5cm x 5cm 7.5cm x 7.5 cm 10cm x 10cm 15cm x 15cm	Gauze Swabs BPC Sterile is produced from bleached cotton fibre, woven in the amount of 17cm threads per cm2. The advantage is a good absorbency, breathability and softness. Class B Shelf Life: 2 Years	**Approved** subject to verification of fee.

6.	-do- Evaluated by: AD-I	Doctor's Crepe Bandage 7.5cm x 3m 10cm x 3cm 15cm x 3m	Cotton Crepe bandage consist of characteristic fabric plain weave in one continuous length, with no joins and has fast edges. The regain length is not more than 80% of the fully stretched length Class C Shelf Life: 2 Years	**Approved** subject to verification of fee.
7.	-do- Evaluated by: AD-I	Doctor's Gauze Swabs X-Rays Detectable BPC 4" x 4"	Lab Sponges /Abdominal Sponges BPC incorporated with an inert filament impregnated barium sulphate with cannot be washed away. Class B Shelf Life: 2 Years	**Approved** subject to verification of fee.

Additional Agenda

17th MDB Meeting held on 13th July, 2020

Case 1: <u>ESTABLISHMENT LICENCE TO IMPORT MEDICAL DEVICES AND REGISTRATION OF UMV-001 EUA</u>

An application for Establishment License to import medical devices and product registration namely UMV-001 EUA (Emergency Resuscitator) was forwarded by PEC. The following facts were noticed in the application:

i) The applicant was Umbulizer LLC based in USA, whereas it should be an authorized agent of the principal abroad based in Pakistan with an authorization letter;
ii) The applicant has an authorization agreement with M/s Ferozsons in Pakistan for marketing, so the application for product registration should come from M/s Ferozsons;
iii) M/s Ferozsons already got the Establishment License to import (ELI) medical devices therefore there is no need for application for ELI;
iv) The product UMV -001 EUA is an Emergency Resuscitator authorized by the FDA for Emergency Used Authorization (EUA) on 14-04-2020 under Public Health Emergency for COVID-19;
v) EUA is for a certain period and will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of ventilators, ventilator tubing connectors, and ventilator accessories during the COVID-19 pandemic is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act;
vi) The firm has applied for Clinical Trial for the said product. The information is available on clinicltrials.gov with the title "Evaluating safety and efficiency of Umbulizer in patients requiring Intermittent Positive Pressure Ventilation" with number NTC 0403028. The actual starting date was 04-09-2018 and the estimated primary completion date is 31-12-2020. The principal investigator is Dr. Kamran Cheema, Services Hospital.

The matter is placed before the MDB for deliberation.

<u>Discussion:</u>

MDB discussed the matter at length and also allowed the applicant representative, namely, Mr. Zeeshan Hashmi Advocate, Legal Advisor for Umbilizer Inc. to present his view point. He informed that a group of Pakistani students in USA including Mr. Shaeer Piracha made this Emergency Resuscitator and the Clinical Trials were conducted in Pakistan at Services Hospital by Dr. Kamran Cheema as Principal Investigator. He confirmed that the trial is incomplete and the product has been authorized by FDA under Emergency Use

Authorization (EUA) and they are in process for submission of application for market authorization with FDA.

The Board members were of the following opinion:

- At present the product is only authorized by FDA under EUA;
- Clinical Trial is yet to be completed and the expected date of completion is 31-12-2020, therefore the product although cannot be considered completely safe unless and until the clinical trial study is completed, therefore potential benefits over potential risks and availability of approved alternatives may be considered while giving authorization for its usage;
- At present there is no shortage of ventilators, CPAPs and BiPAPs and the number of COVID-19 patients is declining.

Decision:

1. Medical Devices Board (MDB) considering that a product may be approved for enlistment / registration for import, if it is approved by the stringent regulatory authority including USA under sub-rule 2 of rule 15 of Medical Device Rules, 2017. Accordingly MDB approved / authorized UMV-001 EUA (Emergency Resuscitator) for its import and usage on similar terms and conditions as authorized by FDA under Emergency Use Authorization (EUA) (**Annex-A**).

2. Moreover, the authorization for import and usage of product in Pakistan shall be terminated or revoked, if its authorization is terminated or revoked by FDA under EUA.

3. Furthermore, keeping in view that emergency has not been declared in Pakistan, the authorization is subject to advice by National Command & Operation Center (NCOC) whether the product under prevailing circumstances is required or not, when other alternatives (ventilators, CPAPs and BiPAPs) are available and number of COVID-19 patients is declining.

Case 2: APPLICATION BY NATIONAL ELECTRONICS COMPLEX OF PAKISTAN (NECOP) FOR ESTABLISHMENT LICENCE TO MANUFACTURE MEDICAL DEVICES AND PRODUCT REGISTRATION - COVRAID ARTIFICAIL INTELLIGENCE-BASED XRAY SOFTWARE TOOL FOR DETECTION OF COVID-19.

An application was forwarded by Pakistan Engineering Council (PEC) for M/s National Electronics Complex of Pakistan for Establishment License to manufacture medical devices and to

register their product, namely, COVRAID, an AI-based Xray software tool to detect COVID-19 patients.

2. Analytical & Operational Test Report along with Acceptance Test Procedure (ATP) was forwarded by PEC on 23rd June, 2020 with the following statement on covering letter:

> *"The product is approved as secondary level detection of COVID patients. It may be used in hospital OPD as cost efficient solution for common patients and at airport. It may also be applied on self-quarantined persons."*

The report recommendation is as follow:

> *"The Covraid tool works within a sensitivity of 0.84-0.98 for cases in which COVID-19 has affected lungs. However, the tool is not effective in diagnosis for COVID-19 related patients where the lungs are not affected and the X-ray does not show any COVID-19 trace. The diagnosis results are provided extremely quick, when compared to the reference standard of PCR. However, due to the operational limitation of the tool, in its current form, it can be used as a service operated by trained individuals. The next step is validation of the product in deployed environment i.e hospitals, airports and self-quarantined persons as suggested by Section 6 of the ATP. Keeping in view the analytical and operational qualification activity, following is the recommendation from the evaluation team:*
>
> 1. *The product is approved for deployment as cited in para 4.2 and processed for registration with DRAP.*
> 2. *OEM to prepare an SOP of disinfecting or safely using X-ray machines to avoid spread of virus due to this diagnosis method. The SOP to include the data confidentiality of the patients, whose data is received by OEM.*
> 3. *The various constraints on X-ray images (brightness, dimension, quality, angle) must be clearly documented by the OEM."*

3. Recently an MOU was signed between Ministry of Science and Ministry of National Health Services, Regulations & Coordination on 12TH June, 2020 and PEC was given a task to approve designs of electromedical equipments and approve standards / ATPs in consultation with Pakistan Standard Quality Control Authority (PSQCA).

4. An Expert Group under the Chairmanship of Dr. Muhammad Nadeem Ahmad, Radiologist Agha Khan Hospital, Karachi and member MDB has been proposed to Authority which shall soon be notified to assess /evaluate the COVRAID AI-based XRAY software tool for diagnosis of COVID-19 patients and other similar technologies.

The case is placed before the MDB for deliberations.

Decision: The Board discussed the matter at length. During discussion it transpired that Pakistan Engineering Council (PEC) in its own recommendation stated *that the tool is not effective in diagnosis for COVID-19 related patients where lungs are not affected and the X-ray does not show any COVID-19 trace.* PEC has also stated that *it is approved as secondary level detection of COVID patients.* The Board was of the opinion that alternative tools which are quite accurate such as CT scan and High resolution X-ray are available for diagnosis. PCR is available for detection / diagnosis of COVID 19 and if required can be repeated. The Board decided that the product, namely, COVRAID shall be referred to the Expert Group constituted by Authority for clinical assessment / evaluation of software based diagnostic tools and the recommendation of the Expert Group should be brought in the Board meeting for consideration.

Case 3. APPLICATION FOR ESTABLISHMENT LICENSE TO MANUFACTURE MEDICAL DEVICES BY M/S ALSONS INDUSTRIES (PVT) LTD.

M/s Alsons Industries (Pvt) Ltd has applied for Establishment License to manufacture medical devices. The application is under process of evaluation. They intend to manufacture CPAP namely Alloventura. The report for design approval along with Acceptance Test Procedure (ATP) is still awaited from PEC.

The matter is placed before MDB for consideration.

Decision: The Board decided to constitute following panel of experts from different fields to inspect the production facility of the said firm and if the panel recommends the manufacturing facility is suitable to manufacture the ventilators, the Secretary MDB may issue the Establishment License to Manufacture medical devices to the firm:-

(i) Dr. Akhtar Aziz Khan, Anesthesist Indus Hospital, Karachi
(ii) Dr. Syed Amjad Ali, Associate Professor, Biomedical Engineer, Mehran University, Jamshoro
(iii) Area FID
(iv) Assistant Direcator, DRAP.

Case 4. **APPLICATION FOR ESTABLISHMENT LICENSE TO MANUFACTURE MEDICAL DEVICES BY NATIONAL RADIO TELECOM CORPORATION (NRTC).**

M/s NRTC has applied for Establishment License to manufacture medical devices, which is under process of evaluation. They intend to manufacture / assemble ventilator under license from M/s Karel, Turkey.

The matter is placed before MDB for consideration.

Mr. M.Hussain (Program Manager) and Mr. Sohail Tayyab (Marketing Manager) from M/s NRTC briefed the Board about the ventilator which is being assembeled in Pakistan by the M/s NRTC under the license from M/s Karel, Turkey. The reprentatives of the firm also informed the Board that the same ventilator is approved by the Health Regulatory Authority of Turkey and also on free sale in Turkish market.

The said ventilator has seven operational modes and 5000 units are in use in diffrent healthcare facilities in Turkey and will costs Rs.433000/piece to the Pakistani public.

Decision: The Board decided to constitute following panel of experts from different fields to inspect the production facility of the said firm and if the panel recommends the manufacturing facility is suitable to manufacture the ventilators, the Secretary MDB may issue the Establishment License to Manufacture medical devices to the firm:-

(v) Maj. Gen. Dr. S.M. Shahab Naqvi, Anesthetist Rawal Institute of Health Sciences, Islamabad
(vi) Dr. Muhammad Shafique, Biomedical Engineer, Riphah University, Islamabad
(vii) Area FID
(viii) Assistant Director, DRAP.

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