Government of Pakistan
Ministry of National Health Services, Regulation & Coordination
Drug Regulatory Authority of Pakistan
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MINUTES OF THE 16TH MEETING OF THE MEDICAL DEVICE BOARD (MDB) HELD ON 03-02-2020

15th 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 3rd February, 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 Mr. Muhammad Tahir Aziz, COO, Shaukat Khanum Memorial Cancer Hospital & Research Centre, Peshawarto preside over the meeting as Chairman. Subsequently meeting was chaired by Mr. Muhammad Tahir Aziz, COO, Shaukat Khanum Memorial Cancer Hospital & Research Centre, Peshawar and was attended by the following:-

S.No.	Name and Designation / Department	Position in the MDB
1.	Mr. Muhammad Tahir Aziz, COO, Shaukat Khanum Memorial Cancer Hospital & Research Centre, Peshawar	Chairman
2.	Mr. Azhar Jamal Saleemi, Director Pharamcy, (Nominee of Director General Health, Punjab).	Member
3.	Mr. Imranullah, Chief Drug Inspector, Abbottabad, KPK, (Nominee of Director General Health, Khyber Pukhtunkhwa).	Member
4.	Mr. Syed Abdul Saleem, Chief Drug Inspector, Balochistan, Quetta. (Nominee of Director General Health, Khyber Pukhtunkhwa).	Member
5.	Mrs. Tazeen S. Bukhari, Biomedical Equipment Planner, Saleem Memorial Trust Hospital, Lahore.	Member
6.	Prof. Dr. Ejaz Hassan Khan, Professor of Pathology, Prof. / Dean, Noth West School of Medicine, Peshawar.	Member
7.	Dr. Muhammad Nadeem Ahmad, Departmetn of Radiology, Aga Khan University Hospital, Karachi.	Member
8.	Dr. Ghazanfar Ali Khan, Additional Director (MDMC), DRAP, Islamabad.	Secretary / Member

Dr. Zafar Hashmi, CEO B.Braun 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 15TH MEDICAL DEVICE BOARD MEETING**

Decision: The Board confirmed the minutes of the 15th 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 recommendations of the panels are as mentioned against each is submitted for consideration of MDB please:-

S.No	Name of Establishment	Director/Proprietor/ partners	Name of panel Inspector (s)	Cold Chain (Yes/No)	Recommendations by the panel.
1.	M/s Assuza Incorporation, 17-Rabbani Road, Old Anarkali, Lahore.	Mr. Naveed Hassan	Mr. Muhammad Shoaib, Federal Inspector of Drugs, DRAP, Lahore. Ms. Uzma Barkat, Assistant Director, DRAP, Lahore.	No	**Approved** for storage of room temperature medical devices without cold chain facility.
2.	M/s CCL Pharmaceuticals (Pvt) Ltd. 65 Industrial Estate, Kot Lakhpat, Lahore. **Godown:** 15-M, Industrial Estate, Kot Lakhpat, Lahore.	Mr.Kashif Sajjad Sheikh Mr. Hassan Zubair Sheikh Mr. Asim Dilawar Sheikh Mr.Nadeem B.J Sheikh	-do-	No.	**Approved** for storage of room temperature medical devices without cold chain facility.

3.	M/s Merlin International, 3rd Floor, Office No 341, Jail Road, Land Mark Plaza, Lahore.	Muhammad Qasim.	Ajmal Sohail Asif, FID, DRAP, Lahore. Dr. Akbar Ali, Assistatn Director, DRAP, Lahore.	No	**Approved** for storage of room temperature medical devices without cold chain facility.
4.	M/s Future D Pakistan, House No. 482, G3, Johar Town, Lahore.	Mr. Umer Hayat	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility.
5.	M/s The Cure, 1st Floor, Office No. 6, Capri Center, Firdous Market, Gulberg III, Lahore	Mr. Umair Mughees	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility.
6.	M/s Swiss HealthCare, Office No. 204, Meriums Complex, Bahadurabad, Karachi. **Godown Address:** VA.6/1, Block-A Nazimabad, Karachi.	Mr. Adamjee Edhi	Mr. Sajjad Abbasi, FID, DRAP, Karachi. Mrs. Hira Bhutto, Assistant Director, CDL, Islamabad.	No	**Approved** for storage of room temperature medical devices without cold chain facility.
7.	M/s Bombay Optical Co., Shop No. A-1, Ground Floor, Plot No. Z-103, Block-3, Dehli Co-Operative Housing Society, Karachi.	Mr. Atif Jamil- Ur-Rehman Mr. Aamir Rehman	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility.
8.	M/s Medtrade, 16-G, Al-Riaz Society, Justice Inamullah Road, Karachi.	Mr. Mansoor Jakhhio Mr. Inayatullah Jakhio	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility.

9.	M/s Ultra Vision (Pvt) Ltd, CC-16 & 17/B, Hasan Centre, Block 16, Gulshan-e-Iqbal, Karachi.	Mr. Muhammad Naveed Najmi. Mr. S.M. Mohsin Rasheed Zaidi	-do-	No	**Approved** for storage of room temperature medical devices without cold chain facility.

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

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

S.No	Name of Establishment	Address	Name of Qualified Person	Name of QC Incharge	Inspection panel & date of inspection	Recommenda-tions
1.	M/s Medical Devices Development Center (MDDC)	National University of Sciences & Technology (NUST), Sector H-12, Islamabad.	Dr. Murtaza Najabat Ali (Production Incharge)	Ms. Marium Mir (QC Incharge)	Mr. Muhamad Tahir Aziz, COO, SKMH, Peshawar/ Member MDB. Maj Gen (R) Azher Mehmood Kiyani, ED, RIC, RWP. Dr. Abdul Haleem Khan, Chairperson, Deptt. of Pharmacy, FC College, Lahore/ Member MDB Mahwish Ansari,	Based on the facility visited, people met and documents reviewed, facility is suitable for the manufacturing of medical devices, complying with GMP requirements with some observations which have been discussed with management and recommended for improvements. Panel unanimmously decided and advised to submit an action plan to

					DD/FID, DRAP, Islamabad. Dr. Shahid M. Iqbal AD-III (MDMC), DRAP, Islamabad.	the Authority of above findings/ observations within one week. Furthermore, clinical trial report is needed to review /analyze the safety and efficacy of products. Decision of approval will be taken after satisfaction response and course of action.

Decision: The Board approved the M/s Medical Devices Development Center (MDDC), NUST for Establishment Licence to Manufacture Medical Devices subject to submission of CAPA / Action Plan regarding addressal of observations / findings by the panel and subsequent verification by Mrs. Mahwash Ansari, FID.

2.	M/s Whitesun Pharma	Mari Road, Mustafabad, Tehsil Kamoke, District Gujranwala.	Ms. Ruqayya Nawaz (Pharm-D) (Production Incharge)	Bilawal Hussain (BS-Hons) (QC Incharge)	**Dr. Abdul Haleem Khan,** Chairperson, Deptt. of Pharmacy, FC College, Lahore/ Member MDB **Mr. Ajmal Sohail Asif,** FID, DRAP, Lahore. **Dr. Ghazanfar Ali Khan,** Additional Director	The panel of inspectors recommends the grant of Establishment Licence for manufacturing of medical devices (**cotton bandage, cotton crepe bandage and non-sterile surgical gauze**) in respect of above mentioned sections to M/sWhitesun Pharma, situated

					(MDMC), DRAP, Islamabad. **Hafiz M. Asif Iqbal**, AD-V(MDMC), DRAP, Islamabad.	at Marri Road, Mustafabad, Tehsil Kamoke, District,Gujranwala.

Submitted for consideration of MDB please**.**

Decision: The Board approved M/s Whitesun Pharma, Mari Road, Mustafabad, Tehsil Kamoke, District Gujranwala for grant of Establishment Licence to Manufacture Medical Devices subject to verification of Quality Control, Incharge as per Medical Device Rules, 2017.

Item No.IV. <u>APPLICATION FOR RENEWAL OF ESTABLISHMENT LICENSE TO MANUFACTURE MEDICAL DEVICES.</u>

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 Silver Surgical Complex (Pvt) Ltd.	C-40, SITE-II, Super Highway Industrial Area, Kaachi.	Mr. Syed Akber Ali (Production Manager)	Syed Zafarullah Shah, QC Manager	Syed Muied Ahmed, Member, Licensing Board. Abdul Rasool Shaikh, Area FID, DRAP, Karachi. Mr. Awais Ahmed , FID/	M/s Silver Surigcal Complex (Pvt) Ltd, C-40, SITE-II Super Highway Industrial Area, Karachi was inspected on 20-12-2019 in compliance to the direction of DRAP. The panel inspected all the

					AD, DRAP, Karachi.	manufacturing sections, stores and QC lab and found the facility as per approved lay out plan. The facility has been provided with necessary utilities, machineries and equipment as required under the guidelines. Necessary documents relating to QC, QA, installation / qualification of machines, HVAC and other utilities were also verified under the scope and noted an optimal level of compliance. Based on the sabove stated the panel unanimously recommends the grant of Establishment License under current prevailing MDMC Rules for the following Class-B medical devices:- Syringes (1cc Insulin Syringe, 3ml & 5ml)

						IV Canulla (Wing Type, Pen Type, Silver I/V Cath & Silver Cath.

Decision: The Board approved M/s Silver Surigcal Complex (Pvt) Ltd, C-40, SITE-II Super Highway Industrial Area, Karachi for grant of Renewal of Establishment Licence to Manufacture Medical Devices.

2	M/s Cotton Craft (Pvt) Ltd.	Plot NO.407-408, Sunder Industrial Estte, Lahore.	Mr. Tariq Mehmood, (Production Manager)	Ms. Nuzhat Kasar, QC Manager	Ajmal Sohail Asif, FID, DRAP, Lahore. Ufaq Tanveer, FID, DRAP, Lahore.	Keeping in view the production and Quality Control facilities provided in the building, the technical personnel and the documents reviewed, and commitment of the firm's management, the panel of inspectors recommends the grant of estabishment licence to M/s Cotton Craft (Pvt) Ltd., Lahore for medical devices. **<u>Sections.</u>** 1. Absorbent Cotton Wool Section. 2. Plaster of Pris (POP) Bandage Section. 3. Guaze Section(GAuze

						Swabs (sterile/non-sterile) - Absorbent Gauze Ribbon) 4. Surgical Tulle Dressing Section. 5. Paraffin Gauze Section. 6. Lint Section. 7. Bandage Section. 8. Lapponges Section. 9. Cotton Crepe Bandage Section. 10. Eye Pad Section. 11. Gauze Roll Section. 12. Packing Section. 13. QC and Microbiological Lab.

Decision: The Board approved M/s Cotton Craft (Pvt) Ltd., Plot NO.407-408, Sunder Industrial Estte, Lahore for grant of Renewal of Establishment Licence to Manufacture Medical Devices.

Item No. V. <u>CHANGE OF MANAGEMENT OF M/S KRESTA CORP, KARACHI.</u>

M/s Kresta Corp, Karachi has informed that ownership status of their firm has been changed from Partnership to Proprietor as Mr. Kanwar Abdul Haseeb (1st Partner) has gifted his complete share in the firm to Mr. Kanwar Nouman Haseeb (2nd Partner). The firm has requested for approval of change of particulars in their ELI No.00258, issued on 19-10-2018 as per detail given below:-

Existing Particulars	Proposed Particulars
1 Mr. Kanwar Abdul Haseeb (CNIC.42301-1444230-7). 2. Mr. Kanwar Nouman Haseeb (CNIC # 42301-1007673-3).	Mr. Kanwar Nouman Haseeb (CNIC # 42301-1007673-3).

The firm has submitted following documents:-

(i) Fee of Rs.10,000/-
(ii) Copy of Declaration of Oral Deed.
(iii) Copy of Deed of Dissolution of Partnership.
(iv) Copy of ELI-00258.

Submitted for consideration of MDB please.

Decision: The Board acceded to the request of M/s Kresta Corp and approved Mr. Kanwar Nouman Haseeb (CNIC # 42301-1007673-3) as the sole proprietor of the establishment.

Item No.VI.(i) <u>EXEMPTION FROM INSPECTION OF MANUFACTURER ABROAD</u>.

The MDB in its 12th meeting held on 13-05-2019 considered and approved the following medical device of M/s Krestacorp, Karchi subject to foriegn inspection of manufacturer:-

Sr No.	Name of Importer	Name of Manufacturer	Name of Medical Device	Brief Description	Remarks
1.	M/s Krestacorp, 76-C, 3rd Floor, Suit No.2, Khayaban-e-Jami, Street No.9, DHA Phase 7, Karachi (ELI-00258) Evaluator: Unum Zia Shamsi	**Legal Manufacturer/ Manufacturing Site:** M/s Jei Daniel Biotech Corp., Jinan Facility, A201, 1st Building No69, Hua Yang Road Jinan, ShangDong, China. (FSC China Valid Till10-05-2020)	Klear Human Chorionic Gonadotropin (HCG) Rapid Test Kit (Colloidal Gold) Class B Shelf Life: 3 Years Fee submitted: Rs.50,000/-	Rapid Self Pregnancy Test Strip	**Approved** subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts. **Only one brand shall be given.**

Meanwhile, the firm has provided the Embassy attested Free Sale Certificate of Germany issued on 25-11-2019 by Ministry of Health and Consumer Protection, Hamburg for the above mentioned medical device which is a reference country and exempted from inspection.

Submitted for consideration of MDB please.

Decision: The Board approved the product, namely, Klear Human Chorionic Gonadotropin (HCG) Rapid Test Kit (Colloidal Gold) for registration.

(ii) <u>EXEMPTION FROM INSPECTION OF MANUFACTURER ABOARD</u>.

The MDB in its 14th meeting held on 11-10-2019 considered and approved the following medical device of M/s Zenith International, Karachi subject to foriegn inspection of manufacturer:-

Sr No.	Name of Importer	Name of Manufacturer	Name of Medical Device	Brief Description	Remarks
1.	M/s Zenith International, Room No. 104, Tahir Plaza, A/20, Block 7&8, KCHSU, Karachi (ELI-00090) Evaluator: Ms. Hira Bhutto	**Legal Manufacturer:** Yangzhou Medline Industry Co., Ltd No. 108, Jinshan Road, Economic Development Zone, 225009 Yangzhou Jiangsu. P.R China. (FSC Valid 07-12-2019)	Perfect Fine A.D. Disposable Auto Disable Syringe, Sterile with needle Class B Shelf Life: 5 Years Codes: 1ml, 2ml, 3ml, 5ml, 10ml, 20ml Rs.25,000/-	Disposable Auto Disable Syringe can be used in intravenous injection, hypodermic injection and drawing blood from vein.	**Approved** subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017.

Meanwhile, the firm has informed that their above mentioned medical devide is CE marked and exempted from inspection abroad.

Submitted for consideration of MDB please.

Decision: The Board approved the product, namely, Perfect Fine A.D., Disposable Auto Disable Syringe, Sterile with needle 1ml, 2ml, 3ml, 5ml, 10ml, 20ml subject to verification of CE marked documents for registration.

Item No.VII. <u>ADDITIONAL SIZES OF ALREADY REGISTERED MEDICAL DEVICES OF M/S PHARMA CONSULTANT PAKISTAN, LAHORE.</u>

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

S.No	Regn.No.	Name of Medical Device	Name of Manufacturer	Existing Approved Sizes/Codes	Demanded Additional Sizes/ Codes.
1.	MDIR-0000919	Sovering Mitral Band	M/s. Sorin Group Italia S.r.I., Via Benigno Crespi 17, 20159 Milano (MI), Italy	ICV0826/SB26M, ICV0827/SB28M, ICV0828/SB30M, ICV0829/SB32M, ICV0830/SB34M, ICV0832/SB38M, ICV0833/SB40M, ICV0824, ICV0825, ICV0664.	ICV0831/SB36M (As per Free Sale Certificate of Italy)

The firm has deposited fee of Rs.5,000/-. Firm has also submitted copy of valid Free Sale Certificate of Italy mentioning the requested additional codes.

Submitted for consideration of MDB Please.

Decision: The Board acceded to the request of M/s Pharma Consultant Pakistan, Lahore and approved the additional codes of the product, namely, Sovering Mitral Band.

Item No.VIII. <u>CHANGE OF TECHNICAL PERSON OF M/S ABBOTT LABORATORIES (PAKISTAN) LTD, KARACHI.</u>

M/s Abbott Laboratories (Pakistan) Ltd, Karachi has applied for change of qualified person in their establishment license to import medical devices (ELI- 00019). The detail of previous and newly appointed technical staff is mentioned below:

Previous Technical Staff Details	New Technical Staff Details
Syed Muhammad Ali CNIC No: 40304-0665662-3	Ms Nimrah Saeed CNIC No: 42201-7157244-6

The firm provided following documents for change of technical staff

1. Form 2 for change of qualified person
2. Copy of establishment license to import medical devices
3. Copy of CNIC, academic documents, experience certificates, photographs and registration certificate of Punjab pharmacy council of newly appointed qualified person
4. Requisite fee of Rs 10000/- for change in particulars in establishment license to import medical devices under Medical devices Rules, 2017

Submitted for consideration of MDB please.

Decision: The Board acceded to the request of M/s Abbott Laboratories (Pakistan) Ltd., Karachi and approved Ms Nimrah Saeed CNIC No: 42201-7157244-6 as technical person for the establishment.

Item No. IX. CHANGE OF TECHNICAL PERSON OF M/S OPTISURG, LAHORE.

M/s Optisurg, Lahore has applied for change of qualified person in their establishment license to import medical devices (ELI- 00305). The detail of previous and newly appointed technical staff is mentioned below:-

Previous Technical Staff Details	New Technical Staff Details
Mr Umair Tayyab 581/10. New Railway Colony, Opposite UET, District, Lahore. CNIC No:35202-5255303-9	Miss. Zunaira Rehman (Pharm-D) Main Street, Allah Rakha Market, House No.E-734/7-B, Mohallah Meherabad , Ali Park, Badian Road, Lahore Cantt. CNIC:35401-1013963-6.

The firm provided following documents for change of technical person :-

1. Form 2 for change of qualified person
2. Copy of establishment license to import medical devices
3. Copy of CNIC, academic documents and certificate of Punjab pharmacy council of newly appointed qualified person
4. Fee Rs. 10,000/-

Submitted for consideration of MDB please.

Decision: The Board acceded to the request of M/s Optisurg, Lahore and approved Miss Zunaira Rehman, CNIC # 35401-1013963-6 as technical person of the establishment.

Item No. X. CHANGE OF TECHNICAL PERSON OF M/S AKRAM BROTHERS & CO., LAHORE.

M/s Akram Brothers & Co, Lahore has applied for change of qualified person in their establishment license to import medical devices (ELI- 00324). The detail of previous and newly appointed technical staff is mentioned below:-

Previous Technical Staff Details	New Technical Staff Details
Munazzah Fatima, House No.6, Street No.2, Al-Faisal Town, Zarar Shaheed Road, Lahore Cantt. CNIC No:35201-7029125-1.	Miss. Varda Zafar, House No.13, Mohallah Khawaja Street Chohan Road, Islam Pura, Lahore. CNIC:35202-0227144-6.

The firm provided following documents for change of technical person :-

1. Form 2 for change of qualified person.
2. Copy of establishment license to import medical devices

3. Copy of CNIC, academic documents and certificate of Punjab pharmacy council of newly appointed qualified person.
4. Copy of new DSL.
5. Fee Rs. 10,000/-

Submitted for consideration of MDB please.

Decision: The Board acceded to the request of M/s Akram Brothers & Co., Lahore and approved Miss Varda Zafar, CNIC # 35202-0227144-6 as technical person for the establishment.

Item No.XI: <u>VIOLATION OF LABELING REQUIREMENTS ON BY M/S ALI GOHAR& COMPANY (PVT) LTD, KARACHI.</u>

The FID-IX Karachi, visited M/s Ali Gohar & Company Pvt Ltd., B-23, SITE Karachi on 13-12-2019, for National Task Force activity and found Misbranded medical devices violating labeling of medical device Rule 38(1) which states "*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*".

The FID-IX Karachi, ordered "not to dispose of" the misbranded medical device and an explanation letter of even number dated 19th December 2019 was issued to the firm for justification in this respect. The reply of M/s Ali Gohar & Company Pvt Ltd. is as under:-

(i) The registration of said medical devices having numbers MDIR-0000614 to MDIR-0000618 and MDIR-0000710 to MDIR-0000714 were issued on 3rd and 17th of September, 2019 and hence M/s Ali Gohar & Company Pvt Ltd., were not able to comply labeling requirements for the stock already shipped or manufactured or under manufacturing process.

(ii) Intra Ocular Lens (IOLs) are packaged in global packs at the manufacturing site which are sold to all countries. Redressing country´s specific requirements for bulk quantities can only be done at the legal manufacturer´s site which can take approximately one year.

(iii) Some IOL types are only ordered in a very limited quantity as per patient´s need for which it is hardly possible for the manufacturer to comply country specific labeling.

(iv) These IOL are only supplied to the clinics and hospitals directly and they are not sold to retailers or to patients, hence, text in Urdu is not necessary.

The firm requested to exempt them from country specific labeling under Rule 38 of Medical Device Rules 2017. The firm also requested to release their held stock as "Not to dispose off".

The Area FID requested for permission of extension in the period of order made "Not to dispose of" till the decison of case or otherwise.

Letter to M/s Ali Gohar & Company (Pvt) Ltd, Karachi has been issued for personal hearing before the MDB.

Submitted for considertion of MDB please.

Decision: The Board discussed the matter at length and decided as under:

i) **the establishment M/S Ali Gohar & Company (Pvt) Ltd, Karachi should adhere to the country (Pakistan) specific lebeling of the products;**

ii) **the stocks of the above products should 'not to dispose of' till the decision of the case by the MDB,**

iii) **the establishment management be called for personal heaing in the next MDB meeting.**

ITEM NO.XII: <u>INSPECTION OF M/S ELILILLY PAKISTAN (PVT) LIMITED, KARACHI- STOCK ORDERED NOT TO DISPOSE OF ON FORM-1 UNDER SECTION 18 (1) OF THE DRUG ACT, 1976.</u>

The FID-IX Karachi, visited the premises of M/s Eli Lilly Pakistan (Pvt) Limited, Karachi on 13-12-2019 in light of National Task Force for eradication of spurious un-registered sub-standard products. During the course of inpsection he found below mentioned medical devices, place in an authorized warehouse (owned by M.s Ali Gohar & Company (Pvt) Ltd, B23, SITE, Karachi M/s Ali Gohar & Company Pvt Ltd., B-23,SITE, Karachi stock of such medical devices was ordered "Not to Dispose of" on Form-1 under Section 18(1) of the Drug Act, 1976 for 28 days initially and was requested for permission for extension in the period of order made Not to Dispose Of on Form-1 under the Drugs Act, 1976/DRAP Act, 2012 and rules framed thereunder till the fate of the case which is still awaited:-

S.No	Name of Product	Batch No.	Quantity	Mfg. Date	Exp.Date	Mfg by
1	Humapen Ergo	D12101015	15840	02/2019	01/2019	M/s Eli Lilly & Cpmpany, USA.

An explanation letter dated 19th December, 2019 was issued to the firm by the FID, Karachi for justification. In this respect M/Eli Lilly Pakistan (Pvt) Limited, Karachi vide their letter received on 6th January, 2020 submitted their explanation *that they have plans to expland the existing designated area of medical devices and the extra stock will be moved to this facility once the expansion is compoleted. The estimated completion time for this expansion would be 3 months. Additionaly, they will be maintaining import quantities as per the requirements by using smooth supply chain and distribution mechanism.*

The firm has requested for releasing their stocks that were put on hold during the aforesaid inspection.

The FID, DRAP, Karachi submitted the case for information and further necessary action into the matter.

Submitted ror consideration of MDB please.

Decision: The Board discussed the matter at length and decided to extend the 'not to dispose of' of stocks till establishment expands their storage area and inspection for verfication is conducted.

ITEM NO.XIII:CHANGE OF BRAND NAME OF REGISTERED MEDICAL DEVICE.

M/s Premier Agencies, Karachi have informed that they got registration of their following medical devices in which due to an error in technical dossier, the correct description **BD Ultra-Fine ™ Pen Needle 0.23mm 32G * 4mm** was replaced with the **BD Micro-Fine ™+ Needle (0.23mm) 32G * 4mm**.Firm has requested for change of brand name as tabulated below:-

S.No.	Reg.No.	Existing Name	Proposed Name of Medical Device
1	MDIR-0000488	BD Micro-Fine ™ + Pen Needle 0.23mm 32G * 4mm	BD Ultra-Fine ™ Pen Needle 0.23mm 32G * 4mm

In this regard, the firm has provided following documents for the said purpose:-

(i) Application on Form 7-A.

(ii) Fee of Rs.12,500/-.

(iii) Explanation letter from M/s B.D Singapore.

(iv) Technical file for BD Pen Needle.

(v) Copy of registration letter.

(vi) Copy of Establishment Licence to Import Medical Devices.

Submitted for consideration of MDB please.

Decision: The Board acceded to the request of M/s Premier Agencies, Karachi and approved the new name of the product, namely, BD Ultra-Fine ™ Pen Needle 0.23mm 32G * 4mm.

Item No. XIV. CHANGE OF TECHNICAL STAFF OF M/S KARIM INDUSTRIES, LAHORE.

M/s KarIm Industries, Lahore have surrendered their original Drug Manufacturing License No.000254 issued on 08-12-2015 in lieu of fresh issuance of Establishment License to manufactur Medical Devices under Medical Devices Rules, 2017. The firm had declared following persons as Production Incharge and Quality Control Incharge:-

Production Incharge	Quality Control Incharge
Mr. Ashfaq Ullah (B (Pharm)	Muhammad Latif (M.Sc Chemistry)

It is submitted that as per Rule 6 of Medical Device Rules, 2017, the Quality Control Incharge shall possess a degree in Pharmacy or biomedical engineering & biotechnology but the firm has declared Muhammad Latif as Quality Control Incharge having qualification of M.Sc Chemistry. Accordingly firm was asked to change their Quality Control Incharge according to MDR, 2017.

Now the firm has applied for change of their Quality Control Inchage. The firm has submitted all relevant documents alongwith fee of Rs.5,000/- and requested for alpproval of new Quality Control Incharge as detail given below:-

Existing QC Incharge	**Proposed QC Incharge**
Muhammad Latif (M.Sc Chemistry)	Muhammad Sardraz Akhtar (Pharm-D)

Submitted for consideration of MDB please.

Decision: The Board accede to the request of the firm and approved Mr. Muhammad Sardraz Akhtar as QC Incharge subject to submission of differential fee of Rs. 45000/- for change in particular of the licence.

Item No.XV. <u>EXEMPTION FROM INSPECTION OF MANUFACTURER ABOARD</u>.

The MDB in its 15th meeting held on 30-12-2019 considered and approved the following medical devices of M/s. M&M Pharma, Javaid Plaza, Opposite Pepsi Factory Gate #II, Guru Mangat Road, Gulberg II, Lahore subject to inspection of manufacturer abroad:-

Sr No.	Name of Importer	Name of Manufacturer	Name of Medical Device	Brief Description	Remarks
1.	M/s. M&M Pharma, Javaid Plaza, Opposite Pepsi Factory Gate #II, Guru Mangat Road, Gulberg II, Lahore. ELI-00159 **<u>Evaluator</u>:** Ms. Hira Bhutto	**Legal manufacturer** M/s. HLL Lifecare Limited, Akkulam Plant, Sreekariym P.O. Thiruvanathapuram – 695 017, Kerala State, India. **Manufacturing Site:** M/s. Akkulam, sreekariyam, P.O. thiruvananthapuram, Kerala, India-695017 FSC India Issued on 16.01.2019	**T-Care** (Cooper-T 380 A) Class D Shelf Life : 05 years Rs.50,000/-	It is intended for male to help prevent pregnancy and the transmission of sexually transmitted diseases.	**Approved** subject to foreign inspection of manufacturer and provision of Notarized full QA certificate & Original Notarized Credentials of manufacturer aboard. The Board also authorized the Secretary MDB to issue registration of the product, if the panel of experts approves the manufacturing plant.
2.	-do-	**Legal Manufacturer** M/s. HLL Lifecare Limited, Akkulam Plant, Sreekariym P.O. Thiruvanathapuram – 695 017, Kerala State,	**MOODS** (Male Lubricated Latex Comdoms) Class C Shelf Life : 05 years **Rs.50,000/-**	Male Lubricated Latex Comdoms. It is intended for male to help prevent pregnancy and the transmission of sexually transmitted diseases.	**Approved** subject to foreign inspection of manufacturer or provision of CE marked documents and provision of Notarized full QA certificate & Original Notarized

		India. **Manufacturing Site:** M/s. Peroorkada, Thiruvananthapuram, Kerala, India-695005 FSC India Issued on 12.10.2018			Credentials of manufacturer aboard. The Board also authorized the Secretary MDB to issue registration of the product, if the panel of experts approve the manufacturing plant.
3.	-do-	**Legal manufacturer** M/s Suzhou Colour-way enterprise DEVELOPMENT Co., Ltd 83-1 Changping Rd, Dongqiao area Xiangcheng District, Suzhou China FSC China Date of issue 24th April, 2017	**M.Dior** (Male latex condoms) Class : C Shelf life 5 Years	It is intended for male to help prevent pregnancy and the transmission of sexually transmitted diseases.	**Approved** subject to foreign inspection of manufacturer or provision of CE marked documents and provision of Notarized ISO 13485. The Board also authorized the Secretary MDB to issue registration of the product, if the panel of experts approves the manufacturing plant.

Meanwhile, the firm has provided the WHO Prequalification documents for the above mentioned medical devices which can be verified online from WHO Website. Under rule 71 (3) of MDR, 2017, the medical devices pre-qualified by the World Health Organization shall be exempted from inspection of manufacturing units abroad.

Submitted for consideration of MDB please.

Decision: The Board approved the above products, namely, T-Care (Cooper-T 380 A), MOODS (Male Lubricated Latex Condoms) and M.Dior (Male Latex Condoms) for registration.

Item No.XVI. **REQUEST FOR IMPORTATION OF FIRST SHIPMENT WITH ENGLISH/ARABIC PACK FOR REGISTERED MEDICAL DEVICES.**

M/s IBL Healthcare Limited, Karachi has enclosed a letter of their foreign manufacturer of registered medical devices namely, **Artelac Nighttime gel (Reg.No.PDIR-0000936)** and **Artelac Advanced (Reg.No.MDIR-0000937)** stating that the pack of Pakistan (English/Urdu specific pack) is under process at their manufacturing site Dr. Gerhard Mann, however, the first production with any new pack of a new product takes time at the manufacturing site for the finalization and setup to start and finish. The quantities to be import for first shipment are as under:-

Artelac Nighttime gel (Reg.No.PDIR-0000936) English Pack : 1000.
Artelac Advanced (Reg.No.MDIR-0000937) English/Arabic Pack : 33,000.

They have requested for approval to allow the importation of the first shipment only with the **English/Arabic pack ofArtelac Advanced (Reg.No.MDIR-0000937)** andwith **English pack of Artelac Nighttime gel (Reg.No.PDIR-0000936)** to enable them to fulfill their commitment to the Pakistan patients and Healthcare professionals.

They have further stated that the second shipment will be imported with Pakisgan specific pack (English/Urdu pack).

Submitted fof consieration of MDB please.

Decision: The Board acceded to the request of the firm subject to printing in their licenced premises.

Item No.XVII. **EXEMPTION/WAIVER OF DRUG SALE LICENSE(DSL) AND EMBASSY OF PAKISTAN ATTESTATION OF FREE SALE CERTIFICATE IN COUNTRY OF ORIGIN.**

Healthcare Devices Association of Pakistan (HDAP), Pakistan Chemists and Druggist Association of Pakistan (PCDA) and Pharma Bureau has requested to waive off the condition of Drug Sale Licence (Form-2) and Embassy of Pakistan attestation of Free Sale Certificate in the country of origin for importers of medical devices (Form 6-A & 7-A) for ease of business. They are of the opinion that Drug Sale Licence is not required for medical devices and that the Paksitan Embassy Attestation in country of origin is time taking and expensive.

Submitted for consideration and delibration of MDB please.

Decision: The Board discussed the matter at length and considerd all the pros and cons, however, could not reach to the consensus, therefore, the matter was deferred for futher deliberation.

Item No.XVIII. CLARIFICATION REGARDING CHANGE OF BRAND NAME.

The MDB in its 14th meeting held on 11-10-2019 considered and approved the following medical devices of M/s Medichem Enterprises, 331/C, Block No.3, DMCH Society Alamgir Road, Karachi subject to **change of brand name**:-

1.	M/s Medichem Enterprises, 331/C, Block No.3, DMCH Society Alamgir Road, Karachi (ELI-00252) **Evaluator: Hafiz Muhammad Asif Iqbal**	**Manufacturer:** M/s Zhejiang Huafu Medical Equipment Co., Ltd., No.688 Xingxing 1st Road., Economic Development Zone, Pinghu, Zhejiang, China (FSC UK Issued on 21-12-2018)	**Promed** Disposable Infusion Set with needle with Y connector Class B Shelf Life: 3 Years Code: ISN-Va-1 **Rs.25,000/-**	Infusion Set with Y Connector
2.	--do-	**-do-**	**Promed** Disposable Syringe with Needle Class B Shelf Life: 3 Years Codes/sizes: 1ml, 2ml, 5ml, 10ml, 20ml, 30ml, 50ml **Rs.25,000/-**	Disposable Syringe with needle

Accordingly the dcision of the MDB was conveyed to the firm for change of brand name of their above mentioned medical devices.

Now the firm has clarified that their brand/trade name "Promed" is registered with Government of Pakistan, Intellectual Property Organization (Trade Marks Registry) since 12-08-2015. Firm has also enclosed a copy of acknowledgement /registration certificate.

Submitted for consideration of MDB please.

Decision: The acceded to the request of M/s Medichem Enterprises and approved the brand names of the product, namely, Promed Disposable Infusion Set with needle with Y connector and Promed Disposable syringe with Needle 1ml and 10ml.

Item No.XIX. <u>SITE VERIFICATION OF M/S KYOTO MEDICAL CORPORATION, FAISALABAD.</u>

M/s Kyoto Medical Corporation, plot No.A-30, Phase 1A, M3 Industrial City, Faisalabad has informed that they are interested to install Manufacturing Unit for Medical Devices. The proposed plot for the construction of the Industiral City, Faisalabad. 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, Lahore and Dr. Akbar Ali, Assistant Director, DRAP, Lahore was nominated for inspection of site verification. They have submitted site verification report as below:-

Location	The proposed site is located at plot plot No.A-30, Phase 1A, M3 Industrial City, Faisalabad. This in an industrial area established under Faisalsabad Industrial Estate Development & Management Company (FIEDMC).
Surrounding	• On the easte side of the plot was a factory. • On the north side of the plot was a vacant plot as master plan of FIEDMC. • On the west side of the plot was a vacant plot as master plan of FIEDMC. • On the south side of the plot was 150 feet wide road.
Size	The size of the plot is 72,000 ft^2 (2.0 Acres) approx. as per allotment letter. The plot was properly demarcated at the time of inspection.
Recommendations	In the light of physical verification of the site and scrutiny of documents provided by the applicant, the proposed site (plot No. A-30 Phase 1A, M3 Industrial City, Faisalabad) is suitable for establishment of a medical device manufactruing unit.

Decision: The Board approved the site of M/s Kyoto Medical Corporation, plot No.A-30, Phase 1A, M3 Industrial City, Faisalabad for establishment of manufacturing unit of medical devices.

Item No.XX. APPROVAL OF NEWLY CONSTRUCTED COTTON WOOL SECTION OF M/S GENERAL PHARMA, GUJRANWALA.

M/s General Pharma, Farm Road, 3--KM, G.T. Road, Manhes (Kotli Wagha) Kamonke, Gujranwala has applied for approval of their newly constructed Cotton Wool Section. Accordingly a panel comprising Malik Irshad Hussain, Secretary Phamacy Council, Lahore, Mrs. Aisha Irfan, FID, DRAP, Lahore and Mst. Uzma Barkat, FID, DRAP, Lahore was constituted for inspection of their newly constructed Cotton Wool Section. The recommendation/conclusion of the report are as under:-

"Based on the findings of the inspection, the panel of inspectors recommends the grant of additional section i.e. "Cotton Wool Section" to the firm M/s General Pharma, Farm Road, 3-KM, G.T. Road (Kotli Wagha), Kamonke, Gujranwala.

Decision: The approved the additional section "Cotton Wool Section" of the firm M/s General Pharma, Farm Road, 3-KM, G.T. Road (Kotli Wagha), Kamonke, Gujranwala.

Item No.XXI. FAST TRACK REGISTRATION/ENLISTMENT OF MEDICAL DEVICES IN CASE OF ANY EMERGENCY.

It is submitted that due to Corona Virus situation in China and its spread to 23 other countries, the emergency situation has arisen. Under current circumsatances, no vaccine or medicine is available and the only option is to adopt preventive measures through the use of Personal Protective Equipments (PPEs) such as Tyvek suits, gowns, gloves, goggles, face shield, booties, sleeves, normal mask, N95 mask, N100 mask and disposal bags. DRAP has also issued a letter to Federal and Provincial Drug Inspectors to visit the importers/distributors dealing with PPEs and provide details of stock in hand to ensure that these items are not exported out of country.

Keeping in view the above situation, there is dire need to formulate a mechanism of **fast track registration of medical devices** in case any emerency arises in the country.It is proposed that the registration of such medical devices as deem necessary in case of prospective emergency

situation may be issued by the Division of Medical Devices & Medicated Cosmetics with the approval of Director MDMC/ CEO,DRAP subject to provision of prescribed Fee, respective applicatiom Form, Letter of Authorization, Free Sale certificate of country of origin and/or Reference country and relevent documents from the notified bodies.Such registration/enlistment cases will then be placed before MDB for their post-fato approval / ratification / endorsement.An undertaking shall be submitted by the applicant for the provision of all other required documents according to FORM 6A & 7A within a time period as specified by the MDB, failing in any of the above conditions the granted registration/ enlistment letter will be cancelled by the MDB after providing a chance of personal hearing.

Decision: The Board approved the fast track registration / enlistment of medical devices and import licence in case of emergency or pandemic (Corono virus etc) or any other calamity, on the submission of respective registration / enlistment and import licence forms, fee and copy of Letter of Authorization, Free Sale Certificate and CE marked documents along with undertaking on stamp paper that the original documents shall be provided within a period of 3 months and in case failure to do so the registration / enlistment or import licence may be suspended or cancelled as the MDB deems fit. The Board directed to Secretary MDB to bring such approvals for MDB post-facto approval / ratiofication / endorsement.

Item No.XXII. <u>EXEMPTION FROM INSPECTION OF MANUFACTURER ABOARD</u>.

<u>Case No. (i)</u>The following auto disable syringe of M/s Nisa Impex (Pvt) Ltd., Islamabad was approved in 14th Meeting of MDB subject to inpection of manufacturer abroad:

Name and Addresses of Establishment	Manufacture Details	Name of Medical Device with sizes/Class/Shelf Life	Brief Description	Decisions
M/s Nisa Impex (Private) Limited., Maxim Arcade, Plot No. 13-14, Usman Block, Jeddah Town, Phase I, Opp. DHA-II, G.T. Road, Islamabad	**Legal Manufacturer:** M/s Chengdu Xinjin & Instrument Co. Ltd., Room No.30, 3rd Floor, A2 Building, Tianfu Life Science Park,	Nisa Auto Disable Syringe (Self Destructive Disposable Syringe with Needle)	Syringe	**Approved** subjet to inspection of manufacturer abroad under Rule 71 of MDR, 2017 and provision

(ELI-00064) **<u>Evaluator:</u>** **Ms. Hira Bhutto**	No.88, South Keyuan Road, Chengdu, P.R. China. (FSC Issuance 20-09-2018)	Sizes: 1ml, 2ml, 5ml, 10ml Needle Size: 0.4, 0.45, 0.5, 0.55, 0.6, 0.7, 0.8, 0.9 Class B Shelf Life : 5 Years **Rs, 25000/-**		original Notraized FSC.

The MDB may consider the product for registration on basis of CE Mark documents. The firm has also requested to include the following permisable variants 0.05ml, 0.5ml, 2.5ml and 3ml.

Decision: The Board approved the product with permissible varieants 0.05 ml, 0.5 ml, 1 ml, 2 ml, 2.5 ml, 3 ml, 5 ml and 10 ml auto-disable syringes subject to verification of CE marked documents.

<u>Case No. (ii)</u> The following products of M/s Nisa Impex (Pvt) Ltd., Islamabad were approved in 12th Meeting of MDB subject to inpection of manufacturer abroad:

Name and Addresses of Establishment	Manufacture Details	Name of Medical Device with sizes/Class/Shelf Life	Brief Description	Decisions
M/s. Nisa Impex (Private) Ltd., Maxim Arcade, Plot No. 13-14, Usman Block, Jeddah Town, Phse I, Opp: DHA-II, G.T. Road, Islamabad.	**Legal manufacturer** M/s. Chengdu Xinjin Shifeng Medical Apparatus & Instrument Co. Ltd., No. 46, 7th Group, Wanjie Village, Xinping Town, Xinjin County, Chengdu City, P.R. China.	Nisa IV Cannula Sizes: 0.7 x19, 0.9x19,0.9x258, 1.1 x 32, 1.1 x 38, 1.3 x 45, 1.6x 38, 1.6x45, 2.1x38, 2.1x45 Class B Shelf Life : 05 years	Intra venous Disposable Cannula	**Approved** subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing

(ELI-00064) Evaluator: Muhammad Ayub Naveed	FSC China Valid until March 27, 2020 Rs. 100,000 (Already submitted on 15-3-2016)			plant is approved by the panel of experts.
-do- Evaluator: Muhammad Ayub Naveed	**Legal manufacturer** M/s. Chengdu Xinjin Shifeng Medical Apparatus & Instrument Co. Ltd., No. 46, 7th Group, Wanjie Village, Xinping Town, Xinjin County, Chengdu City, P.R. China. FSC China Valid until June 6, 2019 Rs. 100,000 (Already submitted)	Nisa Blood Transfusion Set Sizes: 0.7, 0.8, 0.9 & 1.2 Class B Shelf Life : 05 years	Blood Transfusion Set	**Approved** subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts.
-do- Evaluator: Muhammad Ayub Naveed	**Legal manufacturer** M/s. Chengdu Xinjin Shifeng Medical Apparatus & Instrument Co. Ltd., No. 46, 7th Group, Wanjie Village, Xinping Town, Xinjin County, Chengdu City, P.R. China. FSC China Valid until March 27, 2020 Rs. 100,000 (Already submitted)	Nisa Wound Plast (Wound Plast) Sizes: 60x30, 70x18, 70x35, 70x45, 70x60, 70x90, 70x110, 80x50, 80x120 Class B Shelf Life : 05 years	Wound Plast	**Approved** subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts.

-do- Evaluator: Muhammad Ayub Naveed	**Legal manufacturer** M/s. Chengdu Xinjin Shifeng Medical Apparatus & Instrument Co. Ltd., No. 46, 7th Group, Wanjie Village, Xinping Town, Xinjin County, Chengdu City, P.R. China. FSC China Valid until March 27, 2020 Rs. 100,000 (Already submitted)	Nisa Stomach Tube Sizes: 5F,6F, 8F, 12F, 14F, 16F, 18F, 20F, 22F, 24 F Class B Shelf Life : 05 years	Stomach Tube	**Approved** subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts.
-do- Evaluator: Muhammad Ayub Naveed	**Legal manufacturer** M/s. Chengdu Xinjin Shifeng Medical Apparatus & Instrument Co. Ltd., No. 46, 7th Group, Wanjie Village, Xinping Town, Xinjin County, Chengdu City, P.R. China. FSC China Valid until March 27, 2020 Rs. 100,000 (Already submitted)	Nisa Scalp Vain Set Sizes: 14G - 27 G Class B Shelf Life : 05 years	Scalp Vain Set	**Approved** subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts.

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

Submitted for consideration of MDB please.

Decision: The Board approved the above products, namely, Nisa IV Cannula, Nisa Blood Transfusion Set, Nisa Wound Plast, Nisa Stomach Tube and Nisa Scalp Vain Set with the sizes mentioned against each subject to verification of CE marked documents.

Case No. (iii) The following product of M/s Nasir Brother., Karachi was approved in 12th Meeting of MDB subject to inpection of manufacturer abroad:

Name and Addresses of Establishment	Manufacture Details	Name of Medical Device with sizes/Class/Shelf Life	Brief Description	Decisions
M/s Nasir Brothers, 22B, 2nd Floor, Zeenat Medicine Market, North Napire Road, Karachi (ELI-00036) Evaluator: Hafiz Muhammad Asif Iqbal	**Manufacturer:** M/s Longfian Scitech Co. Ltd., 2F & 3F, East Section, Building 12, Power Valley PioneerPark, No.369, Huiyang Street, 071051, Baoding, Hebei Province, China (FSC China Valid Till 02-09-2020) **Fee Submitted Rs.25,000/-**	LONGFIANG Medical Oxygen Concentrator Class B Shelf Life: 5 Years or 20000Hrs Model: JAY-5 (20172540088)	Medical Oxygen Concentrator	**Approved** subject to foreign inspection of manufacturer abroad. The Board also authorized the Secretary MDB to issue registration of the product, if the panel of experts approve the manufacturing plant. Also subject to provision of Stability study.

The MDB may consider the above product for registration on basis of CE Mark and MHRA Free Sale Certificate/ Registration documents.

Submitted for consideration of MDB please.

Decision: The Board approved the above product, namely,LONGFIANG Medical Oxygen Concentrator with the above model subject to verification of CE marked documents.

Case No. (iv) The following product of M/s Fresenius Medical Care., Karachi wasapproved in 13th Meeting of MDB subject to inpection of manufacturer abroad:

M/s. Fresenius Medical Care Pakistan Pvt. Ltd., TAMC, First Floor, 27-C III, M.M. Alam Road Gulberg III, Lahore 54660 ELI-00315	**Legal manufacturer** M/s. Vital Healthcare Sdn. Bhd., Lot 3, Jalan Sultan mohamed 3, Bandar Sultan Sulaiman, 42000 Pelabuhan Klang, Selangor Darul Ehsan, Malaysia. FSC Malaysia Issued on 6th February, 2018	**Vital** (Tubing Set for Hemolialysis) Tubing Sets for Hemodialysis – BLU001E -do- – BLU002E -do- – BLU003E -do- – BLU004E -do- – BLU005E -do- – BLU006E -do- – BLU007E -do- – BLU008E -do- – BLU009E -do- – BLU010E -do- – BLU011E -do- – BLU012E -do- – BLU013E Class B Shelf Life : 03 years Rs.25,000/-	It consists of a collection of tubing required to transport blood or other fluid from a patient's vascular access device to the appropriate dialyzer unit for processing.	**Approved** subject to inspection by the panel of inspectors. The board also authorized secretary MDB to issue registration certificate in case of recommendation by panel of inspectors

The MDB may consider the above product for registration on basis of Free Sale Certificate of Germany.

Submitted for consideration of MDB please.

Decision: The Board approved the above product, namely, Vital (Tubing Set for Hemolialysis)with the above model subject to verification of CE marked documents.

Case No. (v) The following product of M/s Hashir Surgical, Peshawar was approved in 13th Meeting of MDB subject to inpection of manufacturer abroad:

M/s Hashir Surgical Services, 1. Office No.16,	**Legal Manufacturer:** M/s. USM Healthcare Factory	**Favocath IV Catheter** (I.V catheter with injection valve)	IV catheter with injection valve	**Approved** subject to foreign inspection

Street 1, F-2, Phase 6, Hayatabad, Peshawar. 2. Office No.05, 2nd Floor, Syed's Tower, University Road, Peshawar. 3. House No.2, Street No.1, Gulshan Colony, GT Road, Peshawar ELI-00075	JSC, Lot I - 4b -1.3, Street N3, Saigon Hi-tech Park, Long thanh My Ward, District 9, Ho Chi Minh City, Vietnam. FSC Vietnam Issued on 25.03.2019	Codes/Sizes: 14G, 16G, 17G Class B Shelf Life : 05 years Rs.25,000/-		of manufacturer abroad. The Board also authorized the Secretary MDB to issue registration of the product, if the panel of experts approve the manufacturing plant.

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

Submitted for consideration of MDB please.

Decision: The Board approved the above product, namely, Favocath IV Catheterwith the above codes / sizes subject to verification of CE marked documents.

Case No. (vi) The following product of M/s Zenith International, Karachi was approved in 12th Meeting of MDB subject to inpection of manufacturer abroad:

M/s Zenith International, Room No. 104, Tahir Plaza, A/20, Block 7&8, KCHSU, Karachi (ELI-00090)	**Manufacturer:** M/s Tianchang Hengsheng Medical Devices Co. Ltd., Qinlan Industrial Park Tianchang City, Anhui Province, China (FSC China Valid Till 18-03-2020) Fee submitted Rs. 25,000/-	Perfect Disposable Sterile Latex Surgical Gloves Class B Shelf Life: 5 Years 6, 6.5, 7, 7.5, 8, 8.5, 9 Letter made due to corona virus emergency 31-01-2020	Disposable Latex Surgical Gloves, Sterile is used during Surgical Operations to Protect patient and user, may prevent cross infection	**Approved** subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts.

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

Submitted for consideration of MDB please.

Decision: The Board approved the above product, namely, Perfect Disposable Sterile Latex Surgical Gloves subject to verification of CE marked documents.

Case No. (vii) The following product of M/s Mira Khan & Co., Peshawar was approved in 13th Meeting of MDB subject to inpection of manufacturer abroad:

M/s Mira Khan & Co., House No. 12/14, Swati Gate Hakimabad, Peshawar Correspondence Office: Flat No. 414, 4th Floor, Park Tower, F-10/3, Islamabad (ELI-00332) **Evaluator:** Hafiz Muhammad Asif Iqbal	**Manufacturer:** M/s RAYS S.p.A., Via Francesco Crispi 26-60027 Osimo (AN), Italy (FSC Italy Issuance Date 07-08-2018)	Vinyl PF Plus Examination Gloves (Powder Free Clear Vinyl Examination Gloves) Class A Shelf Life: ? Rs.5000/-	VINYL Examination Gloves	**Approved** subject to provision of Stability Data to Support 5 Years Shelf Life Claim. MDB-13

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

Submitted for consideration of MDB please.

Decision: The Board approved the above product, namely, Vinyl PF Plus Examination Gloves (Powder Free Clear Vinyl Examination Gloves) with the above codes / sizes subject to verification of CE marked documents.

Case No. (viii) The following product of M/s Al Hamd Enterprises, Karachi was approved in 15th Meeting of MDB subject to inpection of manufacturer abroad:

M/s Al Hamd Enterprises FL-11/1/1, Block-6, Gulshan-e-Iqbal, Karachi.	Manufacturer: Suzhou Colour-way Enterprise Development Co., Ltd. Dongqiao Industrial Area,	Surgitex® Latex Surgical Gloves (Powdered) Class B Sizes 6, 6.5, 7, 7.5, 8, 8.5	Sterile, single use latex rubber surgical gloves	**Approved** subject to foreign inspection of manufacturer or provision of CE

(ELI-00285) **Evaluator:** Ms. Unum Zia Shamsi	Xiangcheng District, Suzhou. Manufacturing site: Longsha industrial park, Huashi Town, Jiangyin (FSC China valid till 03-01-2020)	Shelf Life: 5 Years Fee submitted: Rs. 50,000/-		marked documents. The Board also authorized the Secretary MDB to issue registration of the product, if the panel of experts approve the manufacturing plant.

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

Submitted for consideration of MDB please

Decision: The Board approved the above product, namely, Surgitex® Latex Surgical Gloves (Powdered) subject to verification of CE marked documents.

Case No. (ix) The following product of M/s Kaumedex, Lahore was approved in 15th Meeting of MDB subject to inpection of manufacturer abroad:

M/s Kaumedex, E-14/2, New Super Town, Link-2, Defence Road, Lahore. (ELI-00162) **Evaluator:** Hafiz Muhammad Asif Iqbal [490-P]	**Legal Manufactuer:** M/s.Supermax Glove Manufacturing SDN. BHD. LOT 38,& 42 Putra Industrial Park, Bukit Rahman, Putra, 47000 Sungai Buloh, Selangor DarulEhsan, Malaysia. FSC Malaysia Valid till 30.10.2019	**High-Max** (Latex Powdered Surgical Gloves) Codes/Sisez: SGLP 5.5 SGLP 6.0 SGLP 6.5 SGLP 7.0 SGLP 7.5 SGLP 8.0 SGLP 8.5 SGLP 9.0 Class : B Shelf Life: 5Years Rs.25,000/-	Latex Powdered Surgical Gloves	**Approved** subject to inspection of foreign manufacturer and provision of Credentials of the manufacturer abroad, ISO 13485, Full Quality assurance and original Embassy attested. The Board also authorized the Secretary MDB to issue

				registration of the product, if the panel of experts approves the manufacturing plant.

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

Submitted for consideration of MDB please.

Decision: The Board approved the above product, namely, High-Max (Latex Powdered Surgical Gloves) subject to verification of CE marked documents.

Case No. (x) The following product of M/s The Searle Company Limited, Karachi was approved in 15th Meeting of MDB subject to inpection of manufacturer abroad:

M/s The Searle Company Limited, 1st Floor, NICL Building, AbbasiShaheed Road, Karachi (ELI-00057) **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** TG Meducak SDN BHD LOT 5091, JalanTeratai, Batu 5, Off JalanMeru, 41050 Klang, Selangor D.E. Malaysia. (FSCMalaysia Valid till 08-01-2024)	**Protiex** Sterile Latex Surgical gloves (Powder Free) Class B Shelf Life: 5 Years Sizes & Codes: Sterile Latex Surgical Gloves (Powder Free)/ ProTieX Code:GB8417368816 Rs.25,000/-	Sterile Latex Surgical gloves((Powder Free)	**Approved** subject to foreign inspection of manufacturer provision of CE marked documents and valid &notarized Agency Agreement & ISO 13485 of the facility TG Meducak SDN BHD LOT 5091, Jalan Teratai, Batu 5, Off Jalan Meru, 41050 Klang, Selangor D.E. Malaysia. The Board also authorized the Secretary MDB to issue registration of the product, if the panel of experts approve the manufacturing plant.

				Valid & notarizes Agency Agreement required.

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

Submitted for consideration of MDB please.

Decision: The Board approved the above product, namely, Protiex Sterile Latex Surgical gloves (Powder Free) subject to verification of CE marked documents.

Case No. (xi) The following product of M/s Pharma Supply Corporation, Karachi was approved in 13th Meeting of MDB subject to inpection of manufacturer abroad:

M/s Pharma Supply Corporation. 49-J, Block-6, PECHS, Nursery Karachi. (ELI-00092) **Evaluator:** Ms. Unum Zia Shamsi	**Legal Manufacturer:** Yixing HBM Latex Production Co., Ltd No. 136 Yipu road Dinghsu Town Yixing city China. (FSC Issuance25-02-2019)	Medispo Surgical Gloves Class B Shelf Life: 05 Years Codes: 6.5, 7.0, 7.5, 8.0, 8.5 Rs.25,000/-	Surgical Gloves personal protection latex gloves used for surgical process.	**Approved** subject to Inspection abroad by the panel of inspectors. The board also authorized the secretary MDB to issue registration certificate if recommended by the panel of inspectorsand EPSP

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

Submitted for consideration of MDB please

Decision: The Board approved the above product, namely, Medispo Surgical Gloves subject to verification of CE marked documents.

Case No. (xii) The following products of M/s Endoaid Biomedica, Lahore were approved in 14th Meeting of MDB subject to inpection of manufacturer abroad:

1. M/s. ENDOAID BIOMEDICA, 185 C, DHA EME Sector, Lahore. 2. 85 D Second Floor, Commercial Area DHA EME Sector Multan Road Lahore. ELI-00169	**Legal manufacturer** M/s. Raysen (Tianjin) Healthcare Products Co., Ltd., No.3, Huanyuxi Road, Tianyu Technology Park, Jinghai, Tianjin, China. FSC China Issued on 11.03.2019	Raysen (Latex (Powder Free) Surgical Gloves) Codes as per FSC Class B Shelf Life : Not mentioned	Surgeons and clinical personnel are using this type of gloves in a sterile environment such as operating theater to perform operation.	**Approved** subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017 and provision of Stability data, Credentials of manufacturer abroad and ISO 13485.
-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal manufacturer** M/s. Raysen (Tianjin) Healthcare Products Co., Ltd., No.3, Huanyuxi Road, Tianyu Technology Park, Jinghai, Tianjin, China. FSC China Issued on 11.03.2019	Raysen (Latex Powdered Surgical Gloves) Codes: as per FSC Class B Shelf Life : Not mentioned	Surgeons and clinical personnel are using this type of gloves in a sterile environment such as operating theater to perform operation.	**Approved** subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017 and provision of Stability data, Credentials manufacturer abroad and ISO 13485.

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

Submitted for consideration of MDB please

Decision: The Board approved the above two products, namely, Raysen (Latex Powder Free Surgical Gloves) and Raysen (Latex Powdered Surgical Gloves)subject to verification of CE marked documents.

Case No. (xiii) The following products of M/s Care and Cure International, Rahim Yar Khan was approved in 14th Meeting of MDB subject to inpection of manufacturer abroad:

M/s. Care and Cure International.65 -B Satellite Town Rahim Yar Khan. (ELI-00192) **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** M/s. AnHui AnYu Latex Products Co., Ltd., No. 95, YuHe Road, 233010, Bengbu, AnHui, China. FSC China valid till 19.12.2020	Cure™Sterile Latex Surgical Gloves (powder-free) Class B Size: 6, 6.5, 7, 7.5, 8, 8.5 (2 pcs or 1 pair per pack) Shelf Life: 03 years Fee submitted: Rs. 25,000/-	Powder free, sterile, single-use, latex surgical gloves	**Approved** subject to foreign inspection of manufacturer abroad. The Board also authorized the Secretary MDB to issue registration of the product on basis of CE marking or if the panel of experts approves the manufacturing plant.

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

Submitted for consideration of MDB please.

Decision: The Board approved the above product, namely, Cure™ Sterile Latex Surgical Gloves (powder-free) subject to verification of CE marked documents.

ITEM NO.XXIII INCREASE IN SHELF LIFE.

It is submitted that M/s Sadqain Healthcare (Pvt) Ltd, Rawalpindi has requested for extension in shelf life from 2 Years to 5 years which is approved in 11th MDB meeting of following imported medical device:-

Name of Medical Device	**Name of Manufacturer**	**Approved Shelf Life in MDB 11th Meeting**	**Demanded Shelf Life**
Clear-Therm Micro HMEF with Luer Port Clear-Therm Mini HMEF with Luer Port	Manufacturer: M/s Intersurgical Limited., Crane House, Molly Millars Lane, Wokingham, Berkshire, UK	3 Years	5 Years

The firm has submitted following documents:-

(i) Fee Deposited Rs.25,000/-
(ii) Copy for five years shelf life validation report.
(iii) Copy of stability for sterility test.
(iv) Copy of establishment licence to import medical devices.

Submitted for consideration of MDB please.

Decision: The Board approved the shelf life of the product, namely, Clear-Therm Micro and Mini HMEF with Luer Port from three years to five years.

ITEM NO.XXIV ADDITION OF FOLLOWING FORMS FOR NOT TO DISPOSE OFF STOCK, SEIZURE OF STOCK, INTIMATION, MEMORANDUM TO GOVERNMENT ANALYST AND CERTIFICATE OF TEST/ANALYSIS BY FEDERAL LABORATORY

The following forms are not included in the Medical Device Rule, 2017 which are required for not to dispose off stock of medical devices, seizure of stocks of medical devices, intimation from whom samples of medical devices were taken, memorandum to government analyst and certificate of test/analysis by Federal Laboratory. These forms are essential for the aforementioned activities:

FORM 23

[See rule 50]

ORDER UNDER SCHEDULE-V OF THE DRAP ACT 2012, REQUIRING A PERSON NOT TO DISPOSE OF STOCK IN HIS POSSESSION

Whereas I have reason to believe that the stock of medical devices in your possession detailed below contravenes the provisions of the Drap Act, 2012 or rules made thereunder; and whereas I have reported the facts to the Board concerned or the authority and have been authorised by it to take action under Schedule-V, Section 1 of the said Act;

I hereby require you not to dispose of the said stock for a period of .....days from this date.

Inspector .....

Date.....

Details of stock of medical devices

Inspector .....

FORM 24

[See rule 50]

RECEIPT FOR STOCK OF MEDICAL DEVICES SEIZED UNDER SCHEDULE-V, SECTION 1(f) OF THE DRAP ACT, 2012

The stock of medical devices detailed below has this day been seized by me under the provision of clause (f) of Section 1 of the Schedule-V of the DRAP Act, 2012, from the premises of ..... situated at.....

Inspector .....

Date .....

Details of medical devices seized

Inspector.....

FORM 25

[See Rule 50]

INTIMATION TO PERSON FROM WHOM SAMPLE(S) IS/ARE TAKEN.

To .....

I have this day taken from the premises of .....situated at .....sample(s) of the medical devices specified below for the purposes of test or analysis.

Inspector

.....Date .....

Details of sample taken

Inspector .....

FORM 26

[See Rule 50 & 51]

MEMORANDUM TO GOVERNMENT ANALYST

Serial No .....

From .....

To

The Federal Government Analyst.

The portion of sample/container described below is sent herewith for test and analysis under the provisions of rule 51(2) of Medical Devices Rules, 2017 and Schedule-V of the DRAP Act, 2012.

The portion of sample/container has been sealed and marked by me with the following mark:

Details of portion of sample or container with name of medical devices which it purports to contain:

Date..... Inspector .....

FORM 27

[See rule 51]

CERTIFICATE OF TEST OR ANALYSIS BY THE (FEDERAL LABORATORIES) /GOVERNMENT ANALYST

Certified that the samples, bearing number..... purporting to be a sample of ..... received on .....with Memorandum No ..... Dated .....from..... has been tested/analyzed and that the result of such test/analysis is as stated below:

2. The condition of the seals on the packet of receipt was follows.....

3. In the opinion of the undersigned the sample is not/is adulterated/ substandard/ misbranded/ spurious, as defined in the DRAP Act, 2012 for the reasons given below:

Details of results of test or analysis: (with protocols of tests applied}.

Director, (Federal Laboratories)
Or other authorized officer/Government Analyst.

Under Sub Rule 3 of Rule 63 of Medical Devices Rules, 2017the authority has the power, to amends the forms so as to omit any enter therefrom, add any entry thereto or amend any entry therein on the recommendation of the MDB.

Submitted for consideration of MDB please

Decision: **The Board deliberated the above Forms and approved them with following amendments. The Board also approved the Forms to be placed before the Authority for approval.**

FORM 23

[See rule 50]

ORDER UNDER SCHEDULE-V OF THE DRAP ACT 2012, REQUIRING A PERSON NOT TO DISPOSE OF STOCK IN HIS POSSESSION

Whereas I have reason to believe that the stock of medical devices in your possession detailed below contravenes the provisions of the Drap Act, 2012 or rules made thereunder; and whereas I have reported the facts to the Board concerned or the authority and have been authorised by it to take action under Schedule-V, Section 1 of the said Act;

I hereby require you not to dispose of the said stock for a period of .....days from this date.

Inspector .....

Date.....

Details of stock of medical devices

S.No	Name of medical device(s)	Batch / Lot No.	Quantity	Manufacturer

Inspector .....

Witness:- 1) _____ 2) _____

Person from whom sample taken _____

FORM 24

[See rule 50]

RECEIPT FOR STOCK OF MEDICAL DEVICES SEIZED UNDER SCHEDULE-V, SECTION 1(f) OF THE DRAP ACT, 2012

The stock of medical devices detailed below has this day been seized by me under the provision of clause (f) of Section 1 of the Schedule-V of the DRAP Act, 2012, from the premises of ..... situated at.....

Inspector .....

Date .....

Details of medical devices seized

S.No	Name of medical device(s)	Batch / Lot No.	Quantity	Manufacturer

Dated:-

Inspector.....

Certified that the above items were actually in my Store / Godown/ Premises/possession referred above at the time of inspection by the Inspector. I have signed this form and I have got a copy of this Form.

Signature of the Owner of the
Chemist Shop / Pharmacy / Premises /Establishment,
Qualified Person or person present during inspection

Witnesses:-

Certified that the search of the premises was conducted by the Inspector in my presence and the items referred above were recovered from the above premises.

1) _____ 2) _____

FORM 25

[See Rule 50]

INTIMATION TO PERSON FROM WHOM SAMPLE(S) IS/ARE TAKEN.

To

.....

.....

I have this day taken from the premises of .....situated at .....sample(s) of the medical devices specified below for the purposes of test or analysis.

Inspector

.....Date .....

Details of sample taken

S. No.	Name of medical device(s) & Regn / Enlist. No.	Batch / Lot No.	Mfg. date	Exp. date	Quantity	Manufacturer

Inspector .....

CERTIFICATES

i) Certified that the sample(s) of the medical devices, the particulars of which are given below were taken from my/our premises /store/ warehouse/godown and sealed in my presence.

ii) Certified that the sample(s) were taken from the original container / packing from the company / manufacturer.

iii) Certified that I have received a copy of this Form 25, and a portion of the said sealed sample(s) as required under the Schedule V of DRAP Act, 2012 and Rules made thereunder.

iv) I shall provide prescribed bills / invoices with warranty of medical devices taken for test / analysis within 7(seven) days.

Signature of the person

Present at the time of inspection

Witnesses:

1) _____ 2) _____

FORM 26

[See Rule 50 & 51]

MEMORANDUM TO GOVERNMENT ANALYST

Serial No .....

From .....

To

The Federal Government Analyst.

The portion of sample/container described below is sent herewith for test and analysis under the provisions of rule 51(2) of Medical Devices Rules, 2017 and Schedule-V of the DRAP Act, 2012.

The portion of sample/container has been sealed and marked by me with the following mark:

Details of portion of sample or container with name of medical devices which it purports to contain:

Sample No.	Name of medical device(s) & Batch / Lot No.	Quantity	Manufacturer

Date..... Inspector .....

FORM 27

[See rule 51]

CERTIFICATE OF TEST OR ANALYSIS BY THE (FEDERAL LABORATORIES) /GOVERNMENT ANALYST

Certified that the samples, bearing number..... purporting to be a sample of ..... received on .....with Memorandum No ..... Dated .....from..... has been tested/analyzed and that the result of such test/analysis is as stated below:

2. The condition of the seals on the packet of receipt was follows.....

3. In the opinion of the undersigned the sample is not/is adulterated/ substandard/ misbranded/ spurious, as defined in the DRAP Act, 2012 for the reasons given below:

Details of results of test or analysis: (with protocols of tests applied}.

Director, (Federal Laboratories) Or other authorized officer/Government Analyst.

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

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 and are submitted for consideration of MDB:-

Sr. No	Name and Addresses of Establishment	Manufacture Details	Name of Medical Device with sizes/Class/ Shelf Life	Brief Description	Decisions
1.	M/s Musaji Adam & Sons, Office No. C-285, Block-10, Federal B Area, Karachi. (ELI-00239) **<u>Evaluator:</u>** Unum Zia Shamsi	**Manufacturer:** Microbiologics, Inc 200 Cooper Avenuem, North Saint Cloud, MN USA 56303 (FSC US FDAvalid till 03-10-2021)	• KWIK-STIK™ microorganism • KWIK-STIK Plus™ microorganism • LYFO DISK™ microorganism Class-A Shelf Life: (Codes not mentioned on FSC. Numerous codes against each brand name provided on Declaration of Conformity) Fee submitted: Rs. 5,000/-	Intended to be use as controls to verify the performance of assays, reagents, or mediathat are intended to be used in microbial testing for detection and identification of a cultured microorganism isolate	**Approved** subject to differential fee and shelf life.
2.	M/s Martin Dow Marker Specialties (Private) Limited. D-7, Parveen Building, Shaheed-e-Millat Road	**Manufacturer:** Boule Medical AB, Domnarvasgatan 4, SE-163 53 Spanga, Sweden. (FSC Sweden Valid till 25-05-	Swelab Alfa Reagents Class-A Codes; Article No. 1504124 Swelab	• Swelab Alfadiluent is a hematology diluent used for cell counting and sizing in the Swelab Alfa	**Approved** subject to submission of differential fee.

	Karachi, Pakistan. (ELI-00160) **Evaluator:** Unum Zia Shamsi	2022)	AlfaDiluent, Article No. 1504125 Swelab AlfaLyse, Article No. 1504127 Swelab Alfa ComboPack 200, Article No. 1504462 Swelab AlfaDiluent, RFID, Article No. 1504463 Swelab AlfaLyse, RFID, Article No. 1504464 Swelab Alfa Combopack, RFID. Shelf Life: 36 Months Fee submitted: Rs. 5,000/-	Series, automated, hematology analyzers. • Swelab AlfaLyse is a hematology cyanide free lytic reagent used for cell counting and sizing in the Swelab Alfa Series, automated, hematology analyzers. • Swelab Alfa ComboPack is combination pack with hematology diluent and a cyanide-free lytic reagent used for cell cyanide-free lytic reagent used for cell counting and sizing in the swelab Alfa Series, automated, hematology analyzers.	
3.	-do- **Evaluator:** Unum Zia Shamsi	**Manufacturer:** Boule Medical AB, Domnarvsgatan 4, SE-163 53 Spanga, Sweden. (FSC Sweden Valid till 25-05-	Boule Calibrator and Control Class A Codes: Article No. 1504025 Boule Cal 1x	Boule Cal Hematology Calibrator is manufactured for calibration of multi-parameter hematology analyzers.	**Approved**

		2022)	3.0ml Shelf life: 70 days Article No. 1504045 Boule Cal 2x3.0 ml Shelf life: 70 days Article No. 1504020 Boul Con-Diff Low 1x4.5 ml Shelf life: 140 days Article No. 1504176 Boule Con-Diff Low 6x4.5 ml, Shelf life: 140 days Article No. 1504019 Boule Con-Diff Normal 1x4.5ml, Shelf life: 140 days Article No. 1504043 Boule Con-Diff Normal 6x4.5ml, Shelf life: 140 days Article No. 1504021 Boule Con-Diff High 1x4.5ml, Shelf life: 140 days	Boule Hematology Control is intended to be used to monitor the performance of multi parameter automated and semi-automated hematology analyzers	

			Article No. 1504216 Boule Con-Diff High 6x4.5ml, Shelf life: 140 days Article No. 1504022 Boule Con-Diff Tri-Level 6x4.5ml. Shelf life: 140 days Fee submitted: Rs. 5,000/-		
4.	M/s Innovate Medical Technology (Pvt) Ltd., Plot No.A-7/2, Block 13/D3, Gulshan e Iqbal, Karachi (ELI-00352) **Evaluator**: Abdul Waheed	**Manufacturer:** M/s Coloplast A/S Holtedam 1 3050 Humlebaek, Denmark (FSC Denmark Valid Till 14-11-2020)	Assura/AlternaOstomy Bag 1-Piece, Closed (Original) Class A Shelf Life: 3 Years **Rs.5,000/-**	Ostomy Care Ostomy Bag 1 Piece	**Approved** subject to submission of Original FSC, shelf life, original Agency Agreement and ISO 13485.
5.	-do- **Evaluator**: Abdul Waheed	**Manufacturer:** M/s Coloplast A/S Holtedam 1 3050 Humlebaek, Denmark (FSC Denmark Valid Till 08-10-2020)	Conveen Standard Urine Bag (Sterile) Class A Shelf Life: 5 Years **Rs.5,000/-**	ExtenalCath SeT	**Approved** subject to submission of Original FSC, shelf life, original Agency Agreement and ISO 13485.
6.	-do- **Evaluator**: Abdul Waheed	**Manufacturer:** M/s Coloplast A/S Holtedam 1 3050 Humlebaek, Denmark	Coloplast Paste, Paste, Brava Paste Class A	Ostomy Paste	**Approved** subject to submission of Original FSC, shelf life, original Agency

		(FSC Denmark Valid Till 14-11-2020)	Shelf Life: 2 Years **Rs.5,000/-**		Agreement and ISO 13485.
7.	-do- **Evaluator**: Abdul Waheed	**Manufacturer:** M/s Coloplast A/S Holtedam 1 3050 Humlebaek, Denmark (FSC Denmark Valid Till 14-11-2020)	Biatain Foam Dressing Class A Shelf Life: 3 Years **Rs.5,000/-**	Antibacyerial Foam Dressing	Approved subject to submission of Original FSC, shelf life, original Agency Agreement and ISO 13485.
8.	-do- **Evaluator**: Abdul Waheed	**Manufacturer:** M/s Coloplast A/S Holtedam 1 3050 Humlebaek, Denmark (FSC Denmark Valid Till 14-11-2020)	ColoplastOstomy Powder Class A Shelf Life: 2 Years **Rs.5,000/-**	Ostomy Care Powder	Approved subject to submission of Original FSC, shelf life, original Agency Agreement and ISO 13485.
9.	-do- **Evaluator**: Abdul Waheed	**Manufacturer:** M/s Coloplast A/S Holtedam 1 3050 Humlebaek, Denmark (FSC Denmark Valid Till 08-10-2020)	ColoplastAlterna Base Pate Class A Shelf Life: 3 Years **Rs.5,000/-**	Base Plate/Waffer	Approved subject to submission of Original FSC.
10.	-do- **Evaluator**: Abdul Waheed	**Manufacturer:** M/s Coloplast A/S Holtedam 1 3050 Humlebaek, Denmark (FSC Denmark Valid Till	ColoplastAlterna Colostomy Bag Class A Shelf Life: 3 Years **Rs.5,000/-**	Colostomy Bag/ Drainable Pouch	Approved subject to submission of Original FSC and shelf life.

		14-11-2020)			
11.	-do- **Evaluator**: Abdul Waheed	**Manufacturer:** M/s Coloplast A/S Holtedam 1 3050 Humlebaek, Denmark (FSC Denmark Valid Till 14-11-2020)	ColoplastAlterna Clamp Class A Shelf Life: 5 Years **Rs.5,000/-**	Colostomy Clamp	Approved subject to submission of Original FSC, shelf life, original Agency Agreement and ISO 13485.
12.	-do- **Evaluator**: Abdul Waheed	**Manufacturer:** M/s Coloplast A/S Holtedam 1 3050 Humlebaek, Denmark (FSC Denmark Valid Till 14-11-2020)	Coloplast, Ostomy Strip Paste Class A Shelf Life: 2 Years **FSC Copy not Attached** **Rs.5,000/-**	Ostomy Paste	Approved subject to submission of Original FSC, shelf life, original Agency Agreement, Full Quality Assurance and ISO 13485.
13.	-do- **Evaluator**: Abdul Waheed	**Manufacturer:** M/s Coloplast A/S Holtedam 1 3050 Humlebaek, Denmark (FSC Denmark Valid Till 25-03-2020)	Comfeel Plus Ulcer Dressing with Alginate Class A Shelf Life: 3 Years **Rs.5,000/-**	Wound Hydrocolloid Dressing	Approved subject to submission of Original FSC, shelf life, original Agency Agreement and ISO 13485 and differential fee of Rs. 20000/- since the product falls in Class B and to apply on Form 7A.
14.	-do- **Evaluator**: Abdul Waheed	**Manufacturer:** M/s Coloplast A/S Holtedam 1 3050 Humlebaek, Denmark (FSC Denmark	Coloplast, Alterna Belt Class A Shelf Life: 5 Years	Ostomy Belt	Approved subject to submission of Original FSC, shelf life, original Agency Agreement and ISO 13485.

		Valid Till 14-11-2020)	**Rs.5,000/-**		
15.	-do- **Evaluator**: Abdul Waheed	**Manufacturer:** M/s Coloplast A/S Holtedam 1 3050 Humlebaek, Denmark (FSC Denmark Valid Till 14-11-2020)	ColoplastAlterna Urostomy Bag Class A Shelf Life: 5 Years **Rs.5,000/-**	Urostomy Bag/ Drainable Pouch	Approved subject to submission of Original FSC, shelf life, original Agency Agreement and ISO 13485.
16.	M/s Jasani Scientifics, SC-45, Marium Square, ChandniChow k, Stadium Road, Karachi. (ELI-00416) **Evaluator**: Abdul Waheed	**Manufacturer:** Huvitz Co., Ltd., 38, Burim-ro 170beon-gil, Dong-gu, Anyang-si, Gyeonggi-do Korea. (FSC issuance 04-06-2019)	HUVITZ CO., Ltd ® Slit Lamp Microscope HS-5500(LED) (ONLY) Class A FEE:5000 Shelf Life: 7 Years Sizes & Codes as per FSC Slit Lamp Microscope HS-5500 **Rs.5,000/-**	The Slit Lamp HS-5500 is intended for use in eye examination of the anterior eye segments, form the cornea epithelium to the posterior capsule. It is used to aid in the diagnosis of disease or trauma which affects the structural properties of the anterior eye segments.	Approved subject to submission of valid Original FSC, Agency Agreement and ISO 13485.
17.	-do- **Evaluator**: Abdul Waheed	**Legal Manufacturer:** Huvitz Co., Ltd., 38, Burim-ro 170beon-gil, Dong-gu, Anyang-si, Gyeonggi-do Korea.	HUVITZ CO., Ltd ® Auto Ref/ Keratometer HRK-1 Class A Fee Submitted Rs 5000	Auto Ref/ Keratometer HRK-1 isintended to be used to measure the refractive power of the eye.	Approved subject to submission of valid Original FSC, Agency Agreement and ISO 13485.

		(FSC REPUBLIC OF KOREA ISSUED ON 11-01-2019)	Life: 7 Years Sizes & Codes as per FSC Auto Ref/ Keratometer HRK-1 **Rs.5,000/-**		
18.	-do- **Evaluator**: Abdul Waheed	**Legal Manufacturer:** Huvitz Co., Ltd., 38, Burim-ro 170beon-gil, Dong-gu, Anyang-si, Gyeonggi-do Korea. (FSC Republic Of Korea issued on 11-01-2019)	HUVITZ CO., Ltd ® CHART PROJECTOR HCP 7000. Class A Fee submitted 5 Rs 5000 Shelf Life: 7 Years **Rs.5,000/-**	It is an automatic chart projector which provides 41 different charts including red/green and polarized filters for the eye optometry.	Approved subject to submission of valid Original FSC, Agency Agreement and ISO 13485.
19.	-do- **Evaluator**: Abdul Waheed	**Legal Manufacturer:** Huvitz Co., Ltd., 38, Burim-ro 170beon-gil, Dong-gu, Anyang-si, Gyeonggi-do Korea. (FSC Republic Of Korea issued on 11-01-2019)	HUVITZ CO., Ltd ® Applanation Tonometer HT-5000 Class A Fee submitted Rs 5000 Shelf Life: 7 Years Applantation Tonometer HT-5000 **Rs.5,000/-**	Applantation Tonometer HT-5000 used for measuring intraocular pressure.	Approved subject to submission of valid Original FSC, Agency Agreement and ISO 13485.
20.	-do- **Evaluator**:	**Legal Manufacturer:**	HUVITZ CO., Ltd ®	The Huvitz digital Chart (HDC-9000) is a	Approved subject to submission of valid Original

	Abdul Waheed	Huvitz Co., Ltd., 38, Burim-ro 170beon-gil, Dong-gu, Anyang-si, Gyeonggi-do Korea. (FSC Republic Of Korea issued on 11-01-2019)	Digital chart HDC-9000N/ HDC9000PF Class A Life: 7 Years Sizes & Codes as per FSC Classification Huvitz Digital Chart HDC-9000N Huvitz Digital Chart HDC-9000PF **Rs.5,000/-**	computerized chart presenting device that provides charts for refractive correction test and various functional test such as cross cylinder, red/green, binocular balance, fusion and suppression, heterophobia, associated phoria, aniseikonia, stereopsis, and dominant eye test for hetrophoria.	FSC, Agency Agreement and ISO 13485.
21.	-do- **Evaluator**: Abdul Waheed	**Legal Manufacturer:** Huvitz Co., Ltd., 38, Burim-ro 170beon-gil, Dong-gu, Anyang-si, Gyeonggi-do Korea. (FSC Republic of Korea issued on 11-01-2019)	Huvitz Co., Ltd ® Slit Lamp Microscope Hs-7000(Led Or Hlg Only One Model Considered) Class A Fee Submitted Rs 5000 Shelf Life: 7 Years Sizes & Codes As Per Fsc Slit Lamp Microscope Hs-7000 Note. Stab provides hs series 2ea.	The Slit lamp HS-7000 is intended for use in eye examination of the anterior eye segment, form the cornea epithelium to the posterior capsule. It is used to aid in the diagnosis of disease or trauma.	Approved subject to submission of valid Original FSC, Agency Agreement and ISO 13485.

			Fsc only HS 7000 MENTIONED **Rs.5,000/-**		
22.	-do- **Evaluator**: Abdul Waheed	**Manufacturer:** Huvitz Co., Ltd., 38, Burim-ro 170beon-gil, Dong-gu, Anyang-si, Gyeonggi-do Korea. (FSC Republic of Korea issued on 11-01-2019)	HUVITZ CO., Ltd Digital Refractor HDR-9000. Configuration. Digital refractor Digital refractor(JB) Digital refractor(OP) Class A Fee submitted Rs:5000 Shelf Life: 7 Years Sizes & Codes as per FSC Digital Refractor HDR-9000 **Rs.5,000/-**	The Huvitz Digital Refractor HDR-9000 system is computerized auto refractor used for the subjective refraction by regarding the patient's accommodation power and facilities. Also the digital refractor is used for detecting and measuring any anomalies in binocular vision such as muscle balance binocular balance, aniseikonia, fusion and stereopsis.	Approved subject to submission of valid Original FSC, Agency Agreement and ISO 13485.
23.	-do- **Evaluator**: Abdul Waheed	**Legal Manufacturer:** Huvitz Co., Ltd., 38, Burim-ro 170beon-gil, Dong-gu, Anyang-si, Gyeonggi-do Korea. (FSC REPUBLIC OF KOREA ISSUED ON 11-	HUVITZ CO., Ltd ® Optical cohearnce Tomography • HOCT-1F • HOCT-1 Class B FEE SUBMITTED RS 25000	The HOCT-1F, HOCT-1 is intended for use to aid in the diagnosis and management of ocular disease such as macular holes, cystoid macular edema, diabetic retinopathy and aged related macular	Approved subject to submission of valid Original FSC, Agency Agreement and ISO 13485 and verification of CE marked documents otherwise subject to the inspection of manufacturer abroad.

		01-2019)	Life: 7 Years **Rs.5,000/-**	degeneration.	
24.	-do- **Evaluator**: Abdul Waheed	**Legal Manufacturer:** Huvitz Co., Ltd., 38, Burim-ro 170beon-gil, Dong-gu, Anyang-si, Gyeonggi-do, 14055,Republic of Korea. (FSC issuance 11-01-2019)	HUVITZ CO., Ltd ® Instrument Table HRT-7000 Class A FEE:5000 Shelf Life: 7 Years Sizes & Codes as per FSC Refraction Table HRT-7000 Classification: Ophthalmic refractometer. **Rs.5,000/-**	This equipment is the product which is composed with the table which the equipment and parts can be put on in the optometrist, optician shop and the chair for the examinee for the eyesight test, and it is produced for being used by loading the necessary equipment for the medical care act. After the AC100-120/200-220 V power supply is approved in the control PCB Through the transformer, it can be controlled by operating the power supply for the lamp, ARM Chair.	Approved subject to submission of valid Original FSC, Agency Agreement and ISO 13485.
25.	-do- **Evaluator**: Abdul Waheed	**Legal Manufacturer:** Huvitz Co., Ltd., 38, Burim-ro 170beon-gil, Dong-gu, Anyang-si,	HUVITZ CO., Ltd ® SLIT LAMP HS-5000(LED). Class A	The slit lamp, HS-7000 is intended for use in eye examination of the anterior eye segments, from the cornea	Approved subject to submission of valid Original FSC, Agency Agreement and ISO 13485.

		Gyeonggi-do, 14055,Republic of Korea. (FSC issuance 11-01-2019)	FEE: 5000 Shelf Life: 7 Years Sizes & Codes as per FSC Visual acuity projector Models. 1.HS 5000(LED) 2.HS 5000 (X2)(LED) 3.HS 5000 (X3)(LED) (AS MENTIONED IN DOC) **Rs.5,000/-**	epithelium to the posterior capsule. It is used to aid in the diagnosis of disease or trauma which affect the structural properties of the anterior eye segment.	
26.	-do- **Evaluator**: Abdul Waheed	**Legal Manufacturer:** Huvitz Co., Ltd., 38, Burim-ro 170beon-gil, Dong-gu, Anyang-si, Gyeonggi-do Korea. (FSC Republic of Korea issued on 11-01-2019)	HUVITZ CO., Ltd ® Non-Contact Tonometer HNT1. • HNT1 Class B FEE SUBMITTED Rs 25000 Life: 7 Years Sizes & Codes as per FSC Non-Contact Tonometer HNT1 (ONLY CONSIDERED) **Rs.5,000/-**	The non-Contact Tonometer HNT-1 is intended to be used to measure the intraocular pressure of the human eye.	Approved subject to submission of valid Original FSC, Agency Agreement and ISO 13485 and verification of CE marked documents otherwise subject to the inspection of manufacturer abroad.

27.	-do- **Evaluator**: Abdul Waheed	**Legal Manufacturer:** Huvitz Co., Ltd., 38, Burim-ro 170beon-gil, Dong-gu, Anyang-si, Gyeonggi-do Korea. (FSC Republic of Korea issued(11-01-2019).	HUVITZ CO., Ltd ® Auto Ref/ Keratometer HRK-9000A Class A Fee Submitted Rs:5000 Shelf Life: 7 Years Auto Ref/ Keratometer HRK-9000A **Rs.5,000/-**	The Auto Ref/ Keratometer HRK-9000A is intended to measure the refractive power of the eye.	Approved subject to submission of valid Original FSC, Agency Agreement and ISO 13485.
28.	M/s Zenith International, Room No. 104, Tahir Plaza, A/20, Block 7&8, KCHSU, Karachi (ELI-00090) **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer & Manufacturing Site:** Huaian Angel Medical Instrument Co., Ltd. 19 East Zhuhai Road, Huaian, 223001 Jiangsu, China. FSC Germany Validity 06-05-2019 FSC China Validity 01-02-2020	Perfect Fine Sterile Urine Bag, 2000ml Class A Shelf Life: 5 Years Rs.5,000/-	Urine Bag is used for drainages/collection of urine in patients with urinary incontinence or retention.	Approved.
29.	M/s Hamza Trading Co., Office No. 302, 3rd floor, Makkah Market, Katchi gali No. 1, Marriot road, Densohall, Karachi.	**Legal Manufacturer & Manufacturing Site:** M/s Changzhou Baidelin Healthcare Material Co.,	Recoo **Wound Dressing Strip Wound Dressing Roll** Sizes according to FSC Class A	Disposable Medical Dressing & Surgical Tape	Approved subject to submission of shelf life.

	(ELI-00280) **Evaluator:** Shahid Muhammad Iqbal	Ltd., No.218, Sanhe Road Jiaoxi Industrial Zone Zhenglu Town Tianning District Changzhou City, Jiangsu Province, China. FSC China Validity 21-11-2020	Shelf Life: 3 Years Rs.5,000/-		
30.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** M/s Changzhou Dahua Medical Devices Co., Ltd., San He Kou Industry Park, Tianning District, Changzhou, Jiangsu, P.R. China. FSC China Validity 04-03-2020	Recoo Disposable Urine Bag 2000ml, 1500ml, 1000ml, 750ml, 500ml Class A Shelf Life: 5 Years Rs.5,000/-	Urine Collection Bag	Approved subject to submission of shelf life.
31.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer & Manufacturing Site:** M/s Changzhou Baidelin Healhcare Material Co., Ltd., No.218, Sanhe Road Jiaoxi Industrial Zone Zhenglu Town Tianning District Changzhou City, Jiangsu Province,	Recoo PE Tape 1.25cm×4m 2.5cm×4m 5cm×4m 7.5cm×4m 10cm×4m Class A Shelf Life: 3 Years Rs.5,000/-	Disposable Medical Dressing & Surgical Tape	Approved subject to submission of shelf life.

		China. FSC China Validity 21-11-2020			
32.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer & Manufacturing Site:** M/s Changzhou Baidelin Healhcare Material Co., Ltd., No.218, Sanhe Road Jiaoxi Industrial Zone Zhenglu Town Tianning District Changzhou City, Jiangsu Province, China. FSC China Validity 21-11-2020	Recoo Zinx Oxide Ahesive Plaster Sizes according to FSC Class A Shelf Life: 3 Years Rs.5,000/-	Disposable Medical Dressing & Surgical Tape	Approved subject to submission of shelf life.
33.	M/s. CARDIAC CARE 848-C Shadman-I, Lahore ELI 00070 **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer & Manufacturing Site:** Pacific Hospital Supply Co, Ltd 4F, No. 160, Daye Road, Beitou District, (11268) Taipei,Taiwan FSC Germany Date of issue 05.06.2018	PHASCO® **Urine Meter with Drainage Bag** M06450, Meter capacity 450ml, Bag capacity 2000ml Class-A Shelf Life: 3 years Rs.5,000/-	Urine Meter with Drainage Bag is a closed system used to accurately measure urine output and collect the urine.	Approved subject to submission of shelf life and MRP.
34.	M/s. Muslim Trading	**Legal Manufacturer**	**URYXXXON® 500**	Reflectometer for evaluation of	Approved subject to signed Form

	Agencies 3 Syed Moj Darya Road, Lahore ELI-00359 **Evaluator:** Shahid Muhammad Iqbal	**& Manufacturing Site:** MACHEREY-NA GEL GmbH & Co.KG Neumann-Neander Street 6-8, 52355 Dueren Germany FSC: Germany Issuance: 22.06.2018	**930080** Class A Shelf Life n/a Rs.5,000/-	urine multi-constituent test strips	6A and stability studies supporting shelf life.
35.	M/s Mira Khan & Co. House No. 12/4. Swato Gate Hakim Abad Peshawar; Correspondence Office: Flat No. 414, 4th Floor Park Tower, F10/3, Islamabad ELI: 00332 **Evaluator:** Shahid Muhammad Iqbal	Legal Manufacturer RAYS S.p.A Via Francesco Crispi 26-60027 Osimo (AN), Italy FSC: Italy Issuance: 07.08.2018	BioSafe Plus Powdered Latex Examination gloves Class: A Self Life 5 years Rs.5,000/-	Disposable Latex Examination gloves with powder (Unsterile).	Approved subject to submission of valid Original FSC, ISO 13485 and Full Quality Assurance.

Item No.XXVI **REGISTRATION OF MEDICAL DEVICES FOR IMPORT.**

The following applications for grant of enlistment of medical devices for import on prescribed form 7-A under Medical Devices Rules, 2017 were received in the Division and are submitted for consideration of MDB.

S. No	Name and Addresses of Establishment	Manufacture Details	Name of Medical Device with sizes/Class/Shelf	Brief Description	Decisions

			Life		
1.	M/s Medtronic Pakistan (Private) Limited, Office No.1301, 13th Floor Dilkusha Forum Tariq Road, Karachi (ELI-00273) **(1301)** **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA **Manufacturing Site:** Medtronic Puerto Rico Operations Co., villalba Rd. 149, KM. 56.3 Call Box 6001 Villalba, PR USA 00766 (FSC Valid 12-11-2020)	Torqr™ (Intracardiac Electrode Catheter) Cardiac Mapping Catheter, percutaneous Class D Shelf Life: 5 Years (Sizes & Codes as Per FSC) **Rs.50,000/-**	The Medtronic Torqr electrode catheter is a flexible, radiopaque catheter constructed of extruded polyurethane over stainless steel braided and platinum electrodes, used in diagnostic electrophysiological procedure/studies.	Approved subject to submission of notorized Design Examination Certificate, label and DOC.
2.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal [1499]	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN 55432 USA **Manufacturer:** M/s Medtronic Mexico S.de R.L. de CV Av. PaseoCucapah 10510 El Lago Tijuana, Baja California CP 22210, Mexico (FSC valid till 01 - 08-2023) Original	Sprinter OTW Balloon Dilatation Catheter Class D Shelf Life: 2 Years Sizes & Codes As Per FSC **Rs.50,000/-**	A Sterile, flexible tube designed to be used in percutaneous transluminal coronary angioplasty (PTCA) to dilate a stenotic coronary artery by controlled inflation of a distensible balloons at its distal tip. It is typically available as an other the wire type that has a double or triple lumen.	Approved subject to submission of valid Full Quality Assurance Certificate and Design Examination Certificate.

3.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal [1362]	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN 55432 USA **Manufacturing Facility:** M/s Medtronic Mexico S.de R.L. de CV Av. PaseoCucapah 10510 El Lago Tijuana, Baja California CP 22210, Mexico (FSC USA Valid 08-03-2020)	Bio-Medicus™ Pediatric Venous Cannulae and Introducer Cardiopulmonary Bypass cannulal, Venous Class D Shelf Life: 4 Years (Sizes & Codes as Per FSC) **<u>Rs.50,000/-</u>**	Pediatric Cannula and Introducer are used to cannulate vessels, perfuse vessels or organs and or connect with accessory extracorporeal equipment. The cannula Introducer is intended to facilitate proper insertion and placement of the appropriate sized cannula within the vessel for cardiopulmonary bypass.	Approved subject to submission of ISO 13485.
4.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal [1360]	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA **Manufacturing Facility:** M/s Medtronic Mexico S.de R.L. de CV Av. PaseoCucapah 10510 El Lago Tijuana, Baja California CP 22210, Mexico (FSC USA Valid 08-03-2020)	Bio-Medicus™ Adult Venous Cannulae and Introducer Cardiopulmonary bypass cannula, arterial. Class D Shelf Life: 4 Years (Sizes & Codes as Per FSC) Rs.50,000/-	A Sterile, rigid or semi-rigid tube desgined to be inserted into a femoral artery or vein during cardiopulmonary bypass procedures. It is typically a 9 to 24 Fr Tube with an end hole (some may include silde holes). It is short enough to keep the distal tip inside the feoral vessel.	Approved.

		(FSC USA Valid 08-03-2020)		The tube is used in set-ups/ systemsintended to divert the patient's blood to and form external tubing and an arterial pump, by passing the heart and lungs completely. This is single-use device.	
5.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal [1340]	**Legal Manufacturer:** ev3, Inc 4600 Nathan LN. North Plymouth, MN USA 55442 (FSC USA valid 27-01-2021)	SpiderFx™ Embolic Protection Device Emboli Capture Guidwire Class D Shelf Life: 2 Years (Sizes & Codes as Per FSC) Rs.50,000/-	The Spider FX Embolic Protection devices provide distal embolization protection during general vascular use, including peripheral, coronary, and carotid interventions.	Approved subject to submission of Stability data not provided. LoA of ev 3. Inc. Or link up letter with Medtronic. Notarized Design Examination certificate required.
6.	-do- **<u>Evaluator</u>:** Hafiz Muhammad Asif Iqbal [1338]	**Legal Manufacturer:** ev3, Inc 4600 Nathan LN. North Plymouth, MN USA 55442 (FSC USA valid 27-01-2021)	Nancross™ Elite 0.014 Over-the-wire PTA Balloon Dilatation Catheter Peripheral Angioplasty Balloon Catheter Class B Shelf Life: 3	Peripheral angioplasty baloon catheter. The PTA Balloon Dilatation Catheter is intended to dilate stenosis in the iliac, femoral, ilio-femoral, popliteal,	Approved.

			Years (Sizes & Codes as Per FSC) Rs.50,000/-	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.	
7.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal [1354]	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN 55432 USA **Manufacturer:** Medtronic Perfusion Systems 7611 Northland Dr Minneapolis, MN 49504 USA **Contractor Manufacturer:** Vention Medical Inc, 620 Watson SW GR, MI USA 49504 MAX HAUSER SUDDEUTSCHE CHIRURGIE MECHANIK GMBH FOEHRENSTRASSE 33 TUTTLINGEN, BADEN-WURTTEMBERG	CLEARVIEW® Intracoronary Shunt (Arterivenous Shunt) Class: B Shelf Life: 3 Years (Sizes & Codes as Per FSC) Rs.50,000/-	A Surgically-Implanted device designed to provide a passage for blood to flow between an artery typically located in an arm, and a peripheral vein, central vein or right atrium, creating a graft fistula that provides blood access for external procedures, espically haemodialysis. It is a synthetic vascular graft/graft assembly with a thin wall and	

		GERMANY D-7853 KLUGE DESIGN Inc. 14150 Northdale Blvd Rogers, MN USA 55374 (FSC USA Valid 02-03-2019)		appropriate size (commonly 6mm diameter) and configuration to facilitate essel puncturing. It is typically used when it is not possible or convienient to create a direct arteriovenous fistula or for patients who have exhausted peripheral venous acess. Disposable devices associated with implantation may be included. This is a single-use device.	
8.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [1345]	**Legal Manufacturer:** ev3, Inc 4600 Nathan LN. North Plymouth, MN USA 55442 (FSC USA valid 27-01-2021) (FSC USA valid 27-01-2021)	Amplatz Goose Neck® Snare and Kit Intravascular Catheter-Snare Class D Shelf Life: 5Years (Sizes & Codes as Per FSC) Rs.50,000/-	The Amplatz Goose Neck Snare is intended for use in the cardiovascular system or hollow viscus to retrieve and manipulate foreign objects. Manipulation procedures include indwelling venous	Approved.

				catheter fibrin sheath stripping, and central venous access venipuncture procedure assistance.	
9.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [1353]	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN 55432 USA **Manufacturing Facility:** M/s Medtronic Mexico S.de R.L. de CV Av. PaseoCucapah 10510 El Lago Tijuana, Baja California CP 22210, Mexico (FSC USA Valid 08-03-2020)	Bio-Medicus™ Adult Arterial Cannulae and Introducer (Cardiopulmonary Bypass cannula, Femoral|) Class D Shelf Life: 4 years (Sizes & Codes as Per FSC) Next Generation Bio-Medicus™ Adult Arterial Cannulae and Introducer 96570-115_BioMedicus™ Adult Cannula and Introducer 96570-117_BioMedicus™ Adult Cannula and Introducer 96570-119_BioMedicus™ Adult Cannula and Introducer 96570-	A Sterile, Rigid or Semi-rigid tube designed to be inserted into a femoral artery or vein during cardiopulmonary bypass procedures. It is typically a 9 to 24 Fr Tube with an end hole (Some May Include side holes) It is short enough to keep the distal tip inside the femoral vessel. The tube is used in set-ups/systems intended to divert the patient's blood to and from external tubing and an arterial pump, by passing the heart and lungs completely. This is a single use device.	Approved.

			121_BioMedicus ™ Adult Cannula and Introducer 96570-123_BioMedicus ™ Adult Cannula and Introducer 96570-125_BioMedicus ™ Adult Cannula and Introducer Rs.50,000/-		
10.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal [1498]	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN 55432 USA **Manufacturer:** Medtronic Ireland Parkmore Business Park Est Galway Ireland. (FSC valid 15-11-2022)	Reliant Stent Graft Balloon Catheter Class D Shelf Life : 2 Years (Sizes & Codes): Reliant Stent Graft Balloon Catheter AB46 Rs.50,000/-	The Reliant ™ stent graft balloon catheter is designed to assist in the expansion of self – expanding stents grafts use for the treatment of abdominal aortiv aneurysms (AAA) and thoracic aortic aneurysms (TAA).	Approved subject to submission of valid Original FSC and valid Full Quality Assurance.
11.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [1499]	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA **Manufacturer:** Medtronic Perfusion Systems 7611 Northland Dr Minneapolis, MN USA	DLP® Vent Plugs Cardiopulmonary bypass cannula, arterial Class A Shelf Life: 3 Years (Sizes & Codes as Per FSC)	A Sterile, Semi-rgid or rigid tube intended to be used during open heart surgery where it is surgically inserted for perfusion of the ascending aorta, serving as a channel for the	Approved as Class D subject to submission of Form 7A.

		Contractor Manufacturer: Medplast Medical Inc, 620 Watson SW GR, MI USA 49504 (FSC USA Valid 08-03-2020)	Rs.50,000/-	transport of pumped, oxygenated, blood from a cardiopulmonary by pass system (heart lung machine) tubing circuit. It is typically a moulded plastic tube with stainless wire reinforcement, to prevent kinking/ collapse, have multiple perforations or flutes at the distal end which help diffuse and disperse incoming blood. It may be inserted using a compatible trocar blade; sometypes may be heparin coated and include a pressure monitoring port. This is a single –use device.	
12.	M/s Galaxy Pharma (Pvt.) Ltd. D-180, Rojhan Street, Block 5, Clifton Karachi.	**Legal Manufacturer:** Setpa Tibbi Gerecler ITH.IHR.SAN.VE.TIC.LTD. STI (1145/4 Sk.No. 13/1 Konak/	Neocryl Rapid Absorbable Surgical suture PGA(Polyglycolic acid) No:1 30mm	Synthetic, Absorbable sterile surgical Sutures	Approved subject to submission of stability data and inspection of manufacturer

	(ELI-00402) **Evaluator:** Hafiz Muhammad Asif Iqbal [1231]	Izmir / Turkiye) (FSC Expires After 36 Months off issuance) .	Round B. ½ 75cm sterile surgical suture. (PG0130YV1275 Class C Shelf Life: 3 Years (Sizes & Codes not mentioned in FSC) Rs.50,000/-		abroad.
13.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [1232]	**Legal Manufacturer:** Setpa Tibbi Gerecler ITH.IHR.SAN.VE.TIC.LTD. STI (1145/4 Sk.No. 13/1 Konak/ Izmir / Turkiye) (FSC Expires After 36 Months off issuance) .	Neoxone PDS Absorbable Surgical Suture PDS (Polydioxanone) 4/0 16mm Round B. 3/8 75cm sterile surgical suture. (PDS4016YV3875) Class C Shelf Life: 3 Years (Sizes & Codes not mentioned in FSC) Rs.50,000/-	Neoxone PDS, is a sterile, synthetic and absorbale monofilament surgical suture material obtained by polymerization of te p-dioxanone monomer. It is dyed in (D& C Violet No. 2) to make it easily distinguishable.	Approved subject to submission of stability data and inspection of manufacturer abroad.
14.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [1229]	**Legal Manufacturer:** Setpa Tibbi Gerecler ITH.IHR.SAN.VE.TIC.LTD. STI (1145/4 Sk.No. 13/1 Konak/ Izmir / Turkiye)	Neolact Rapid Absorbable Surgical Suture. Rapid PGLA (Absorbable Polyglycolide-Co-L-Lactide) (90%:10%) 3/0	Neolact (Polyglycolide-Co-L-Lactide)PGLA is a synthetic, absorbable, sterile, braided and coated surgical suture	Approved subject to submission of stability data and inspection of manufacturer abroad.

		(FSC Expires After 36 Months off issuance) .	26MM Rev. Cut. 3/8 75cm sterile surgical suture. (PLR3026AK3875) Class C Shelf Life: 3 Years (Sizes & Codes not mentioned in FSC) Rs.50,000/-	made up of 90% Glycolic Acid + 10% Lactic Acid. It is dyed in D & C Violet No. 2 to make it easily distinguish able.	
15.	-do- **<u>Evaluator</u>:** Hafiz Muhammad Asif Iqbal [1230]	**Legal Manufacturer:** Setpa Tibbi Gerecler ITH.IHR.SAN.VE.TIC.LTD. STI (1145/4 Sk.No. 13/1 Konak/ Izmir / Turkiye) (FSC Expires After 36 Months off issuance) .	Neolact Absorbable Surgical Suture PGLA (Polyglycolide-Co-L-Latctide) (90%:10%) No:1 45mm Round B. ½ 75 cm sterile surgical suture. (PL0145YV1275 Class C Shelf Life: 3 Years (Sizes & Codes not mentioned in FSC) Rs.50,000/-	NEOLACT PGLA, is a sterile, synthetic braided and coated surgical suture material made of 90 % Glycolic Acid + 10% Lactic Acid. It is dyed in (D& C Violet No.2) to make it easily Distinguishable.	Approved subject to submission of stability data and inspection of manufacturer abroad.
16.	M/s Hoora Pharma (Pvt) Ltd., WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi (ELI-00037)	**Legal Manufacturer/ Manufacturing Site:** M/s Siemens Healthcare Diagnostics Products Limited, Glyn	Siemens Immulite 2000 CMV IgG Assay kit Siemens Immulite 2000 IgG/IgM Sample Diluent	IgG Antibodies to Cytomegalovirus Assay	Approved subject to submission of valid Agency Agreement, ISO 13485 and Full Quality

	Evaluator: Hafiz Muhammad Asif Iqbal [494]	Rhonwy, Llanberis, Caernarfon, LL55 4EL, UK (FSC UK Valid Till 16-10-2020)	Class C Shelf Life: 12 Months SMN 10381309 REF L2KCVG2 SMN 10387663 REF L2IGZ2 Rs.50,000/-		Assurance Certificate.
17.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [495]	**Legal Manufacturer/ Manufacturing Site:** M/s Siemens Healthcare Diagnostics Products Limited, Glyn Rhonwy, Llanberis, Caernarfon, LL55 4EL, UK (FSC UK Valid Till 16-10-2020)	Siemens Immulite 2000 CMV IgM kit Siemens Immulite 2000 IgG/IgM Sample Diluent Class C Shelf Life: 12 Months SMN 10381320 REF L2KCM2 SMN 10387663 REF L2IGZ2 Rs.50,000/-	IgM Antibodies to Cytomegalovirus Assay	Approved subject to submission of valid Agency Agreement, ISO 13485 and Full Quality Assurance Certificate.
18.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [496]	**Legal Manufacturer/ Manufacturing Site:** M/s Siemens Healthcare Diagnostics Products Limited, Glyn Rhonwy, Llanberis, Caernarfon, LL55 4EL, UK (FSC UK Valid Till 16-10-2020)	Siemens Immulite 1000 CMV IgM Assay Siemens Immulite 1000 IGG/IGM (ID1) Sample Diluent Module Class C Shelf Life: 12 Months SMN 10381296 REF LKCM1 SMN 10387608	IgM Antibodies to Cytomegalovirus Assay	Approved subject to submission of valid Agency Agreement, ISO 13485 and Full Quality Assurance Certificate.

			REF L1KIGW1 Rs.50,000/-		
19.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [497]	**Legal Manufacturer/ Manufacturing Site:** M/s Siemens Healthcare Diagnostics Products Limited, Glyn Rhonwy, Llanberis, Caernarfon, LL55 4EL, UK (FSC UK Valid Till 16-10-2020)	Siemens Immulite 1000 Toxoplasma Quantitative IgG Assay kit Class C Shelf Life: 12 Months SMN 10381268 REF LKTXP1 Rs.50,000/-	IgG Antibodies to Toxoplasma gondii Assay	Approved subject to submission of valid Agency Agreement, ISO 13485 and Full Quality Assurance Certificate.
20.	M/s Sorabjee Patel & Co., 45 Badri Building I.I Chundrigar Road, Karachi (ELI-00067) **Evaluator:** Hafiz Muhammad Asif Iqbal [1028]	**Legal Manufacturer:** Arcadophta Sarl (Fabricant/ Manufacturer) 11, rue Antoine Ricord-31100 Toulouse – France. (FSCFrance Valid till 21-03-2020)	1. Mono Blue SafR/ Trypan blue 0.055% 0.75ml Syringe. Solution of purified Trypan Blue 0.055% SafR for staining the retinal membrane. Class C Shelf Life: 3 Years Sizes and Codes As per FSC Rs.50,000/-	Staining of the retinal membrane.	Approved.
21.	M/s WasimCo. Kutchi Gali No.1, Marriott Road Karachi. (ELI-00185)	**Legal Manufacturer:** Changzhou Yuandong Medical Equipments Co., Ltd. Sanhekou Street,	Classic Fine (Disposable Scalp Vein Set, Sterile) Class B Shelf Life: 5	Disposable Scalp Vein Set	Approved.

	Evaluator: Hafiz Muhammad Asif Iqbal [1267]	Chanzhou city, 213115 Jiangsu, P.R. China. (FSC Germany Issuance Date:05-06-2119.	Years. (Sizes & Codes as Per FSC) 19G, 21G, 23G, 25G Rs.25,000/-		
22.	M/s A.M. Distributors, 4th Floor , Plot 37-C, Bukhari Phase VI, D.H.A, Lane 8, Bukhari Commercial Area Phase 6 Defence Housing Authority , Karachi. (ELI-00248) **Evaluator:** Hafiz Muhammad Asif Iqbal [1054]	**Legal Manufacturer:** United Medical industries Co. Ltd Street# 215 3rd industrial City, Riyadh 11553 Saudi Arabia (FSC Saudi Arabia Valid till 30-07-2022)	UNICRYL (Braided Polyglycolic acid Synthetic Absorbable Surgical Suture) Class D Shelf Life: 4 Years (Sizes & Codes Not provided in Free Sale Certificate) Rs.50,000/-	It is intended for use in general soft tissue approximation and / or ligation, including use in ophthalmic surgery.	Approved subject to submission of notorized ISO 13485, stability data and notorized credentials.
23.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [1242]	**Legal Manufacturer:** United Medical industries Co. Ltd Street# 215 3rd industrial City, Riyadh 11553 Saudi Arabia (FSC Saudi Arabia Valid till 30-07-2022)	UNISILK (Sterile Single Use non-capillary Braided Silk Natural Non-Absorbable Surgical Suture and Ligatures coated with silicon). Class D Shelf Life: 5 Years (Sizes & Codes as Per FSC)	Unisilk Sterile Non-Absorbable Surgical Suture composed of an organic protein called Fibroin. The protein is derived from the domestic species Bombyx mori (B mori) of the family bombycidae. UniSilk Silk	Approved subject to submission of notorized ISO 13485, stability data and notorized credentials.

			Unisilk (Sterile Single Use non-capillary Braided Silk Rs.50,000/-	For braided material is impregnatd with silicone.	
24.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [1243]	**Legal Manufacturer:** United Medical industries Co. Ltd Street# 215 3rd industrial City, Riyadh 11553 Saudi Arabia (FSC Saudi Arabia Valid till 30-07-2022)	UNIESTER (Sterile Single Use Braided Polyester Synthetic Non-Absorbable Surgical Suture and Ligature) Class D Shelf Life: 5 Years (Sizes & Codes as Per FSC) Uniester (Sterile Single Use Braided Polyester Synthetic Non-Absorbable Surgical Suture and Ligature Rs.50,000/-	Uniester suture is indicated for use in general soft tissue approximation and / or ligation including use in ophthalmic, cardiovascular and neurological/ procedures.	Approved subject to submission of notorized ISO 13485, stability data and notorized credentials.
25.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [1244]	**Legal Manufacturer:** United Medical industries Co. Ltd Street# 215 3rd industrial City, Riyadh 11553 Saudi Arabia (FSC Saudi Arabia Valid till 30-07-2022)	Uniester C Uniester C (Sterile Single Use Coated Braided Polyester Synthetic Non-Absorbable surgical Suture and Ligature. Class D Shelf Life: 5 Years (Sizes & Codes	Uniester C Suture is a coated Braided, non absorbable Sterile Surgical Suture Composed of polyethylene Terephthalate. The suture is coated with Filodell (Dispersion of Thyl	Approved subject to submission of notorized ISO 13485

			as Per FSC) Uniester C (Sterile Single Use Coated Braided Polyester Synthetic Non-Absorbable surgical Suture and Ligature. Rs.50,000/-	Cellulose). Which acts as lubricants to ease the passage throught tissue and the overall handling property of the suture?	
26.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [1245]	**Legal Manufacturer:** United Medical industries Co. Ltd Street# 215 3rd industrial City, Riyadh 11553 Saudi Arabia (FSC Saudi Arabia Valid till 30-07-2022)	UNIMIDE (Sterile Single use Monofilament Polyamide 6, 6/6 Synthetic Non-Absorbable Surgical suture and ligature. Class D Shelf Life: 5 Years (Sizes & Codes as Per FSC) Unimide (Sterile Single use Monofilament Polyamide 6, 6/6 Synthetic Non-Absorbable Surgical suture and ligature. Rs.50,000/-	Unimide Suture is indicated for skin closure and / or ligation.	Approved subject to submission of notorized ISO 13485
27.	M/s. Cardiac Care, 848-C Shadman-I, Lahore. (ELI-00070)	**Manufacturer** M/s. Pasific Hospital Supply Co., Ltd. 4F, No. 160, Daye Road,Beitou District 112 Taipei	**PAHSCO Chest Drainage Bottle** (Chest Drainage Device)	Underwater Chest Drainage Bottle is a closed (airtight) chest drainage	Approved subject to submission of stability data.

	Evaluator: Hafiz Muhammad Asif Iqbal [437-P]	Taiwan (ROC) FSC Germany Issue date 05-06-2019.	Class B Shelf Life : 03 years (Sizes & Codes) H03180 1800ml	systems are used to facilitate the evacuation of fluid, blood, and air from the pleural space or the mediastinum or both; restore negative pressure tothe pleural space; and promote re-expansion of a collapsed lung.	
28.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [437-P]	M/s. Eurosets srl STRADA STATALE 12, n.143 41036 MEDOLLA (MO) ITALY. FSC Italy Issued on March 23, 2018.	SKIPPER A.F PLUS STERILE (OXYGENATORS) Class B Shelf Life : 03 years AG5254 Rs.25,000/-	Skipper AF is a device 76pecifically designed to perform the various cardiopulmonary bypass techniques.	Approved subject to submission of notorized ISO 13485, Full Quality Assurance Certificate.
29.	M/s Medica, House No. 188-1-B (First Floor) near Nursery area, Block 2, PECHS Karachi. (ELI-00237) **Evaluator:** Hafiz Muhammad Asif Iqbal [1258]	**Legal Manufacturer:** SaSan Saglik Malzemeler I Uretim Ve Pazarlama a.s. (Dagyaka Mah. 2004 Cad. No: 6 Kahramankazan/ Ankara/ Turkiye). Turkey. (FSC Turkey Valid till 09-03-2020)	Sasan Tubing Set Infant (Extracorporeal tubing set) Class B Shelf Life: 3 Years. (Sizes & Codes): SD920303/C SD921303/A SD920303/D SD921303/C	Extracorporeal tubing set is used with cardiopulmonary pump and oxygenator allows the blood to be sent to the oxygenator and then to the patient.	Approved subject to submission of stability data.

			SD921303/B **Rs.25,000/-**		
30.	M/s. Optisurg 17- C-1, Valencia Town, Lahore. ELI-00305 **Evaluator:** Hafiz Muhammad Asif Iqbal [475-P]	**Manufacturer:** M/s. Ellex Medical Pty Ltd., 3-4 Second Avenue, Mawson Lakes, SA 5095, Australia. FSC Australia. (Issued on 18-12-2018)	**Ellex Ultra Q™ LQP3106-U** (Lasers, Ophthalmic, Nd: YAG) Class C Service Life: 7 Years (Sizes & Codes): N/A	The device is LASER instrument used in the ophthalmic surgery(capsulotomies and iridotomies).	Approved subject to Distribution agreement d with the manufacturer to establish the validity of Letter of Authorizatin, Valid & attested FSC, ISO 13485, and Full Quality Assurance System certificate.
31.	M/s Noor International Noor House, 29-D, Block 6, PECHS, Karachi (ELI-00061) **Evaluator:** Hafiz Muhammad Asif Iqbal [1220]	**Legal Manufacturer:** Hoffricheter GmbH mettenheimer Str. 12/14 19601 Schwerin Germany. (FSC issuance 18-12-2018)	Point 2 CPAP (Respiratory Therapy and Ventilation) Class B Shelf Life: Not Applicable. (Sizes & Codes): 00012944 **Rs.25,000/-**	The point 2 is a respiratory therapy device desgined for the treatment of sleep-related breathing disorders in patients weighing 30 kg or more.	Approved subject to submission of ISO 13485.
32.	M/s Popular International (Pvt) Ltd., House No. 141, Justice Inamullah Road, Block 7 & 8 KMCHS, Near Hill Park, Karachi	**Manufacturer:** M/s HUMAN Gesellschaft Fur Biochemica und Diagnostica mbH Max-Planch-Ring 21 65205 Wiesbaden, Germany (FSC Germany	HUMAN T3 (Total Triiodothyronine), ELISA Class B Shelf Life: 36 Months.	ELISA Test for the Quantitative Determination of Total Triiodothronine (T3) in Human Serum	Approved.

	(ELI-00091) **Evaluator:** Hafiz Muhammad Asif Iqbal [1411]	Issuance Date 21-11-2018)	54010 **Rs.25,000/-**		
33.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [1405]	**Manufacturer:** M/s HUMAN Gesellschaft Fur Biochemica und Diagnostica mbH Max-Planch-Ring 21 65205 Wiesbaden, Germany (FSC Germany Issuance Date 21-11-2018)	HUMAN T4 (Total Thyroxine), ELISA Class B Shelf Life: 18 Months (Sizes & Codes): 54020 **Rs.25,000/-**	ELISA Test for the Quantitative Determination of Total Thyroxine (T4) in Human Serum or Plasma	Approved.
34.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [1404]	**Manufacturer:** M/s HUMAN Gesellschaft Fur Biochemica und Diagnostica mbH Max-Planch-Ring 21 65205 Wiesbaden, Germany (FSC Germany Issuance Date 21-11-2018)	Syphilis Screen, ELISA Class D Shelf Life: 16 Months. 51005 Rs.50,000/-	ELISA for the Detection of Antibodies toTreponema Pallidum in Human Serum and Plasma.	Approved.
35.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal [1408]	**Manufacturer:** M/s HUMAN Gesellschaft Fur Biochemica und Diagnostica mbH Max-Planch-Ring 21 65205 Wiesbaden, Germany (FSC Germany Issuance Date 21-11-2018)	HUMAN TSH (Thyroid Stimulating Hormone), ELISA Class B Shelf Life: 24 Months. 54030	ELISA Test for the Quantitative Determination of Thyreotropin (TSH) in Human Serum	Approved.

			Rs.25,000/-		
36.	-do- **<u>Evaluator:</u>** Shahid Muhammad Iqbal	**Legal Manufacturer & Manufacturing Site:** M/s HUMAN Gesellschaft Fur Biochemica und Diagnostica mbH Max-Planck-Ring 21, 65205 Wiesbaden, Germany FSC Germany Issuance 21-11-2018	Human **LH ELISA 53010** Class B Shelf Life: 36 Months. Rs. 25,000	ELISA Test for the Quantitative Determination of Luteinizing Hormone (LH) in Human Serum	Approved subject to submission of valid Full Quality Assurance Certificate.
37.	-do- **<u>Evaluator:</u>** Shahid Muhammad Iqbal	**Legal Manufacturer & Manufacturing Site:** M/s HUMAN Gesellschaft Fur Biochemica und Diagnostica mbH Max-Planck-Ring 21, 65205 Wiesbaden, Germany FSC Germany Issuance 21-11-2018	Human **Prolactin (PRL) ELISA 53030** Class B Shelf Life: 36 Months. Rs. 25,000	ELISA Test for the Quantitative Determination of Prolactin (PRL)	Approved subject to submission of valid Full Quality Assurance Certificate.
38.	-do- **<u>Evaluator:</u>** Shahid Muhammad Iqbal	**Legal Manufacturer & Manufacturing Site:** M/s HUMAN Gesellschaft Fur Biochemica und Diagnostica mbH Max-Planck-Ring 21, 65205 Wiesbaden, Germany	Human **fT3 ELISA 54015** Class B Shelf Life: 36 Months. Rs. 25,000	ELISA Test for the Quantitative Determination of Free Triiodothyronine (fT3) in Human Serum	Approved subject to submission of valid Full Quality Assurance Certificate.

		FSC Germany Issuance 21-11-2018			
39.	-do- **Evaluator:** Unum Zia Shamsi	**Legal Manufacturer:** Covidien LLC, 15 Hampshire Street, Mansfield, MA USA 02048 **Manufacturing Site:** Covidien 60 Middletown Ave North Haven, CT USA 06473 Covidien Building 911-67 Sabanetas Industrial Park Ponce, PR USA 00731 (FSC US FDA valid till 06-09-2019)	GIA™ Auto Suture™ Loading Unit with DST Series™ Technology Class D Codes: GIA10038L GIA10048L GIA6025L GIA6038L GIA6048L GIA8038L GIA8048L Shelf Life: 5 Years Fee submitted: Rs. 50,000/-	Have applications in abdominal, gyneocological, pediatric and thoracic surgical procedures for resection, transection and creation of anastomosis. Sterile, single-use	Approved subject to submission of FSC and Design Examination.
40.	-do- **Evaluator:** Unum Zia Shamsi	**Legal Manufacturer:** Covidien LLC, 15 Hampshire Street, Mansfield, MA USA 02048 **Manufacturing Site:** Covidien 60 Middletown Ave North Haven, CT USA 06473 Covidien Building 911-67 Sabanetas Industrial Park Ponce, PR USA 00731	EEA™ Auto Suture™ Circular stapler with DST Series™ Technology Class C Codes: EEA21 EEA2135 EEA25 EEA2535 EEA28 EEA2835 EEA31 EEA33 EEAXL21	Has application throughout the alimentary tract for the creation of end-to-end, end-to-side, and side-to-side anastomoses.in both open and laproscopic surgeries. Sterile, single-use	Approved subject to submission of FSC.

		(FSC US FDA valid till 06-09-2019)	EEAXL2135 EEAXL25 EEAXL2535 EEAXL28 EEAXL2835 EEAXL31 EEAXL33 Shelf Life: 5 Years Fee submitted: Rs. 50,000/-		
41.	-do- **Evaluator:** Unum Zia Shamsi	**Legal Manufacturer:** Covidien LLC, 15 Hampshire Street, Mansfield, MA USA 02048 **Manufacturing Site:** Covidien 60 Middletown Ave North Haven, CT USA 06473 Covidien Building 911-67 Sabanetas Industrial Park Ponce, PR USA 00731 (FSC US FDA valid till 06-09-2019)	EEA™ Auto Suture™ Circular stapler with DST Series™ Technology Class C Codes: EEA21 EEA2135 EEA25 EEA2535 EEA28 EEA2835 EEA31 EEA33 EEAXL21 EEAXL2135 EEAXL25 EEAXL2535 EEAXL28 EEAXL2835 EEAXL31 EEAXL33 Shelf Life: 5 Years Fee submitted: Rs. 50,000/-	Has application throughout the alimentary tract for the creation of end-to-end, end-to-side, and side-to-side anastomoses.in both open and laproscopic surgeries. Sterile, single-use	Approved subject to submission of FSC.

42.	M/s Ali Gohar & Company (Pvt) Ltd., State Life Building 1-B, I.I Chundrigar Road, Karachi (ELI-00004) **Evaluator:** Hafiz Muhammad Asif Iqbal [1280]	**Legal Manufacturer:** Smith Medical ASD Inc 10 Bowman Drive Keene NH 03431, USA **Manufacturing Site:** Smiths Medical International Ltd 52 Grayshill Road, Westfield, Glasgow, Cumbernauld G68 9HQ, United Kingdom. (FSC UK Valid till 15-06-2023)	RapID® Spinal/Epidural minipack Spinal/Epidural Access Needles Class D Shelf Life: 5 Years (Sizes & Codes): 100/491/116 100/491/618 100/491/816 100/491/818 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 allow modification of the spinal analgesia if necessary or bolus injections or continuous infusion of local anaesthtics or other drugs into the epidural space for subsequent pain relief if required.	Approved subject to submission of ISO 13485.
43.	M/s Platinum Corporation, F-10/7/6 Near Arfeen Masjid Barrage Colony Sukkur. **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s Yangzhou Medilne Industry Co., Ltd., No. 108. Jinshan Road, Economic Development Zone, Yangzhou, China (FSC China Valid 28-08-2021)	Medilne Sterile Auto-Disable Syringe with Needle Class B Shelf Life: 4 Years Sizes & Codes: 3ml, 5ml, 10ml,	It is intended for the aspiration of fluids or for injection of fluids immediately after filling.	Approved subject toverification of CE marked documents.

	[1877]		20ml **Rs.25,000/-**		
44.	M/s Allmed Solutions, A-21/3 KDA Scheme 1 (Ext) Opposite National Stadium Road, Karachi (ELI-00029) **Evaluator:** Hafiz Muhammad Asif Iqbal [282]	**Manufactured By:** M/s Ameco Medical Industries, Industrial Zone B4-Part 119 East 10th of Ramadan City, Egypt (FSC Egypt Issuance Date 10-06-2018)	Central Venous Catheters Kit Class D Shelf Life: 36 Months Rs.50,000/-	Venous Catheters Kits	Approved subject to CE marked documents or inspection of manufacturer abroad.
45.	M/s. Global Marketing Services, 111-B, Hali Road, Westridge 1, Rawalpindi (ELI-00109) Evaluator: Shahid Muhammad Iqbal	**Legal Manufacturer and Manufacturing Site:** BioMérieux SA 376 chemin de l'Orme 69280 Marcy l'Etoile – France. FSC France Issued on 13.12.2017	**VIDAS Fertility Panel** – VIDAS LH (30406) Shelf Life: 12 months – VIDAS FSH (30407) Shelf Life: 12 months – VIDAS Progesterone (30409) Shelf Life: 12 months – VIDAS Prolactin (30410) Shelf Life: 12 months – VIDAS Estradiol II (30431) Shelf Life: 12 months – VIDAS	The VIDAS Fertility panel includes 6 fully automated hormone tests for the quantitative measurement of luteinizing hormone (LH), follicle-stimulating hormone (FSH), estradiol, prolactin, progesterone, &testosterone.	Approved subject to differential fee and Full Quality Assurance Certificate.

			Testosterone II (414320) Shelf Life: 15 months Class B Shelf Life: 12 months		
46.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer and Manufacturing Site:** BioMérieux SA 376 chemin de l'Orme 69280 Marcy l'Etoile – France. FSC France Issued on 13.12.2017	**VIDAS Thyroid Panel** – VIDAS TSH (30400) Shelf Life: 12 months – VIDAS FT3 (30402) Shelf Life: 12 months – VIDAS T3 (30403) Shelf Life: 12 months – VIDAS T4 (30404) Shelf Life: 12 months – VIDAS FT4 (30459) Shelf Life: 12 months – Vidas Anti-TG (30462) Shelflife 15 months Class B Shelf Life: 12 months	The VIDAS Thyroid panel includes 6 automated tests for TSH, FT4, T4, FT3, T3,& Anti-Tg to aid clinicians in the diagnosis and treatment monitoring of thyroid disorders.	Approved subject to differential fee and Full Quality Assurance Certificate.
47.	-do- **Evaluator:** Unum Zia Shamsi	Manufacturer: OPTI MEDICAL SYSTEMS INC. 235 Hembree Park Drive, Roswell, GA USA 30076	OPTI Critical Care Analyzer (OPTI CCA-TS2) Part no: GD7046 Class: C	Intended to be used for the measurement of pH, pCO2, pO2, Na+, K+, Ca++, CI-, Glucose,	Approved.

		FSC US FDA valid till 04-03-2020	Shelf Life: N/A Fee submitted: Rs. 50,000/-	BUN (Urea), lactate, tHb, and SO2 in samples of whole blood, and pH, Na+ K+, Ca++, CI, Glucose and BUN (Urea) in serum and plasma, in a clinical laboratory setting or point of care location.	
48.	M/s Yousaf& Co., Office NO. 131, Tippu block garden town, Lahore ELLI- 00302 **Evaluator:** Shahid Muhammad Iqbal	Legal Manufacturer: M/s GRENA Ltd, 1000 Great West Road, Brentford, Middlesex, TW8 9DW, UK. FSC UK Validity 13.04.2021	**Click´aV Plus Ligating clip** **0301-10L** **0301-10ML** **0301-10XL** **Class C** **Shelf Life 05 years** **Rs. 50,000**	intended for marking and ligating of any linear tissue structure or vessels during an operation for homeostasis or marking purpose where use of non absorbable clips is required	Approved subject to manufacturign and QC data.
49.	M/s. Mezan International 59 BR II, Opp.DCO, House Haji Meherban Road, Jhelum ELI-00096. **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** M/s ACTO Pharma HIJYEN SANAYI TIC .A.S Akcaburgaz Mahallesi, 3038 SoK No 11, 34522 Esenyurt Istanbul Turkey FSC Turkey Validity 16.03.2021	**ACTODIACIT 5L** L- Citric acid based disinfectant for hemodialysis machines 8680152463704 Class B Shelf Life: 03 years Rs. 25,000	Medical device disinfectant	Approved.

50.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** M/s ACTO Pharma HIJYEN SANAYI TIC .A.S Akcaburgaz Mahallesi, 3038 SoK No 11, 34522 Esenyurt Istanbul Turkey FSC Turkey Validity 16.03.2021	**ACTOSED ENDO TERRA** 5 liter 4250108347026 2 liter 8680152464718 Class C Shelf Life: 03 years Rs. 25,000	Medical device disinfectant Biguanide based concentrate disinfectant for medical instruments and endoscopes	Approved.
51.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** M/s ACTO Pharma HIJYEN SANAYI TIC .A.S Akcaburgaz Mahallesi, 3038 SoK No 11, 34522 Esenyurt Istanbul Turkey FSC Turkey Validity 16.03.2021	ACTOSED PA SOLUTION Code……. Class C Shelf Life: 03 years **Rs. 50,000**	Medical device disinfectant	Approved according tto FSC codes.
52.	M/s Life-Tec Unit-B, 1st Floor, Block 20-D, G-8, Markaz, Islamabad. ELI-00155 **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** M/s Sichuan Nigale Biotechnology Co, Ltd Office # 901-910,9/F,Unit 2, Bldg 1, No, 401 Sheng an street, Hi-Tech Dist. Chengdu, Sichuan, P.R, China. **Manufacturing site:** M/s Sichuan Nigale Biotechnology Co, Ltd.No.28, Kuixing Road, dongxi Town, &41400 Jianyang,	Nigale **Disposable Plasma Apheresis Set** **(P-4018)** Class-C **Shelf Life: 4 years** **Rs. 50,000**	The plasma Apheresis Set is being used in combination with Nigale Plasma separator Machine (XCJ-2000) & ACD solution also it separates Plasma from Blood.	Approved subject to submission of Valid FSC, CE marked documents or inspection of manufacturer abroad.

		Sichuan, China FSC China Validity: 16.06. 2019			
53.	M/s Hamza Trading Co., Office No. 302, 3rd Floor, Makkah Market, KatchiGali No. 1, Marriot Road, Densohall, Karachi. (ELI-00280) **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer & Manufacturing Site:** HuaianTianda Medical Instruments Co., Ltd. No. 106 East Songjiang Raod, Huaiyin Economic & Technological Developemtn Zone 223002 Huaian City, Jiangsu China. FSC China validity 16-09-2020	Recoo **Sterile Blood Lancet** **18G, 21G, 23G, 26G, 28G, 30G** Class B Shelf Life: 3 Years	N/a	Approved subject to submission of Notarized credentials and Stability studies, CE marked documents or inspection of manufacturer abroad.
54.	M/s Nipro Medical (Pvt) Ltd Building # 24, Central Commercial Area, DHA Phase 8 (Ex-Park View) Lahore. ELI- **<u>Evaluator:</u>** Shahid Muhammad Iqbal	**Legal Manufacturer & Manufacturing Site:** PT. Nipro Indonesia Jaya Kawasan Industri Suryacipta., JI. Surya Utama Kay, 1-22B, 23, 24 Desa Kutamekar, Kec Ciampel, Karawang, Jawa Barat, Indonesia. FSC Indonesia Issued date 22.02.2019	Nipro Set Blood Tubing Set A071 (I)(8mm)/V648(I), A071 (I)/V648(I) Class B Shelf Life 05 years	This blood tuing set is indicated for use durig hemodialysis to provide access to a patiens's blood. When used in hemodialysis. It is part of an artificial kidney system for treatment of partients with renal failure or toxemic conditions.	Approved subject to stability studies, CE marked documents or inspection of manufacturer abroad.
55.	-do- **<u>Evaluator:</u>** Shahid Muhammad	**Legal Manufacturer & Manufacturing Site:**	Nipro AV Fistula Needle Size G 14,15.16	The AV fistula is the opreferred type of accesss to	Approved subject to submission of stability studies, CE

	Iqbal	PT. Nipro Indonesia Jaya Kawasan Industri Suryacipta., JI. Surya Utama Kay, 1-22B, 23, 24 Desa Kutamekar, Kec Ciampel, Karawang, Jawa Barat, Indonesia. FSC Indonesia Issued date 22.02.2019	&17 Class B Shelf Life 05 years	bloodstream for hemodialysis treatments. .	marked documents or inspection of manufacturer abroad.
56.	M/s. Physiomed (Pvt) Ltd 268/3, Kamal Road, Saddar, Rawalpindi. ELI 00199 **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer & Manufacturing Site:** St Jude Medical, Inc 15900 Valley View Ct SYLMAR CA USA FSC Belgium Date of issue 21.04.2017	**CPS Direct™ PL** Peelable Outer Guide Gatheter 410210 410211 410212 410213 410214 410215 410216 410217 410218 410219 410220 410221 410222 410223 410224 410225 Class-D Shelf Life: 3 years	For intracardiac access of the venous system of the heart and aid in the delivery of the left ventricular lead CRT procedures.	Approved subject to submission of stability studies.
57.	M/s B.Braun Pakistan (Pvt) Ltd., The Forum, Suite 216, Khayaban-e-Jami, Block No.9, Clifton, Karachi (ELI-00006)	**Legal Manufacturer:** B. Braun Melsungen AG Carl-Braun-StraBe 1, 34212 Melsungen Germany **Manufacturing Site:** Terang Nusa SDN.	**Vasco® surgical Powdered** **6035500APL** **6035518APL** **6035526APL** **6035534APL** **6035542APL** **6035559APL** Class B	Surgical Powdered Gloves, Sterile	Approved.

	Evaluator: Shahid Muhammad Iqbal	BHD. 1, Jalan 8, Pengkalan Chepa 2, Industrial Zone 16100 Kota Bharu, Kelantan Malaysia. FSC Germany issuance 15-05-2019	Shelf Life: 5 Years Rs. 25,000		
58.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** B. Braun Melsungen AG Carl-Braun-StraBe 1, 34212 Melsungen Germany **Manufacturing Site:** Terang Nusa SDN. BHD. 1, Jalan 8, Pengkalan Chepa 2, Industrial Zone 16100 Kota Bharu, Kelantan Malaysia. FSC Germany issuance 15-05-2019	**Vasco® Surgical Powder-Free** **6081101APL** **6081111APL** **6081121APL** **6081131APL** **6081141APL** **6081151APL** **6081161APL** Class B Shelf Life: 5 Years Rs. 25,000	Surgical Powder Free Gloves, Sterile	Approved.
59.	-do- **Evaluator:** Abdul Waheed	**Legal Manufacturer:** B. Braun Melsungen AG Carl-Braun-StraBe 1 34212 Melsungen Germany **Product Facility:** B.BraunMelsungen AG Pfieffewiesen 34212 Melsungen Germany (FSC Germany issued 23-05-2019)	Infusomat® Compact Plus General-Purpose Infusion Pump. Class C Shelf Life: Not Applicable (Sizes & Codes As Per Fsc) Infusomat® Compact^{plus} Volumetric Infusion Pump Art No. 8717050 Connection Lead	The Infusomat® Compact Plus Infusion pump System is a transportable volumetric infusion pump used in combination with specific infusion lines and accessories. The pump is intendedfo use in adults, children and new borns for the	Approved subject to submission of Full Quality Assurance Certificate.

			12v Cp Staff Call Cable Compact Plus Short Stand Sp **Rs.50,000/-**	intermittent or continuos administration of parenteral and enteral solution through standar medical access routes.	
60.	-do- **<u>Evaluator:</u>** Abdul Waheed	**Legal Manufacturer:** B. Braun Melsungen AG Carl-Braun-StraBe 1 34212 Melsungen Germany Production Facility: B. Braun Melsungen AG Pfieffewiesen 34212 Melsungen Germany (FSC Germany issued on 22-05-2019)	Infusomat® Space General-Purpose infusion pump Class C FEE SUBMITTED RS 50000 Shelf Life: Not Applicable Infusomat® Space Code: 8713050 **Rs.50,000/-**	The Infusomat® Space Volumetric Infusion Pump System includes and external transportable electronic volumetric infusion pump, dedicated administration sets, and pumps accessories. The system is intended for used on adults, pediatrics, and neonates for the intermittent or continuous delivery of parenteral and and enteral fluids through clinically accepted routes of administration	Approved subject to submission of Full Quality Assurance Certificate.
61.	-do-	**Legal Manufacturer:** B. Braun Melsungen	Perfusor® Compact Plus	Perfusor® Compact Plus Infusion	Approved subject to submission of

	Evaluator: Abdul Waheed	AG Carl-Braun-StraBe 1 34212 Melsungen Germany **Production Facility:** B. Braun Melsungen AG Pfieffewiesen 34212 Melsungen Germany (FSC Germany issued 22-05-2019)	Syringe Pump Class C Fee Rs. 50000 Shelf Life: Not Applicable FSC Code of Perfusor® Compact Plus :8717030 1.Connection lead 12v cp 8718020 2.Staff call cable compact plus 8718030 Rs.50,000/-	syringe Pump system is a transportable infusion syringe pump used together with authorized syringes and accessories. The pump is intended for use in adults, children and new borns for the intermittent or continuos administration of parenteral and enteral solutions through standard medical access routes. These access routes include, but are not limited to, intravenous, intra-arterial, subcutaneous, epidural and enteral routes.	Full Quality Assurance Certificate.
62.	-do- **Evaluator:** Abdul Waheed	**Legal Manufacturer:** B. Braun Melsungen AG Carl-Braun-StraBe 1 34212 Melsungen Germany P**roduction Facility:** B. Braun Melsungen AG Pfieffewiesen 34212 MelsungenGermany	Perfusor® Space Syringe Pump Class C FEE SUMITTED RS 50000 Shelf Life: Not Applicable (Sizes & Codes	The Perfusor® Space Infusion Syringe Pump System includes an external transportable electronic infusion syringe pump and pump accessories.	Approved subject to submission of Full Quality Assurance Certificate.

		(FSC Germany issued 22-05-2019)	as Per FSC) Perfusor® Space 8713030 Rs.50,000/-	The system is intended for use on adults, pediatrics, and neonates for use on adults, pediatrics, and neonates for the intermittent or continuous delivery of parenteral and enteral fluids through clinically accepted routes of administration	
63.	M/s. Fresenius Kabi Pakistan Private Limited. First Floor, Tanwir Ahmed Medical Center (TAMC), MM Alam Road, 27-C/3, Gulberg III, Lahore, Pakistan. (ELI-00266) **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** M/s. Fresenius Kabi AG, 61346, Bad Homburg Germany **Manufacturing Site:** Fresenius Kabi Warrendale, 770 Commonwealth Drive, Warrendale, PA 150, USA. FSC USA Validity: 09-08-2020	**Amicus Separator** 6R4580 Class: C Shelf Life : Not applicable **Rs. 50,000**	Automated blood cell separator intended for use in therapeutic apheresis applications.	Approved subject to submission of ISO 13485 and Shelf/service life Label.
64.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** M/s. Fresenius Kabi AG, 61346, Bad Homburg Germany **Manufacturing Site:**	**Amicus Apheresis Kit-Single Needle with Platelet Additive solution Connector**	The kit is designed for use with the Amicus separator for the collection of leuko-reduced	Approved subject to submission of stability studies.

		Fenwal International Inc., Carretera Sanchez Km 18.5, Parque Industrial Itabo, Zona Franca Ind. De S.C. Haina, Dominican Republic FSC Germany Issuance: 28-09-2018	**X6R2301** Class: C Shelf Life :24 months **Rs. 50,000**	platelet concentrate, plasma and red cells.	
65.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** M/s. Fresenius Kabi AG, 61346, Bad Homburg Germany **Manufacturing Site:** Fenwal International Inc., Carretera Sanchez Km 18.5, Parque Industrial Itabo, Zona Franca Ind. De S.C. Haina, Dominican Republic FSC Germany Issuance: 28-09-2018	**Amicus Apheresis Kit-Double Needle with Platelet Additive solution Connector** X6R2302 Class: C Shelf Life :24 months **Rs. 50,000**	The kit is designed for use with the Amicus separator for the collection of leuko-reduced platelet concentrate and plasma.	**Approved** subject to submission of stability studies.
66.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** M/s. Fresenius Kabi AG, 61346, Bad Homburg Germany **Manufacturing Site:** Fresenius HemoCare Brasil Ltda. Rua Roque Gonzales, 128 Itapecerica da serra/SP Brazil Fresenius Kabi (Guangzhou) Co., Ltd., No. 43 Baoying Street, Free Trade	**Compoflex® 2F 63 ml CPDA-1 - PDS-V** **T211150** Class: D Shelf Life : 24 months **Rs. 50,000**	Blood donation system with anti coagulant solution intended for collection, processing and storage of blood and blood components.	Approved subject to submission of stability studies.

		Zone, 510730 Guanzhou, China Fresenius Kabi Horatev CZ s.r.o. Horatev 104, 289 13, Czech Republic FSC Germany Issuance: 12-10-2018			
67.	-do- **<u>Evaluator:</u>** Shahid Muhammad Iqbal	**Legal Manufacturer:** M/s. Fresenius Kabi AG, 61346, Bad Homburg Germany **Manufacturing Site:** Fresenius HemoCare Brasil Ltda. Rua Roque Gonzales, 128 Itapecerica da serra/SP Brazil Fresenius Kabi (Guangzhou) Co., Ltd., No. 43 Baoying Street, Free Trade Zone, 510730 Guanzhou, China Fresenius Kabi Horatev CZ s.r.o. Horatev 104, 289 13, Czech Republic FSC Germany Issuance: 12-10-2018	**Compoflex® 1F 63 ml CPDA-1 - PDS-V** **T111150** Class: D Shelf Life :24 months **Rs. 50,000**	Blood donation system with anti coagulant solution intended for collection, processing and storage of blood and blood components.	Approved subject to submission of stability studies.
68.	-do- **<u>Evaluator:</u>** Shahid Muhammad Iqbal	**Legal Manufacturer:** M/s. Fresenius Kabi AG, 61346, Bad Homburg Germany **Manufacturing Site:**	**Compoflex® 3F 63 ml CPD/100ml SAG-M - PDS-V** **T331150**	Blood donation system with anti coagulant solution intended for collection, processing	Approved subject to submission of stability studies.

		Fresenius HemoCare Brasil Ltda. Rua Roque Gonzales, 128 Itapecerica da serra/SP Brazil Fresenius Kabi (Guangzhou) Co., Ltd., No. 43 Baoying Street, Free Trade Zone, 510730 Guanzhou, China Fresenius Kabi Horatev CZ s.r.o. Horatev 104, 289 13, Czech Republic FSC Germany Issuance: 12-10-2018	Class: D Shelf Life : 24 months **Rs. 50,000**	and storage of blood and blood components.	
69.	-do- **<u>Evaluator:</u>** Shahid Muhammad Iqbal	**Legal Manufacturer:** M/s. Fresenius Kabi AG, 61346, Bad Homburg Germany **Manufacturing Site:** Fresenius HemoCare Brasil Ltda. Rua Roque Gonzales, 128 Itapecerica da serra/SP Brazil Fresenius Kabi (Guangzhou) Co., Ltd., No. 43 Baoying Street, Free Trade Zone, 510730 Guanzhou, China Fresenius Kabi Horatev CZ s.r.o. Horatev 104, 289 13, Czech Republic FSC Germany	**Compoflex® 4F 63 ml CPD/100ml SAG-M - PDS-V** **T431150** Class: D Shelf Life : 24 months **Rs. 50,000**	Blood donation system with anti coagulant solution intended for collection, processing and storage of blood and blood components.	Approved subject to submission of stability studies.

		Issuance: 12-10-2018			
70.	M/s. Tech Zone, 764 Askari 9, Zarar Shaheed Road Cantt Lahore. ELI-00040 **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer &Manufacturing Site:** Pikdare S.p. A Via Saldarini Catelli 10, 22070 Casnate con Bernate COMO Italy. FSC : Italy Issuance: 24.05.2019	PIC INSUPEN (Insulin Pen Needles) Class B Shelf Life 5 years. Rs. 25,000	Insulin pen needle used in conjunction with insulin pen to deliver insulin in the Human Body.	Approved subject to submission of MRP.
71.	M/s. Mian Scientific Corporation (Pvt) Ltd 534-Jinnah Colony Faisalabad ELI: 00442 **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer &Manufacturing Site:** Guangzhou Improve Medical Instruments Co., Ltd. No 102, Kaiyuan Avenue, Science City, Guangzhou Economic & Technological Development District, Guangzhou, China. FSC: China Validity: 15.07.2020	**Improve®** Blood Collection Set 0.5×19, 0.5×20, 0.55×19, 0.55×20, 0.6×19, 0.6×20, 0.7×19, 0.7×20, 0.7×24, 0.7×25, 0.8×20, 0.8×24, 0.8×25, 0.8×28 Class: B Self Life 3 years **Rs. 50,000**	Blood collection needle is used matching with Vacuum Blood Collection Tube for the purpose of venous blood collection.	Approved subject to clarification for brand name since LOA mention Improve while documents show Improvacuter, CE marked documents or inspection of manufacturer abroad.
72.	M/s. Remington Pharmaceutical Industries (Pvt) Ltd., 18-Km Multan Road, Lahore ELI-00395 **Evaluator:**	**Manufacturer** URSAPHARM Arzneimittel GmbH Industriestrasse 35, 66129 Saarbrucken Germany. FSC: Germany Issuance: 17.01.2019	**HYLO-COMOD** (eye drops) Class B Shelf Life: 3 years. Rs. 25,000	Sodium Hyluronate, 1 mg/ml, eye drops	Approved subject to submission of stability studies and differential fee of PKR 25000.

	Shahid Muhammad Iqbal				
73.	M/s Amtronech 560 A-Block, Faisal Town. Lahore 54700 ELI:00173 **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer &Manufacturing Site:** Cortex Biophysik GmbH Walther-Kohn-Str. 2d, 04356 Leipzig. Germany FSC Germany issuance: 25.10.2018	**MetaMax ® 3B** Ergospirometry-Systems Class: B Self Life N/A Rs. 25,000	Spiroergometry devices are used to perform cardio pulmonary exercise testing (CPET). During a CPET test a patient is subjected to a defined physical load over a period of 10-20 minutes. In that process measurement data of ventilation, gas exchange and heart rate are recorded and displayed.	Approved subject to submission of stability studies for shelf life or life service and EPSP.
74.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer &Manufacturing Site:** Cortex Biophysik GmbH Walther-Kohn-Str. 2d, 04356 Leipzig. Germany FSC Germany issuance: 25.10.2018	**MetaLyzer ® 3B** Ergospirometry-System Class: B Shelf Life: N/A Rs. 25,000	Spiroergometry devices are used to perform cardio pulmonary exercise testing (CPET). During a CPET test a patient is subjected to a defined physical load over a period of 10-20 minutes. In	Approved subject to submission of stability studies for shelf life or life service and EPSP.

				that process measurement data of ventilation, gas exchange and heart rate are recorded and displayed.	
75.	M/s. Progressive Corporation 147-D, Commercial Broadway, Phase-8 DHA, Lahore Pakistan ELI-00114 **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer &Manufacturing Site:** Farcomake for Advanced Medical Industry, New Borg Al-Arab Industrial city, area 4, block 2 part 7,16, Alexandria, Egypt. FSC: Egypt Issuance: 08.09.2019 FSC: Germany Issuance: 20.03.2019	FARCOLINE Sterile Blood Line FBL00FR FBL00GM Class: B Shelf Life: 5 years Rs. 25,000	Intended for extracorporeal access to the patient's blood during Haemodialysis.	Approved subject to submission of stability studies for shelf life or life service and EPSP.
76.	M/s. AL YAHYA Enterprises Office 206, Sana Plaza Garrison Golf Club, Bahar Shah Road,Lahore ELI 00111 **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** LUX-SUTURES AG LOCATED AT 22, GRUUSS-STROOS 9991 WEISWAMPACH-LUXEMBOURG FSC LUXEMBOURG Valid till 17.06.2020	**LUXYLENE Polypropylene** Class C Shelf life 5 years Rs.5,000/-	**Sterile Non absorbable suture**	Approved subject to additional Fee endorsement by Budget & Accounts.
77.	M/s. Fresenius Medical Care Pakistan Pvt. Ltd., TAMC, First Floor, 27-C III, M.M.	Legal Manufactuer: Fresenius Medical Care AG & Co. KGaA, 61346, Bad Homburg Germany.	Fistula Needle (Rotating Wing) (Dialysis needle) Class B	Single-use ETO sterilized fistula needles intended for haemodialysis,	Approved.

	Alam Road Gulberg III, Lahore. (ELI-00315) **Evaluator:** Unum Zia Shamsi	Manufacturing Site: Nipro Corporation, 3-9-3, Honjo-Nishi, Kita-ku Osaka 531-8510, Japan. (FSC Germany issued on 11-11-2016)	Shelf Life: 5 Years Codes: 5082501 5082511 5082521 5082631 5082641 5082651 Fee submitted: Rs. 25,000/-	hemofiltyration and haemodiafiltration. Can also be used in other treatments requiring an extracorporeal circuit or larger volumes of blood to be drawn from a patient's circulation such as in plasmapheresis, hemoperfusion or cell separation.	
78.	M/s Muslim Trading Agencies, Ground Floor, 3 Syed Moj Darya Road, Lahore. (ELI-00359) -do- **Evaluator:** Unum Zia Shamsi	Manufacturer: Randox Laboratories Limited, Ardmore, 55 The Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom (FSC UK MHRA valid till 18-08-2021)	Acusera ® Assayed Chemistry Control Premium Plus Class C Codes: HUMAN ASSAYED MULTI-SERA/ASSAYED CHEMISTRY PREMIUM PLUS-LEVEL 3 (HUM ASY CONTROL 3) Code: HE1532 Size: 20 x 5 ml HUMAN ASSAYED MULTI-SERA/ASSAYE	Intended for in vitro diagnostic use in the quality control of diagnostic assays. It is for the control of accuracy	Approved.

			D CHEMISTRY PREMIUM PLUS-LEVEL 3 (HUM ASY CONTROL 3) Code:HN1530 Size: 20 x 5 ml Shelf Life: 4 years Fee submitted: Rs. 50,000/-		
79.	-do- **Evaluator:** Unum Zia Shamsi	Manufacturer: Randox Laboratories Limited, Ardmore, 55 The Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom (FSC UK MHRA issued on 24/05/2018)	Acusera ® Assayed Bovine Multisera (Control) Class C Codes : Code: AE1032 Bovine Chemistry Assayed Level 3 (BOV ASY CONTROL 3) Size: 20 x 5 ml Code: AN1026 Bovine Chemistry Assayed Level 2 (BOV ASY CONTROL 2) Size: 20 x 5 ml Shelf Life: 48 Months Fee submitted: Rs. 50,000/-	Intended for in vitro diagnostic use in the quality control of diagnostic assays. It is for the control of accuracy	Approved.
80.	M/s Anwar & Sons, Apartment No.10, Safari Villas-2,	Manufacturer: M/s Ningbo Advan Electrical Co, Ltd, Industrial	Advan Disposable Skin Stapler Class B	Steile, single-use hand held mecial device used for wound closure	Approved subject to submission of EPSP.

	Commercial Complex, Bahria Town Phase 7, Rawalpindi (ELI-00017) **Evaluator:** Unum Zia Shamsi	Development Zone, Fuhai Town, 315332 CiXi City, Ningbo, Zhejiing Province, People's Republic of China. FSC China valid till 10-02-2020 FSC Spain issued on 30-5-2019	Codes: F-35W, F-35R Shelf Life 05 years Fee submitted: Rs. 25,000/-	in surgery	
81.	M/s Ferozsons LaboratoriesLimited, P.O Ferozsons, Amangarh, Nowshera (KPK). (ELI-00120) **Evaluator:** Unum Zia Shamsi	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)	FloSwitch™ HP High Pressure Flow Control Device Class B Codes: UPN: M001442001 FloSwitch™ HP High Pressure Flow Control Device (Bx 12) UPN: M001442011 FloSwitch™ HP High Pressure Flow Control Device (Bx 24) Shelf Life: 5 Years Fee submitted: Rs. 25,000/-.	An angiographic accessory intended for use as an on/off device for angiography and other high pressure applications	Approved subject to submission of Agency Agreement.
82.	-do- **Evaluator:** Unum Zia Shamsi	Manufacturer: Hemoteq Ag Adenauerstrabe 15 52146 Wurselen Germany	Agent™ MONORAIL Paclitaxel-Coated PTCA Balloon Catheter	Indicated for Percutaneous Transluminal Coronary Angioplasty	Approved subject to submission of Agency Agreement.

		(FSC Germany issued on 21-08-2018)	Class D Codes: H749392222008 10 H749392222208 10 H749392222508 10 H749392222708 10 H749392223008 10 H749392223208 10 H749392223508 10 H749392223708 10 H749392224008 10 H749392222012 10 H749392222212 10 H749392222512 10 H749392222712 10 H749392223012 10 H749392223212 10 H749392223512 10 H749392223712 10 H749392224012 10 H749392222015 10 H749392222215 10 H749392222515 10 H749392222715 10	(PTCA) in the coronary arteries to treat in –stent restenosis (ISR) and de novo /small vessel disease. Sterile, single-use	

			H749392223015 10 H749392223215 10 H749392223515 10 H749392223715 10 H749392224015 10 H749392222020 10 H749392222220 10 H749392222520 10 H749392222720 10 H749392223020 10 H749392223220 10 H749392223520 10 H749392223720 10 H749392224020 10 H749392222030 10 H749392222230 10 H749392222530 10 H749392222730 10 H749392223030 10 H749392223230 10 H749392223530 10 H749392223730 10 H749392224030 10 Shelf life: 24		

			Months Fee submitted: Rs. 50,000/-		
83.	-do- **Evaluator:** Unum Zia Shamsi	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)	Coil Pusher-16 Class B Code : UPN: M0014012160 Shelf Life : 3 Years Fee submitted: Rs. 25,000/-	Intended to be used in conjunction with the microcatheter to deliver and deploy 0.018 pushable occlusion coils that are intended for arterial and venous embolizations in the peripheral vasculature. Sterile, single-use.	Approved subject to submission of Agency Agreement.
84.	-do- **Evaluator:** Unum Zia Shamsi	Legal Manufacturer: Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA. 01752 USA. Manufacturing site: Boston Scientific Limited , Ballybrit Business Park, Galway, Ireland. (FSC Ireland valid till 03-07-2023)	Charger™ PTA Balloon Dilatation Catheter (OTW) Class B Shelf life: 36 Months Codes: H74939206030240 Charger 3.0mm x 20mm x 40cm H74939206030340 Charger 3.0mm x 30mm x 40cm H74939206030440 Charger 3.0mm x	Indicated for Percutaenous Transluminal Angioplasty (PTA) in the peripheral vasculature, and for the treatment of obstructive lesions of native or syntheric arteriovenous dialysis fistulae. Not for use in the coronary or cerebral vasculature. Sterile, Single-use	Approved subject to submission of Agency Agreement.

			40mm x 40cm H749392060306 40 Charger 3.0mm x 60mm x 40cm H749392060308 40 Charger 3.0mm x 80mm x 40cm H749392060310 40 Charger 3.0mm x 100mm x 40cm H749392060302 70 Charger 3.0mm x 20mm x 75cm H749392060303 70 Charger 3.0mm x 30mm x 75cm H749392060304 70 Charger 3.0mm x 40mm x 75cm H749392060306 70 Charger 3.0mm x 60mm x 75cm H749392060308 70 Charger 3.0mm x 80mm x 75cm H749392060310 70 Charger 3.0mm x 100mm x 75cm H749392060312		

			70 Charger 3.0mm x 120mm x 75cm H749392060315 70 Charger 3.0mm x 150mm x 75cm H749392060318 70 Charger 3.0mm x 180mm x75cm H749392060320 70 Charger 3.0mm x 200mm x 75cm H749392060302 10 Charger 3.0mm x 20mm x 135cm H749392060303 10 Charger 3.0mm x 30mm x 135cm H749392060304 10 Charger 3.0mm x40mm x 135cm H749392060306 10 Charger 3.0mm x 60mm x 135cm H749392060308 10 Charger 3.0mm x 80mm x 135cm H749392060310 10 Charger 3.0mm x 100mm x 135cm		

			H749392060312 10 Charger 3.0mm x 120mm x 135cm H749392060315 10 Charger 3.0mm x 150mm x 135cm H749392060318 10 Charger 3.0mm x 180mm x 135cm H749392060320 10 Charger 3.0mm x 200mm x 135cm H749392060402 40 Charger 4.0mm x 20mm x 40cm H749392060403 40 Charger 4.0mm x 30mm x 40cm H749392060404 40 Charger 4.0mm x 40mm x 40cm H749392060406 40 Charger 4.0mm x 60mm x 40cm H749392060408 40 Charger 4.0mm x 80mm x 40cm H749392060410 40		

			Charger 4.0mm x 100mm x40cm H749392060402 70 Charger 4.0mm x 20mm x 75cm H749392060403 70 Charger 4.0mm x 30mm x 75cm H749392060404 70 Charger 4.0mm x 40mm x 75cm H749392060406 70 Charger 4.0mm x 60mm x 75cm H749392060408 70 Charger 4.0mm x 80mm x 75cm H749392060410 70 Charger 4.0mm x 100mm x 75cm H749392060412 70 Charger 4.0mm x 120mm x 75cm H749392060415 70 Charger 4.0mm x 150mm x 75cm H749392060418 70 Charger 4.0mm x 180mm x 75cm		

			H749392060420 70 Charger 4.0mm x 200mm x 75cm H749392060402 10 Charger 4.0mm x 20mm x 135cm H749392066403 10 Charger 4.0mm x 30mm x 135cm H749392060404 10 Charger 4.0mm x 40mm x 135cm H749392060406 10 Charger 4.0mm x 60mm x 135cm H749392060408 10 Charger 4.0mm x 80mm x 135cm H749392060410 10 Charger 4.0mm x 100mm x 135cm H749392060412 10 Charger 4.0mm x 120mm x 135cm H749392060415 10 Charger 4.0mm x 150mm x 135cm H749392060418 10 Charger 4.0mm x		

			180mm x 135cm H749392060420 10 Charger 4.0mm x 200mm x 135cm H749392060502 40 Charger 5.0mm x 20mm x 40cm H749392060503 40 Charger 5.0mm x 30mm x 40cm H749392060504 40 Charger 5.0mm x 40mm x 40cm H749392060506 40 Charger 5.0mm x 60mm x 40cm H749392060508 40 Charger 5.0mm x 80mm x 40cm H749392060510 40 Charger 5.0mm x 100mm x 40cm H749392060512 40 Charger 5.0mm x 120mm x 40cm H749392060502 70 Charger 5.0mm x 20mmx 75cm H749392060503		

			70 Charger 5.0mm x 30mm x 75cm H749392060504 70 Charger 5.0mm x 40mm x 75cm H749392060506 70 Charger 5.0mm x 60mm x 75cm H749392060508 70 Charger 5.0mm x 80mm x 75cm H749392060510 70 Charger 5.0mm x 100mm x 75cm H749392060512 70 Charger 5.0mm x 120mm x 75cm H749392060515 70 Charger 5.0mm x 150mm x 75cm H749392060518 70 Charger 5.0mm x 180mm x 75cm H749392060520 70 Charger 5.0mm x 200mm x 75cm H749392060502 10 Charger 5.0mm x 20mm x 135cm		

			H749392060503 10 Charger 5.0mm x 30mm x 135cm H749392060504 10 Charger 5.0mm x 40mm x 135cm H749392060506 10 Charger 5.0mm x 60mm x 135cm H749392060508 10 Charger 5.0mm x 80mm x 135cm H749392060510 10 Charger 5.0mm x 100mm x 135cm H749392060512 10 Charger 5.0mm x 120mm x 135cm H749392060515 10 Charger 5.0mm x 150mm x 135cm H749392060518 10 Charger 5.0mm x 180mm x 135cm H749392060520 10 Charger 5.0mm x 200mm x 135cm H749392060602 40		

			Charger 6.0mm x 20mm x 40cm H749392060603 40 Charger 6.0mm x 30mm x 40cm H749392060604 40 Charger 6.0mm x 40mm x 40cm H749392060606 40 Charger 6.0mm x 60mm x 40cm H749392060608 40 Charger 6.0mm x 80mm x 40cm H749392060612 40 Charger 6.0mm x 120mm x 40cm H749392060610 40 Charger 6.0mm x 100mm x40cm H749392060602 70 Charger 6.0mm x 20mm x 75cm H749392060603 70 Charger 6.0mm x 30mm x 75cm H749392060604 70 Charger 6.0mm x 40mm x 75cm		

			H749392060606 70 Charger 6.0mm x 60mm x 75cm H749392060608 70 Charger 6.0mm x 80mm x 75cm H749392060610 70 Charger 6.0mm x 100mm x 75cm H749392060612 70 Charger 6.0mm x 120mm x 75cm H749392060615 70 Charger 6.0mm x 150mm x 75cm H749392060618 70 Charger 6.0mm x 180mm x 75cm H749392060620 70 Charger 6.0mm x 200mm x 75cm H749392060602 10 Charger 6.0mm x 20mm x 135cm H749392060603 10 Charger 6.0mm x 30mm x 135cm H749392060604 10 Charger 6.0mm x		

			40mm x 135cm H749392060606 10 Charger 6.0mm x 60mm x 135cm H749392060608 10 Charger 6.0mm x 80mm x 135cm H749392060610 10 Charger 6.0mm x 100mm x 135cm H749392060612 10 Charger 6.0mm x 120mm x 135cm H749392060615 10 Charger 6.0mm x 150mm x 135cm H749392060618 10 Charger 6.0mm x 180mm x 135cm H749392060620 10 Charger 6.0mm x 200mm x 135cm H749392060702 40 Charger 7.0mm x 20mm x 40cm H749392060703 40 Charger 7.0mm x 30mm x 40cm H749392060704		

			40 Charger 7.0mm x 40mm x 40cm H749392060706 40 Charger 7.0mm x 60mm x 40cm H749392060708 40 Charger 7.0mm x 80mm x 40cm H749392060710 40 Charger 7.0mm x 100mm x 40cm H749392060702 70 Charger 7.0mm x 20mm x 75cm H749392060703 70 Charger 7.0mm x 30mm x 75cm H749392060704 70 Charger 7.0mm x 40mm x 75cm H749392060706 70 Charger 7.0mm x 60mm x 75cm H749392060708 70 Charger 7.0mm x 80mm x 75cm H749392060710 70 Charger 7.0mm x 100mm x 75cm		

			H749392060712 70 Charger 7.0mm x 120mm x 75cm H749392060715 70 Charger 7.0mm x 150mm x 75cm H749392060718 70 Charger 7.0mm x 180mm x 75cm H749392060720 70 Charger 7.0mm x 200mm x 75cm H749392060702 10 Charger 7.0mm x 20mm x 135cm H749392060703 10 Charger 7.0mm x 30mm x 135cm H749392060704 10 Charger 7.0mm x 40mm x 135cm H749392060706 10 Charger 7.0mm x 60mm x 135cm H749392060708 10 Charger 7.0mm x 80mm x 135cm H749392060710 10		

			Charger 7.0mm x 100mm x 135cm H749392060712 10 Charger 7.0mm x 120mm x 135cm H749392060715 10 Charger 7.0mm x 150mm x 135cm H749392060718 10 Charger 7.0mm x 180mm x 135cm H749392060720 10 Charger 7.0mm x 200mm x 135cm H749392060802 40 Charger 8.0mm x 20mm x 40cm H749392060803 40 Charger 8.0mm x 30mm x 40cm H749392060804 40 Charger 8.0mm x 40mm x 40cm H749392060806 40 Charger 8.0mm x 60mm x 40cm H749392060808 40 Charger 8.0mm x 80mm x 40cm		

			H749392060810 40 Charger 8.0mm x 100mm x40cm H749392060802 70 Charger 8.0mm x 20mm x 75cm H749392060803 70 Charger 8.0mm x 30mm x 75cm H749392060804 70 Charger 8.0mm x 40mm x 75cm H749392060806 70 Charger 8.0mm x 60mm x 75cm H749392060808 70 Charger 8.0mm x 80mm x 75cm H749392060810 70 Charger 8.0mm x 100mm x 75cm H749392060812 70 Charger 8.0mm x 120mm x 75cm H749392060815 70 Charger 8.0mm x 150mm x 75cm H749392060818 70 Charger 80mm x		

			180mm x 75cm H749392060820 70 Charger 8.0mm x 200mm x 75cm H749392060802 10 Charger 8.0mm x 20mm x 135cm H749392060803 10 Charger 8.0mm x 30mm x 135cm H749392060804 10 Charger 8.0mm x 40mm x 135cm H749392060806 10 Charger 8.0mm x 60mm x 135cm H749392060808 10 Charger 8.0mm x 80mm x 135cm H749392060810 10 Charger 8.0mm x 100mm x 135cm H749392060812 10 Charger 8.0mm x 120mm x 135cm H749392060815 10 Charger 8.0mm x 150mm x 135cm H749392060818		

			10 Charger 8.0mm x 180mm x 135cm H749392060820 10 Charger 8.0mm x 200mm x 135cm H749392060902 40 Charger 9.0mm x 20mm x 40cm H749392060903 40 Charger 9.0mm x 30mm x 40cm H749392060904 40 Charger 9.0mm x 40mm x 40cm H749392060906 40 Charger 9.0mm x 60mm x 40cm H749392060908 40 Charger 9.0mm x 80mm x 40cm H749392060902 70 Charger 9.0mm x 20mm x 75cm H749392060903 70 Charger 9.0mm x 30mm x 75cm H749392060904 70 Charger 9.0mm x 40mm x 75cm		

			H749392060906 70 Charger 9.0mm x 60mm x 75cm H749392060908 70 Charger 9.0mm x 80mm x 75cm H749392060902 10 Charger 9.0mm x 20mm x 135cm H749392060903 10 Charger 9.0mm x 30mm x 135cm H749392060904 10 Charger 9.0mm x 40mm x 135cm H749392060906 10 Charger 9.0mm x 60mm x 135cm H749392060908 10 Charger 9.0mm x 80mm x 135cm H749392061002 40 Charger 10.0mm x 20mm x 40cm H749392061003 40 Charger 10.0mm x 30mm x 40cm H749392061004 40		

			Charger 10.0mm x 40mm x 40cm H749392061006 40 Charger 10.0mm x 60mm x 40cm H749392061008 40 Charger 10.0mm x 80mm x40cm H749392061002 70 Charger 10.0mm x 20mm x 75cm H749392061003 70 Charger 10.0mm x 30mm x 75cm H749392061004 70 Charger 10.0mm x 40mm x 75cm H749392061006 70 Charger 10.0mm x 60mm x 75cm H749392061008 70 Charger 10.0mm x 80mm x 75cm H749392061002 10 Charger 10.0mm x 20mm x 135cm H749392061003 10 Charger 10.0mm x 30mm x 135cm		

			H749392061004 10 Charger 10.0mm x40mm x 135cm H749392061006 10 Charger 10.0mm x 60mm x 135cm H749392061008 10 Charger 10.0mm x 80mm x 135cm H749392061202 40 Charger 12.0mm x 20mm x 40cm H749392061203 40 Charger 12.0mm x 30mm x 40cm H749392061204 40 Charger 12.0mm x 40mm x 40cm H749392061206 40 Charger 12.0mm x 60mm x 40cm H749392061208 40 Charger 12.0mm x 80mm x 40cm H749392061202 70 Charger 12.0mm x 20mm x 75cm H749392061203 70 Charger 12.0mm		

			x 30mm x 75cm H749392061204 70 Charger 12.0mm x 40mm x 75cm H749392061206 70 Charger 12.0mm x 60mm x 75cm H749392061208 70 Charger 12.0mm x 80mm x 75cm H749392061202 10 Charger 12.0mm x 20mm x 135cm H749392061203 10 Charger 12.0mm x 30mm x 135cm H749392061204 10 Charger 12.0mm x 40mm x 135cm H749392061206 1 0 Charger 12.0mm x 60mm x 135cm H749392061208 10 Charger 12.0mm x 80mm x 135cm Fee submitted: Rs. 25,000/-		
85.	-do- **Evaluator:**	Legal Manufacturer: M/s. Boston Scientific	Accustick™ Needle Introducer	Sterile, single-use introducer needle	Approved subject to submission of

	Unum Zia Shamsi	Corporation , 300 Boston Scientific Way, Marlborough, MA. 01752 USA. Manufacturing Site: M/s. Boston Scientific Corporation, 780 Brookside Drive Spencer, IN, USA 47460 FSC US FDA valid till 05-08-2020	Needle Class B Codes: M001206041 08714729133766 Needle (Bx/10) Shelf life: 36 Months Fee submitted: Rs. 25,000/-		Agency Agreement.
86.	-do- **Evaluator:** Unum Zia Shamsi	Legal Manufacturer: Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA Manufacturer: Boston Scientific Corporation, 2546 First Street, Propark El Coyol, Alajuela, Costa Rica, 20904 (FSC US FDA valid till 19-12-2019)	Flexima™ Ureteral Stent System Kit Class C Codes: M001274100 08714729201151 Flexima Ureteral Stent 6F/20cm Kit M001274110 08714729323853 Flexima Ureteral Stent 6F/22cm Kit M001274120 08714729323860 Flexima Ureteral Stent 6F/24cm Kit M001274130 08714729323877 Flexima Ureteral Stent 6F/26cm Kit M001274140	Intended to provide drainage from the ureteropelvic junction to the bladder and stenting of the ureter for all patients in whom it is desirable to place a drain which doest not extend externally. Sterile, single-use	Approved subject to submission of Agency Agreement.

			08714729323884 Flexima Ureteral Stent 6F/28cm Kit M001274150 08714729323891 Flexima Ureteral Stent 8F/20cm Kit M001274160 08714729323907 Flexima Ureteral Stent 8F/22cm Kit M001274170 08714729323914 Flexima Ureteral Stent 8F/24cm Kit M001274180 08714729323921 Flexima Ureteral Stent 8F/26cm Kit M001274190 08714729323938 Flexima Ureteral Stent 8F/28cm Kit Shelf Life: 4 Years **Fee submitted: Rs. 50,000/-**		
87.	-do- **Evaluator:** Unum Zia Shamsi	**Legal Manufactuer:** Legal Manufacturer: Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA	PeriVac™ (Pericardial Fluid Aspiration Procedure Kit) Class D	Pericardiocentesis kit intended for use in pericardial aspiration and drainage in the	Approved subject to submission of Agency Agreement.

		01752 USA Manufacturer: Boston Scientific Corporation, 2546 First Street, Propark El Coyol, Alajuela, Costa Rica, 20904 (FSC Ireland valid till 05-04-2020)	Shelf Life: 2 Years Codes: M00443051 M00443151 Fee submitted: Rs. 50,000/-	presence of pericardial effusion or tamponade. Sterile, single-use	
88.	-do- **<u>Evaluator:</u>** Unum Zia Shamsi	Legal Manufacturer: Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA. 01752 USA. Manufacturer: Boston Scientific Corporation 2546 First Street, Propark El Coyol, Alajuela Costa Rica 20904 (FSC US FDA valid till 19-12-2019)	Expel™ Ureteral Stent System Ureteral Stent System Class C Codes: H7493936106120 08714729861003 Ureteral Stent System (6.3F/12cm) H7493936106140 08714729861010 Ureteral Stent System (6.3F/14cm) H7493936106160 08714729861027 Ureteral Stent System (6.3F/16cm) H7493936106200 08714729861034 Ureteral Stent System (6.3F/20cm)	Is delivered percutaneously and is intended to establish drainage from the ureteropelvic junction to the bladder and stenting of the ureter for all patients in whom it is desireable to place a drain which does not extended externally. Sterile, single-use	Approved subject to submission of Agency Agreement and valid FSC.

			H749393610622 0 08714729861041 Ureteral Stent System (6.3F/22cm) H749393610624 0 08714729861058 Ureteral Stent System (6.3F/24cm) H749393610626 0 08714729861065 Ureteral Stent System (6.3F/26cm) H749393610628 0 08714729861072 Ureteral Stent System (6.3F/28cm) H749393610812 0 08714729861089 Ureteral Stent System (8.3F/12cm) H749393610814 0 08714729861096 Ureteral Stent System (8.3F/14cm) H749393610816 0 08714729861102		

			Ureteral Stent System (8.3F/16cm) H749393610820 0 08714729861119 Ureteral Stent System (8.3F/20cm) H749393610822 0 08714729861126 Ureteral Stent System (8.3F/22cm) H749393610824 0 08714729861133 Ureteral Stent System (8.3F/24cm) H749393610826 0 08714729861140 Ureteral Stent System (8.3F/26cm) H749393610828 0 08714729861157 Ureteral Stent System (8.3F/28cm) H749393611012 0 08714729861164 Ureteral Stent System (10.3F/12cm) H749393611014		

			0 08714729861171 Ureteral Stent System (10.3F/14cm) H749393611016 0 08714729861188 Ureteral Stent System (10.3F/16cm) H749393611020 0 08714729861195 Ureteral Stent System (10.3F/20cm) H749393611022 0 08714729861201 Ureteral Stent System (10.3F/22cm) H749393611024 0 08714729861218 Ureteral Stent System (10.3F/24cm) H749393611026 0 08714729861225 Ureteral Stent System (10.3F/26cm) H749393611028 0 08714729861232 Ureteral Stent System		

			(10.3F/28cm) Shelf Life: 3 Years Fee submitted: Rs. 25,000/-		
89.	-do- **Evaluator:** Unum Zia Shamsi	Legal Manufacturer: M/s. Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, MA. 01752 USA. Manufacturing Site: M/s. Boston Scientific Corporation. Two Scimed Place, Maple Grove, MN USA 55311 FSC US FDA valid till 03-05-2019	Journey™ Guidewire Class B M001391260 08714729789826 Journey, Intermediate, Straight, 185cm M001391270 08714729789833 Journey, Intermediate, Angled, 185cm M001391280 08714729789840 Journey, Intermediate, Straight, 300cm M001391290 08714729789857 Journey, Intermediate, Angled, 300cm M001391300 08714729789864 Journey, Floppy, Straight, 185cm M001391310 08714729789871 Journey, Floppy, Angled, 185cm M001391320	Intended to facilitate placement and exchange of balloon dilatation catheters or other therapeutic devices during Percutaneous Transluminal Angioplasty (PTA) or other intravascular interventional procedures. Not for use in coronary or cerebral vasculature.	Approved subject to submission of Agency Agreement.

			08714729789888 Journey, Floppy, Straight, 300cm M001391330 08714729789895 Journey, Floppy, Angled, 300cm Shelf life: 24 Months Fee submitted: Rs. 25,000/-		
90.	-do- **Evaluator:** Unum Zia Shamsi	Legal Manufacturer: Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, MA. 01752 USA. Manufacturing site: Boston Scientific Corporation Two Scimed Place, Maple Grove, MN USA 55311 FSC US FDA valid till 26-08-2020	iSLEEVE INTRODUCER SET Class B Codes: H74939349140 08714729950660 iSLEEVE Introducer Set 14F H74939350150 08714729950677 iSLEEVE Introducer Set 15F Shelf life: 2 years Fee submitted: Rs. 25,000/-	Intended to facilitate femoral access to the vascular system. Sterile, single-use.	Approved subject to submission of Agency Agreement.
91.	-do- **Evaluator:** Unum Zia Shamsi	Legal Manufacturer: M/s. Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA. 01752 USA. Manufacturing Site:	Encore™ 26 Inflation Device Class B Codes: H74904526011 Encore 26 Single	Indicated for use with balloon dilation catheters to create and monitor pressure in the balloon and to	Approved subject to submission of Agency Agreement.

		M/s. Boston Scientific Limited, Business and Technology Park Model Farm Road Cork, Ireland. FSC Ireland valid till 23-03-2022	H74904526052 Encore 26 5-Pack M001151050 Encore 26 Single M001151062 Encore 26 5-Pack Shelf Life: 03 years Fee submitted: Rs. 5,000/-	deflate the balloon. Sterile, single-use	
92.	M/s. Verizon 60-D,FCC, Zahoor Elahi Road, Gulberg IV, Lahore ELI 00087 **Evaluator:** Unum Zia Shamsi	Manufacturer: Cook Ireland Ltd O'Halloran Road, National Technology Park, Limerick, Ireland FSC Ireland valid till 16-03-2022	Zilver Flex ™ 35 Vascular Stent Class C Codes: ZFV6-125-5-2.0, ZFV6-125-5-3.0, ZFV6-125-5-4.0, ZFV6-125-5-6.0, ZFV6-125-5-8.0, ZFV6-125-5-10.0, ZFV6-125-5-12.0, ZFV6-125-5-14.0, ZFV6-125-6-2.0, ZFV6-125-6-3.0, ZFV6-125-6-4.0, ZFV6-125-6-6.0, ZFV6-125-6-8.0, ZFV6-125-6-10.0, ZFV6-125-6-12.0, ZFV6-125-6-14.0, ZFV6-125-7-2.0, ZFV6-125-7-3.0,	Intended for use in the Iliac, superficial femoral artery (SFA) and above the knee popliteal artery for the treatment of arterioscleroti c stenosis and total occlusions that have been recanalized. The product provides mechanical support constant blood flow of the vessel. Sterile, single-use	Approved.

			ZFV6-125-7-4.0, ZFV6-125-7-6.0, ZFV6-125-7-8.0, ZFV6-125-7-10.0, ZFV6-125-7-12.0, ZFV6-125-7-14.0, ZFV6-125-8-2.0, ZFV6-125-8-3.0, ZFV6-125-8-4.0, ZFV6-125-8-6.0, ZFV6-125-8-8.0, FV6-125-8-1 0.0 ZFV6-125-8-12.0, ZFV6-125-8-14.0, ZFV6-125-9-2.0, ZFV6-125-9-3.0, ZFV6-125-9-4.0, ZFV6-125-9-6.0, ZFV6-125-9-8.0, ZFV6-125-9-10.0, ZFV6-125-9-12.0, ZFV6-125-9-14.0, ZFV6-125-10-2.0, ZFV6-125-10-3.0, ZFV6-125-10-4.0, ZFV6-125-10-6.0, ZFV6-125-10-8.0, ZFV6-125-10-10.0, ZFV6-125-10-12.0, ZFV6-125-10-14.0, ZFV6-80-5-2.0, ZFV6-80-5-3.0, ZFV6-80-5-4.0,		

			ZFV6-80-5-6.0, ZFV6-80-5-8.0, ZFV6-80-5-10.0, ZFV6-80-5-12.0, ZFV6-80-5-14.0, ZFV6-80-6-2.0, ZFV6-80-6-3.0, ZFV6-80-6-4.0, ZFV6-80-6-6.0, ZFV6-80-6-8.0, ZFV6-80-6-10.0, ZFV6-80-6-12.0, ZFV6-80-6-14.0, ZFV6-80-7-2.0, ZFV6-80-7-3.0, ZFV6-80-7-4.0, ZFV6-80-7-6.0, ZFV6-80-7-8.0, ZFV6-80-7-10.0, ZFV6-80-7-12.0, ZFV6-80-7-14.0, ZFV6-80-8-2.0, ZFV6-80-8-3.0, ZFV6-80-8-4.0, ZFV6-80-8-6.0, ZFV6-80-8-8.0, ZFV6-80-8-10.0, ZFV6-80-8-12.0, ZFV6-80-8-14.0, ZFV6-80-9-2.0, ZFV6-80-9-3.0, ZFV6-80-9-4.0, ZFV6-80-9-6.0, ZFV6-80-9-8.0, ZFV6-80-9-10.0, ZFV6-80-9-12.0, ZFV6-80-9-14.0, ZFV6-80-10-2.0, ZFV6-80-		

			10-3.0, ZFV6-80-10-4.0, ZFV6-80-10-6.0, ZFV6-80-10-8.0, ZFV6-80-10-10.0, ZFV6-80-10-12.0, ZFV6-80-10-14.0, ZFV6-80-5-17.0, ZFV6-80-5-20.0, ZFV6-80-6-17.0, ZFV6-80-6-20.0, ZFV6-80-7-17.0, ZFV6-80-7-20.0, ZFV6-80-18-17.0, ZFV6-80-8-20.0, ZFV6-125-5-17.0, ZFV6-125-5-20.0, ZFV6-125-6-17.0, ZFV6-125-6-20.0, ZFV6-125-7-17.0, ZFV6-125-7-20.0, ZFV6-125-8-17.0, ZFV6-125-8-20.0 Shelf life: 3 years Fee submitted: Rs. 50,000/-		
93.	-do- **<u>Evaluator:</u>** Unum Zia Shamsi	Manufacturer: Cook Ireland Ltd O'Halloran Road, National Technology Park, Limerick, Ireland	**Zilver 635 Biliary Stent** **Class C** **Codes:** ZIB6-40-6-4.0,	Used in palliation of malignant neoplasms in the biliary tree. Sterile, single-use	Approved.

		FSC Ireland valid till 16-03-2022	ZIB6-40-6-6.0, ZIB6-40-6-8.0, ZI86-40-8-4.0, Z1B6-40-8-6.0, ZIB6-40-8-8.0, Z1B6-40-9-4.0, ZIB6-40-9-6.0, ZIB6-40-9-8.0, ZIB6-40-10-4.0, Z1B6-40-10-6.0, ZIB6-40-10-8.0, ZIB6-40-12-4.0, Z1B6-40-12-6.0, ZIB6-40-12-8.0, ZIB6-40-14-4.0, ZIB6-40-14-6.0, ZIB6-40-14-8.0 ZIB6-40-6.0-20, ZIB6-40-6.0-30, ZIB6-40-6.0-40, ZIB6-40-6.0-60, ZIB6-40-6.0-80, ZIB6-40-8.0-20, ZIB6-40-8.0-30, ZIB6-40-8.0-40, ZIB6-40-		

			8.0-60, ZIB6-40-8.0-80, ZIB6-40-9.0-40, ZIB6-40-9.0-60, ZIB6-40-9.0-80, ZIB6-40-10.0-20, ZIB6-40-10.0-30, ZIB6-40-10.0-40, ZIB6-40-10.0-60, ZIB6-40-10.0-80, ZIB6-40-12.0-40, ZIB6-40-12.0-60, ZIB6-40-12.0-80, ZIB6-40-14.0-40, ZIB6-40-14.0-60, ZIB6-40-14.0-80, ZIB6-80-4.0-80, ZIB6-80-5.0-20, ZIB6-80-5.0-30, ZlB6-80-5.0-40, ZIB6-80-5.0-60,		

			ZIB6-80-5.0-80, ZIB6-80-6.0-20, ZIB6-80-6.0-30, ZlB6-80-6.0-40, ZIB6-80-6.0-60, ZlB6-80-6.0-80, ZIB6-80-7.0-20, ZIB6-80-7.0-30, ZIB6-80-7.0-40, ZIB6-80-7.0-60, ZIB6-80-7.0-80, ZIB6-80-8.0-20, ZIB6-80-8.0-30, ZlB6-80-8.0-40, ZIB6-80-8.0-60, ZIB6-80-8.0-80, ZIB6-80-9.0-20, ZIB6-80-9.0-30, ZlB6-80-9.0-40, ZIB6-80-9.0-60,		

			ZIB6-80-9.0-80, ZIB6-80-10.0-20, ZIB-80-10.0-30, ZIB6-80-10.0-40, ZlB6-80-10.0-60, ZIB6-80-10.0-80, ZIB6-80-12.0-30, Z1B6-80-12.0-40, Z1B6-80-12.0-60, ZIB6-80-12. 0-80, Z1B6-80-14.0-30, Z1B6-80-14.0-40, ZIB6-80-14.0-60, ZIB6-80-14.0-80, ZIB6-125-4.0-80, ZIB6-125-5.0-20,ZIB6-125-5.0-30, Z1B6-125-5.0-40, Z1B6-125-5.0-60, ZIB6-		

			125-5.0-80, Z1B6-125-6.0-20, ZIB6-125-6.0-30, Z1B6-125-6.0-40, Z1B6-125-6.0-60, ZIB6-125-6.0-80, Z1B6-125-7.0-20, Z186-125-7.0-30, Z1B6-125-7.0-40, Z1B6-125-7.0-60, Z1B6-125-7.0-80, Z1B6-125-8.0-20, Z1B6-125-8.0-30, Z1B6-125-8.0-40, Z1B6-125-8.0-60,		

			Z1B6-125-8.0-80, Z1B6-125-9.0-20, Z1B6-125-9.0-30, Z1B6-125-9.0-40, Z1B6-125-9.0-60, Z1B6-125-9.0-80, Z1B6-125-10.0-20, Z1B6-125-10.0-30, Z1B6-125-10.0-40, Z1B6-125-10.0-60, ZIB6-125-10.0-80, ZIB6-125-12.0-30, ZIB6-125-12.0-40, ZIB6-125-12.0-60, ZIB6-125-12.0-80, ZIB6-125-14.0-		

			30, ZIB6-125-14.0-40, ZIB6-125-14.0-60, ZIB6-125-14.0-80. **Shelf life: 3 years** **Fee submitted: Rs. 50,000/-**		
94.	-do- **Evaluator:** Unum Zia Shamsi	Legal Manufacturer: BentleyInnoMed GmbH Lotzenacker 25, 72379 Hechingen, Germany Manufacturer Site: Bentley InnoMed GmbH Lotzenacker 25 D-723779 Hechingen,Germany FSC Germany issued on 23.04.2019	BeGraft Aortic Stent Graft System Class D BGA1912_1, BGA2912_1, BGA3912_1, BGA4912_1, BGA5912_1, BGA1912_2, BGA2912_2, BGA3912_2, BGA4912_2, BGA5912_2 BGA1914_1, BGA2914_1, BGA-3914_1, BGA-4914_1, BGA5914_1, BGA1914_2, BGA2914_2, BGA3914_2, BGA4914_2, BGA5914_2 BGA1916_1, BGA2916_1, BGA3816_1, BGA4816_1, BGA5816_1, BGA1916_2, BGA2916_2, BGA3816_2,	Indicated for the implantation in the native and/or recurrent coarcta-tion of the aorta on adolescent or adult patients. Sterile, single-use	Approved.

			BGA4816_2, BGA5816_2 BGA2918_2, BGA3818_2, BGA4818_2, BGA2720_2, BGA3720_2, BGA4820_2, BGA3722_2, BGA4822_2, BGA3724_2, BGA4824_2 Shelf life: 3 years Fee submitted: Rs. 50,000/-		
95.	-do- **Evaluator:** Unum Zia Shamsi	Legal Manufacturer: BentleyInnoMed GmbH Lotzenacker 25, 72379 Hechingen, Germany Manufacturer Site: Bentley InnoMed GmbH Lotzenacker 25 D-723779 Hechingen,Germany FSC Germany issued on 23.04.2019	BeGraft Peripheral Stent Graft System Class D BGP1805_1, BGP1806_1, BGP1807_1, BGP1808_1, BGP1809_1, BGP1810_1, BGP2205_1,BGP2206_1, BGP2307_1, BGP2805_1, BGP2806_1, BGP2707_1, BGP2708_1, BGP2709_1, BGP2710_1, BGP3805_1, BGP3806_1, BGP3707_1, BGP3708_1, BGP3709_1, BGP3710_1, BGP5805_1, BGP5806_1,	Indicated for intraluminal chronic placement in iliac and renal arteries for restoring and improving the patency and treating aneurysms, acute perforations, acute ruptures and fistulas. Sterile, single-use	Approved.

			BGP5707_1, BGP5708_1, BGP5709_1, BGP5710_1, BGP1805_2, BGP1806_2, BGP1807_2, BGP1808_2, BGP1809_2, BGP1810_2, BGP2205_2, BGP2206_2, BGP2307_2, BGP2805_2, BGP2806_2, BGP2707_2, BGP2708_2, BGP2709_2, BGP2710_2, BGP3805_2, BGP3806_2, BGP3707_2, BGP3708_2, BGP3709_2, BGP3710_2, BGP5805_2, BGP5806_2, BGP5707_2, BGP5708_2, BGP5709_2, BGP5710_2 Shelf life: 3 years Fee submitted: Rs. 50,000/-		
96.	-do- **<u>Evaluator:</u>** Unum Zia Shamsi	Legal Manufacturer: BentleyInnoMed GmbH Lotzenacker 25, 72379 Hechingen, Germany Manufacturer Site: Bentley InnoMed GmbH Lotzenacker 25 D-723779	**BeGraft Coronary Stent Graft System** Class D Codes: BG08250, BG12250, BG16250,	Indicated for transluminal implantation in coronary arteries or aorto-coronary bypass grafts for the treatment of acute	Approved.

		Hechingen,Germany FSC Germany issued on 23.04.2019	BG18250, BG21250, BG24250, BG08275, BG12275, BG16275, BG18275, BG21275, BG24275, BG08300, BG12300, BG16300, BG18300, BG21300, BG24300, BG08350, BG12350, BG16350, BG18350, BG21350, BG24350, BG08400, BG12400, BG16400, BG18400, BG21400, BG24400, BG16450, BG18450, BG21450, BG24450, BG16500, BG18500, BG21500, BG24500 Shelf life: 3 years Fee submitted: Rs. 50,000/-	perforation or rupture of coronary arteries.aneurysm of coronary arteries or coronary bypass-vein graft. Sterile, single-use	
97.	M/s. Al Waali Care Concepts, 86-Allama Iqbal Road, Chah Baba Shadiwal Street, Garhi	Manufacturer: Curatia Medical Limited. 198 Xiangjiang Road New District, Suzhou, Jiangsu, China, 215011.	Vela RX PTA Balloon Dilatation Catheter Codes as per US FDA FSC issued	Intended for use in percutaneous transluminal angioplasty (PTA) of the femoral	Approved subject to submission of Stability studies supporting the claimed shelf

	Shahu, Lahore **Evaluator:** Unum Zia Shamsi	FSC US FDA valid till 22.05.2021	on 22.5.2021 Class B Shelf life: 3 years Fee submittted: Rs. 25,000/-	popliteal, infra popliteal and renal arteries. Not for use in coronary vasculature and neuro-vasculature .	life and labels.
98.	M/s. Sadqain Health Care (Pvt) Ltd., Safari Villas II, Commercial Complex, 3rd Floor, Bahria Town, Phase 7, Rawalpindi. ELI-00020 **Evaluator:** Unum Zia Shamsi	**Manufacturer** M/s. Intersurgical Limited, Crane House, Molly Millars Lane, Wokingham, Berkshire, United Kingdom. FSC U.K issued on 01.03.2016	SILVER KNIGHT breathing system 1.6m (22mm Anti-microbial flextube breathing system) Class B Ref No. 2000100 Shelf Life: 5 years Fee submitted: Rs. 25,000/-	Breathing system to deliver and remove respiratory gases from a patient via a system of tubing and connectors. Single-use and non-sterile	Approved subject to submission of stability studies and Full Quality Assurance Certificate.
99.	M/s. Haji S. Ameer Din & Sons, 305-A, Upper Mall, Lahore. ELI-00059 **Evaluator:** Unum Zia Shamsi	Manufacturer: UNICOS Co, Ltd. 282-30, Munji-ro, Yuseong-Gu Daejeon,Korea FSC Korea issue date 08-04-2018	Unicos ULC-900 (LCD Chart) Class-A Service life: 7 years Fee submitted: Rs. 5,000/-	Digital chart that provide necessary chart for visual acuity measurement and images for additional explainations	Approved subject to submission of MRP, CE marked documents or inspection of manufacturer abroad.
100.	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:**	SOMATOM family (SHC) • SOMATOM go.All Part No. 11061630 • SOMATOM go.Top	Whole -body computer tomography scanner	Approved subject to Expert opinion from Dr. Muhammad Nadeem Ahmed, member MDB

	ELI-00146 **Evaluator:** Unum Zia Shamsi	M/s. Siemens Healthcare GmbH, Computed Tomography (CT), Siemensstr. 1, 91301 Forchheim, Germany. FSC Germany issued on 06.09.2018	Part No. 11061640 • SOMATOM go.Up Part No. 11061620 • SOMATOM go.Now Part no. 11061610 • SOMATOM Edge Plus Part No. 10267000 • SOMATOM Drive Part No. 10431700 • SOMATOM Confidence Part No. 10590100 • SOMATOM Force Part No. 10742326 • SOMATOM Definition Flash Part No. 10430603 • SOMATOM Definition Edge Part No. 10590000 • SOMATOM Definition AS Part No. 8098027 • SOMATOM Perspective (16/32 slice configuration) Part No. 10046734 • SOMATOM Perspective		and Mrs. Tazeen Bokhari, member MDB since the firm has applied multiple models on one application as FAMILY and MRP.

			(64/128 slice configuration) Part No. 10046733 • SOMATOM Scope (Power configuration) Part No. 10046799 Class C Service Life : 10 years Fee submitted: Rs. 50,000/-		
101.	-do- **Evaluator:** Unum Zia Shamsi	Legal manufacturer: Siemens Shanghai Medical Equipment Ltd (SSME), 278 Zhou Zhu Road, 201318 China Manufacturing site: Siemens Shanghai Medical Equipment Ltd (SSME), 278 Zhou Zhu Road, 201318 China FSC Germany issued on 2-11- 2018 FSC China valid till 2-1-2021	LUMINOS Family LUMINOS FUSION (VE10 l.l.) Part No. 10893488 LUMINOS FUSION (VE10 FD) Part No. 10893489 Class C Service Life: 10 years Fee submitted: Rs 50,000/-	X-ray diagnostic system	Approved subject to Expert opinion from Dr. Muhammad Nadeem Ahmed, member MDB and Mrs. Tazeen Bokhari, member greement, MRP and ISO 13485.
102.	-do- **Evaluator:** Unum Zia Shamsi	Legal manufacturer: Siemens Shanghai Medical Equipment Ltd (SSME), 278 Zhou Zhu Road, 201318 China Manufacturing site:	SOMATOM family (SSME) • SOMATOM go.All Part No. 11061638 • SOMATOM go.Top	Whole-body computer tomography scanner	Approved subject to Expert opinion from Dr. Muhammad Nadeem Ahmed, member MDB

		Siemens Shanghai Medical Equipment Ltd, CT facility, 278 Zhou Zhu Road, 201318 China FSC Germany issued on 21.06.2018	Part No 11061648 • SOMATOM go.Up Part No. 11061628 • SOMATOM go.Now Part No. 11061618 • SOMATOM Perspective Part No.10495568 • SOMATOM Perspective Part No. 10891666 • SOMATOM Scope Part No. 10967666 Class C Service Life : 10 years Fee submitted: Rs. 50,000/-		and Mrs. Tazeen Bokhari, member MDB since the firm has applied multiple models on one application as FAMILY and MRP and ISO 13485.
103.	-do- **<u>Evaluator:</u>** Unum Zia Shamsi	**Legal Manufacturer**: M/s Siemens Healthcare GmbH Henkestr 127 91052 Erlangen Germany **Manufacturing site:** M/s Siemens Healthcare GmbH Advanced Therapies Siemensstr. 1, 91301 Forchheim Germany FSC Germany issued on 11-1-2017	ARTS Q/Q zen Family • Artis Q Floor-10848280 • Artis Q ceiling-10848281 • Artis Q biplane-10848282 • Artis Q zen floor-10848353 • Artis Q zen ceiling-10848354	Stationary angiographic x-ray system, digital **Artis Q Floor**: Floor mounted system for interventional radiology **Artis Q ceiling:** Ceiling mounted system for inventional radiology	Approved subject to Expert opinion from Dr. Muhammad Nadeem Ahmed, member MDB and Mrs. Tazeen Bokhari, member greement, MRP.

			• Artis Q zen biplane-10848355 Class C Service Life: 10 years Fee submitted: Rs 50,000/-	**Artis Q biplane:** Biplane mounted system for inventional radiology **Artis Q zen floor:** Floor mounted system for interventional radiology **Artis Q zen ceiling:** Ceiling mounted system for inventional radiology **Artis Q zen biplane:** Biplane mounted system for inventional radiology	
104.	-do- **<u>Evaluator:</u>** Unum Zia Shamsi	Legal Manufacturer: M/s Siemens Healthcare GmbH Henkestr 127 91052 Erlangen Germany Manufacturing site: M/s Siemens Healthcare GmbH, Advanced Therapies Siemensstr. 1, 91301 Forchheim Germany FSC Germany issued on 11-1-2017	Artis Zee family • Artis zee floor-10094135 • Artis zee ceiling-10094137 • Artis zee multi-purpose-10094139 • Artis zee biplane-10094141 • Artis zeego-10280959	Stationay Angiographic x-ray system, digital **Artis zee floor**: Floor mounted system for interventional radiology **Artis zee ceiling-** Ceiling mounted system for	Approved subject to Expert opinion from Dr. Muhammad Nadeem Ahmed, member MDB and Mrs. Tazeen Bokhari, member MDB since the firm has applied multiple models on one application as

			Class C Service Life: 10 years Fee submitted: Rs 50,000/-	inventional radiology **Artis zee multi-purpose**- Multi-purpose system for fluoroscopy and angiography **Artis zee biplane**: Biplane mounted system for inventional radiology **Artis zeego**: Multi-axis system for inventional radiology	FAMILY and MRP.
105.	-do- **<u>Evaluator:</u>** Unum Zia Shamsi	Legal Manufacturer: M/s Siemens Healthcare GmbH Henkestr 127 91052 Erlangen Germany Manufacturing site: M/s Siemens Healthcare GmbH, X-Ray Products (XP) Siemensstr. 1, 91301 Forchheim, Germany FSC Germany issued on 11-1-2017 FSC Germany issued on 18-6- 2018	Luminos Family Luminos dRF Max-10762471 Luminos Agile Max-10762472 Class C Service Life: 10 years Fee submitted: Rs 50,000/-	X-ray system for whole body diagnosis	Approved subject to Expert opinion from Dr. Muhammad Nadeem Ahmed, member MDB and Mrs. Tazeen Bokhari, member greement, MRP and documents of Luminos Agile Max.
106.	M/s Lab Link Enterprises M-203, Block	**Manufacturer:** M/s PT. Nipro Indonesia Jaya,	Nipro Syringe Without Needle	Sterile, single-use syringe without needle	Approved subject to CE marked

	2, P.E.C.H.S Opp Ghousiya Masjid, Karachi. (ELI-00007) **Evaluator:** Unum Zia Shamsi	Kawasan Industri Suryacipta Jl. Surya Utama Kav. I 22B, 23 & 24 Desa Kutamekar, Kec. Ciampel, Karawang Jawa Barat, Indonesia (FSC Indonesia Valid Till 22-04-2020)	Class A Sizes:30ml, 50ml Shelf Life: 5 Years Fee submitted: Rs. 25,000/-		documents or inspection of manufacturer abroad.
107.	M/s S.Ejazuddin & Co., Zia Plaza, Altaf Hussain Road, Karachi (ELI-00078) **Evaluator:** Unum Zia Shamsi	**Manufacturer:** HemoCue AB, Kuvettgatan 1, Anglelholm, SE-262 71 Sweden (FSC Sweden valid till 25-05-2022)	HemoCue® Hb 301 Analyzer Article No 121802 Class B Shelf Life: N/A Fee submitted: Rs. 25,000/-	Portable device designed for quantitive point-of -care whole blood (capillary, venous and arterial) hemoglobin determination in primary care or blood donation settings	Approved.
108.	M/s Roche Pakistan Limited, 1st floor, 37-B, Block-6, P.E.C.H.S, Karachi. (ELI-00009) **Evaluator:** Unum Zia Shamsi	**Manufacturer:** Roche Diagnostics GmbH, Sandhofer Str. 116, 68305 Mannheim, Germany. **Manufacturing Site:** Roche Molecular System Inc., 1080 US Hwy 202, South Branchburg, NJ 08876 USA. (FSC Germany issued on 15-10-2018)	Cobas ® Kras Test Kit Class C Cobas ® Kras Mutation Test Sizes: 24 Tests Code 0582170190 Shelf Life: 24 Months Fee submitted: Rs. 50,000/-	Is a real-time PCR test for the detection of seven somatic mutaions in codons 12 and 13 of the KRAS gene in DNA derived from formalin-fixed paraffin embedded human colorectal cancer (CRC) tumor tissue. For use with the cobas ® 4800 System,	Approved.

109.	-do- **Evaluator:** Unum Zia Shamsi	**Manufacturer:** Roche Diagnostics GmbH, Sandhofer Str. 116, 68305 Mannheim, Germany. **Manufacturing Site:** Roche Molecular Systems Inc., 1080 US Hwy 202, South Branchburg, NJ 08876 USA. (FSC Germany issued on 09-07-2019) (FSC Germany issued on 15-10-2018)	Cobas® EGFR Mutation Test V2 Kit Class C Cobas® EGFR Mutation Test V2 Size: 24 Tests Code: 07248563190 Shelf Life: 24 Months Cobas® cfDNA Sample Preparation Kit Sizes: 24 Tests Code: 07247737190 Shelf Life: 24 Months Fee submitted: Rs. 50,000/-	A real time PCR test for the qualitative detection of defined mutations of the epidermal growth factor receptor (EGFR) gene in non small cell lung cancer (NSCLC) patients. Defined EGFR mutations using DNA isolated from formalin-fixed paraffin embedded tumor tissue (FFPET) or circulating free tumor DNA (cfDNA) from plasma derived from EDTA anti-coagulated peripheral whole blood.	Approved.
110.	-do- **Evaluator:** Unum Zia Shamsi	**Manufacturer**: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany (FSC Germany issued on 15-03-2017) (FSC Germany issued on 22-02-2018)	Cobas ® Thyroid Cluster Class B 1. cobas Elecsys T3 Size: 200 Tests Code: 11731360122 Shelf life: 18 months	1. Immunoassay for the in vitro quantitative determination of total triiodothyronine in human serum and plasma. 2. Immunoassay for the in vitro	Approved subject to differential fee.

			2. cobas Elecsys T3 Size: 300 Tests Code: 07027869190 Shelf life: 18 months 3. cobas Elecsys T3 Calset Code: 11731548122 Shelf life: 24 months 4. cobas Elecsys T4 Size : 200 Tests Code : 12017709122 Shelf life: 18 months 5. cobas Elecsys T4 Size:300 Tests Code: 07027885190 Shelf life: 18 months 6. cobas Elecsys T4 Calset Code:12017717122 Shelf life: 18 months 7. cobas Elecsys FT3 III Size: 200 Tests Code: 06437206190 Shelf life: 18 months 8. cobas Elecsys FT3 III	quantitative determination of total triiodothyronine in human serum and plasma 3. T3 CalSet is used for calibrating the quantitative Elecsys T3 assay on the Elecsys and cobas e immunoassay analyzers 4. Immunoassay for the in vitro quantitative determination of thyroxine in human serum and plasma. 5. Immunoassay for the in vitro quantitative determination of thyroxine in human serum and plasma. 6. T4 CalSet is used for calibrating the quantitative Elecsys T4 assay on the Elecsys and cobas e immunoassay analyzers 7. Immunoassay for the in vitro quantitative determination	

			Size: 300 Tests Code: 07027362190 Shelf life: 18 months 9. Roche cobas Elecsys FT3 III Calset Code: 06437222190 Shelf life: 18 months 10. cobas Elecsys FT4 II Size:300 Tests Code:07027397190 Shelf life: 18 months 11. cobas Elecsys FT4 II Calset Code: 06437290190 Shelf life: 18 months 12. cobas Elecsys FT4 III Size:200 Tests Code:07976836190 Shelf life: 15 months 13. cobas Elecsys FT4 III Calset Code:07976879190 Shelf life: 18 months 14. cobas Elecsys TSH Size:400 Tests Code:117314591	of free triiodothyronine in human serum and plasma. 8. Immunoassay for the in vitro quantitative determination of free triiodothyronine in human serum and plasma. 9. FT3 III CalSet is used for calibrating the quantitative Elecsys FT3 III assay on the Elecsys and cobas e immunoassay analyzers. 10. Immunoassay for the in vitro quantitative determination of free thyroxine in human serum and plasma. 11. FT4 II CalSet is used for calibrating the quantitative Elecsys FT4 II assay on the Elecsys and cobas e immunoassay analyzers 12. Immunoassay	

			22 Shelf life: 18 months 15. cobas Elecsys TSH Size:300 Tests Code:07028091190 Shelf life: 18 months 16. cobas Elecsys TSH Calset Code: 04738551190 Shelf life: 18 months 17. cobas PreciControl Thyro Sensitive Code:06445918190 Shelf life: 36 months 18. cobas Elecsys Tg Size:100 Tests Code:06445896190 Shelf life: 15 months 19. cobas Elecsys Tg Calset Code:06445900190 Shelf life: 18 months 20. cobas Elecsys T-Uptake Size:100 Tests Code:07028105190 Shelf life: 18	for the in vitro quantitative determination of free thyroxine in human serum and plasma. 13. CalSet FT4 III is used for calibrating the quantitative Elecsys FT4 III assay on the Elecsys and cobas e immunoassay analyzers. 14. Immunoassay for the in vitro quantitative determination of thyrotropin in human serum and plasma. 15. Immunoassay for the in vitro quantitative determination of thyrotropin in human serum and plasma. 16. TSH CalSet is used for calibrating the quantitative Elecsys TSH assay on the Elecsys and cobas e immunoassay analyzers. 17.	

			months 21. cobas Elecsys T-Uptake Size:200 Tests Code:11731394122 Shelf life: 18 months 22. cobas Elecsys T-Uptake Calset Code:06528309190 Shelf life: 24 months	PreciControl Thyro Sensitive is used for quality control of the Elecsys TSH and Elecsys Tg II immunoassays on the Elecsys and cobas e immunoassay analyzers 18. Immunoassay for the in vitro quantitative determination of thyroglobulin in human serum and plasma. Determination of Tg is used as an aid in monitoring after thyroid ablation. 19. Tg II CalSet is used for calibrating the quantitative Elecsys Tg II assay on the Elecsys and cobas e immunoassay analyzers. 20. Immunoassay for the in vitro quantitative determination of thyroxine-binding capacity (TBC	

				or T-uptake) in human serum and plasma. 21. Immunoassay for the in vitro quantitative determination of thyroxine-binding capacity (TBC or T4-uptake) in human serum and plasma. 22. T-Uptake CalSet is used for calibrating the quantitative Elecsys T-Uptake assay on the Elecsys and cobas e immunoassay analyzers	
111.	-do- **<u>Evaluator:</u>** Unum Zia Shamsi	**Manufacturer:** Roche Diagnostics GmbH, Sandhofer Str. 116, 68305 Mannheim, Germany. **Manufacturing Site:** Roche Diagnostics GmbH, Sandhofer Str. 116, 68305 Mannheim, Germany. (FSC Germany issued on 15-3-2017) (FSC Germany issued on 22-02-2018)	Cobas® Elecsys Thyroid antibodies and Anti-CCP Cluster Class B 1. Anti-TSHR Shelf Life: 18 Months Size 100 Tests Code: 04388780 2. Anti-TSHR Shelf Life: 18 Months Sizes: 300 Test Code: 07026951190	1. Immunoassay for the in vitro quantitative determination of autoantibodies to TSH receptor in human serum using a human thyroid stimulating monoclonal antibody. The anti-TSH receptor determination is used as an aid in the differential	Approved subject to differential fee.

			3. Anti-TPO Shelf Life: 15 months Sizes 100 Test Code: 06368590 4. Anti-TPO Shelf Life: 15 months Sizes 300 Test Code: 07026935190 5. Anti-TPO Calset Shelf Life: 18 Months Code: 06472931 6. Anti-TG Shelf Life: 15 Months Size: 100 Tests Code: 06368697 7. Anti-TG Shelf Life: 15 Months Sizes: 300 Tests Code" 07026919190 8. Anti-TG CalSet Shelf Life: 15 Months Code: 06368603 9. PreciControl Thyro AB Shelf Life: 15 Months Size: 100 Tests Code: 05042666 10.Anti-CCP Shelf Life: 7 Months	diagnosis of Graves' disease. 2-Immunoassay for the in vitro quantitative determination of autoantibodies to TSH receptor in human serum using a human thyroid stimulating monoclonal antibody. The anti-TSH receptor determination is used in the assessment of patients with suspect Graves' disease (autoimmune hyperthyroidism). 3-Immunoassay for the in vitro quantitative determination of antibodies to thyroid peroxidase in human serum and plasma. The anti-TPO determination is used as an aid in the diagnosis of autoimmune	

			Size: 100 Tests Code: 05031656 11.Anti-CCP Shelf Life: 7 Months Size: 100 Tests Code: 07251670190 12. PreciControl Anti-CCP Shelf Life: 36 Months Code: 05031664	thyroid diseases. 4- Immunoassay for the in vitro quantitative determination of antibodies to thyroid peroxidase in human serum and plasma. The anti-TPO determination is used as an aid in the diagnosis of autoimmune thyroid diseases 5- Anti-TPO CalSet is used for calibrating the quantitative Elecsys Anti-TPO assay on the Elecsys and cobas e immunoassay analyzers. 6- Immunoassay for the in vitro quantitative determination of antibodies to thyroglobulin in human serum and plasma. The anti-Tg determination	

				is used as an aid in the detection of autoimmune thyroid diseases. 7- Immunoassay for the in vitro quantitative determination of antibodies to thyroglobulin in human serum and plasma. The anti-Tg determination is used as an aid in the detection of autoimmune thyroid diseases. 8- Anti-Tg CalSet is used for calibrating the quantitative Elecsys Anti-Tg assay on the Elecsys and cobas e immunoassay analyzers. 9- PreciControl ThyroAB is used for quality control of the Elecsys Anti-TSHR, Anti-TPO and Anti-Tg	

				immunoassays on the Elecsys and cobas e immunoassay analyzers. 10-Immunoassay for the in vitro semi-quantitative determination of human IgG autoantibodies to cyclic citrullinated peptides in human serum and plasma. The results of the assay are intended to be used as an aid in the diagnosis of rheumatoid arthritis in combination with other clinical and laboratory findings. 11-Immunoassay for the in vitro semi-quantitative determination of human IgG autoantibodies to cyclic citrullinated peptides in human serum and plasma. The results of the assay are	

				intended to be used as an aid in the diagnosis of rheumatoid arthritis in combination with other clinical and laboratory findings. 12-PreciControl Anti-CCP is used for quality control of the Elecsys Anti-CCP immunoassay on the Elecsys and cobas e immunoassay analyzers.	
112.	M/s La-Vie (Pvt) Ltd Behind PSO Petrol Pump, Peco Road, Kot Lakhpat, Lahore (ELI:00113) **Evaluator:** Unum Zia Shamsi	Manufacturer: M/s Betatech Medikal Cihazler Sanayi, Mumessillik Ic ve, Dis, Tic. Ltd. Sti. Iki Telli Organize Sanayi Bolgesi, Ataturk Oto Sanayi Sitesi, 22 Sok Unal Is Merkezi No.9/Basaksehir/Istanbul, Turkey FSC Turkey valid till 3-12-2021 FSC MHRA issued on 19-01-2019	Betamix® Adhesion Barrier Gel ABG01-ABG105-ABG02-ABG205-ABG03-ABG305-ABG04-ABG05-ABG705-ABG10-ABG15-ABG20 Class-D Shelf Life: 2 years Fee submitted: Rs. 50,000/-	Clear, sterile, single use flowable cross-linked sodium hyaluronate gel thats used during different surgeries to help prevent adhesion, or internal scar tissue formation. Acts as a temporary, protective barrier to separate tissues and reduce fibrosis and formation	Approved subject to submission of stability studies and MRP.

				of post surgical adhesions	
113.	M/s. Pharma Consultant Pakistan (Pvt) Ltd., Suit NO. 207, 207 A Khan Tower, DHA Square Walton Road, Lahore. **Evaluator**: Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s. LivaNova USA, Inc. 14401 West 65th Way Arvada, CO 80004 USA. FSC USFDA Valid till October 18, 2020	**LivaNova Cardioplegia Solution Administration Adapters** Codes & Sizes as Per FSC of USFDA Class C Shelf Life : 05 years	The Adapter is indicated for use during cardiopulmonary bypass surgery for connecting deliver, recirculating cardioplegia solutions.	Approved.
114.	-do- **Evaluator**: Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s. LivaNova USA, Inc. 14401 West 65th Way Arvada, CO 80004 USA. FSC USFDA Valid till October 18, 2020	**LivaNova Ventricular Vent Catheters** Codes & Sizes as Per FSC of USFDA Class C Shelf Life : 03 years	Ventricular Vent Catheters	Approved.
115.	M/s Nasir Brothers, 22B, 2nd Floor, Zeenat Medicine Market, North Napire Road, Karachi (ELI-00036) **Evaluator**: Abdul Waheed	**Manufacturer:** Jiangsu Kanbao Medical Equipment Co Ltd, No 78, North Suzhong Road, Baoying 225800, Yangzhou, Peoples Republic of China (FSC OF CHINA ISSUED 20-02-2021`)	I.V Cannula Pen Type(Only considered) I.V cannula butterfly wingtype with instopper I.V Cannula injection Port type. Class B FEE SUBMITTED RS 25000 Shelf Life: 5 Years	I.V Cannula is mainly applicable for clinical infusion to peripheral vessels systems	**Approved subject to submission of MRP, original FSC, EC Certificte and ISO 13485.**

			Sizes & Codes as Per FSC Rs. 25,000		
116.	-do- **Evaluator**: Abdul Waheed	**Legal Manufacturer:** Changzhou Hekang Medical Instruments Co Ltd, Room 1106 Xin Hui mansion 301 Tongjinag Central Road, Changzhou 213022, China. (FSC Issue 31-12-2018)	Healthcare micro drip extension tube Micro drip extension tube Class B Shelf Life: 5Years Fee Rs .25000 Sizes & Codes as Per FSC Rs. 25,000	The Micro Drip extension tube is made of non-toxic polypropylene or other polymer materils	Approved subject to submission of MRP, agency agreement, attested FSC and DOC.
117.	M/s Johnson & Johnson (Pvt) Ltd., Office No.806, 8th Floor, Horizon Towers, Block 3, Scheme 5, Clifton, Karachi (ELI-00154) **Evaluator**: Unum Zia Shamsi	**Legal Manufacturer/Manufacturing site:** Ethicon, LLC. Highway 183 Km. 8.3 San Lorenzo, PR USA 00754 (FSC USFDA valid till 10-04-2020)	Ethicon® Mersilene™ Tape Code: RS22 Class C Shelf Life: 60 Months Fee submitted: 50,000/-	Sterile, single-use, non-absorbable tape indicated for circular suture of the cervix and as retraction and/or fixing tape during surgery.	Approved subject to submission of MRP.
118.	-do- **Evaluator**: Unum Zia Shamsi	**Legal Manufacturer/Manufacturing site:** Ethicon, LLC. Highway 183 Km. 8.3 San Lorenzo, PR USA 00754	Surgicel® Fibrillar™ Absorbable Haemostat Class D Codes:	Oxidized regenerated cellulose used adjunctively in surgical procedures to assist in the control of	**Approved subject to submission of MRP and stability studies.**

		(FSC USFDA valid till 13-12-2019)	411961 411962 411963 (Code as per DOC not on FSC) Shelf Life: 36 Months Fee submitted: Rs. 50,000/-	capillary, venous, and small arterial hemorrhage when ligation or other conventional methods of control are impractical or ineffective.	
119.	M/s Usmanco International, 220, Block: 3, DMCHS, S. Abdul Tawwab Road, Karachi. (ELI-00121) **Evaluator:** Abdul Waheed	**Legal Manufacturer:** Bicakcilar Global TibbiChazlarsanayiGazi Cad. No.21 Esenyurt 34522 Istanbul / Turkiye. (FSC Turkeyvalid 11-08-2017)	Suction Catheter w/Kapkon Suction Catheter W/ Kapkon Class B FEE SUBMITTED RS 25000 Shelf Life: 5 Years (Sizes & Codes as Per FSC) 6, 8 , 10, 12, 14, 16 & 18ch **Rs.25,000/-**	Suction Catheter is a single use, sterile medical devices, consisting of a flexible tube which can be fitted with a connector to a drainage system for introduction into a respiratory tract to remove fluids/ material by suction IFU attached.	Approved subject to submission of agency agreement, CE marked documents or inspection of manufacturer abroad.
120.	-do- **Evaluator:** Abdul Waheed	**Legal Manufacturer:** Bicakcilar Global TibbiChazlarsanayiGazi Cad. No.21 Esenyurt 34522 Istanbul / Turkiye. (FSC Turkey valid 11-08-2017)	BCAT2 I.V Cannula with injection port Class B FEE SUBMITTED RS 25000 Shelf Life: 5 Years (Sizes & Codes	Single use, Sterile, over the needle peripheral intravascular catheter designed for the introduction or withdrawal of liquids into or from the peripheral vascular system	Approved subject to submission of agency agreement and stability studies**,** CE marked documents or inspection of manufacturer abroad. **Already Approved in**

			as Per FSC) G-14 to G-16, G-18 to G-20, G-22 & G-24 **Rs.25,000/-**	injection port option with one way valve and color coded cap for intermittent and safe administration of drug infusion.	**M-15.**
121.	-do- **Evaluator:** Abdul Waheed	**Legal Manufacturer:** Bicakcilar Global TibbiChazlarsanayiGazi Cad. No.21 Esenyurt 34522 Istanbul / Turkiye. (FSC Turkey valid 11-08-2017)	BCAT I.V Cannula with stopper Class B FEE SUBMITTED RS 25000 Shelf Life: 5 Years (Sizes & Codes as Per FSC) G-14, G-16, G-18 G-20, G-22 & G-24 **Rs.25,000/-**	Single use, Sterile, over the needle peripheral intravascular catheter designed for the introduction or withdrawal of liquids into or from the peripheral vascular system with blood stopper highly transparent flashback chamber for instant blood back flow indicating vessel entry	**1** Approved subject to submission of stability studies, agency agreement, CE marked documents or inspection of manufacturer abroad.
122.	-do- **Evaluator:** Abdul Waheed	**Legal Manufacturer:** Bicakcilar Global TibbiChazlarsanayiGazi Cad. No.21 Esenyurt 34522 Istanbul / Turkiye. (FSC Turkeyvalid 11-08-2017)	Nasogastric Catheter Nasogastric Catheter-levin with radiopaque line 123 cm Class B Shelf Life: 5 Years (Sizes & Codes	Nasogastric Catheter is used for transient stomach drainage.	Approved subject to submission of stability studies, specimen of label, CE marked documents or inspection of manufacturer abroad.

			as Per FSC) 12CH, 14CH, 16CH, 18CH, 20CH **Rs.25,000/-**		
123.	M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi (ELI-00019) **Evaluator:** Shahid Muhammad Iqbal	**Manufacturer** Fujirebio Diagnostics, Inc. 201, Great Valley Parkway Malvern, PA USA 19355 Fujirebio Diagnostics, Inc. 940 Crossroads Blvd Seguin, TX USA 78155 FSC USA Validity 24-05-2020, 23-01-2022	ARCHITECT Cyclosporine **ARCHITECT Cyclosporine Calibrators 1L75-01** **ARCHITECT Cyclosporine Reagent Kit 1L75-25** **ARCHITECT Cyclosporine whole Blood Precipitation Reagent Kit 1L75-55** Class C Shelf Life : 12 Months	Intended for quantitative determination of cyclosporine in human whole blood.	Approved subjet to Embassy attested FSC.
124.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Manufacturer:** Fujirebio Diagnostics, Inc. 201, Great Valley Parkway Malvern, PA USA 19355 Fujirebio Diagnostics, Inc. 940 Crossroads Blvd Seguin, TX USA 78155 FSC USA Validity 24-05-2020, 23-01-2022	ARCHITECT Tacrolimus **ARCHITECT Tacrolimus Calibrators 1L77-01** **ARCHITECT Tacrolimus Reagent Kit 1L77-25** **ARCHITECT Tacrolimus Whole blood Percipitation Reagent**	Assay for the quantitative determination of tacrolimus in human whole blood.	Approved subjet to Embassy attested FSC.

			1L77-55 Class C Shelf Life: 18 Months		
125.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Manufacturer** Fujirebio Diagnostics, Inc. 201, Great Valley Parkway Malvern, PA USA 19355 Fujirebio Diagnostics, Inc. 940 Crossroads Blvd Seguin, TX USA 78155 FSC USA Validity 24-05-2020, 23-01-2022	ARCHITECT Sirolimus **ARCHITECT Sirolimus Calibrators 1L76-01** **ARCHITECT Sirolimus Reagent kit 1L76-25** **ARCHITECT Sirolimus whole blood Percipitation reagent 1L76-55** Class C Shelf Life: 18 Months	Assay for the quantitative determination of Siromlimus in human whole blood.	Approved subjet to Embassy attested FSC.
126.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** Mircogenics Corporation 46500 Kato Road, Fremont, CA USA 94538 FSC USA Validity 06-11-2020	Abbott Gentamicin Class C 1E11-20 Gentamicin Shelf Life: 12 month	Intended for the quantitative determination of gentamicin in human serum or plasma on the architect system.	Approved subjet to Embassy attested FSC.
127.	-do- **Evaluator:** Shahid	**Legal Manufacturer:** Abon Biopharm	ABON™ **Multi-Drug One Step Screen Test Panel**	Multiple Drugs of Abuse/Toxicology Rapid	Approved subject to submission of MRP and

	Muhammad Iqbal	(Hangzhou) Co., Ltd. # 198 2th Street East, Hangzhou Economic & Technological Development Area, Hangzhou, 310018 P.R. China. FSC Germany Issuance 21-03-2019 FSC China Validity 24.02.2020 Certificate of Export China Validity 08.01.2020 FSC China Validity 17.10.2019	**(Urine)** **DOA-124** **DOA-134** **DOA-144** **DOA-154** **DOA-164** **DOA-174** **DOA-184** **DOA-194** **DOA-1104** **DOA-1114** **DOA-1124** Class B Shelf Life: 24 Months	Test **DOA-124** Cocaine, Marijuana **DOA-134** Cocaine, Amphetamine, Marijuana **DOA-144** Cocaine, Amphetamine, Marijuana, Benzodiazepines **DOA-154** Methampheta mine, Marijuana, Opiate, Benzodiazepin es, Buprenorphin e **DOA-164** Cocaine, Amphetamine, Methampheta mine, Marijuana, Opiate, Benzodiazepin es **DOA-174** Cocaine, Amphetamine, Marijuana, Morphine, Tramadol, Barbiturates, Benzodiazepin es **DOA-184** Cocaine, Amphetamine, Methampheta mine,Marijuan a, Opiate, Tramadol,	differential fee for cluster.

				Benzodiazepines, K2 (synthetic cannabinoids) **DOA-194** Cocaine, Amphetamine, Methamphetamine,Marijuana, Methadone, Morphine, Phencyclidine, Barbiturates, Benzodiazepines **DOA-1104** Cocaine, Amphetamine, Methamphetamine,Marijuana, Methadone, Morphine, Phencyclidine, Barbiturates, Benzodiazepines, Tricyclic Antidepressants **DOA-1114** Cocaine, Amphetamine, Methamphetamine,Marijuana, Methadone, Ecstasy, Morphine, Barbiturates, Benzodiazepines, Tricyclic Antidepressants K2 (synthetic cannabinoids) **DOA-1124** Cocaine, Amphetamine, Methamphetamine,Marijuana, Methadone,	

				Ecstasy, Morphine, Opiate, Phencyclidine, Barbiturates, Benzodiazepines, Tricyclic Antidepressants	
128.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** Abon Biopharm (Hangzhou) Co., Ltd. # 198 2th Street East, Hangzhou Economic & Technological Development Area, Hangzhou, 310018 P.R. China. FSC Germany Issuance 21-03-2019 FSC China Validity 24.02.2020 FSC China Validity 04.06.2019	ABON™ **hCG One Step Pregnancy Test Strip (Urine) FHC-101** **hCG One Step Pregnancy Test Device (Urine) FHC-102** **hCG One Step Pregnancy Test Strip (Urine/Serum) FHC-201** **hCG One step Pregnancy Test Device (Urine/Serum) FHC-202** **Early Detection One Step Pregnancy Test Urine) FHC-103** Class B Shelf Life:24 Months	The hCG One step pregnancy test Strip(Urine) is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin for early detection of pregnancy.	Approved subject to submission of differential fee for cluster.
129.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** Abon Biopharm (Hangzhou) Co., Ltd. # 198 2th Street East,	ABON™ **Multi-Drug One Step Multi-Line Screen Test Device (Urine) DOA-125,**	Multiple Drugs of Abuse/Toxicology Rapid Test	Approved subject to submission of MRP and differential fee for cluster.

		Hangzhou Economic & Technological Development Area, Hangzhou, 310018 P.R. China. FSC Germany Issuance 21-03-2019 Certificate of Export China Validity 08.01.2020	**DOA-135, DOA-145, DOA-155, DOA-165, DOA-175, DOA-185, DOA-195, DOA-1105, DOA-1115, DOA-1125** Class B Shelf Life: 24 Months	**DOA-125** Morphine, Marijuana **DOA-135** Amphetamine, Morphine, Marijuana **DOA-145** Amphetamine, Morphine, Methampheta mine,Marijuan a **DOA-155** Amphetamine, Cocaine, Morphine, Marijuana, Benzodiazepin e **DOA-165** Methampheta mine,Ampheta mine, Cocaine, Morphine, Marijuana, Benzodiazepin e **DOA-175 DOA-185, DOA-195, DOA-1105** Methampheta mine,Ampheta mine, Cocaine, Morphine, Marijuana, Benzodiazepin e, Tricyclic Antidepressan ts, Barbiturates, Ecstasy, Methadone **DOA-1115, DOA-1125**	

				Methampheta mine,Ampheta mine, Cocaine, Morphine, Marijuana, Benzodiazepin e, Tricyclic Antidepressan ts, Barbiturates, Ecstasy, Methadone, Opiate, Phencyclidine **DOA-1135**	
130.	M/s Imtiaz Brothers Suite No 7B, 2nd Floor, Abrar Business Center, 25-Mian Wahdat Road Lahore ELI- 00133 **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** M/s Changzhou Kangxin Medical Insturments Co., Ltd Qiuzhuang, Luoxi town Xinbei District , Changzhou, Jiangsu, China FSC China Validity 19.03.2020	KANGXIN Extracorporeal Circuit auxiliary Cannulae (Venous Cannulae) Sizes according to FSC Class D Shelf Life 03 years **Rs.25,000/-**	In cardiac operation under direct vision, it can be inserted into the vein for blood flow in extracorporeal circulation.	Approved subject to submission of Valid Full Quality Assurance, EPSP and Stability studies, verification of CE marked documents or inpection of manufacturer abroad.
131.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** M/s Changzhou Kangxin Medical Insturments Co., Ltd Qiuzhuang, Luoxi town Xinbei District , Changzhou, Jiangsu, China FSC China Validity 19.03.2019	KANGXIN Extracorporeal Circuit auxiliary Cannulae (Aortic Root Cannulae) Sizes according to FSC Class D Shelf Life 03 years	In cardiac operation under direct vision, the perfusion cannula is inserted into root of aorta which could arrest liquid perfused.	Approved subject to submission of Valid Full Quality Assurance, EPSP and Stability studies, verification of CE marked documents or inpection of manufacturer

			Rs.25,000/-		abroad.
132.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** M/s Changzhou Kangxin Medical Insturments Co., Ltd Qiuzhuang, Luoxi town Xinbei District , Changzhou, Jiangsu, China FSC China Validity 19.03.2019	KANGXIN Extracorporeal Circuit auxiliary Cannulae (Vents) Sizes according to FSC Class D Shelf Life:03 years **Rs.25,000/-**	In cardiac operation for attracting the blood in left atrium through a trail sepal or upper lung vein, inserting in left atrium.	Approved subject to submission of Valid Full Quality Assurance, EPSP and Stability studies, verification of CE marked documents or inpection of manufacturer abroad.
133.	M/s Kiswa Cares Office NO. 7, 1st Floor Gul Plaza Chandni Chowk Rawalpindi. ELI-00211 **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer & Manufacturing Site:** Eye Kon Medical Inc. 2451 Enterprise raod Clearwater FL 33763, USA Certificate of Exportability USA Validity 12.02.2020 FSC UK Isusuance: 18-02-2019	**ISOTECHNICS HPMC VISCOELASTICS** **ISo Gel,** **Iso GelPlus** Class C Shelf Life 02 years **Rs.50,000/-**	HPMC Viscoelastic is indicated for use as an ophthalmic surgical aid in the anterior segment in patients undergoing cataract extraction and IOL implantation.	Approved subject to Full Quality Assurance Certificate.
134.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer & Manufacturing Site:** EyeKon Medical Inc. 2451 Enterprise raod Clearwater FL 33763, USA	ISOTECHNICS **Hydrophilic Acrylic Posterior chamber Intraocular Lenses** Models: HP25B,	Hydrophilic Acrylic Posterior chamber Intraocular Lenses	Approved subject to Full Quality Assurance Certificate.

		Certificate of Exportability USA Validity 12.02.2020 FSC UK Issuance 18.02.2019	HP25BNY, Class C Shelf Life 05 years **Rs.50,000/-**		
135.	AK Pharma (Pvt) Limited Plot No. SXLI-1-S, Building No. 2557, Floor No. 2, Firdous Market, Gulberg-III, Lahore. (ELI- 00360) **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** AK Pharma INC 12203 SW 131 AVE Miami, FL 33186 USA . FSC USA Issuance 13-05-2019	**Eikonha Cross Linked Sodium Hyaluronate 20mg/ml gel** **ADFB001 ADFB002** Class D Shelf Life: 2 Years **Rs.50,000/-**	Injectable Hyaluronic acid for cosmetic body shaping procedures: Areas for application include: • Trauma/Surgical scars • Buttock Volume • Aesthetic Gynecology • Chest shaping • Body Depressions • Calves Shaping/ Augmentation.	Approved subject to agency agreement, Embassy attested FSC, Notarized Full Quality Assurance Certificate and Design Exam Certificate.
136.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** AK Pharma INC 12203 SW 131 AVE Miami, FL 33186 USA . FSC USA Issuance 13-05-2019	**Prizmah PRP PlateletRich Plasma of Vacuum Blood collection Tube** EQP008-Kit-1 EQP009-Kit-2 EQP008B-Kit-1 EQP009A-Kit-2 Class C	The Prizmah kit is designed to be used for the safe and rapid preparation of autologous platelet-rich plasma (PRP) from a small sample of blood at the patient's point	Approved subject to agency agreement, Embassy attested FSC, Notarized Full Quality Assurance Certificate and differential fee of Rs. 25000/-.

			Shelf Life: 2 Years **Rs.25,000/-**	of care. Prizmah can be used for wound management, orthopedics, dentistry,gynecology, sports medicines, surgery and Aesthetic applications.	
137.	M/s Zenith International, Room No. 104, Tahir Plaza, A/20, Block 7&8, KCHSU, Karachi (ELI-00090) **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer & Manufacturing Site:** Huaian Angel Medical Instrument Co., Ltd. 19 East Zhuhai Road, Huaian, 223001 Jiangsu, China. FSC Germany Validity 06-05-2019 FSC China Validity 01-02-2020	Perfect Fine Polyglactin 910 (PGLA 910) Absorbable Surgical Suture, Model: USP8/0-3, Point Type: round bodied, cutting Type of needle shape: ½ circle, 3/8 circle, straight cutting Class D Shelf Life: 3 Years **Rs.50,000/-**	Polyglactin 910 absorbable Surgical Suture is indicated for use in general soft tissue approximation and or ligation including use in ophthalmic procedures; plastic surgery; subcuticular; Obstetrics; gynecology and hepatic surgeries.	Approved subject to stability studies, ISO 13485 and Notarized Full Quality Assurance Certificate.
138.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer & Manufacturing Site:** Huaian Angel Medical Instrument Co., Ltd. 19 East Zhuhai Road, Huaian, 223001 Jiangsu, China. FSC Germany Validity 06-05-2019	Perfiect Fine Polypropylene (Monofilament) Non-absorbable Surgical Suture, USP10/0-3, round bodied, cutting. Shelf Life: 5 Years Class C	A Single-Strand Synthetic, non-absorbable thread used to join the edges of a soft tissue wound or incision by stitching or to ligate soft tissues.	Approved subject to ISO 13485 and Full Quality Assurance Certificate and manufacturing labels.suture. labels

		FSC China Validity 01-02-2020	**Rs.50,000/-**		
139.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer & Manufacturing Site:** Huaian Angel Medical Instrument Co., Ltd. 19 East Zhuhai Road, Huaian, 223001 Jiangsu, China. FSC Germany Validity 06-05-2019 FSC China Validity 01-02-2020	Perfect Fine Silk Braided Non-Absorbable Surgical Suture, USP6/0-2, Round bodied cutting. Class C Shelf Life: 5 Years **Rs.50,000/-**	A Sterile Non –absorbable thread made from raw silk and is used to join the edges of a soft tissue wound or incision by stiching or to ligate soft tissues. This is a single use device.	Approved subject to ISO 13485 and Full Quality Assurance Certificate and manufacturing labels.suture. Labels**.**
140.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer & Manufacturing Site:** Huaian Angel Medical Instrument Co., Ltd. 19 East Zhuhai Road, Huaian, 223001 Jiangsu, China. FSC Germany Validity 06-05-2019 FSC China Validity 01-02-2020	Perfect Fine Disposable Surgical Blades with plastic handle 10, 11, 12, 15, 20, 21, 22, 23, 24 Class B Shelf Life: 5 Years **Rs.25,000/-**	Surgical Blade (Carbon Steel) are used for cutting skin and tissue during surgicfal procedures.	Approved subject to submission of labels.
141.	M/s. GENOME PHARMA, House No. 166-A, Street NO,9, Chaklala Scheme-III, Rawalpindi. ELI- 00267	**Legal Manufacturer &Manufacturing Site:** Innate SRL,Viale Industria 11-13, 15067 Novi Ligure, (AL), Italy FSC-Italy	**Promovia 80mg/4ml Sodium Hyaluronate 2% for inra-articular use** Class D	Sodium Hyaluronate 2% for inra-articular use.	Approved.

	Evaluator: Shahid Muhammad Iqbal	Issuance: 19.06.2019	Shelf Life: 36 months **Rs.50,000/-**		
142.	M/s JK Traders Suite No. 13, 2nd Floor, Majeed Plaza, Bank Road Saddar Rawalpindi. ELI-00014 **Evaluator:** Shahid Muhammad Iqbal	**Manufacturer:** Xiamen New Concept Medical Technology Co., Ltd Floor 1-2, No.7 Haicang Biomedicine Building No.2026, West Wengjiao Road Haicang disctrict, Xiamen, Fujian, China Certificate of Export: China validity: 04-12-2019 FSC China validity: 02-06-2021 FSC Spain Issuance: 11-07-2019	NCMT **INTRODUCER SHEATH SETS** **DQ-A-5F** **DQ-A-6F** **DQ-A-7F** Class B Shelf life 3 years	INTRODUCER SHEATH SETS	Approved subject to notorized credentials, stability studies and Full Quality Assurance Certificate.
143.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Manufacturer:** Xiamen New Concept Medical Technology Co., Ltd Floor 1-2, No.7 Haicang Biomedicine Building No.2026, West Wengjiao Road Haicang disctrict, Xiamen, Fujian, China Certificate of Export: China validity:	NCMT **Guide Wires** **DS-B-035** **Class B** Shelf life 3 years Rs.25,000/-	This product is mainly used for ureteral calculi, kidney stones and other surgical operation, used in conjunction with pigtail catheter, providing the catheter lumen support and guidance.	Approved subject to notorized credentials, stability studies, Full Quality Assurance Certificate. Apply separately for hydrophilic wires.

		25-01-2020 FSC China validity: 02-06-2021 FSC Spain Issuance: 11-07-2019			
144.	M/s Al Hamd Enterprises FL-11/1/1, Block-6, Gulshan-e-Iqbal, Karachi. (ELI-00285) **Evaluator**: Unum Zia Shamsi	Manufacturer: Suzhou Colour-way Enterprise Development Co., Ltd. Dongqiao Industrial Area, Xiangcheng District, Suzhou. Manufacturing site: Longsha industrial park, Huashi Town, Jiangyin (FSC China valid till 03-01-2020)	Surgitex® Latex Surgical Gloves (Powder-free) Class B Sizes 6, 6.5, 7, 7.5, 8, 8.5 Shelf Life: 5 Years Fee submitted: Rs. 50,000/-	Sterile, single use latex rubber powder-free surgical gloves	Approved subject to verification of CE marked documents or inspection of manufacturer abroad.
145.	M/s. Sudais Associates, Sudais House, 01, Street No.7, , Khan Bahadur Colony Duran Pur Peshawer. (ELI-00031) **Evaluator**: Abdul Waheed	Manufacturer Dr. Japan Co.Ltd. 1-1 kagurazaka, hinjuku-ku-tokyo 162-0825 Japan.	DR. JDISPOSABLE SPINAL NEEDLE Class D Fee Submitted Rs. 50,000/- Shelf life: 5 years	For use in subarachnoid injection of local anesthetics for spinal anesthesia before surgery.	Approved subject to submission of EC and valid Design Examination Certificate.

Item No. XXVII. **REGISTRATION OF MEDICAL DEVICES FOR LOCAL MANUFACTURER**

The following applications for grant of registration of medical devices for local manufacturer on prescribed form 7 under Medical Devices Rules, 2017 was received in the Division and are submitted for consideration of MDB.

Sr No.	Name and Address of Firm	Name of Medical Device/ Shelf Life/ Class of MD	Brief Description	Remarks
1.	M/s Amson Vaccines & Pharma (Pvt) Ltd., 115, Industrial Triangle, Kahuta Road, Islamabad (ELM-0005) Evaluator: Hafiz Muhammad Asif Iqbal	AMJECT Auto Disable Syringe 2.5ml	Amject Auto Disable Syringe 2.5ml is designed for medical use for the injection of a set dosage of 2.5ml of a medicine or vaccine into the human body. Class B 5 Years Rs.20,000/-	Approved subject to verification of stability data and shelf life.
2.	-do- **Evaluator**: Hafiz Muhammad Asif Iqbal	Amject Auto Disable Syringe 5ml	Amject Auto Disable Syringe 5ml is designed for medical use for the injection of a set dosage of 5ml of a medicine or vaccine into the human body. Class B 5 Years Rs.20,000/-	Approved subject to verification of stability data and shelf life.
3.	-do- **Evaluator**: Hafiz Muhammad Asif Iqbal	Amject Auto Disable Syringe 3ml	Amject Auto Disable Syringe 3ml is designed for medical use for the injection of a set dosage of 3ml of a medicine or vaccine into the human body. Class B 5 Years Rs.20,000/-	Approved subject to verification of stability data and shelf life.

4.	-do- **Evaluator**: Hafiz Muhammad Asif Iqbal	Amject Auto Disable Syringe 10ml	Amject Auto Disable Syringe 10ml is designed for medical use for the injection of a set dosage of 10ml of a medicine or vaccine into the human body. Class B 5 Years Rs.20,000/-	Approved subject to verification of stability data and shelf life.
5.	-do- **Evaluator**: Hafiz Muhammad Asif Iqbal	Amject Auto Disable Syringe 2ml	Amject Auto Disable Syringe 2ml is designed for medical use for the injection of a set dosage of 2ml of a medicine or vaccine into the human body. Class B 5 Years Rs.20,000/-	Approved subject to verification of stability data and shelf life.
6.	M/s NISA SF, 10-KM Muridke-Sheikhupura Road, Muridke District, Sheikhupura, Punjab. Pakistan HO: Office No.1, 1st Floor Maxim Arcade Usman Block, Jeddah Town, Phase 1, Opposite DHA Phase II G.T. Road, Islamabad **Evaluator:** Hafiz Muhammad Asif Iqbal	BM Auto Disable (AD) Syringes 2ml & 2.5ml	Hypodermic Disposable Syringes Class B 5 Years Rs. 20,000/-	Approved subject to undertaking by the firm that "before marketing of product, we shall conduct stability studies, validation of analytical testing methods as per ICH/WHO/FDA Guidelines& the same shall be submitted to DRAP."
7.	M/s Atco Laboratories Limited, B-18, SITE Karachi	Hiclean Hand Disinfectant foam (Odorless, Lemon, Vanilla) Hand Disinfectant	HAND DISINFECTANT Class C	Approved subject to undertaking that the firm shall adhere to the

	Evaluator: Abdul Waheed	50ml, 500ml, 600ml, 1000ml Hiclean 500ml refill, 1 Ltr Bottle-Sanitiser Refill, 5 Liter Can-Sanitiser Refill	2 Years Rs.20,000/-	submitted labels.
8.	-do- **Evaluator:** Abdul Waheed	Hiclean disinfectant tablets 100 Tablet Jar	Disinfectant tablets Class C 5 Years Rs.20,000/-	Approved subject to undertaking that the firm shall adhere to the submitted labels.
9.	-do- **Evaluator:** Abdul Waheed	Hiclean CHX Surgical Disinfectant Scrub 50ml Bottle, 500ml Pump Bottle, 1 Liter Pump Bottle, 1 Liter Refill Bottle	Chlorhexidine Gluconate Surgical Disinfectant Scrub Class C 2 Years Rs.20,000/-	Approved subject to undertaking that the firm shall adhere to the submitted labels.
10.	-do- **Evaluator:** Abdul Waheed	Hiclean Purification Tablets 100 Tablets Jar	Disinfectant Tablets Class C 5 Years Rs.20,000/-	Approved subject to undertaking that the firm shall adhere to the submitted labels.
11.	-do- **Evaluator:** Abdul Waheed	Hiclean Effervescent Tablets 100 Tablets Jar	Disinfectant Tablets Class C 5 Years Rs.20,000/-	Approved subject to undertaking that the firm shall adhere to the submitted labels.
12.	-do- **Evaluator:** Abdul Waheed	Hiclean Antibacterial Liquid Disinfectant hand Wash (Odorless, Lemon) 500ml Bottle, 1000ml Refill, 5 Liter Can, 20 Liter Can	Antibacterial Liquid Disinfectant Class C 2 Years Rs.20,000/-	Approved subject to undertaking that the firm shall adhere to the submitted labels.

13.	-do- **Evaluator:** Abdul Waheed	Hiclean Instrument Disinfectant 1 Liter Bottle, 5 Liter Can, 20 Liter Can	Instrument Disinfectant Class C 2 Years Rs.20,000/-	Approved subject to undertaking that the firm shall adhere to the submitted labels.
14.	-do- **Evaluator:** Abdul Waheed	Hiclean Advance Hard Surface disinfectant (Odorless, Lemon) 1 Liter Bottle, 5 Liter Can, 20 Liter Can	Hard surface disinfectant Class C 2 Years Rs.20,000/-	Approved subject to undertaking that the firm shall adhere to the submitted labels.

Item No.XXVIII. ENLISTMENT OF MEDICAL DEVICES FOR LOCAL MANUFACTURER.

The following applications for grant of enlistment of medical devices for local manufacturer on prescribed form 6 under Medical Devices Rules, 2017 was received in the Division and are submitted for consideration of MDB.

Sr No.	Name and Address of Firm	Name of Medical Device	Brief Description/ Shelf Life/ Class of MD	Remarks
1.	M/s Usman Enterprise 4th Floor , Plot # 16-C, Lane # 8 Ittehad Commercial, Phase-VI, D.H.A, Karachi. Factory: Plot No. A/116, S.I.T.E., Highway, Phase-I, Karachi. **Evaluator:** Unum Zia Shamsi	NEXPLAS (First aid bandage) Class A Sizes: NEXPLAS MEDIUM 20mmx72mm 20's 20mmx72mm 100's NEXPLAS LARGE 25mmx72mm 20's 25mmx72mm 100's NEXPLAS SPOT 25mm Ø 20's 25mm Ø 100's NEXPLAS SQUARE 38mmx38mm 20's 38mmx38mm 100's NEXPLAS MEDIUM	First aid bandage	Approved subject to submission of stability data provision.

		JUNIOR 20mmx56mm 20's NEXPLAS ASSORTED 20's 20mmx72mm (Medium) 8 Strips 25mmx72mm (Large) 4 Strips 25mm Ø (Spot) 4 Strips 38mmx38mm(Square) 4 Strips Shelf life: 2 years Fee submitted: Rs. 5,000/-		
2.	-do- **Evaluator:** Unum Zia Shamsi	NEPORE (Paper Surgical Tape) Class A Sizes: 1/2" x 4.5meter 1 Box of 24 Rolls 1" x 4.5meter 1 Box of 12 Rolls 2" x 4.5meter 1 Box of 6 Rolls 3" x 4.5meter 1 Box of 4 Rolls 4" x 4.5meter 1 Box of 3 Rolls 20 mm x 4.5meter 1 Box of 12 Rolls 40 mm x 4.5meter 1 Box of 6 Rolls 60 mm x 4.5meter 1 Box of 4 Rolls Shelf life: 3 years Fee submitted: Rs. 5,000/-	Paper surgical tape	Approved subject to submission of stability data provision.

Item No.XXIX. <u>RENEWAL OF ENLISTMENT OF MEDICAL DEVICES FOR LOCAL MANUFACTURER.</u>

The following applications for grant of renewal of enlistment of medical devices for local manufacturer on prescribed form 6 under Medical Devices Rules, 2017 were received in the Division and are submitted for consideration of MDB.

S. No	Name and Addresses of Establishment	Name of Medical Device with sizes/Class/Shelf Life	Brief Description	Remarks
1.	M/s Usman Enterprise 4th Floor , Plot # 16-C, Lane # 8 Ittehad Commercial, Phase-VI, D.H.A, Karachi. Factory: Plot No. A/116, S.I.T.E., Highway, Phase-I, Karachi. **<u>Evaluator:</u>** Unum Zia Shamsi	First Aid Bandage Class A Sizes: 20mm x72mm (Medium strip)Box of 100's 20mm x72mm (Medium strip)Box of 20's 20mm x56mm (Small Junior strip) Box of 20's 25mm x72mm (Large strips)Box of 100's 25mm x72mm (Large strip) Box of 20's 25mmØ (Spot strip) Box of 100's 25mm Ø (Spot strip) Box of 20's 38mmx38mm (Square strip) Box of 100's 38mmx38mm (Square strip) Box of 20's Assorted Pack Box of 20's 20mmx72mm (Medium) 8 Strips	Miniplast (First Aid Bandage) Reg No. 055999	Approved subject to clarification of stability data.

		25mmx72mm (Large) 4 Strips 25mm Ø (Spot) 4 Strips 38mmx38mm(Square) 4 Strips Shelf life: 2 years Fee submitted: Rs. 5,000/-		
2.	-do- **Evaluator:** Unum Zia Shamsi	Paper Surgical Tape Class A Sizes: 1/2" x 4.5meter 1 Box of 24 Rolls 1" x 4.5meter 1 Box of 12 Rolls 2" x 4.5meter 1 Box of 6 Rolls 3" x 4.5meter 1 Box of 4 Rolls 4" x 4.5meter 1 Box of 3 Rolls 20 mm x 4.5meter 1 Box of 12 Rolls 40 mm x 4.5meter 1 Box of 6 Rolls 60 mm x 4.5meter 1 Box of 4 Rolls Shelf life: 3 years Fee submitted: Rs. 5,000/-	Nitto Surgical Tape (Paper Surgical Tape) Reg No.015568	Approved subject to clarification of stability data.

Item No. XXX **RENEWAL OF REGISTRATION OF MEDICAL DEVICES FOR LOCAL MANUFACTURER**

The following applications for grant of renewal of registration of medical devices for local manufacturer on prescribed form 7 under Medical Devices Rules, 2017 was received in the Division and are submitted for consideration of MDB.

Sr No.	Name and Address of Firm	Name of Medical Device/ Shelf Life/ Class of MD	Brief Description	Remarks
1.	M/s Amson Vaccines & Pharma	Apple Therapeutic Auto Disable Syringe.	Auto Disable Syringe	Approved subject to submission of

	(Pvt) Ltd., 115, Industrial Triangle, Kahuta Road, Islamabad (ELM-0005) **Evaluator**: Hafiz Muhammad Asif Iqbal	Reg No. 060892	20ml Class B 5 Years	stability data.
2.	-do- **Evaluator**: Hafiz Muhammad Asif Iqbal	Apple K1 BCG Auto Disable Syringe Reg No. 060893	Auto Disable Syringe 0.05ml Class B Shelf Life: 5 Years	Approved subject to submission of stability data.
3.	-do- **Evaluator**: Hafiz Muhammad Asif Iqbal	Apple Insulin Auto Disable Syringe. Reg No. 060894	Auto Disable Syringe 1ml Class B Shelf Life: 5 Years	Approved subject to submission of stability data.
4.	-do- **Evaluator**: Hafiz Muhammad Asif Iqbal	Apple Therapeutic Auto Disable Syringe. Reg No. 060895	Auto Disable Syringe 10ml Class B Shelf Life: 5 Years	Approved subject to submission of stability data.
5.	-do- **Evaluator**: Hafiz Muhammad Asif Iqbal	Apple K1 Auto Disable Syringe. Reg No. 060897	Auto Disable Syringe 1ml Class B Shelf life: 5 Years	Approved subject to submission of stability data.

Item No.XXXI. **REGISTRATION OF MEDICAL DEVICES FOR IMPORT (AUTO DISABLE SYRINGES ON PRIORITY BASIS).**

The following applications for grant of registrartion of Auto-disable syringes for import on prescribed form 7-A under Medical Devices Rules, 2017 were received in the Division and are submitted for consideration of MDB.

S. N	Name and Addresses of	Manufacture Details	Name of Medical Device	Brief Description	Remarks

o	Establishment		with sizes/Class/Shelf Life		
1.	M/s Tech Zone, 764 Askari 9, Zarar Shaheed Road, Lahore Cantt. ELI: 00040 **Evaluator:** Unum Zia Shamsi	**Manufacturer:** International Company for Medical Necessities, Industrial Zone, Block No. 19&67, El-Zarby, Abu-Tig, Assiut, Egypt FSC Egypt valid till .15-03-2021	I.CO Safety Syringe Auto disable Class: B Sizes: 0.5 ml, 3 ml, 5 ml, 10ml Shelf Life: 5 years Fee : 25,000/-	Used to inject fluid into, or withdraw fluid from the body with a self disabling safety feature to prevent re-use.	Approved subject to translated agency agreement, EPSP, MRP and CE marked documents or inspection of manufacturer abroad.
2.	M/s Safe Health Pakistan Bizcon, Office No. 25, 2nd Floor, Dilkushan Chamber, Marston Road, Karachi (ELI-00275) **Evaluator:** Unum Zia Shamsi	**Manufacturer:** M/s Guangdong Intmed Medical Appliance Co., Ltd., 1 No. South Shunhe Road, 3th Part, Europe industry Park Shunde District Foshan, Guangdong, China (FSC China valid till 30-06-2019) (FSC Ireland valid till 23-07-2019)	Auto-lock safety syringe (Sterile Safety Auto-Disable Syringe with Needle) Class B Sizes: 1ml, 3ml, 5ml, 10ml Shelf Life: 5 Years Fee not submitted	Sterile, single-use auto-lock safety syringe	Approved subject to submission of Fee slip, valid FSC of China and Ireland and agency agreement.
3.	-do- **Evaluator:** Unum Zia Shamsi	**Manufacturer:** M/s Guangdong Intmed Medical Appliance Co., Ltd., 1 No. South Shunhe Road, 3th Part, Europe industry Park Shunde District Foshan, Guangdong, China (FSC Ireland valid till 23-07-2019)	Retract-lock safety syringe (Sterile Safety Auto-Disable Syringe with Needle) Class B Sizes: 1ml, 3ml, 5ml, 10ml Shelf Life: 5 Years Fee not submitted	Sterile, single-use retract-lock safety syringe	Approved subject to submission of Fee slip, valid FSC of China and Ireland and agency agreement.

4.	M/s A.Feroz & Co, Medicine street No. 1, Marriot Road, Karachi ELI-00066 **Evaluator**: Unum Zia Shamsi	Manufacturer: Zhejing Lingyang Medical Apparatus Co. LTD Baishuiyang Town, Linhai city, Zheijiang province. China FSC China valid till 10-11-2021	Star-LY-Sterile Auto-disable syringes with needles Class B Sizes: 1ml, 2ml, 3ml, 5ml, 10ml (as per FSC) Shelf Life: Not mentioned Fee submitted: Rs. 100,000/- on 22-11-2016	Sterile, single-use auto-disable syringe	Approved subject to agency agreement, DOC, Manufacturing and QC processes, MRP, stability data for shelf life, attested FSC, ISO 13485, CE marked documents or inspection of manufacturer abroad.
5.	M/s Batla Impex, Sh.40, Namco Centre, Cambell, Street, Karachi (ELI-00170) **Evaluator**: Abdul Waheed	**Legal Manufacturer:** M/s Zibo Eastmed Healthcare Products Co. Ltd., No. 118, Huaguang Road, Zhangdian District, Zibo 255000, Shandong China (FSC ChinaValid 03-09-2019)	New Golden Auto Disposable Syringes with needle Class B Shelf Life: 5 Years Sizes & Codes as Per FSC 2ml, 3ml, 5ml, 10ml Rs. 25,000	The Sterile Syringe with Needle is a device intended to inject below the surface of the skin. The device consists of a metal tube that is sharpened at one end and at the other end joined to a hub designed syringe. It is used for clinical injection	Approved subject to submission of agency agreement, embassy attested original free sale certificate, MRP and 2ml specimens.
6.	M/s Grace Pharmaceuticals, Office No. 503, 5th Floor, Plot No.42C/2, Lane No.8, Bukhari Commercial, DHA Phase-6,	**Legal Manufacturer:** M/s Jiangxi Hongda Medical Equipment Group Ltd., No. 39, South Shengli Road, Jinxian County, Nanchang City, Jiangxi Province,	Alpha Auto-Disable Syringe 0.5ml for single use. Class B Fee submitted Rs 25000 rps	Sterile auto-disable syringe for fixed dose is used for delivering a fixed dose of vaccine.	Approved subject to MRP, agency agreement, original free sale certificate, ISO 13485, DOC, CE marked

	Karachi (ELI-00254) -do- **Evaluator**: Abdul Waheed	China (FSC China Valid upto 26-11-2020)	Shelf Life: 5 Years Sizes & Codes as Per FSC Rs. 25,000		documents or CE marked documents or inspection of manufacturer abroad.
7.	-do- **Evaluator**: Abdul Waheed	**Legal Manufacturer:** M/s Jiangxi Hongda Medical Equipment Group Ltd., No. 39, South Shengli Road, Jinxian County, Nanchang City, Jiangxi Province, China (FSC China Valid 26-11-2020)	Alpha Auto-Disable Syringe 0.1ml for fixed dose Class B Fee submitted Rs 25000 rps Shelf Life: 5 Years Sizes & Codes as Per FSC Rs. 25,000	Sterile auto-disable syringe for fixed dose is used for delivering a fixed dose of vaccine.	**1. Proposed** Approved subject to MRP, agency agreement, original free sale certificate, ISO 13485, DOC, CE marked documents or CE marked documents or inspection of manufacturer abroad.
8.	-do- **Evaluator**: Abdul Waheed	**Legal Manufacturer:** M/s Jiangxi Hongda Medical Equipment Group Ltd., No. 39, South Shengli Road, JinxianCounty, Nanchang City, Jiangxi Province, China (FSC China Valid 26-11-2020)	Alpha Auto-Disable Syringe 0.05ml for fixed dose. Class B Fee submitted Rs 25000 rps Shelf Life: 5 Years Sizes & Codes as Per FSC Rs. 25,000	Sterile auto-disable syringe for fixed dose is used for delivering a fixed dose of vaccine.	Approved subject to MRP, agency agreement, original free sale certificate, ISO 13485, DOC, CE marked documents or CE marked documents or inspection of manufacturer abroad.
9.	M/s Sultansons, 133 Kutchi Gali #1, Marriott Road,	**Manufacturer:** M/s Shandong Wuzhou Medical Equipment Co. Ltd.	ST Classic Disposable Auto Disable Syringe, Sterile	This device used to inject and aspiremedicin	Approved subject to submission of ISO 13485,

	Karachi (ELI-00051) **Evaluator**: Abdul Waheed	**ADDRESS**: Dingtao County(YanTai) Industrial Zone,11 eze City,274100,Shandong,China. (FSC ChinaValid 05-02-2020)	Class B Fee submitted Rs 25000 rps Shelf Life: 5 Years Sizes : 2ml, 3ml, 5ML, 10ML) Rs. 25,000	e liquid, and can be auto-destroyed by reverse locker after use. This is a Single use medical device.	stability data, Original FSC and labels, CE marked documents or inspection of manufacturer abroad.
10.	-do- **Evaluator**: Abdul Waheed	**Manufacturer:** M/s Shandong Zhushi Pharmaceutical Group Co., Ltd., South of Fan Lou road of Development Zone OF shan xian CountRy Shandong province, China. (FSC ChinaValid 11-07-2020)	Classic AD Disposable Auto Disable safety syringe, sterile, with needle Class B Shelf Life: 3 Years Sizes: 2ml, 3ml, 5ml, 10ml Rs. 25,000	It can be used in intravenous injection, hypodermic injection and drawing blood from vein	Approved subject to original free sale certificate, or CE marked documents or inspection of manufacturer abroad.
11.	M/s. Trow Medic International building No.117, Sagian T 4, Opposite Sanda stop Band Road Lahore (ELI-00069) **Evaluator:** Shahid Muhammad Iqbal	**Manufacturer:** M/s. Shandong wuzhou medical equipment co., LTD. Dingtao County (Yantai) Industrial Zone 274100, Heze City, Shandong Province, China FSC: China Issuance: 20-03 2018 valid till 2023-03-19	TrowJect Sterile self-destruction safety syringes (0.05ml; 0.5ml; 1ml; 2ml; 2.5ml; 3ml; 5ml; 10ml; 20ml) Disposable syringe Auto-Disable Class: B Shelf Life :05 years	Disposable syringe Auto-Disable	Approved subject to submission of agency agreement, attested FSC for 2.5 ml, valid ISO 13485, stability studies, CE marked documents or inspection of manufacturer abroad.

			Rs.25,000/-		
12.	M/s Hospital Services & Sales, 13-C, Annex, Block PECHS, Karachi (ELI-00081) **<u>Evaluator:</u>** Shahid Muhammad Iqbal	**Manufacturer:** M/s Guangdong Haiou Medical Apparatus Co. Ltd., Nanyuan Industrial Zone, North Liusha, Puning City, Guangdong, China FSC China Validity 01-12-2019 2, 5 and 10 ml WHO prequalified	Haiou Auto Disable Syringe with Needle 1ml; 2ml; 2.5ml; 3ml; 5ml; 10ml; 20ml; 30ml and 50ml Class B Shelf Life: 5 Years **Rs.25,000/-**	Auto Disable Syringe with Needle	Approved subject to submission of MRP, manufacturing and QC details, stability studies, Valid FSC, Valid ISO 13485, CE marked documents or inspection of manufacturer abroad.
13.	-do- **<u>Evaluator:</u>** Shahid Muhammad Iqbal	**Manufacturer:** M/s Guangdong Haiou Medical Apparatus Co. Ltd., Nanyuan Industrial Zone, North Liusha, Puning City, Guangdong, China FSC China Validity 01-12-2019 3, 5 and 10 ml WHO prequalified	Haiou Needle Retractable Safety Syringe with needle 3ml, 5ml and 10ml Class B Shelf Life: 5 Years **Rs.25,000/-**	Single Handed Operation and activation	Approved subject to submission of MRP, manufacturing and QC details, stability studies, Valid FSC, Valid ISO 13485, CE marked documents or inspection of manufacturer abroad.

MINUTES ADDITIONAL AGENDA FOR 16TH MEETING OF MDB HELD ON 03-02-2020.

Item No.I: SITE VERIFICATIONS.

It is submitted that Medical Device Board in its 13th meeting held on 05-08-2019 discussed the cases of site verification of M/s Ali Raza Surgimed (Pvt) Ltd, 1KM, Malikwal Road, Near Motorway, Bhera, Punjab and M/s Med Tex Pharma, Mouza Gopay Ra, Link Sialkot Road, Near Gujranwala Dry Port G.T. Road, Gujranwala Tool Plaza and decided as under:-

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

Accordingly the requirements for site verification have been prepared and are listed below:-

(i) **Location**: that premises shall be located preferably in an industrial area and in any case not in any residential or commercial area.

(ii) **Surroundings:** Premises shall be situated in an environment that, when considered together with measures to protect the manufacturing process, present minimum risk of causing any contamination of materials or products. It shall be away from filthy surroundings and shall not be adjacent to an open sewerage, drain, public lavatory or any factory which produces a disagreeable or obnoxious odour or fumes or large quantity of soot, dust or smoke which may contaminate the medical devices being manufactured are adversely affect their quality. Existing units shall keep the surroundings under their control to be clean.

Submitted for the consideration of MDB please.

Decision: The Board discussed the matter at length and approved the requirements for site verification as follow:

(i) **Location**: that premises shall be located preferably in an industrial area.

(ii) **Surroundings:** Premises shall be situated in an environment that, when considered together with measures to protect the manufacturing process, present minimum risk of causing any contamination of materials or products. It shall be away from filthy surroundings and shall not be adjacent to an open sewerage, drain, public lavatory or any factory which produces a disagreeable or obnoxious odour or fumes or large quantity of soot, dust or smoke which may contaminate

the medical devices being manufactured or adversely affect their quality. Existing units shall keep the surroundings under their control to be clean.

(iii) The manufacturing of product and its storage should not impose threat to the environment, population in surroundings and personnels.

Decision: The Board approved the site verifications of M/s Ali Raza Surgimed (Pvt) Ltd, 1 Km, Malikwal Road, Near Motorway, Bhera, Punjab and M/s Med Tex Pharma, Mouza Gopay Ra, Link Silkot Road, Near Gujranwala Dry Port G.T Road, Gujranwala Tool Plaza submitted earlier in the 13th MDB Meeting.

Item No.II: REGISTRATION OF MEDICAL DEVICE NAMELY VIZUMAX HD (BARIUM SULFATE 98% W/W) REGISTRATION NO. MDIR-0000515

It is submitted that Medical Device Board in its 12th meeting held on 13-05-2019 approved the medical device namely **VIZUMAX HD (BARIUM SULFATE 98% W/W)**. Accordingly it was granted registration vide No. **MDIR-0000515.** The registration was granted on the basis of Declaration of Conformity (DoC) from the manufacturer abroad (M/s Vizumax Diagnostics LLC 609 Broadway Avenue, Orlando, Florida 32803, USA)declaring it as medical device. However, similar products namely E-Z HD Powder (Barium Sulphate 98% w/w) and Polibar ACB Powder (Enema Kit) (Citrated Barium Sulphate 97.2050% w/w) have been registered as drug vide Regn.No.027379 dated 26-06-2002 and Regn.No.027378 dated 26-06-2002 respectively. This raised an ambiguity that two products having same composition and similar indication of use have different regulatory status.

Upon examination of its status in different reference regulatory authorities, the above stated products are registered as drug (for diagnostic use). It is also present as official monograph in B.P. and U.S.P.

Accordingly the importer of VIZUMAX HD namely M/s Global Marketing Services 111-B, Hali Road, Westridge 1, Rawalpindi was directed to provide clarification alongwith supporting legal documents to prove that their subject product is a medical device within two weeks as only DoC is not a sufficient evidence to classify it as a medical device. Till date no response has been received from the firm.

Submitted for consideration of MDB please.

Decision: **The Board was informed that the registered product bearing registration No. MDIR-0000515 VIZUMAX HD (Barium Sulphate 98% w/w) of M/s Global Marketing Services, Rawalpindi contains Barium Sulphate which is a 'drug' in official monographs of BP / USP. Mr. Muhammad Nadeem Ahmed, member was of the opinion that Barium Sulphate kit without Barium Sulphate is a medical device whereas the Barium Sulphate alone is a drug. Barium Sulphate is filled into the kit and sometimes it is available as pre-filled Barium Sulphate kit. He further explained that the primary function is of Barium Sulphate whether it is alone or as pe-filled kit, therefore it is a drug. The Board decided to issue the Show Cause Notice to the firm for cancellation of the VIZUMAX HD (Barium Sulphate 98% w/w) of M/s Global Marketing Services, Rawalpindi and asked the firm to appear for personal hearing in the forthcoming meeting of MDB.**

Item No.III **GROUPING OF DIFFERENT IN-VITRO DIAGONSTIC KITS AS CLUSTER AND FEE THEREOF**

Cluster is one of the grouping method for Class A and Class B in-vitro diagnostics kits (IVDs) Medical Devices in Medical Devices Rules, 2017.

"(17) *An in-vitro medical device shall be grouped as in-vitro diagnostic cluster if it comprises of a number of in-vitro diagnostic reagents or articles that are, —*

(a) from the same manufacturer;

(b) within risk classification A or B;

(c) of a common test methodology as listed in the Table 5 under this rule; and

(d) of the same in vitro diagnostic cluster category as listed in Table 5 under this rule.

(18) The in-vitro diagnostic cluster may include analyzers that are designed for use with the reagents in the in-vitro diagnostic cluster.

(19) Information on all reagents or articles within an in-vitro diagnostic cluster shall be submitted as part of one medical device registration application.

(20) Reagents or articles within an in-vitro diagnostic cluster that are listed on the medical device register shall be supplied in the market.

(21) Individual reagents or articles that are listed as part of a cluster can be supplied

separately.

(22) If a reagent or article is intended for multiple usage categories and can be grouped in more than one in-vitro diagnostic cluster, the applicant can choose to group the reagent or article as part of any one of the in-vitro diagnostic clusters it qualifies and information to support all the intended uses of the reagent or article must be submitted as part of the medical device registration application"

Some firms applied different components of cluster as separate products but most of the firms intends to apply different in-vitro diagnostic kits (IVDs) used for the identification/ diagnosis of different diseases as one cluster which could include upto to 50 or even more than 50 IVDs. Fee for class-A medical devices is Rs.5000/- and for Class-B medical device is Rs.25,000/- and firms want to cover different IVDs in one application. The evaluation of dossiers of such clustered IVDs is cumbersome and requires extensive analysis/review of applications.

In the light of the above it is proposed that applications and fee for cluster IVDs should be rationalized e.g in addition to base fee of RS.5000/- for Class-A IVD, the firm may submit Rs.2000/- for every subsequent product. For Class -B IVD in addition to base fee of Rs.25,000/- the firm may submit Rs.2000/- for every subsequent product.

Submitted for the consideration of MDB.

Decision: The Board discussed the matter at length and deliberated that the proposed Rs. 2000/- additional fee makes 40% of base fee (Rs. 5000/-) of Class A and similarly Rs. 2000/- additional fee makes 8% of base fee (Rs. 25000/-) of Class B medical device. On insistence of HDAP representative namely, Dr. Zafar Hashmi, CEO B.Braun, the Board decided to approve additional fee of 10% of base fee for each product in cluster along with base fee for both Class A and Class B IVD medical devices.

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