DECISIONS OF THE 21st MEETING OF THE MEDICAL DEVICE BOARD (MDB) HELD ON 16-10-2020

1. APPLICATIONS FOR GRANT OF ESTABLISHMENT LICENSE TO IMPORT MEDICAL DEVICES.

S.No	Name of Establishment	Director/Proprietor/ partners	Cold Chain (Yes/No)	Decision
1.	M/s Fresnius Medical Care,27C-III, 1st Floor, TAMC Building, M.M. Alam Road, Gulberg-III, Lahore. **Addition of New Godown**: Al-Madina Warehouse, 28-KM, Multan Road, Lahore.	Mr. Javaid Nasir Qureshi Mr. Kwong Leung Tsang Mr. Jan Walter Mr. Andreas Hendrik De Wit	No.	**Approved** the additional godown for storage of room temperature medical devices without cold chain facility on below mentioned address:- Al-Madina Warehouse, 28-KM, Multan Road, Lahore.
2.	M/s Capri Medicals, 51/C-1, Park Avenue, University Town, Peshawar.	Mr. James Iqbal	No.	**Approved** for storage of room temperature medical devices without cold chain facility.
3.	M/s IBS Pharmaceuticals, Office No.634, 6thFloor, Pak Medical Center, Khyber Bazar, Peshawar.	1. Inamullah 2. Irfanullah	No.	**Approved** for storage of room temperature medical devices without cold chain facility.
4.	M/s Shah's Brothers & Co., Flat No.02, 1st Floor, Khan Plaza, Dalazak Road, Peshawar.	Syed Munawar Shah	No	**Approved** for storage of room temperature medical devices without cold chain facility.
5.	M/s Divine Enterprises, House No.B-8, Street No.2, Amjad Colony, Dalazak Road, Peshawar.	Mr. Haroon Altaf Mr. Sajjad Ahmed	No	**Approved** for storage of room temperature medical devices without cold chain facility.

6.	M/s M.A Traders, Khan G Arked Main Gulbahar Road Back Side Gulbahar Police Station, Peshawar.	Mr. Javed Khan	No	**Approved** for storage of room temperature medical devices without cold chain facility.
7.	M/s Hayat Kimya Pakistan (Private) Limited, **Head Office:** No.4,5 & 7, 1st Floor, Park Lane Tower (Mall of Lahore), 172-Tufail Road, Lahore. **Warehouse Address:** Plot No.279,280, 281, Phase-II, M3 Industrial City Zone (FIEDMC), Sahianwala, Faisalabad.	Mr. Saleh Zaki, Proprietor. Mr. Tolga Arslan, CEO. Mr. Mehmet Anvi Kigili (Director) Mr. Ahmet Yahya Kigili (Director)	No	**Approved** for storage of non-cold chain medical devices.

2. <u>APPLICATIONS FOR GRANT OF ESTABLISHMENT LICENSE TO MANUFACTURE MEDICAL DEVICES.</u>

S.#	Name of Establishment & Directors	Address	Name of Production Incharge	Name of QC Incharge
1.	M/s Lab Diagnostic System (Pvt.) Ltd	**Site Address:**Plot No. 36-A, PSIC, SIE, Taxila, Rawalpindi **Head Office Address:** 111-B, Hali Road,Westridge 1, Rawalpindi	Mr. Rohail Bhatti S/o Taj Masih(Pharmacist)	Mr. Nadeem Ahmed Naseer S/o Naseer Ahmed (BS Electronics) with biomedical experience.

Decision: The Board approved the grant of Establishment Licence to Manufacture Medical Devices to Lab Diagnostic System (Pvt) Ltd, Plot No. 36-A, PSIC, SIE, Taxila, Rawalpindi subject to submission of appropriate technical person.

3. APPLICATION FOR RENEWAL OF ESTABLISHMENT LICENSE TO MANUFACTURE MEDICAL DEVICES.

S.No	Name of Establish-ment	Address	Name of Qualified Person	Name of QC Incharge
1.	M/s Asian Fiber	Plot No.41 and 42, Sector-25 Korangi Industrial Area, Karachi.	Mr. Muhammad Ali (Production Incharger)(B.Pharmacy)	Ms. Mehvish Sarfraz QC Incharge (Pharm-D)
2.	M/s Surgi Plast,	Plot No.78, Road No.L-4, Industrial Estate, Gadoown Amazai, KPK.	Mr. Waqar Ghani (Production Incharge) Pharm-D.	Mr. Khurshid Anwar, (Quality Control Incharge), Pharm-D.
3.	M/s Al-Badar Manufacturing (Pvt) Ltd.	Plot No.193/3, Road No.7, Industrial Estate Gadoon Amazai, District Swabi.	Mr. Zia Ul Qadeer, Production Inchage B-Pharm	Mr. Yasir Amin, Quality Control Incharge, Pharm-D

4. SITES VERIFICATION FOR ESTABLISHMENT OF MANUFACTURING UNITS OF MEDICAL DEVICES.

4.1.

M/s Pak Electron Beam Irradiation (Pvt) Ltd., Karachi has informed that they are interested to install Manufacturing Unit for Medical Devices. The proposed plot for the construction of the Unit is located at Plot No.E-65, Noth Western Industrial Zone, Port Qasim, Karachi. They have submitted all relevant documents and requested to depute a team for the verification of plot and for granting NOC to start construction on the proposed site.

Decision: The Board approved the site of M/s Pak Electron Beam Irradiation (Pvt) Ltd., located at Plot No.E-65, Noth Western Industrial Zone, Port Qasim, Karachi for establishment of manufacturing unit of medical devices.

4.2.

M/s Cottex Health Care Industries, Chak NO.47/2L, Tehsil and District, Okara has informed that they are interested to install Manufacturing Unit for Medical Devices. The proposed plot for the construction of the Unit is located at Momin Wala 34/2L, Road Link Depalpur Road, Okara, Near Chak No.47/2L, Tehsil & District, Okara. They have submitted all relevant documents and requested to depute a team for the verification of plot and for granting NOC to start construction on the proposed site.

Decision: The Board rejected the site of M/s Cottex Health Care Industries located at Momin Wala 34/2L, Road Link Depalpur Road, Okara, Near Chak No.47/2L, Tehsil & District, Okara for establishment of manufacturing unit of medical devices due to the reason that there already Aayan Cotton firm is established at the same site; moreover plot is located at area of Chak 47/2L as per land documents whereas address on DRAP letter No.F.12-106/2020-MD dated 02-03-2020 required to be verified is 42/2L Tehsil and District Okara.

4.3.

M/s Arsons Pharmaceuticals Industries (Pvt) Limited, 3KM Off Multan Road, Dina Nath Stop, Near Lakhan K Village, District Kasur has informed that they are interested to install Manufacturing Unit for Medical Devices. The proposed plot for the construction of the Unit is located at 3KM Off Multan Road, Dina Nath Stop, Near Lakhan K Village, District Kasur. 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.

Decision: The Board approved the site of M/s Arsons Pharmaceuticals Industries (Pvt) Limited, located at 3 KM Off Multan Road, Dina Nath Stop, Near Lakhan K Village, District Kasur for establishment of manufacturing unit of medical devices.

4.4.

M/s Aprus Technologies (Pvt) Limited, Plot No.47/48B Industrial Estate, Hayatabad, Peshawar has informed that they are interested to install Manufacturing Unit for Medical Devices. The proposed plot for the construction of the Unit is located at Plot No.47/48B Industrial Estate, Hayatabad, Peshawar. 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.

Decision: The Board approved the site of M/s Aprus Technologies (Pvt) Limited, located at Plot No.47/48B Industrial Estate, Hayatabad, Peshawar for establishment of manufacturing unit of medical devices.

5. APPLICATIONS FOR GRANT OF ADDITIONAL SIZES OF ALREADY REGISTERED MEDICAL DEVICE.

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

S.No	Regn.No.	Name of Medical	Name of Manufacturer	Existing Approved	Demanded Additional

		Device		Sizes/Codes	Sizes/ Codes.
1.	MDIR-0000877	Kaltostat (Calcium Sodium Alginate Wound Dressing)	**Manufacturer:** M/s Conva Tec Limited, First Avenue, Deeside Industrial Park, Deeside, Flintshire, CH5 2NU, UK	168117 2g. 5 dressing	168212, 168214 and 168215. As per Free Sale Certificate of MHRA.

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

Regn.No.	Name of Medical Device	Existing Approved Sizes/Codes	New Approved Additional Sizes/ Codes.
MDIR-0000877	**Kaltostat (Calcium Sodium Alginate Wound Dressing)**	**168117** **2g. 5 dressing**	**168212, 168214 and 168215.**

6. <u>GRANT OF APPROVAL FOR EXTENSION IN SHELF LIFE.</u>

M/s Lab Link Enterprises, M-203, Block 2, P.E.C.H.S, Opp Ghousiya Masjid, Karachi has requested for extension in shelf life from 03 Year to 05 years of their already registered following imported medical device:-

Regn. No.	Name of Medical Device	Name of Manufacturer	Approved Shelf Life	Demanded Shelf Life
MDIR-0001101	Nipro Disposable Syringe (with needle) (1ml, 3ml, 5ml, 10ml & 20ml)	**Legal Manufacturer:** M/s PT ANipro Indonesia Jaya, Kawasan Industri Syryacipta Jl, Surya Utama Kav, 1-22B, 23 & 24 Desa Katamekar, Kec Ciampel, Karawang Jawa Barat, Indonesia.	03 Year	05 Years

Decision: The Board approved the shelf life of the product, namely, Nipro Disposable Syringe (with needle) (1ml, 3ml, 5ml, 10ml & 20ml) from three years to five years.

7. ACTION PLAN FOR INJECTION SAFETY TO BE IMPLEMENTED BY DRAP.

The investigation following last year outbreak of HIV in Ratodero Sindh revealed that one of the leading causes is misuse / reuse of disposable syringes. To safeguard the public from this menace Ministry of National Health Services, Regulations & Coordination constituted National Task Force on Injection Safety.

All the syringe manufacturers, importers, distributors, wholesalers, clinicians, nurses, pharmacists and other health care providers were informed that the Drug Regulatory Authority of Pakistan's Policy Board in its 32nd meeting held on 29-01-2020 on recommendations of Task Force decided as under:-

1. *"DRAP shall instruct local manufacturers to completely stop the manufacturing of 2, 2.5, 3 & 5 ml disposal syringes after 31st March, 2021 and encourage the local production of the same in Auto Disable format.*
2. *DRAP shall instruct importers completely stop the import of disposable syringes of 2, 2.5, 3 & 5ml disposable syringes after 30th September, 2020.*
3. *DRAP shall initiate the process of deregistration of all the registered 2, 2.5, 3 and 5ml conventional disposable after the dates specified in para (1) and (2) above.*
4. *DRAP shall facilitate the registration of auto-disable syringes."*

In the light of foregoing, the Authority issued letters to the manufacturers and importers of disposable syringes vide letter No.F.16-5/2019-MD, dated 20th January, 2020 and same was published as "Public Notice" in the daily newspaper namely Nawa-e-Waqt and Express Tribune. Effective dates for ban on manufacturing and import are mentioned below:-

Import of syringes: 30th September, 2020
Manufacture of syringes: 31st March, 2021

Even after the lapse of 07 months, no firm has submitted any report regarding the preparedness and action taken for the compliance of the decision of the Policy Board.

Submitted for consideration of MDB please.

Decision: The Board was informed that National Injection Task Force has extended the deadline for cancellation of 2, 2.5, 3 and 5ml disposable syringes for import and for manufacture of syringes for further 04 months. The new deadlines for cancellation of the aforementioned syringes are as follow:-

Import of syringes: 31st January, 2021

Manufacture of syringes: 31st July, 2021

8. CORRECTION IN BRAND NAME AND SHELF LIFE (TYPOGRAPHICAL MISTAKE).

M/s Essity Pakistan (Pvt) Ltd**,** A/69, SITE Manghopir Road, Karachi has informed that their product enlistment certificate issued for Flashcast Fiberglass Cast Tape has some typographical errors as per detail given below:-

	Medical Device Name as per Enlistment letter.	**Correction Required**
Name of Medical Device	Flashcast Fiberglass Cast Bandage Tape.	Flashcast Fiberglass Cast Tape
Brief Description	Kintted.	Knitted (Spelling Correction)
Shelf Life	5 years	3 years

2. It is submitted that the MDB in its 11th meeting considered and approved the below mentioned medical device as per detail given below:-

1.	M/s BSN Medical (Pvt) Ltd., A/69, SITE Manghopir Road, Karachi (ELI-00011)	**Legal Manufacturer:** M/s BSN Medical Inc., 5825 Carnegie Blvd, Charlotte, NC 28209, USA **Manufacturing Facility:** M/s BSN Medical SA de CV Av. Parque SN Villa Florida Reynosa, Tamaulipas 88715, Mexico	Flashcast® Fiberglass Cast Bandage Tape Class A Shelf Life: 5 Years 5cm X 3.6m 7.5cm X 3.6m 10cm X 3.6m 12.5cm X 3.6m	Fiberglass Cast Tape manufactured from a heat cleaned fiberglass kintted cloth. The fabric coated with hydrophilic polyurethane resin Brand Name is not provided on Free Sale Certificate	**Approved.**

		(FSC USFDA Valid Till13-06-2019)			

3. The brand name and shelf life of the medical device was inadvertently mentioned wrong in the agenda as well as minutes of the meeting. Enlistment certificate was also issued with the detail as approved by the MDB.

4. Now the firm has requested for correction of brand name and shelf life of the medical device as per detail mentioned in para 1 above.

Submitted for consideration of MDB please.

Decision: The Board discussed and decided to approve the following corrections of below mentioned medical devices as per detail given:-

	Existing detail of medical device as per Enlistment letter.	**New Approved detail of medical device.**
Name of Medical Device	**Flashcast Fiberglass Cast Bandage Tape.**	**Flashcast Fiberglass Cast Tape**
Brief Description	**Kintted.**	**Knitted.**
Shelf Life	**5 years**	**3 years**

9. APPLICATIONS FOR REGISTRATION OF MEDICAL DEVICES OF M/S GALAXY PHARMA (PVT) LIMITED, KARACHI FOR IMPORT (DEFERRED IN 15TH MDB MEETING)

Following products of M/s Galaxy Pharma (Pvt) Limited, Karachi was placed before the MDB in its 15th meeting held on 30-12-2019 and was deferred by the MDB as per remarks given against each:-

1	M/s Galaxy Pharma (Pvt.) Ltd. D-180, Rojhan Street, Block 5, Clifton Karachi. (ELI-00402)	**Legal Manufacturer:** SetpaTibbiGerecler ITH.IHR.SAN.VE .TIC.LTD. STI (1145/4 Sk.No. 13/1 Konak/ Izmir / Turkiye)	Neosilk Ultra Non-Absorbable Surgical Suture Class C Shelf Life: 3 years Code: Atraumatic Silk 3/0	Neosilk is a sterile, braided (twiseted in 8/0 and finer sizes) and non-absorbable surgical suture material that is composed of an organic protein called fibroin, derived from 100 % natural silk fibers	**Deferred** for provision of EPSP, Manufacturing and QC documents, Proof of fee deposited & Stability data supporting shelf life of product.

		(FSC of Turkey issued on 05-04-2018)	26mm Curved cut 3/8 75cm sterile surgical suture Rs.50,000/-	obtained from the cocoons of silk worms by a special purification process called degumming.	
2	-do-	**Legal Manufacturer:** M/sSetpaTibbiGerecler ITH.IHR.SAN.VE .TIC.LTD. STI (1145/4 Sk.No. 13/1 Konak/ Izmir / Turkiye) (FSC of Turkey issued on 05-04-2018) .	Neocryl Absorbable Surgical Suture PGA (Polyglycolic acid suture) Class D Shelf Life: 3 years Code: PGA (Polyglycolic acid) No: 1 30mm Round B.1/2 75cm sterile surgical suture Rs.50,000/-	Neocryl PGA is a sterile, synthetic, synthetic, braided and coated surgical suture material made of 100% Polyglycolic Acid. It is dyed in FDA approved (D & C violet no. 2) to make it easily distinguishable. Neocryl PGA is suitable for use in applications like general wound closures, ophthalmic surgery, orthopedics, gynecology (episiotomy repair) and gastrointestinal tract surgery. It is not intended for use in cardiovascular or neurological surgery and thus should not be used in those procedures.	**Deferred** for provision of EPSPand Stability data supporting shelf life of product.
3.	-do-	**Legal Manufacturer:** SetpaTibbi Gerecler ITH.IHR.SAN.VE .TIC.LTD. STI	Neoplene Ultra Non-Absorbable Surgical Suture (Polypropylene) Class: C	Neoplene Polypropylene is a sterile, synthetic and monofilament non-absorbable surgical suture material made of	**Deferred** for provision of EPSPand Stability data supporting shelf life of product.

		(1145/4 Sk.No. 13/1 Konak/ Izmir / Turkiye) (FSC Expires After 36 Months off issuance)	Shelf Life: 3 years Code: Polypropylene 3/0 26mm curved cut 3/8 75cm sterile surgical suture Rs.50,000/-	polypropylene. It is dyed in blue or black to make it easily distinguishable. It is indicated for use in general soft tissue approximation. It is used in ophthalmic surgery, orthopedic plastic surgery , cardiovascular surgery and neurological surgery	

4	M/s Galaxy Pharma (Pvt.) Ltd. D-180, Rojhan Street, Block 5, Clifton Karachi. (ELI-00402)	**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)	Neocryl Rapid Absorbable Surgical suture PGA(Polyglycolic acid) No:1 30mm Round B. ½ 75cm sterile surgical suture. (PG0130YV1275 Class C Shelf Life: 3 Years Sizes & Codes:- PGA(Polyglycolic acid) No:1 30mm Round B. ½ 75cm sterile surgical suture. (PG0130YV1275 Rs.50,000/-	Synthetic, Absorbable sterile surgical Sutures.	**Approved** subject to submission of stability data and inspection of manufacturer abroad.
5	-do-	**Legal Manufacturer:** Setpa Tibbi Gerecler ITH.IHR.SAN.VE.TIC.LTD. STI (1145/4 Sk.No. 13/1 Konak/ Izmir / Turkiye)	Neoxone PDS Absorbable Surgical Suture PDS (Polydioxanone) 4/0 16mm Round B.	Neoxone PDS, is a sterile, synthetic and absorbale monofilament surgical suture material	**Approved** subject to submission of stability data and inspection of manufacturer

		(FSC Expires After 36 Months off issuance) .	3/8 75cm sterile surgical suture. (PDS4016YV3875) Class C Shelf Life: 3 Years Sizes & Codes:- PDS (Polydioxanone) 4/0 16mm Round B. 3/8 75cm sterile surgical suture. (PDS4016YV3875) Rs.50,000/-	obtained by polymerization of te p-dioxanone monomer. It is dyed in (D& C Violet No. 2) to make it easily distinguishable.	abroad.
6	-do-	**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 Rapid Absorbable Surgical Suture. Rapid PGLA (Absorbable Polyglycolide-Co-L-Lactide) (90%:10%) 3/0 26MM Rev. Cut. 3/8 75cm sterile surgical suture. (PLR3026AK3875) Class C Shelf Life: 3 Years Sizes & Codes:- Rapid PGLA (Absorbable Polyglycolide-Co-L-Lactide) (90%:10%) 3/0 26MM Rev. Cut. 3/8 75cm sterile surgical suture. (PLR3026AK3875) Rs.50,000/-	Neolact (Polyglycolide-Co-L-Lactide)PGLA is a synthetic, absorbable, sterile, braided and coated surgical suture made up of 90% Glycolic Acid + 10% Lactic Acid. It is dyed in D & C Violet No. 2 to make it easily distinguish able.	**Approved** subject to submission of stability data and inspection of manufacturer abroad.
7	-do-	**Legal Manufacturer:** Setpa Tibbi Gerecler	Neolact Absorbable Surgical Suture	NEOLACT PGLA, is a sterile, synthetic	**Approved** subject to submission of

		ITH.IHR.SAN.VE.TIC.LTD. STI (1145/4 Sk.No. 13/1 Konak/ Izmir / Turkiye) (FSC Expires After 36 Months off issuance) .	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:- PGLA (Polyglycolide-Co-L-Latctide) (90%:10%) No:1 45mm Round B. ½ 75 cm sterile surgical suture. (PL0145YV1275 Rs.50,000/-	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.	stability data and inspection of manufacturer abroad.

Decision:- The Board approved the deferred cases at serial No.1, 2 and 3 with a shelf life of 05 years on the basis of submitted documents. The Board approved the products at serial No.4, 5, 6 and 7 with shelf life of 05 years on the absis of submitted CE marked documents.

10. <u>REQUEST FOR NOC TO IMPORT OZODROPS BY M/S DEKHON, LAHORE.</u>

Assistant Director (I&E), DRAP, Lahore has forwarded an application of M/s Dekhon, Lahore for grant of NOC to import Ozodrops 800 packs on donation basis to Director (Pharmacy Services), DRAP, Islamabad for further necessary action. The import of drugs for clinical trial are dealt under Rule 12 of the Drug (I&E) Rules, 1976 and import on donation basis is decided in the light of SRO.577 (1)/2016.

The Pharmacy Services Division has stated that the request has been forwarded to their Division for clinical trial which is governed under Bio-Study Rules, 2017. Hence, firm may be reminded to proceed accordingly as was advised previously. They have further stated that the product is a medical devices as per FSC and aims of the samples is tiral of the product. Therefore, the have refer the case to MDMC Division for opinion.

It is submitted that after review of the instant case, it is submitted that the product Ozodrop is used for lubrication, moisturizing andsoothing of the occular surface of the eye. But the firm wants to use it fpr clinical trial on COVID-19 products. Pharmacy Services Division is the competent forum for the processing of cases of clinical trial.

Additional Difecgor (MDMC) discussed the case with Director (MDMC) and decided to place the case before the MDB for its consideration please.

Decision: The Board discussed the matter at length and deferred the case with the direction to bring forward the details of product.

11. CHANGE OF TECHNICAL PERSON (PRODUCTION INCHARGE) OF M/S HAFIZ PHARMA INDUSTRY, KAMOKE, GUJRANWALA.

M/s Hafiz Pharma Industry, 44-KM (Ghaniya) Kamoke, Gujranwala has requested for approval of change of technical person (Production Incharge). The firm have deposited 50,000/- fee for change in particulars of firm and submitted necessary documents. The details of previous and proposedProduction Incharge is as under:-

Previous Technical staff (Production Incharge)	Proposed Technical staff (Production Incharge)
Mr. Akhtar Hussain, (B-Pharm)	Mr. Fiaz Ahmed (Pharm-D)

Decision: The Board acceded to the request of the firm /company and approved the change of qualified /technical person (production incharge) from Mr. Akhtar Hussain (B-Pharm) to Mr. Fiaz Ahmed (Pharm-D).

12. EXEMPTION FROM LABELING REQUIREMENTS UNDER MDR, 2017 (AD-V).

M/s Sadqain Health Care (Pvt) Limited, Safari Villas-II, Commercial Complex, 3rd Floor, Bahria Town Phase 7, Rawalpindi have stated that theey are registered importer of medical devices under Medical Devices Rules, 2017 with ELI No.00020. Their manufacturer (M/s Intersurgical Limited, UK) is operating from 20 location in more than 150 countries worldwide and has product range about 2-3 thousand products. Operation on such a vast scale makes lebelling of commercial product a very complex and tinme consuyming process. Product are manufactured and packed for global sales so it is practically impossible to print Pakistan's local importer license Number and MRP on each pack specifically for Pakistan market. The demand/use of various devices imported to Pakistan varies both in term of sizes and quantities hence making Pakistan specific printing difficult at the scattered manufacturing site.

They have requested to grant them permission for local inkjet printing as per Medical Devices Rules, 2017 on their registered medical devices at their licensed premises (warehouse approved by DRAP in Establishment License) under the supervision of qualified person. This would enable them to make sure that there are no supply disruption of life saving devices to the Pakistan market.

Decision: The Board allowed only one time permission for printing License No., Registration No., and MRP on each pack at their licensed warehouse. The Board observed that permission of exemption from labeling requirements under Medical Devices Rules, 2017 should be discouraged since the said rules are enforced for the last two and half years and the firms /companies are well aware of the label requirements.

13. CORRECTION OF SHELF LIFE OF ALREADY APPROVED MEDICAL DEVICES.

MDB in its 19th meeting held on 31-10-2020 has considered and approved the below mentioned medical devices of M/s Abbott Laboratories (Pakistan) Ltd, Karachi for import:-

Name and Addresses of Establishment	Manufacture Details	Name of Medical Device with sizes/Class/Shelf Life	Brief Description	Decision
M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi (ELI-00019)	**Legal Manufacturer:** Sentinel Ch. S.p.A Via Robert Koch, 25 Milano (MI) 20152, Italy. (FSC Italy Issue 18-6-2018)	Alinity c Lithium Class C Shelf Life: 24 Months (Sizes & Codes as Per FSC) Lithium 8L25-30	Multigent lithium assay is intended for the quantitation of lithium in serum of plasma using the architect systems	**Approved**

Decision: The Board approved the correction of shelf life of above mentioned medical device for import as mentioned below:-

Name and Addresses of Establishment	Name of Medical Device	Previously Apoproved Shelf Life	New Corrected/ Approved shelf life
M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi	**Alinity c Lithium** **Lithium 8L25-30**	**24 months**	**13 months**

14. IMPORT OF RAW MATERIAL/COMPONENTS FOR FABRICATION OF IV CANULLA.

M/s Lasani Healthcare, Plot No.29A, Industrial Estate, Gadoon Amazai Industrial Estate, Khyber Pakhtunkhwa bearing DML.No.000788 dated 03-02-2014 and renewal application dated 24-01-2019 has applied for release of consignment of raw material/component imported from M/s Neotec Medical

Industries, Singapore to be used in the manufacure of their registered products.The firm has submitted following documents with the application:-

(i) Form-11.
(ii) Bank Challan 961848 dated 26-08-2020 application processing fee PKR.5030/-.
(iii) Copy of certificate of analysis.
(iv) Copy of packing list.
(v) Copy of Bill of lading.
(vi) Commercial invoice.
(vii) ISO Certificate.
(viii) Copy of DML and Renewal application.
(ix) Copy of product registration and renewal application.
(x) Declaration (undertaking on stamp paper).

Decision: The Board discussed the matter at length and observed that frequent change of source affects the quality of products and moreover stability studies are required. However, their is no provision in Medical Devices Rules, 2017 to approve the source of raw material or components, therefore, did not agree to fix the source of raw materials/components of medical devices to be manufacured locally.

15. CORRECTION IN BRAND NAME OF SANIPLAST FABRIC BANDAGE AND SIZE OF DERMAPORE WOULD DRESSINGS.

MDB in its 17th meeting held on 13-07-2020 has considered and approved additional sizes of below mentioned medical devices of Uniferoz (Pvt) Ltd, 32/8, Sector 15, Korangi Industrial Area, Karachi for local manufacture:-

S.No	Regn.No	Name of Product	Existing Approved Sizes	Demanded Additional Sizes.
1.	MDMR-000055	Dermapore Surgical Wound Dreswsing.	6 cm x 7 cm (10 Sheet/Box) 9 cm x 10 cm (25heet/Box)	6 cm x 10 cm 9 cm x 15 cm 9 cm x 25 cm 10 cm x 20 cm

It is submitted that the additional size **6 cm x 10 cm** was written wrong inadvertantly while the **correct size is 7 cm x 10 cm**of the above mentioned medical device. Firm has requested for correction of size.

Furthermore, the brand name of medical device namely Sanyplast Fabric Bandages (Enlistment No.0000007) was also mentioned wrong inadvertently (Typographical mistake) as the correct name of the medical devices is Saniplast Fabric Bandages. Firm has requested for correction of brand name as per detail given below:-

Enlistment No.	Existing Name of Medical Device	Correction Required
MDME-0000007.	**Sanyplast** Fabric Bandages	**Saniplast** Fabric Bandages

Decision: The Board approved the correction of size of above mentioned regisgtered medical devices i.e. 7 cm x 10 cm instead of 6 cm x 10 cm. The Board also approved the correction of brand name of above mentioned registered medical device from Sanyplast Fabric Bandages to Saniplast Fabric Bandages

16. Change of Brand Name of already registered medical devices for Local Manufacture.

M/s Silver Surgical Complex (Pvt) Limited, Karachi has requested for grant of approval of change of brand name of their already registered medical devices for local manufacture:-

S.No.	Reg. No.	Existing/Approved brand Name	Proposed brand Names.
1.	067474	Silvocath I.V. Catheter/Canula Moveable Wings with Heparin Lock. Gauges: 16,18, 20, 22, 24.	Green + IV Cannula Moveable Wings with Heparin Lock. Gauges: 16,18, 20, 22, 24.

Decision: The Board discussed and approved the change of brand name of already registered medical device for local manufacture as detail given below:-

Reg. No.	Previous/Existing brand Name	New Approved brand Names.
067474	**Silvocath I.V. Catheter/Canula Moveable Wings with Heparin Lock.** **Gauges: 16,18, 20, 22, 24.**	**Green + IV Cannula** **Moveable Wings with Heparin Lock.** **Gauges: 16, 18, 20, 22, 24.**

17. REGISTRATION OF MEDICAL DEVICES FOR IMPORT.

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

1.	M/s. Cardiac Care, 848-C Shadman-I, Lahore. (ELI-00070)	**Manufacturer:** VYGON, 5 rue Adeline- 95440 Ecouen, France. FSC FRANCE valid till 09-05-2021	**Octopus3 (Multi-lumen extension tube for IV catheters)** Class: B Code: 841.364 Shelf Life: 3 years Fee submitted: Rs.25,000	An IV access accessory particularly recommended in neonates and pediatrics to change a single-lumen catheter in a multi-lumen catheter Sterile, single-use	**Approved.**
2.	M/s. A.H Distributors, House No. CB-708, Lane No. 5, Peshawar Road, Rawalpindi. (ELI-00225)	**Legal Manufacturer:** M/s. Shunmei Medical Co., Ltd, R401 of building B, No.8 Jinglong 1st Road, Baolong Industrial Zone, LongGang District, 518116 Shenzhen, Guangdong, China. **Manufacturing Location:** M/s. Huizhou Branch of Shunmei Medical Co., Ltd., Vifa 3rd Road, Vifa Industrial Zone, Pingtan town, Huiyang District, Huizhou, guangdon, China. FSC U.K Issued on 20-04-2017	**Shunmei** Introducer sets (Codes not mentioned) Class B Shelf Life: 03 years Fee submitted: Rs.25,000	Introducer sets are single use device allowing for introduction, manipulation, and removal of simulation leads after percutaneous entry is gained with a needle.	**Rejected since the** product is already registered in the name of M/s Alliance Medical, Lahore by the same manufacturer. Under Medical Device Rules, 2017 there should be a sole representative for the product.
3.	M/s UDL Distribution (Pvt) Ltd 1-D-13, Sector 30, Korangi Industrial Area, Karachi. (ELI-00073)	**Legal Manufacturer:** Arrow International, Inc. (Subsididary of Teleflex, Inc 2400 Bernville Road, Reading, PA USA 19605. **Manufacturing sites:**	Arrow Arterial Catherization Arterial catherization Class D Shelf Life: 5 Years	The Arrow ® Arterial Catherization Device permits access to the peripheral arterial circulation.	**Deferred** for provision of following:- Clearly state the brand name of the device required on this application as

		1. Arrow Internacional, De Chihuahua S.A. De C.V Ave. Washington 3701, Interior Circuito Industrial Alta Tecnologia ,Edificio 40 Colonia Chihuahua CP 31200. Mexico 2. Arrow International C.R. A.S. Jamska 2359/47 Zdar Nad Sazavou, Czech Republic. (FSC valid till 10-07-2020)	Arterial Catheter kits and sets Arterial Catherization Fee submitted: Rs.50,000		per the Free Sale Certificate. (i) Free Sale Certificate expired. Provide valid Embassy Attested Free Sale Certificate from country of origin. (ii) Provide stability studies supporting the claimed shelf life of 5 years for the applied product signed by responsible personnel of manufacturer abroad (iii) Provide Declaration of Conformity for the applied product (iv) ISO 13485 expired. Provide valid and notarized certificate (v) Provide MRP of the applied product (vi) Provide labels of all codes required on this application (vii) Provide details of QC tests performed on the applied product
4.	-do-	**Legal Manufacturer:** Arrow International, Inc. (Subsidiary of Teleflex, Inc 2400	Arrow Percutaneous Shealth Introducer Percutaneous	The Percutaneous sheath introducer products permit	**Deferred** for provision of following in particular letter of

		Bernville Road, Reading, PA USA 19605. **Manufacturing facility:** Arrow Internacional de Chihuahua S.A. de C.V. Ave. Washington 3701, interior circuito industrial Alta Technologia Edificious 40 and 2, Colonia Panamericana Chihuahua, Chihuahua Mexico Cp 31200. Arrow International, Inc. 312 Commerece Place Asheboro, NC USA 27203 Arrow international C.R. a.s. Jamska 2359/47 Zdar bad /sazaviym Vysocina Czech Republic 591 01 Arrow International de Chihuahua S.A.de C.V. Ave. Washington 3701, Edificios 4 and 36 Colonia Complejo Industrial Las Americas Chihuahua, Chihuahua Mexico Cp 31114. (FSC valid till 10-07-2020)	Shealth Introducer Class B Shelf Life: 5 Years Sheath Introducers Percutaneous Sheath Introducer. Fee submitted: Rs.25,000	venous or arterial access and device introduction to the central circulation.	authorization:- Free Sale Certificate expired. Provide valid Embassy Attested Free Sale Certificate from country of origin. (i) Provide stability studies supporting the claimed shelf life of 5 years for the applied product signed by responsible personnel of manufacturer abroad (ii) Provide Declaration of Conformity for the applied product (iii) Letter of Authorization (LOA) expired. Provide valid, notarized LOA (iv) ISO 13485 expired. Provide valid and notarized certificate (v) Provide MRP of the applied product (vi) Provide labels and brochure of all codes required on this application (vii) Provide details of QC tests performed on the applied

					product
5.	M/s Medtronic Pakistan (Private) Limited, Office No.1301, 13th Floor Dilkusha Forum Tariq Road, Karachi (ELI-00273)	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA **Manufacturing Site:** Medtronic Europe S.a.r.l., Route du Molliau 31, Case postale, 1131 Toloxhenaz, Switzerland. (FSC Switzerland Valid till 06-03-2021)	Amplia MRI™ CRT-D SureScan™ Model: DTMB2D1 (Cardiac Resynchronization therapy implantable defibrillator, MR conditional) Class D Shelf Life: 18 Months Fee submitted: Rs.50,000	The Medtronic Amplia MRI Dual Chamber, Implantable cardioverter defibrillator with cardiac Resynchronization therapy (CRT-D) is a multipromgrammable cardiac device that monitors and regulates the patient's heart rate by providing single or dual chamber, rate-responsive bradycardia pacing; sequential biventrilcular pacing; ventricular tachyarrhythmia therapies; and atrial tachyarrhythmia therapies. Sterile, single-use	**Approved.**
6.	-do-	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA Manufacturing site: Medtronic Ireland, Parkmore Business Park west, Galway, Ireland. (FSC Ireland Valid till 14-12-2023)	Venaseal™ Closure System Code: SP-101 Class C Shelf Life: 2 Years Fee submitted: Rs.50,000	The VenaSeal Closure System is intended for permanent, complete, endovascular adhesive closure of the great saphenous vein (GSV) and associated varicostities in the treatment of venous reflux	**Approved.**

				disease Sterile, single-use	
7.	**-do-**	**Legal Manufacturer:** Medtronic Inc. 8200 Coral Sea Street NE Mounds View, MN USA 55112 Manufacturing site: Medtronic singapore operations Pte Ltd. 49 Changi South Avenue 2, Nasaco Tech Centre, Singapore, 486056 (FSC US FDA Valid till 15-08-2021)	Attesta™ SR MRI Surescan™ (Model: ATSR01) (Single Chamber pacemaker, rate responsive, MR-conditional) Class D Shelf Life: 18 Months Fee submitted: Rs.50,000	Single chamber implantable pulse generator is a multiprogrammable cardiac device that monitors and regulates patient's heart rate by providing single chamber rate responsive bradycardia pacing. Sterile, single-use	**Deferred** as site mentioned on form is not on FSC for this product. Clearly state the legal manufcturer of this product and its manufacturing site supported by FSC ad label.
8.	-do-	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA **Manufacturing Site:** Medtronic Europe S.a.r.l., Route du Molliau 31, Case postale, 1131 Toloxhenaz, Switzerland. (FSC Switzerland Valid till 06-03-2021)	Amplia MRI™ Quad CRT-D SureScan™ (Model: DTMB2Q1) (Cardiac resynchronization therapy implantable defibrillator, MR Conditional) Class D Shelf Life: 18 Months Fee submitted: Rs.50,000	A sterile, implantable, battery-powered device consisting of a hermetically sealed pacing pulse generator and an intergrated defibrillation pulse generator with leads in the right ventricle, in a coronary vein over te left ventricle, and often in the right atrium triple chamber. Sterile, single-use	**Approved.**
9.	-do-	**Legal Manufacturer:** ev3, Inc. 4600 Nathan LN, North Plymouth, MN USA 55442 **Manufacturing Site:** Lake Region Medical, 340 Lake Hazeltine Dr, Chaska, MN USA 55318	Wholey™ Guidewire System Class D Shelf Life: 37 Months Codes as Per FSC No. 6953-3-2019 except code: WWTD35001 &	Sterile, single-use	**Approved.**

		(FSC USFDA valid 20-03-2021)	WWES35001 Fee submitted: Rs.50,000		
10.	-do-	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA **Manufacturing Site:** Medtronic Europe S.a.r.l., Route du Molliau 31, Case postale, 1131 Toloxhenaz, Switzerland. (FSC Switzerland Valid till 06-03-2021)	Evera™ XT DR (Dual-Chamber implantable cardioverter defibrillator) Class D Shelf Life: 18 months Models: DDBB2D4 DDBB2D1 Fee submitted: Rs.50,000	Intended to provide atrila and/ or ventricular antitachycardia pacing, cardioversion, and defibrillation for automated treatment of atrial and /or life-threatening ventricular tachyarrhythmi as. Sterile, single-use	**Approved.**
11.	-do-	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA **Manufacturing Site:** Medtronic Ireland, Parkmore Business Park west, Galway, Ireland. (FSC Ireland valid till 24-05-2022)	IN.PACT Pacific (Paclitaxel-eluting PTA Balloon Catheter) Class D Shelf Life: 3 Years Codes as Per FSC Ireland No. CFS008539 dated 24-05-2017 Fee submitted: Rs.50,000	Indicated for percutaneous transluminal angioplasty (PTA) in patients with obstructive disease of peripheral arteries. Sterile, single-use	**Deferred** for provision of following in particular Full Quality Assurance Certificate:- Provide details of manufacturing & QC tests performed on the applied product (i) ISO 13485 not provided of the legal manufacturer Minneapolis, USA and not provided for manufacturing site Galway, Ireland. Provide valid and notarized certificates of

					these sites. (ii) Full QA certificate not provided of the legal manufacturer Minneapolis, USA and not provided for manufacturing site Galway, Ireland. Provide valid and notarized certificates of these sites. (iii) Provide labels for all the codes applied and brochure.
12.	-do-	**Manufacturer:** Microtherapeutics, Inc. DBA ev3 Neurovascular 9775 Toledo Way Irvine, CA 92618, USA (FSC Netherlands valid till 13-04-2020)	Onyx™ Liquid Embolic System (Neurovascular Embolization Plug) Class D Shelf Life 3 Years Codes as Per FSC Netherland No. 24669 Fee submitted: Rs.50,000	Non-adhesive liquid embolic agent indicated for embolization of lesions in the peripheral and neurovasculature, including arteriovenous malformations and hypervascular tumors. Sterile, single-use	**Deferred** for provision of following in particular letter of authorization:- (i) Stability studies of quick stop syringe provided. Provide complete stability studies of Onyx™ Liquid Embolic System supporting the shelf life claim of 3 years (ii) Clearly state the difference between difference codes applied on this application with justification of how they can be grouped

					together. Also provide brochure (iii) Credentials and Letter of Authorization (LOA) of Medtronic provided whereas manufacturer is Micro therapeutics Inc. State the link (if any) among the two companies and provide relevant credentials and LOA.
13.	-do-	**Manufacturer:** Mirco Therapeutics, Inc. DBA ev3 Neurovascular 9775 Toledo Way Irvine, CA 92618 USA (FSC Netherlands Valid till 13-04-2020)	Concerto™ Detachable Coil System (Non-neurovascular Embolization Coil) Class D Shelf Life: 3 Years Codes as highlighted in FSC Netherland No. 24669 Fee submitted: Rs.50,000	Indicated for arterial and venous embolizations in the peripheral vasculature	**Deferred** for provision of following in particular letter of authorization:- (i) Free Sale Certificate expired. Provide valid Embassy attested FSC for the applied product from the country of origin. (ii) Provide details of manufacturing & QC tests performed on the applied product (iii) Provide complete stability studies of Concerto™ Detechable Coil System

					supporting the shelf life claim of 3 years (iv) Codes of Concerto PGLA fiber will be considered on this application. Submit separate application for Concerto Nylon Fibre (v) Provide brochureof Concerto™ Detechable Coil System (vi) Credentials and Letter of Authorization (LOA) of Medtronic provided whereas manufacturer is Micro therapeutics Inc. State the link (if any) among the two companies and provide relevant credentials and LOA.
14.	-do-	**Legal Manufacturer** Ev3,Inc. 4600 Nathan LN, North Plymouth, MN USA 55442 **Manufacturing Site:** Lake Region Medical, 340 Lake Hazeltine Dr Chasaka, MN USA 55318 (FSC US FDA valid till 13-12-2020)	Nitrex™ Guidewires (coronary and peripheral vasculature use) Class D Shelf Life 3 Years Codes: N140801 N141802 N143001 N180601 N180603 N180801 N180802	Nitinol guidewires for use in the peripheral and coronary vasculature. Sterile, single-use	**Deferred** for provision of following in particular letter of authorization:- (i) Provide details of manufacturing & QC tests performed on the applied product (ii) Provide

			N181804 N181805 N181806 N183001 N183002 Fee submitted: Rs.50,000		complete stability studies of Nitrex™ Guidewires clearly supporting the shelf life claim of 3 years (iii) Codes of class D Nitrex™ Guidewires as mentioned in Declaration of Conformity (DOC) will be considered on this application. Submit separate application for class B guidewires (iv) Provide readable IFU and brochure ofNitrex™ Guidewires **(v)** Credentials and Letter of Authorization (LOA) of Medtronic provided whereas manufacturer is ev3 Inc. State the link (if any) among the two companies and provide relevant credentials and LOA.
15.	-do-	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA **Manufacturing Site:** Medtronic Europe Sarl, route Du Molliau 31,	Primo MRI™ VR SureScan™ (Model: DVMD3D4) (Single Chamber Implantable Cardioverter Defibrillator with	Multiprogrammable cardiac device that monitors and regulates the patient's heart rate by providing single	**Approved.**

		Case Postale,1131 Tolochenaz, Switzerland 1131 (FSC USA Valid till15-08-2021)	Surescan technology, MR conditional) Class D Shelf Life: 18 Months Fee submitted: Rs.50,000	chamber, rate-responsive bradycardia pacing and ventricular tachyarrythmia therapies Sterile, single-use	
16.	-do-	**Legal Manufacturer** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA **Manufacturing Site:** Covidien Boulevard insurgentes 19030 Libramiento Tijuana, B.C., Mexico 22225 (FSC USA valid till 03-03-2021)	ClosureFast™ Endovenous Radio Frequency Ablation (RFA) Catheter (Peripheral Vascular Electrocautery Catheter) Class C Shelf Life: 2 Years Codes: CF7-3-60 CF7-7-100 CF7-7-60 Fee submitted: Rs.50,000	A flexible catheter with a distal heating element/electrode intended to be connected to an electrical generator and introduced into the peripheral vasculature to ablate venous tissues, through direct application of heat, as treatment for venous reflux disease varicose veins. Sterile, single-use	**Approved.**
17.	-do-	**Legal Manufacturer** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA **Manufacturing Site:** Medtronic Puerto Rico Operations Co., villalba Rd. 149, KM. 56.3 Call Box 6001 Villalba, PR USA 00766 FSC USA Valid till 13-02-2020	Attain Ability Plus (transvenous cardiac vein pacing lead) Class D Codes: 4296-78 4296-88 Shelf Life: 2 Years Fee submitted: Rs.50,000	Steroid eluting, dual electrode, transvenous, over the wire, cardiac vein packing lead, designed for pacing and sensing via cardiac vein. Sterile, single-use	**Approved.**
18.	-do-	**Legal Manufacturer** Invatec S.p.A." Via	Amphirion Deep-PTA Catheter	Over the wire (OTW) and	**Approved.**

		Martiri della Liberta 7, Roncadelle (BS) 25030, Italy Manufacturing Site: Medtronic Mexico S. de CV R.L. de C.V. Av. Paseo Cucapah, 10510 El Lago, C.P. 22210 Tijuana, Baja California, Mexico. (FSC Italy issue 22-03-2017)	Class B Codes: Codes as Per FSC Italy dated 22-03-2017 Shelf Life: 3 Years Fee submitted: Rs.25,000	rapid exchange (RX) cathter dedicated to PTA of small peripheral arteries Sterile, single-use	
19.	-do-	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA Manufacturing Site: Medtronic Ireland, Parkmore Business Park west, Galway, Ireland. (FSC Ireland Valid 16-08-2022)	Talent™ Endoluminal Occluder System Class C Codes: OCL08 OCL10 OCL12 OCL14 OCL16 OCL18 OCL20 OCL22 OCL24 Shelf Life: 2 Years Fee submitted: Rs.50,000	Intended for endoluminal occlusion of the contralateral iliac artery in cases where an abdominal aortic aneurysm is treated with an aoto-uni-iliac stent graft and subsequent femoral-to-femoral bypass procedure. It is to be used as an accessory to an aorto-uni-iliac stent graft device. Sterile, single-use	**Deferred** for provision of following in particular Full Quality Assurance Certificate:- (i) Provide details of QC tests of the applied product (ii) Full QA certificate expired. Provide valid and notarized certificate for the applied product (iii) Provide brochure for the applied product
20.	-do-	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN 55432, USA **Manufacturing Site:**	Attain Command + SureValve Left Heart Delivery System Class D Shelf Life: 18	Left heart delivery system kits are designed to facilitate lead implantation in the left heart via	**Deferred** for provision of following in particular Full Quality Assurance Certificate and

		Medtronic Ireland, Parkmore Business Park west, Galway, Ireland. (FSC Ireland Valid till 05-12-2023)	Months Codes not clear	the coronary sinus. Sterile, single-use	clarification on grouping:- (i) Full QA certificate expired. Provide valid and notarized certificate for the applied product (ii) Design Examination certificate expired. Provide valid and notarized certificate for the applied product (iii) Grouping is not clear as to how the applied codes can be applied on single application. Provide justification. Also provide labels of all codes applied and brochure of the product (iv) IFU of only two models provided. Provide IFU for rest of the codes applied
21.	-do-	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA 55432 **Manufacturing Site:** Medtronic Puerto Rico Operations Co.,	RF Enhancr™ II (Steerable electrode catheter for intracardiac ablation) Cardiac Radio-frequency ablation System catheter	Indicated for use with the Medtronic RF generator to deliver RF energy for intracardiac ablation of accessory	**Deferred** for provision of following in particular Full Quality Assurance Certificate:-

		Villalba Rd. 149, KM. 56.3 Call Box 6001 Villalba, PR USA 00766 (FSC USA Valid till 12-11-2020)	Class D Shelf Life : 2 Years Codes : 31744523 31745523 31745533 39745533 39746534 Fee submitted: Rs. 50,000/-	atrioventricular (AV) conduction pathways associated with tachycardia for the treatment of AV nodal re-entrant tachycardia and for creation of complete AV block in patients with a difficult to control ventricular response to an atrial arrhythmia. Sterile, single-use	(i) ISO13485 expired. Provide valid and notarized certificate for the applied product (ii) Full QA certificate expired. Provide valid and notarized certificate for the applied product (iii) Design Examination certificate expired. Provide valid and notarized certificate for the applied product (iv) Provide details of manufacturing & QC tests of the applied product (v) Original FSC not found in the dossier and reference is also not provided. Either provide original Embassy attested FSC or provide reference if it has already been submitted. (vi) Provide labels of all codes applied and brochure of the product
22.	-do-	**Legal Manufacturer**	Attain Ability Straight	Steroid eluting, dual electrode,	**Approved.**

		Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA **Manufacturing Site:** Medtronic Puerto Rico Operations Co., villalba Rd. 149, KM. 56.3 Call Box 6001 Villalba, PR USA 00766 FSC USA Valid till 13-02-2020	(transvenous cardiac vein pacing lead) Codes: 4396-78 4396-88 Class D Shelf Life: 2 Years Fee submitted: Rs. 50,000/-	transvenous, over the wire, cardiac vein pacing lead, designed for pacing and sensing via cardiac vein. Sterile, single-use	
23.	-do-	**Name of owner operator:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA Manufacturing site: Plexus Manufacturing Sdn. Bhd. Bayan Lepas Free Industrial Zone, Phase II, Bayan Lepas, Pulau Pinang Malaydia 11900 (FSC USA Valid till 31-01-2020)	Single Chamber Temporary Pacemaker (Model 53401) (External Pacemaker, invasive) Class C Shelf Life: Not Applicable. Fee submitted: Rs. 50,000/-	Single chamber EPG pacemaker intended to be used in conjunction with a cardiac pacing lead system for temporary atrial or ventricular pacing in a clinical environment.	**Deferred** for provision of following in particular Full Quality Assurance Certificate:- (i) Provide details of manufacturing and QC tests of the applied product (ii) Provide written statement from manufacturer as to why the product does not have a shelf life signed by responsible personnel and provide **service life** of the product (iii) Free Sale Certificate expired. Provide valid Embassy attested FSC for the applied product from the country of

					origin. (iv) ISO 13485 expired. Provide valid and notarized certificate. Also provide valid and notarized ISO13485 certificate of Malaysia site) Full QA expired. Provide valid and notarized certificate including Malaysia site)Provide brochure of the applied product
24.	-do-	**Manufacturer:** ev3, Inc. 4600 Nathan LN, North Plymouth, MN USA 55442 (FSC US FDA valid till 27-01-2021)	Trailblazer™ Support Catheter (Intravascular Guiding Catheter) Class B Shelf Life: 3 Years Codes as per US FDA CFG NO.4376-1-2019 Dated 27-01-2021 Fee submitted: Rs. 50,000/-	Percutaneous, single lumen catheters designed for use in the peripheral vascular system. Intended to guide and support a guidewire during access of the vasculature, allow for wire exchanges and provide a conduit for the delivery of saline solutions or diagnostic contrast agents. Sterile, single-use	**Deferred** for provision of following in particular Full Quality Assurance Certificate and Letter of Authorization:- (i) Provide details of manufacturing performed on the applied product (ii) Provide readable IFU and brochure ofTrailblazer™ Support Catheter (iii) Credentials and Letter of Authorization (LOA) of Medtronic

					provided whereas manufacturer is ev3 Inc. State the link (if any) among the two companies and provide relevant credentials and LOA. (iv) Original FSC not found in the dossier and reference is also not provided. Either provide original Embassy attested FSC or provide reference if it has already been submitted.
25.	-do-	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA **Manufacturing Site:** Medtronic Puerto Rico Operations Co., villalba Rd. 149, KM. 56.3 Call Box 6001 Villalba, PR USA 00766 (FSC US FDA Valid till 12-11-2020)	RF Conductr® (Steerable Electrode Catheter For intracardiac Ablation) Class D Shelf Life: 2 Years Codes: 0786042, 0786044, 0787533, 0787544 Fee submitted: Rs. 50,000/-	Intended for use with a Medtronic RF power generator to deliver RF energy for intracardiac ablation. May also be used for cardiac stimulation or recording Sterile, single-use	**Deferred** for provision of following in particular Full Quality Assurance Certificate:- (i) Provide details of manufacturing and QC tests of the applied product (ii) ISO 13485 expired. Provide valid and notarized certificate. (iii) Full QA certificate expired. Provide valid and notarized certificate. (iv) Design-Examination certificate

					expired. Provide valid and notarized certificate. (v) Original FSC not found in the dossier and reference is also not provided. Either provide original Embassy attested FSC or provide reference if it has already been submitted. (vi) Provide labels of all codes required of the applied product (vii) Provide brochure of the applied product
26.	-do-	**Manufacturer:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA FSC Netherlands Valid till 15-05-2020	Atakr® Plus RF Generator (Cardiac Radio-frequency ablation system.) Model: 990064 Class C Shelf Life: N/A Fee submitted: Rs. 50,000/-	Designed to deliver radio frequency (RF) energy to selected sites in the heart via an RF catheter	**Deferred** for provision of following in particular Full Quality Assurance Certificate:- (i) Provide QC details or validation report of the applied product (ii) Provide **service life** of the product (iii) Free Sale Certificate expired. Provide valid Embassy attested FSC for the applied product from the country of

					origin. (iv) ISO 13485 expired. Provide valid and notarized certificate. (v) Full QA expired. Provide valid and notarized certificate
27.	-do-	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA **Manufacturing Site:** Medtronic Perfusion Systems 7611 Northland Dr Minneapolis, MN USA 55428 (FSC US FDA Valid till 15-02-2020)	Affinity Pixie™ Hollow fiber Oxygenator and Cardiotomy /venous Reservoir with Balance™ Biosurface (BBP241) Class C Shelf Life: 2 Years Fee submitted: Rs. 50,000/-	The oxygenator is intended to be used in an extracorporeal perfusion ciricuit to oxygenate and remove carbon dioxide from the blood and to cool or warm the blood during routine cardiopulmonary bypass procedures up to 6 hours in duration. Cardiotomy/venous reservoir is intended to be used in extracorporeal perfusion circuit to collect venous and cardiotomy suctioned blood during routine cardiopulmonary procedures upto 6 hours in duration. Sterile, single-use	**Deferred** for provision of following in particular Full Quality Assurance Certificate:- (i) Free Sale Certificate expired. Provide valid Embassy attested FSC for the applied product from the country of origin. (ii) ISO 13485 expired. Provide valid and notarized certificate. (iii) Full QA expired. Provide valid and notarized certificate (iv) Provide brochure of the applied product
28.	-do-	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA	Primo MRI™ VR SureScan™ (Model: DVMD3D1)	Multiprogrammable cardiac device that monitors and	**Approved.**

		Manufacturing Site: Medtronic Europe Sarl, route Du Molliau 31, Case Postale,1131 Tolochenaz, Switzerland 1131 (FSC USA Valid till 15-08-2021)	Single Chamber Implantable Cardioverter Defibrillator with Surescan technology, MR conditional Class D Shelf Life: 18 Months Fee submitted: Rs. 50,000/-	regulates the patient's heart rate by providing single chamber, rate-responsive bradycardia pacing and ventricular tachyarrythmia therapies Sterile, single-use	
29.	-do-	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA **Manufacturing Site:** Medtronic Europe S.a.r.l., Route du Molliau 31, Case postale, 1131 Toloxhenaz, Switzerland. (FSC Switzerland Valid till 06-03-2021)	Claria™ MRI CRT-D SureScan™ (Cardiac resynchronization therapy implantable defibrillator) Models: 1. DTMA2D4 MR conditional 2. DTMA2D1 MR conditional Class D Shelf Life: 18 Months Fee submitted: Rs. 50,000/-	A Sterile, implantable, battery-powered device consisting of the hermetically-sealed pacing pulse generator and an integrated defibrillation pulse generator with leads in the righ ventricle, in a coronary vein over the left ventricle, and often in the right atrium (tripel chamber). Sterile, single-use	**Deferred** for provision of following in particular Full Quality Assurance Certificate:- (i) ISO 13485 expired. Provide valid and notarized certificate. (ii) Full QA certificate incomplete. Provide valid, notarized and complete certificate. (iii) Design-Examination certificate expired. Provide valid and notarized certificate. (iv) Reference manuals of the applied models not provided, and the provided ones are not applied. Provide Reference

					manuals of the applied models DTMA2D4 and DTMA2D1. (v) Provide details of manufacturing and QC tests of the applied product (vi) Provide label of model DTMA2D1 (vii) Provide brochure of the applied models
30.	-do-	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA 55432 **Manufacturing Site:** Medplast Medical Inc 620 Watson SW GR, MI USA 49504. FSC US FDA Valid till 08-03-2020	DLP® Silicone Coronary Artery Ostial Cannulae Class D Code: 30315 30317 30320 Shelf Life: 3 Years Fee submitted: Rs. 50,000/-	Intended for use in conjunction with cardiopulmonary bypass surgery upto six hours or less for delivery of cardioplegia solutions directly to the coronary arteries. Sterile, single-use	**Deferred** for provision of following in particular Full Quality Assurance Certificate:- (i) Product is class IIa in EU so design examination certificate is not available. Shortcomings: (ii) Free Sale Certificate expired. Provide valid Embassy attested FSC for the applied product from the country of origin. (iii) ISO 13485 expired. Provide valid and notarized certificate. Also provide valid, notarized ISO 13485 of manufacturing site Medplast

					Medical Inc. (iv) Full QA expired. Provide valid and notarized certificate (v) Provide details of manufacturing of the applied product (vi) Provide labels of all codes applied (vii) Provide brochure of the applied product
31.	-do-	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA 55432 **Manufacturing Site:** Medplast Medical Inc 620 Watson SW, GR, MI USA 49504. FSC US FDA Valid till 08-03-2020	DLP® Pressure Monitoring Catheter Placement Sets Class D Shelf Life: 3 Years Codes: Not clear Fee submitted: Rs. 50,000/-	A Collection of devices that includes the necessary tuning and other items, e.g connectors, stopcock, clamps and filters, used as an external connection for invasive blood pressure measurement. Sterile, single-use	**Deferred** for provision of following in particular Full Quality Assurance Certificate and clarification on grouping:- (i) Free Sale Certificate expired. Provide valid Embassy attested FSC for the applied product from the country of origin. (ii) Grouping not clear. Clearly state the difference between different codes applied on this application and how they can be applied on one application supported by product brochure, labels

					of all codes, stability studies of all codes. Demonstrate with sample packaging IFU of codes 50005 and 50015 not provided. Provide. Some documents indicate change in intended use of different codes. Clarify? (iii) ISO 13485 expired. Provide valid and notarized certificate. (iv) Full QA expired. Provide valid and notarized certificate **(v)** Provide details of manufacturing and QC of the applied product
32.	-do-	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA 55432 **Manufacturing Site:** Medplast Medical Inc 620 Watson SW GR, MI USA 49504. FSC US FDA Valid till 08-03-2020	MiAR™ Cannulae (Aortic Root with Flow Guard) Class D Shelf Life: 3 Years Codes: Not clear Fee submitted: Rs. 50,000/-	Intended for use during cardiopulmonary bypass for the delivery of cardioplegia for upto 6 hours. May also be used to aspirate air from the aorta at the conclusion of the bypass procedure. Sterile, single-use	**Deferred** for provision of following in particular Full Quality Assurance Certificate:- (i) Class B in EU so DE not available (ii) Free Sale Certificate expired. Provide valid Embassy attested FSC for the applied product from the country of

					origin. (iii) ISO 13485 expired. Provide valid and notarized certificate. (iv) Full QA expired. Provide valid and notarized certificate (v) Provide details of manufacturing and QC of the applied product (vi) Grouping not clear. Clearly state the difference between different codes applied on this application and how they can be applied on one application as the DOC and technical documents only indicate 2 codes i.e 11012L and 11014L under MiAR cannulae. Support the claim of grouping the other 2 codes by providing relevant documents (vii) Provide label of all codes applied and brochure.
33.	-do-	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA	DLP® Single Stage Venous Cannulae (with Right Angled Tip)	Intended for collection of venous blood from the right	**Deferred** for provision of following in particular Full

		55432 **Manufacturing Site:** Medplast Medical Inc 620 Watson SW GR, MI USA 49504. FSC US FDA Valid till 08-03-2020	Class D Shelf Life: 3 Years Codes: 67312 67314 67316 67318 67320 69312 69314 69316 69318 69320 69322 69324 69328 69331 69428 69431 Fee submitted: Rs. 50,000/-	side of the heart via the superior and inferior vena cava during cardiopulmonary bypass surgery upto six hour or less. Sterile, single-use	Quality Assurance Certificate:- (i) Class B in EU so DE not available (ii) Free Sale Certificate expired. Provide valid Embassy attested FSC for the applied product from the country of origin. (iii) ISO 13485 expired. Provide valid and notarized certificate. (iv) Full QA expired. Provide valid and notarized certificate (v) Provide details of manufacturing and QC of the applied product (vi) Provide brochure of the product.
34.	-do-	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA 55432 **Manufacturing Site:** Medplast Medical Inc 620 Watson SW GR, MI USA 49504. FSC US FDA Valid till 08-03-2020	DLP® Arteriotomy Cannulae (Coronary artery perfusion Catheter) Class D Shelf Life: 3 Years Codes: 31002 31003 31102 31103 31104 31105	Intended for the perfusion of cardioplegia solution directly into a cardiac bypass graft or artery, or retrograde flushing of the free internal mammary artery with a vasodilator. Intended for use upto 6 hours or	**Deferred** for provision of following in particular Full Quality Assurance Certificate:- (i) Free Sale Certificate expired. Provide valid Embassy attested FSC for the applied

			31106 Fee submitted: Rs. 50,000/-	less. Sterile, single-use	product from the country of origin. (ii) ISO 13485 expired. Provide valid and notarized certificate. (iii) Full QA expired. Provide valid and notarized certificate (iv) Provide details of manufacturing and QC of the applied product (v) Provide brochure of the product (vi) Codes of Flexible Elongated Arteriotomy Cannulae cannot be considered on this application. Submit separate application for them
35.	M/s. Mian Scientific Corporation (Pvt) Ltd, Office No. 534, Jinnah Colony Faisalabad ELI: 00442	**Manufacturer:** i-SENS, INC. 43, Banpo-daero 28-gil, Seocho-gu, Seoul 06646, Republic of Korea FSC Korea date of Issue 29-05-2020 FSC Germany valid till 10.10.2019 (Expired)	**Nipro Premier S Blood Glucose Meter (Model GM01IAA)** Class: C Shelf Life: Not applicable Fee submitted: Rs. 50,000/-	Blood Glucose meter for self test	**Approved.**
36.	M/s Johnson & Johnson (Pvt) Ltd., Office No.806, 8th Floor, Horizon Towers, Block 3,	**Manufacturer:** Ethicon, LLC. Highway 183 Km. 8.3 San Lorenzo, PR USA 00754	Surgicel™ Snow™ Absorbable Haemostat Class D Shelf Life: Not	With enhanced speed, handling and performance, it is easy to deploy and	**Deferred** for provision of following in particular clarification of manufacturing

	Scheme 5, Clifton, Karachi (ELI-00154)	(FSC US FDA valid till 13-12-2019)	mentioned Fee submitted: Rs. 50,000/-	manipulate in laproscopic surgery. It is non-woven structure increase surface contact to bleeding site.	site:- (i) Free Sale certificate expired. Provide valid, Embassy attested Free Sale Certificate for the applied product (ii) Codes applied are not CE-marked neither on Free Sale Certificate (FSC) of USA. Provide FSC containing the applied codes. Alternatively, apply for codes that are CE marked and present on Design-Examination certificate and Declaration of Conformity. (iii) Manufacturing site not mentioned on Form. Clearly state the legal manufacturer and manufacturing site(s) supported by valid Free Sale Certificate and technical documents (iv) ISO 13485 expired. Provide valid and Notarized ISO13485 (v) Provide labels for the codes needed on this

					application (vi) Provide MRP for the codes needed on this application (vii) Shelf life not mentioned on Form
37.	-do-	**Legal Manufacturer:** Ethicon Endo-Surgery, LLC 475 Calle C Guaynabo, PR USA 00969 **Site not mentioned**	Ligaclip (Brand name not clear) Class C Shelf Life: 60 Months Codes: Not clear Fee submitted: Rs. 50,000/-	Extra Ligating Clips feature proprietary lateral and transverse grooves designed for secure fixation on the structure and increased resistance to dislodgement of a formed clip. Clips are compatible with both open and endoscopic single clip appliers.	**Deferred** for provision of following in particular Full Quality Assurance Certificate``:- (i) Free Sale certificate expired. Provide valid, Embassy attested Free Sale Certificate for the applied product (ii) ISO 13485 expired. Provide valid and Notarized ISO13485 (iii) Full QA expired. Provide valid and notarized certificate (iv) Provide MRP for the codes needed on this application (v) Brand name not clear. On form it is mentioned Ligaclip and codes applied are of Ligaclip Extra. Clarify? (vi) Clearly state the

					difference in codes applied on this application. Also provide product brochure. (vii) Manufacturing site not mentioned on Form. Clearly state the legal manufacturer and manufacturing site(s) supported by valid Free Sale Certificate and technical documents
38.	-do-	**Legal Manufacturer:** Ethicon, LLC Highway 183 Km. 8.3 Sn Lorenzo, PR USA.00754 (FSC US FDA valid till 10-04-2020) **Site not mentioned**	Dermabond ™ Topical Skin Adhesive. (Brand name not clear) Class B Shelf Life: 24 Months Codes: Not clear. Also Not on Free Sale Certificate Fee submitted: Rs. 25,000/-	Dermabond™ Topical Skin Adhesive is intended for total application only to hold closed easily approximated skin edges of wounds from surgical incisions, including incisions from minimally invasive surgery, and simple, thoroughly cleasned, tauma-induced lacerations.	**Deferred** for provision of codes on FSC.
39.	-do-	**Legal Manufacturer:** Ethicon SARL Puits Godet 20 CH-2000 Neuchatel Switzerland. (FSC Switzerland Valid 19-08-2021) **Site not mentioned**	Surgicel® Nu-Knit™ Absorbable Haemostat Class D Shelf life: 60 Months	Surgicel® Nu-Knit™ Absorbable hemostat dense material provides high tensile strength in the presence of heavy	**Deferred** for provision of following in particular Full Quality Assurance Certioficate:-

			Codes: Not on Free Sale Certificate Fee submitted: Rs. 50,000/-	bleeding.	(i) Original FSC not found in the dossier and reference is also not provided. Either provide original Embassy attested FSC or provide reference if it has already been submitted. Also Codes not mentioned on Free Sale Certificate (FSC). Applied codes are not CE-marked also. Provide FSC containing the applied codes. Alternatively, select for codes that are CE marked and present on Design-Examination certificate and Declaration of Conformity. (ii) Full Quality Assurance certificate expired. Provide valid and notarized certificate (iii) Provide MRP for the codes needed on this application (iv) Provide labels of the codes needed in this application

					(v) Manufacturing site not mentioned on Form. Clearly state the legal manufacturer and manufacturing site(s) supported by valid Free Sale Certificate and technical documents (vi) Provide details of QC tests of the product (vii) IFU not readable. Provide readable copy (viii) Declaration on stamp paper not found in the dossier. Provide
40.	Ali Gohar & Company (Pvt) Ltd., State Life Building 1-B, I.I. Chundrigar Road, Karachi (ELI-00004)	Legal Manufacturer: M/s Alcon Laboratories Inc. 6201 South Freeway Fort Worth, Texas 76134-2099, USA Manufacturing Site: M/s Alcon Laboratories Ireland Cork Business & Technology Park Model Farm Road, Cork, Ireland FSC TGA Australia issued on 23-05-2019 FSC Ireland valid till 17-1-2023	Clareon Aspheric Hydrophobic Acrylic IOL with the AutonoMe Pre-Loaded Delivery System (CNA0T0) (Posterior chamber intraocular lens , Pseudophakic) **Model/Code** : CNA0T0 **Shelf Life:** 2years **Class B** Fee submitted: Rs. 50,000/-	Description is not provided in the application Form and the attached reference is illegible.	**Approved.**
41.	-do-	Legal Manufacturer: M/s Covidien LLC 15	**Argyle Feeding Tube**	**Disposable feeding tube.**	**Deferred** for provision of Valid Letter of

		Hampshire Street Mansfield, MA 02048, USA. Manufacturing Site: M/s Covidien, Formerly Kendall-Gammatron 117 Moo 2, Petchkasem Rd., Sampran, Nakhon Pathom 73110, Thailand **(FSC USFDA valid 14-09-2019)**	**Class B** **Shelf Life: 05 Years** **Sizes & Codes:** Not applied in application form.		Authorization and codes of product.
42.	-do-	Legal Manufacuturer: M/s Covidien LLC 15 Hampshire Street Mansfield, MA 02048, USA. Manufacturing Site: M/s Covidien, Formerly Kendall-Gammatron 117 Moo 2, Petchkasem Rd., Sampran, Nakhon Pathom 73110, Thailand (FSC USFDA valid 21-02-2020	**Dover (Indwelling Latex Urinary Catheter)** **Class C** **Shelf Life: 05 Years** **Sizes & Codes:** 1602-02 Dover Silicone Coated Latex Foley Catheter 5 ml,2-Way, Male 24 Fr/Ch (8.0mm)		**Deferred** for provision of Followoing in particular Full Quality Assurance Certificate:- Name of the product mentioned in the application Form is Dover (Indwelling Latex Urinary Catheter) But as per FSC and provided label the name of the product is "Dover Silicon Coated Latex Foley Catheter". FSC of US FDA Expired. Full Quality Assurance System Certificate Expired. Declaration of Conformity (DoC) not

					Provided.
43.	-do-	Manufacturer: M/s Wavelight GmbH Am Wolfsmantel 5 91058 Erlangen Deutschland/Germany FSC Germany Issuance Date: 26-02-2019 FSC TGA Australia issuance date: 15-10-2018	Wavelight EX 500 (Ophthalmic Oxcimer laser System) Class C Model: 1016 Service life: 5 years Fee submitted: Rs. 50,000/-	The System is in the refractory surgery for the treatment of myopia, myopic astigmatism, hyperopia, hyperopic astigmatism, mixed astigmatism	**Deferred** for provision of following :- ISO 13485 Expired. Manufacturer as per FSC is M/s Wavelight whereas LOA is from M/s Alcon Pharmaceuticals Ltd (detailed agreement having details of products authorized is also not provided). The link between the two companies could not be established. LOA is from M/s Alcon Pharmaceuticals , Switzerland but in form applied manufacturer M/s Alcon Laboratories, Inc, USA. Needs Clarity
44.	-do-	Manufacturer: M/s Wavelight GmbH Am Wolfsmantel 5 91058 Erlangen Deutschland/Germany FSC Germany Issuance Date: 26-02-2019	Allegro Topolyzer Vario (Model: 1029) Class C Service life: 5 years Fee submitted: Rs. 50,000/-	A medical diagnostic device for human eye examination	**Deferred** for provision of following:- ISO 13485 expired. Manufacturer as per FSC is M/s Wavelight whereas LOA is from M/s Alcon Pharmaceuticals Ltd (detailed

					agreement having details of products authorized is also not provided). The link between the two companies could not be established LOA is from M/s Alcon Pharmaceuticals , Switzerland but in form applied manufacturer M/s Alcon Laboratories, Inc, USA. Needs Clarity
45.	-do-	Legal Manufacturer: M/s Alcon Laboratories Inc. 6201 South Freeway Fort Worth, Texas 76134-2099, USA Manufacturing Site: M/s Alcon Singapore Manufacturing Pte. Ltd., 19 Tuas South Avenue 14, Singapore 637313 FSC TGA Australia issued on 31-01-2019 FSC Singapore Issuance Date 28-02-2019)	Tears Naturale II Lubricant Eye Drops (15ml) Class C Shelf life: Not mentioned Fee submitted: Rs. 50,000/-	Sterile solution intended for protection against dryness/irritation of the eye	**Deferred** for provision of following:- Legal manufacturer applied on form is Alcon, USA and Manufacturing site applied is Singapore. In TGA Australia FSC the manufacturer is M/s Alcon, USA whereas in Singapore FSC the Legal manufacturer is M/s Alcon Switzerland and site if Singapore. It need to be clarified that who is the legal manufacturer of

					the product? LOA is from M/s Alcon Pharmaceuticals, Switzerland but in form applied manufacturer M/s Alcon Laboratories, Inc, USA Shelf life not mentioned on form. Clearly state the shelf life supported by stability studies
46.	-do-	**Manufacturer:** M/s Wavelight GmbH Am Wolfsmantel 5 91058 Erlangen Deutschland/Germany FSC Germany Issuance Date: 26-02-2019)	Wavelight FS200 (Femtosecond ophthalmic solid-state laser system) Class C Model: 1025 Service life: 5 years Fee submitted: Rs. 50,000/-	Used in refractory surgery for creation of corneal flaps and lamellar resections of cornea	**Deferred** for provision of following:- ISO 13485 expired Manufacturer as per FSC is M/s Wavelight whereas LOA is from M/s Alcon Pharmaceuticals Ltd (detailed agreement having details of products authorized is also not provided). The link between the two companies could not be established LOA is from M/s Alcon Pharmaceuticals, Switzerland but in form applied

					manufacturer M/s Alcon Laboratories, Inc, USA. Needs Clarity
47.	-do-	Manufacturer: M/s Wavelight GmbH Am Wolfsmantel 5 91058 Erlangen Deutschland/Germany Manufacturing site: M/s Wavelight GmbH Rheinstr. 8 14513 Teltow Deutschland/Germany FSC Germany Issuance Date: 26-02-2019	Verion Reference Unit Class B Model: X-RUS-03 Service life: 8 years Fee submitted: Rs. 25,000/-	Used for the diagnostic information of the eye coordinate system	**Deferred** for provision of following:- ISO 13485 expired Manufacturer as per FSC is M/s Wavelight whereas LOA is from M/s Alcon Pharmaceuticals Ltd (detailed agreement having details of products authorized is also not provided). The link between the two companies could not be established LOA is from M/s Alcon Pharmaceuticals , Switzerland but in form applied manufacturer M/s Alcon Laboratories, Inc, USA. Needs Clarity Verion digital marker needs to be applied separately
48.	-do-	Manufacturer: M/s Wavelight GmbH Am Wolfsmantel 5 91058 Erlangen Deutschland/Germany	Wavelight Analyzer II (automatic ophthalmic refractometer)	An optical measuring system for the quantitative evaluation of	**Deferred** for provision of following:- ISO 13485

		FSC Germany Issuance Date: 26-02-2019)	Class C Model: 1082 Service life: 5 years Fee submitted: Rs. 50,000/-	the aberrations of human eye by use of wave front technology	expired Manufacturer as per FSC is M/s Wavelight whereas LOA is from M/s Alcon Pharmaceuticals Ltd (detailed agreement having details of products authorized is also not provided). The link between the two companies could not be established LOA is from M/s Alcon Pharmaceuticals, Switzerland but in form applied manufacturer M/s Alcon Laboratories, Inc, USA. Needs Clarity
49.	-do-	**Manufacturer:** M/s Wavelight GmbH Am Wolfsmantel 5 91058 Erlangen Deutschland/Germany FSC Germany Issuance Date: 26-02-2019	Wavelight Oculyzer II (Anterior eye diagnostic device) Class C Model: 1021 Service life: 5 years Fee submitted: Rs. 50,000/-	Designed to measure and examine the anterior eye section	**Deferred** for provision of following:- ISO 13485 expired Manufacturer as per FSC is M/s Wavelight whereas LOA is from M/s Alcon Pharmaceuticals Ltd (detailed agreement having details of products authorized is also not provided). The

					link between the two companies could not be established LOA is from M/s Alcon Pharmaceuticals , Switzerland but in form applied manufacturer M/s Alcon Laboratories, Inc, USA. Needs Clarity
50.	-do-	Legal Manufacturer: Alcon Pharmaceuticals Ltd Rue Louis D'Affry 6, Case Postale, 1701 Fribourg, Switzerland Manufacturing Site: Alcon Singapore Manufacturing PTE. Ltd. 19 Tuas South Avenue 14, Singapore 637313.	Systane® Ultra Lubricant Eye Drops (10ml) Lubricant Eye Drops Class C Shelf Life: 24 months Sizes & Codes as Per FSC	A Systane Ultra Lubricant Eye drop is a dry eye therapy for the temporary relief of burning and irritation due to dryness of the eye. Can be used with contact lens.	**Approved.**
51.	M/s Ophthalmo-Tec Haji Fazal Ellahi Building opp, Women College ShahRah-e-Liaquat Karachi. (ELI- 00310)	**Legal Manufacturer:** FSSB Chirurgische Nadeln GmbH Allmendweg 2 79798 Jestetten / Germany (FSC issuance 24-01-2018)	FSSB Surgical Sutures FSSB Stahldraht (Steel Wire) Class D Shelf Life: 5 Years Stainless Steel 3/4/5/6/7	Surgical sutures for different surgeries, Consistent of needles attached to thread, Sterile packed.	**Approved.**
52.	M/s M Islam & Sons Near Ghee Mills, Tehsil Dargai, District Malakand, KPK, Pakistan ELI-00594	M/s Shandong Haidike Medical Products Co., Ltd. 88 meters west of Tainfu Road, Dongcheng office, Shan County Heze City Shandong Province, China Exportation certificate: China Dated: 27.02.2022 Reference country's FSC:	RTMED Polyglycolic Acid Suture Class-D Shelf life: 3 years **Sizes & codes** USP 12-0, 11-0, 10-0, 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3, 4, 5 **Needle shape:** Round bodied, straight, cutting,	It is intended for use in general soft tissue closing and/or ligation; ein particularin general surgery, skin closure, gastrointestinal surgery, gynaecology, obstetrics, plastic surgery,	**Approved.**

		Spain: 16-03-2020	reverse, taper cutting, **Needle curvature:** ½ circle, 3/8 circle, straight.	urology, ophthalmic surgery, orthopaedics	
53.	-do-	M/s Shandong Haidike Medical Products Co., Ltd. 88 meters west of Tainfu Road, Dongcheng office Shan County Heze City Shandong Province, China Exportation certificate: China Dated: 27.02.2022	RTMED Chrome Catgut Sutures Class-D Shelf life: 3 years **Sizes & codes** USP 12-0, 11-0, 10-0, 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3, 4, 5 **Needle shape:** Round bodied, straight, cutting, reverse, taper cutting, **Needle curvature:** ½ circle, 3/8 circle, straight	Catgut chrome sutures are intended for use in general soft tissue closing and/or ligation; ein particularin general surgery, gastrointestinal surgery, gynecology, obstetrics, urology, ophthalmic surgery	**Deferered** for provision of following:- 1. Product is not on free sale in the country of origin, and the subject device is also not mentioned in the provided reference FSC of Spain 2. Full quality assurance certificate is missing. 3. Design examination certificate is missing**.**
54.	-do-	M/s Shandong Haidike Medical Products Co., Ltd. 88 meters west of Tainfu Road, Dongcheng office, Shan County Heze City Shandong Province, China FSC: China Dated: 27.02.2022	RTMED Silk Non-absorbable sutures Class-D Shelf life: 3 years **Sizes & codes:** USP 12-0, 11-0, 10-0, 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3, 4, 5 **Needle shape:** Round bodied, straight, cutting, reverse, taper cutting, **Needle curvature:** ½ circle, 3/8 circle, straight	Nonabsorbable natural sutures made of raw silk spun by silkworms (an animal protein). ... Their intended use includes suturing of internal organs and tissues; noncoated silk sutures are usually intended for ophthalmic surgery	**Approved.**
55.	-do-	**M/s Shandong Haidike Medical Products Co., Ltd. 88 meters west of Tainfu Road, Dongcheng**	RTMED Polypropylene sutures with needle (non absorbable) Class- D		**Approved.**

		office, Shan County Heze City Shandong Province, China Exportation certificate: China Dated: 27.02.2022 Reference country's FSC: Spain: 16-03-2020	**Shelf life:** 3 years **Sizes & codes** USP 12-0, 11-0, 10-0, 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3, 4, 5 **Needle shape:** Round bodied, straight, cutting, reverse, taper cutting, **Needle curvature:** ½ circle, 3/8 circle, straight		
56.	M/s Al-Farman Trading, 24-A, Satellite Town, Sargodha. ELI-00588	**Legal manufacturer USM Healthcare Lot I-4b, N3 Street, Saigon Hi-tech Park, Long Thanh My Ward, District 9, Ho Chi Minh City, Vietnam FSC Vietnam Validity 16-08-2018 to 16-08-2020**	Bloomsable + (PTCA Balloon Catheter Class- D Shelf life: 36 months Codes/sizes as per FSC	PTCA Balloon Catheter is long, thin tube called a catheter that has a small balloon on its tip. In order to widen narrowed arteries from inside the vessel, physician inflate the balloon at the blockage site in the artery to flatten or compress the plague against the artery wall.	**Approved.**
57.	-do-	**Legal Manufacturer: amg International GmbH, Boschstrabe 16 21423 Winsen-Luhe, Germany FSC Germany Issue date: 20-05-2020**	ISTAR PTCA Balloon Catheter Class- C Shelf life: 36 months Codes/sizes as per FSC	The ISTAR PTCA Balloon Catheter is used to increase the luminal diameter of a coronary artery at the sites of certain types of stenotic lesions by mechanical dilatation.	**Approved.**
58.	-do-	**Legal Manufacturer: amg International GmbH, Boschstrabe 16 21423 Winsen-**	ISOLV Aspiration Catheter Class-C Shelf life: 36	The ISOLV Aspiration Catheter is used to contain and	**Approved.**

		Luhe, Germany **FSC Germany** **Issue date: 20-05-2020**	months Codes/ models: 6 ISV 14 7 ISV 14	aspirate embolic material (thrombus/debris) by percutaneous suction. The ISLOV Aspiration Catheter is indicated for use in the central and peripheral circulatory system in patients with thrombotic occlusion in coronary and peripheral arterial diseases.	
59.	-do-	Legal Manufacturer: amg International GmbH, Boschstrabe 16 21423 Winsen-Luhe, Germany FSC Germany Issue date: 20-05-2020	ITRIX II RAPAMYCIN-Eluting Coronary stent Class-D Shelf life: 24 months Codes & Sizes as per FSC	The device is indicated for improving coronary luminal diameter in patients with Ischemic diseases	**Deferred** as the drug has already been registered in 273rd meeting of DRB for Cardiovascular medical system.
60.	-do-	Legal manufacturer USM Healthcare Lot I-4b, N3 Street, Saigon Hi-tech Park, Long Thanh My Ward, District 9, Ho Chi Minh City, Vietnam FSC Vietnam Validity 16-08-2018 to 16-08-2020.	Xplosion + Sirolimus eluting coronary stent system Class-D Shelf life: 36 months Codes & sizes as per FSC	The device is used for therapy of acute & imminent stenosis	**Approved.**
61.	M/s Safi Brothers office S-22, Second floor Clock Tower, Shamsi Road, Mardan KPK. ELI-00337	**Legal Manufacturer** Ningbo Yingmed Medical Instruments Co., Ltd Yingsheng Building, No, 456 Tai'an Road Southern Business Zone, 315199 Ningbo, China	**YINGMED** (I.V CANNULA with Wings and Heparin Cap (14G-16G-18G-20G-22G-24G) Class: B	I.V Cannula is used for insertion into body, for delivery or removal of fluid or gathering samples.	**Approved** subject to provision of following:- Yingmed brand is already registered for M/s Ghazali

		FSC: MHRA Date of issue 09.02.2018	Shelf life: 5 years		Brother, Karachi Codes and Sizes are not mentioned in Free Sale Certificate of reference country Quality Management Certificate is missing Free sale certificate of Country of origin is missing
62.	M/s Vertex Medical Pvt Ltd, 70-B-1, Gulberg-III, Lahore. ELI: 00150	**Legal Manufacturer** MIPM Mammendorfer Institute fur Physik und Medizin GmbH Oskar-von-Miller Str, 6 82291 Mammendorf, Germany **FSC: Germany** **Date of issue: 16-04-2020**	MRI Patient Monitoring System Tesla M3 Class: C Service Life: 10 years Models/codes: (Tesla M3)	MRI Patient Monitoring System Tesla M3 is used for monitoring the vital parameters during MRI examinations of patients.	**Approved.**
63.	-do-	**Legal Manufacturer** MIPM Mammendorfer Institute fur Physik und Medizin GmbH Oskar-von-Miller Str, 6 82291 Mammendorf, Germany **FSC: Germany** **Date of issue: 16-04-2020**	MRI Patient Monitoring Tesla ^{DUO} Class: C Service Life: 10 years Models/codes: Tesla ^{DUO}	MRI Patient Monitoring System Tesla ^{DUO}is used for monitoring the vital signs during MRI examinations of patients.	**Approved.**
64.	M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi	**Manufacturer:** Abbott Ireland Diagnostic Division Lisnamuck Longford Co. Longford Ireland. (FSC valid 03-09-2023)	Alinity i Urine NGAL Alinity I Urine NGAL Class B Shelf Life: 18 Months Sizes & Codes As Per FSC	The Alinity i Urine NGAL assay is a chemiluminescent microparticle immunoassay (CMIA) used for the quantitative	**Approved.**

	(ELI-00019)			determination of neutrophil gelatinase associated lipcalin (NGAL) in human urine on the Alinity i analyzer	
65.	-do-	**Legal Manufacturer:** Abbot GmbH & Co, Kg Max-Planck-Ring 2 65205 Wiesbaden Germany. (FSC Germany Issuance 26-09-2017)	Microalbumin Class B Shelf Life: Microalbumin 24 Months Microalbumin Calibrator & Control 15 Months (Sizes & Codes as Per FSC) Microalbumin 2K98-21 Microalbumin Calibrator 2K98-03 Microalbumin Control 2K98-11	Microalbumin assay is used for the quantitative measurement of albumin in human urine on the Architect system.	**Approved.**
66.	-do-	Manufacturer: Standard Diagnostics, Inc.65, Bor ahagl-ro, Giheung-gu, Yongin-si, Gyeonggi-do (FSC issuance 11-08-2017)	SD Bioline H.Pylori SD Bioline H.Pylori Ag SD Bioline Strep A Class B Shelf Life: 24 Months Sizes & Codes As Per FSC SD Bioline H.Pylori Ag (04FK20)		**Approved.**
67.	-do-	Manufactuerer: Abon Biopharm (Hangzhou) Co., Ltd #198 12th Street East, Hangzhou Economic & Technological Development Area, Hangzhou, 310018 P.R. China.	FOB One Step Fecal Occult Blood Test Device (Feces) FOB One Step Fecal Occult Blood Test Class B Shelf Life: 24		**Approved.**

		FSC China valid until 05-01-2021 (FSC Germany issuance 21-03-2019 valid for one year)	Months Sizes & Codes As Per FSC TFO-602 FOB One Step Fecal Occult Blood Test Device (Feces)		
68.	-do-	Legal Manufacturer: Abbott Ireland Diagnostics Division Lisnamuck Longford Co. Longford Ireland. (FSC Ireland issue 03-09-2023)	ARCHITECT TSH ARCHITECT Free T3 ARCHITECT Free T4 ARCHITECT Total T4 ARCHITECT Total T3 Class B Shelf Life: ARCHITECT TSH 18 Months, Calibrators & Controls 13 Months ARCHITECT Free T3 11 Months, Calibrators 12 & Controls 10 Months ARCHITECT Free T4 17 Months, Calibrators 18 & Controls 14 Months ARCHITECT Total T4 12 Months, Calibrators 15 & Controls 22 Months ARCHITECT Total T3 12 Months Sizes & Codes as Per FSC	The Architect TSH Assay is a Chemiluminescent microparticle immunoassay (CMIA) used for the quantitative determination of human thyroid Stimulating Hormone (TSH) in human serum and plasma on the Alinity i Analyzer	**Approved.**
69.	-do-	Legal Manufacturer/ Manufacturing Site: M/s Abbott GmbH & Co. KG	Alinity i HBeAg Kit Class D	CMIA used for the qualitative detection of hepatitis B e	**Approved.**

		Max-Planck-Ring 2 65205 Wiesbaden Germany (FSC Germany Issue 19-07-2018)	(1) Alinity i HBeAg Calibrators Code: 07P6401 Shelf Life: 12 Months (2) Alinity i HBeAg Controls Code: 07P6410 Shelf Life: 12 Months (3) Alinity i HBeAg Reagent Kit Code: 07P6422 Shelf Life: 11 Months (4) Alinity i HBeAg Quantitative Calibrators Code: 09P1001 Shelf Life: 12 Months (5) Alinity i HBeAg Quantitative Controls Code: 09P1010 Shelf Life: 12 Months Fee submitted: Rs. 50,000/- (Challan No. 0580219)	Antigen (HBeAg) in human serum and plasma. Can also be used for quantitative determination of HBeAg	
70.	-do-	Legal Manufacturer/ Manufacturing Site: M/s Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden Germany (FSC Germany Issuance Date 15-10-2018)	Alinity s Anti-HBc Kit Class D (i) Alinity s Anti-HBc Calibrator Kit Code:06P0602 Shelf Life: 12Months (ii) Alinity s Anti-HBc Assay	CMIA used for the qualitative detection of antibody to hepatitis B core antigen (Anti-HBc) in human serum and plasma.	**Approved.**

			Control Kit Code:06P0610 Shelf Life: 12Months (iii) Alinity s Anti-HBc Release Control Kit Code:06P0612 Shelf Life: 12Months (iv) Alinity s Anti-HBc Reagent Kit Code:06P0655 Shelf Life: 12Months Fee submitted: 50,000/-		
71.	-do-	Legal Manufacturer/ Manufacturing Site: M/s Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden Germany (FSC Germany Issuance Date 15-10-2018)	Alinity s HIV Ag/Ab Combo Kit Class D (i) Alinity s HIV Ag/Ab Combo Calibrator Kit Code:06P0102 Shelf Life: 12 Months (ii) Alinity s HIV Ag/Ab Combo Assay Controls Kit Code:06P0110 Shelf Life: 12 Months (iii) Alinity s HIV Ag/Ab Combo Release Control Kit Code:06P0112 Shelf Life: 12 Months (iv) Alinity s HIV Ag/Ab Combo Reagent Kit Code:06P0155	CMIA used for the simultaneous qualitative detection of human immunodeficiency virus (HIV) p24 antigen and antibody to HIV type 1 (HIV-1 group M and group O) and/or type-2 (HIV-2) in human serum and plasma	**Approved.**

			Shelf Life: 12 Months Fee submitted: 50,000/-		
72.	-do-	Manufacturer: M/s Abbott Ireland Diagnostics Division Lisnamuck Longford Co., Longford, Ireland (FSC Ireland Valid Till 29-03-2023)	ARCHITECT STAT High Sensitive Troponin-I Kit Class C i) ARCHITECT STAT High Sensitive Troponin-I Reagent Kit Code: 3P25-25 Shelf Life: 6 Months ii) ARCHITECT STAT High Sensitive Troponin-I Reagent Kit Code: 3P25-35 Shelf Life: 6 Months iii) ARCHITECT STAT High Sensitive Troponin-I Reagent Kit Code: 3P25-36 Shelf Life: 6 Months iv) ARCHITECT STAT High Sensitive Troponin-I Reagent Kit Code: 3P25-26 Shelf Life: 6 Months v) ARCHITECT STAT High Sensitive Troponin-I Controls	CMIA for the quantitive determination of cardiac troponin-I (cTnl) in human plasma and serum	**Approved.**

			Code: 3P25-11 Shelf Life: 6 Months vi) ARCHITECT STAT High Sensitive Troponin-I Calibrators Code: 3P25-02 Shelf Life: 9 Months Fee submitted: 50,000/-		
73.	-do-	Manufacturer: M/s Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo, Ireland (FSC Ireland Valid Till 26-05-2022)	ARCHITECT Rubella IgG Kit Class C (i) ARCHITECT Rubella IgG Reagent Code: 6C17-26 Shelf Life: 12 Months (ii) ARCHITECT Rubella IgG Reagent Code: 6C17-36 Shelf Life: 12 Months (iii) ARCHITECT Rubella IgG Controls Code: 6C17-13 Shelf Life: 12 Months (iv) ARCHITECT Rubella IgG Calibrators Code: 6C17-03 Shelf Life: 12 Months Fee submitted: 50,000/-	CMIA for the quantitive determination and qualitative detection of IgG antibodies to rubella virus in human serum and plasma	**Approved.**
74.	-do-	Manufacturer: M/s Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo, Ireland	Alinity i CMV IgM Kit Class C (i) Alinity i CMV	CMIA used for qualitative detection of IgM antibodies to	**Approved.**

		(FSC Ireland Valid Till 26-05-2022)	IgM Reagent Kit Code: 07P4422 Shelf Life: 12 Months (ii) Alinity i CMV IgM Reagent Kit Code: 07P4432 Shelf Life: 12 Months (iii) Alinity i CMV IgM Calibrator Code: 07P4401 Shelf Life: 07 Months (iv) Alinity i CMV IgM Controls Code: 07P4410 Shelf Life: 12 Months Fee submitted: 50,000/-	cytomegalovirus in human serum and plasma	
75.	-do-	Manufacturer: M/s Abbott Ireland Diagnostics Division Lisnamuck Longford Co., Longford, Ireland (FSC Ireland Valid Till 29-03-2023)	Alinity i Total B-hCG Kit Class C (i) Alinity i Total B-hCG Reagent Kit Code: 07P5120 Shelf Life: 12 Months (ii) Alinity i Total B-hCG Reagent Kit Code: 07P5130 Shelf Life: 12 Months (iii) Alinity i Total B-hCG Calibrators Code: 07P5101 Shelf Life: 10 Months (iv) Alinity i Total B-hCG Controls Code: 07P5110	CMIA used for the quantitative and qualitative determination of beta-human chorionic gonadotropin (b-hCG) in human serum and plasma	**Approved.**

			Shelf Life: 10 Months Fee submitted: 50,000/-		
76.	-do-	Manufacturer: M/s Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo, Ireland (FSC Ireland Valid Till 26-05-2022)	Alinity i AFP Kit Class C (i) Alinity i AFP Reagent Kit Code: 07P9030 Shelf Life: 12 Months (ii) Alinity i AFP Reagent Kit Code: 07P9020 Shelf Life: 12 Months (iii) Alinity i AFP Calibrator Code: 07P9001 Shelf Life: 12 Months (iv) Alinity i AFP Controls Code: 07P9010 Shelf Life: 12 Months Fee submitted: 50,000/-	CMIA used for the quantitative determination of alpha-fetoprotein (AFP) in human serum and plasma	**Approved.**
77.	-do-	Manufacturer: M/s Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo, Ireland (FSC Ireland Valid Till 26-05-2022)	Alinity i CEA Kit Class C (i) Alinity i CEA Reagent Kit Code: 07P6220 Shelf Life: 18Months (ii) Alinity i CEA Reagent Kit Code: 07P6230 Shelf Life: 18Months (iii) Alinity i CEA Calibrators Code: 07P6201 Shelf Life: 26	CMIA used for the quantitative determination of Carcinoembryonic Antigen (CEA) in human serum and plasma	**Approved.**

			Months (iv) Alinity i CEA Controls Code: 07P6210 Shelf Life: 26 Months Fee submitted: 50,000/-		
78.	-do-	Manufacturer: M/s Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo, Ireland (FSC Ireland Valid Till 26-05-2022)	Alinity i Rubella IgG Kit Class C (i) Alinity i Rubella IgG Reagent Kit Code: 08P4622 Shelf Life: 12 Months (ii) Alinity i Rubella IgG Reagent Kit Code: 08P4632 Shelf Life: 12 Months (iii) Alinity i Rubella IgG Calibrators Code: 08P4601 Shelf Life: 12 Months (iv) Alinity i Rubella IgG Controls Code: 08P4610 Shelf Life: 12 Months Fee submitted: 50,000/-	CMIA used for the quantitative determination and qualitative detection of IgG antibodies to Rubella virus in human serum and plasma	**Approved.**
79.	-do-	Manufacturer: M/s Abbott Ireland Diagnostic Division, Finisklin Business Park, Sligo, Ireland (FSC Ireland Valid Till 28-03-2023)	Alinity i Total PSA Kit Class C (i) Alinity i Total PSA Reagent Kit Code: 07P9220 Shelf Life: 12 Months	CMIA used for the quantitative determination of total PSA (both free PSA and PSA complexed to alpha-1-antichymotrypsin) in human	**Approved.**

			(ii) Alinity i Total PSA Reagent Kit Code: 07P9230 Shelf Life: 12 Months (iii) Alinity i Total PSA Calibrators Code: 07P9201 Shelf Life: 12 Months (iv) Alinity i Total PSA Controls Code: 07P9210 Shelf Life: 12 Months Fee submitted: 50,000/-	serum	
80.	-do-	Manufacturer: M/s Alere Technologies Gmbh Loebestedter Strasse 103-105 07749 Jena, Germany (FSC Germany Issuance Date 22-06-2017)	Pima CD4 Class C Pima CD4 (100) Code: 260100100 Shelf Life: 18 Months Pima CD4 (25) Code: 260100025 Shelf Life: 18 Months Pima Bead Standard Code: 260400011 Shelf life: 24 Months Fee submitted: 50,000/-	Automated, image-based, immune hematology test intended for the rapid invitro quantitative measurement of CD3+/CD4+ T cells in capillary or venous whole blood	**Approved.**
81.	-do-	Legal Manufacturer: M/s Alere Medical Co., Ltd., 7F Shinjuku NS Building, 2-4-1 Nishi-Shinjuku, Shinjuku-ku, Tokyo 163-0807, Japan Manufacturing Site: M/s Alere Medical	Alere Determine HBsAg Class D Code: 7D2543 Shelf life: 18 Months Fee submitted: 50,000/-	An invitro visually read qualitative immunoassay for the detection of hepatitis B surface antigen (HBsAg) in human serum,	**Approved.**

		Co., Ltd. Chiba Plant 357 Matsuhidai, Matsudo-shi, Chiba 270-2214, Japan (FSC Japan Issue Date 31-10-2018)		plasma or whole blood.	
82.	-do-	**Manufacturer:** Abbot GmbH & Co, KG. Max-Planck-Ring 2 65205 Wiesbaden Germany. (FSC Germany Issue date 19-07-2018)	Alinity i EBV EBNA-1 IgG Kit Class C (i) Alinity i EBV EBNA-1 IgG Reagent Kit Code: 09P2022 Shelf life: 11 months (ii) Alinity i EBV EBNA-1 IgG Reagent Kit Code: 09P2032 Shelf life: 11 months (iii) Alinity i EBV EBNA-1 IgG Calibrator Code: 09P2001 Shelf life: 18 months (iv) Alinity i EBV EBNA-1 IgG Controls Code: 09P2010 Shelf life: 18 months Fee submitted: 50,000/-	CMIA used for the qualitative detection of IgG antibodies to Epstein-Barr Nuclear Antigen-1 (EBNA-1) in human serum and plasma	**Approved.**
83.	-do-	**Manufacturer:** Abbot GmbH & Co, Kg Max-Planck-Ring 2 65205 Wiesbaden Germany. (FSC Germany Issued	Alinity i Toxo IgG Avidity Kit Class C (i) Alinity i Toxo IgG Avidity	CMIA used for the determination of the avidity of IgG antibodies to toxoplasma	**Approved.**

		on 19-07-2018)	Reagent Kit Code: 07P4622 Shelf Life: 12 Months (ii) Alinity i Toxo IgG Avidity Controls Code: 07P4610 Shelf Life: 12 Months Fee submitted: 50,000/-	gondii in human serum and plasma	
84.	-do-	**Manufacturer:** Sentinel Ch. S.p.A Via Robert Koch, 2 20152 Milano, Italy. (FSC Italy issue 18-6-2018)	CK-MB (kit) Class C (i) CK-MB Code: 6K25-30 Shelf life: 21 Months (ii) CK-MB Calibrator: Code: 6K25-10 Shelf life 24Months (iii) CK-MB Controls Code: 6K25-20 Shelf life: 24 Months Fee submitted: 50,000/- (Challan No. 0580471)	Intended for the kinetic determination of CK-MB and CK-BB isoenzymes of creatine kinase in serum or plasma	**Approved.**
85.	-do-	Manufacturer: M/s Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo, Ireland (FSC Ireland Valid Till 28-03-2023)	Alinity i Free PSA Kit Class C (i) Alinity i Free PSA Reagent Kit Code: 07P9320 Shelf Life: 12 Months (ii) Alinity i Free PSA Reagent Kit	CMIA used for the quantitative determination of free prostate specific antigen (PSA) in human serum	**Approved.**

			Code: 07P9330 Shelf Life: 12 Months (iii) Alinity i Free PSA Calibrators Code: 07P9301 Shelf Life: 12 Months (iv) Alinity i Free PSA Controls Code: 07P9310 Shelf Life: 12 Months Fee submitted: 50,000/-		
86.	-do-	**Manufacturer:** Sentinel Ch. S.p.A Via Robert Koch, 2 20152 Milano, Italy. (FSC Italy Issue 18-6-2018)	Lithium (Kit) Class C Code: 8L25-30 Shelf Life: 24 Months Fee submitted: 50,000/-	Multigent lithium assay is intended for the quantitation of lithium in serum of plasma using the architect systems	**Deferred** for provision of following:- MRP, Full QA, stability studies, details of manufacturing not provided. Form 7A not signed and stamped.
87.	-do-	**Manufacturer:** M/s Abbott Rapid Diagnostics, Jena GmbH., Orlaweg 1, 07743 Jena, Germany. FSC Germany COPY Issue Date 1-09-2020 (NOT Embassy attested)	Panbio COVID-19 Ag Rapid Test Device (Nasopharyngeal) Class C Code: Ref. 41FK10 Shelf Life: 12 Months (based on accelerated study results. The study is ongoing) Fee submitted: Rs. 50,000/-	Panbio COVID-19 Ag Rapid Test Device is an in vitro diagnostics rapid test for the qualitative detection of SARS-CoV-2 antigen (Ag) in human nasopharyngeal swab specimens from individuals who meet COVID-19 clinical and / or epidemiological criteria.	**Deferred** for provision of following:- i) FSC of Germany not original and not Embassy attested; ii) Clarification whether WHO has recommended usage of Rapis Testing Kits or not.

				Panbio COVID-19 Ag Rapid Test Device is for professional use only and is intended to be used as an aid in the diagnosis of SARS-CoV-2 infection. The product may be used in any laboratory and non-laboratory environment that meets the requirements specified in the Instructions for Use and local regulation. The test provides preliminary test results. Negative results don't preclude SARS-CoV-2 infection and they cannot be used as the sole basis for treatment or other management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information. The test is not intended to be used as a donor screening test for SARS-CoV-	

				2.	
88.	M/s. Schazoo SPL Consumer Health Care71 B/C2, Gulberg 3, Lahore. [ELI-00095]	**Legal Manufacturer:** Apharm S.R.L, iyaly FSC: Italy Date of issue 05.04.2019	Vijoint hcc60 mg/3ml. (Hyaluronic acid Sodium Salt, Chondroitin Sulfate, Cyclodextrin) Claimed Shelf Life: 02-years Rs.50,000/-	The Device is a synovial fluid substitute for use in joints with degenerative or mechanical joint disese causing pain or impaired mobility.	**Deferred** for provision of following:- Provide the original FSC as per 4 (xiv) of Form-7A. Provide ISO-13485 as per 5 (vi) of Form-7A for both legal and actual manufacturer of the subject product. Name of manufacturing site involved in the productio, quality control and marketing/ exportation is not mentioned on the application form and FSC, clarified required.
89.	3M Pakistan (Pvt) Ltd., Islamic Chamber of Commerce of Commerce Building, Street No.2/A, Block 9, KDA Scheme 5, Clifton, Karachi (ELI-00259)	**Manufacturer:** M/s 3M Deutschland GmbH Health Care Business Carl-Schurz-Str. 1 41453 Neuss, Germany FSC Germany COPY Issue Date: 04-12-2019 (Not Embassy Attested)	3M Tegaderm Transparent Film Dressing Frame Style Code: 1623W Class B Shelf Life: Not Mentioned on form Fee submitted: Rs.25,000/-	Sterile, single - use	**Approved.**
90.	M/s. M&M Pharma	**Manufacturer:** Zhejiang Bangli	**M Care** (Adhesive Paper	Used to fix the dressing on	**Approved** subject to

	Javaid Plaza, Opp gate No 2 pepsi Factory Gurumanget Road, Gulberg II, Lahore ELI-00159	Medical Products Co., Ltd No. 118, Yuegui, South Road, City West New district,321300, Youngkang City, Zhejiang Province, China FSC China valid till 27-06-2021	Tape) Class-Not mentioned Shelf Life: Not clear Fee submitted: Rs. 50,000/-	injured area, and can also be used for the fixation of intravenous infusion catheter.	provision of following:- The name of the device is not clear whether it is adhesive paper tape or non-woven surgical tape? The shelf life of the device is not mentioned on form. In some documents 3 years is mentioned while 5 years in others. Clearly state the shelf life of the product Clarify if the device required on this application is sterile or non-sterile? Class of the device is not mentioned. Clearly state the device class and the relevant rule under Schedule A of the Medical Device Rules, 2017. If the manufacturer determines the class of the device as per intended use to be Class A, then submit Form 6-A for the product

					Grouping of the device is not provided. Clearly state the grouping option for this application as per Schedule B of the Medical Devices Rules, 2017 and sizes/codes required on this application Provide MRP of the applied device Production Quality Assurance certificate is expired. Provide valid and notarized certificate Undertaking required from the manufacturer that same product with same specifications will be supplied to Pakistan as claimed for CE marking of Europe on the letterhead signed and stamped by responsible personnel Provide labels of all sizes/codes required on this

					application as approved in the country of origin and specimen label for Pakistan and also provide product brochure. Provide sample of the product Credentials as per prescribed format are not provided

18. ENLISTMENT OF MEDICAL DEVICES FOR IMPORT.

Sr. No	Name and Addresses of Establishment	Manufacture Details	Name of Medical Device with sizes/Class/ Shelf Life	Brief Description	Decisions
1.	M/s Medtronic Pakistan (Private) Limited, Office No.1301, 13th Floor Dilkusha Forum Tariq Road, Karachi (ELI-00273)	Manufacturer: Medtronic CryoCath LP 9000 Autoroute Transcanadienne Pointe-Claire, Quebec H9R 5Z8 Canada. (FSC Netherlands valid till 31-03-2021)	Electrical Umbilical Cable Class A Shelf Life: N/A Codes: 2035U 2035UC Fee submitted: Rs. 5,000/-	Designed for use with Medtronic Cryoconsole as it provides an electrical connection to the Medtronic cryoablation catheter Sterile, single use	**Approved.**
2.	M/s Vertex Medical Pvt Ltd, 70-B-1, Gulberg-III, Lahore. ELI: 00150	**Legal Manufacturer** Merivaara Corp-Finland, Puustellintie 2, FI-15150 Lahti **FSC: Finland** **Date of issue: 19-11-2019**	Merivaara Practico Practico Manual operating table Class-A Service Life: 10 years Model/ codes: FI-CA01-2019-1022 100030000, 100030010	Operating Tables used in hospitals.	**Approved.**

3.	-do-	**Legal Manufacturer** Merivaara Corp-Finland, Puustellintie 2, FI-15150 Lahti **FSC: Finland Date of issue: 19-11-2019**	Merivaara operating table Promerix Class-A Service Life: 10 years Model: FI-CA01-2019-1201 Code: 100060000		**Approved.**
4.	-do-	**Legal Manufacturer** Merivaara Corp-Finland, Puustellintie 2, FI-15150 Lahti **FSC: Finland Date of issue: 19-11-2019**	Merivaara Practico Smaeter Practico operating table Class-A Service Life: 10 years Model/ codes:		**Approved.**
5.	-do-	**Legal Manufacturer** Merivaara Corp-Finland, Puustellintie 2, FI-15150 Lahti **FSC: Finland Date of issue: 19-11-2019**	Merivaara Q-Flow surgical light system Class-A Service Life: 10 years Model: FI-CA01-2018-0124 Codes: Q-Flow SOLO 520210, Q-Flow DUO 320 520220, Q-Flow DUO 520222, Q-Flow TRIO 520230, Q-Flow MOBILE 520211		**Approved.**

19. <u>DEFERED CASES OF REGISTRATION/ENLISTMENT FOR IMPORT.</u>

Following applications for registration/enlistment of Medical Devices for import were placed before the MDB in different meetings and deferred for provision of document. Now firm has submitted the shortcomings

Sr.#	**Name and Addresses of Applicant.**	**Manufacture Details**	**Name of Medical Device with sizes /Class/Shelf Life, Description**	**Decisions**
1.	Muller & Phipps Pakistan	Legal Manufacturer:	CONTOUR PLUS ONE	**Approved.**

	(Pvt) Ltd., Uzma Court, Main Clifton Road, Karachi (ELI-00030)	M/s Ascensia Diabetes Care Holdings AG Peter Merian-Strasse 90 4052 Basel, Switzerland Manufacturers: 1. PT PHC Indonesia, Bekasi 17520, Indonesia (for Glucose Meter). 2. PHC Corporation; Ehime 791-0395, Japan (For Test Strips). 3. HTL-Strefa S.A Poland (For Lancets/ Lancing Device)	blood glucose monitoring system. Codes & Sizes as per FSC. Class C Shelf Life: 24 months for strips and 05-years for lancets. Rs.50,000/- (Contour Plus one blood glucose monitoring system consists of a small handheld electronic device, test strips, lancing device, lancets and an app compatible to IOS & Android OS for auto memory and coding of tests.)	
2.	Premier Agencies, 60, Muslimabad, Jamshed Quarters, M.A. Jinnah Road Extension, Karachi Plot No. D-3, D-4 & D-5, Sector 6-F, Mehran Town Industrial Area, Karchi (ELI-00050)	Legal Manufacturer: M/s Becton Dickinson and Company 1 Becton Drive Franklin Lakes, NJ 07417, USA Manufacturing Site: M/s BD Medical - Diabetes Care 1329 West Highway 6 Holdrege, NE 68949, USA. FSC USA expiration Date (20-11-2019)	BD Ultra Fine Insulin Syringe. **Class B** Claimed Shelf Life: 05 Years Rs. 25,000/- Codes & Sizes as per FSC. The BD insulin syringe with the BD Ultra-Fine™ 6mm™ needle features shortest insulin syringe needle, at 53% shorter than the 12.7-mm needle.	**Approved.**
3.	M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi (ELI-00019)	**Legal Manufacturer:** Abbott Ireland Diagnostic Division Lisnamuck Longford Ireland. (FSC Ireland issue 18-10-2018)	Alinityi TSH Alinityi Free T3 Alinityi Free T4 Alinity i Total T4 Alinity i Total T3 Class- B Shelf Life: Alinityi TSH 18 months, Calibrators & Controls 13 Months Alinityi Free T3 11 months Calibrators 08 months & Controls 10	**Approved.**

			Alinityi Free T4 12 Months, Calibrator 18 Months & Controls 14 Months Alinity i Total T4 12 Months, Calibrator 12 Months & Controls 14 Months Alinity i Total T3 11 Month, Calibrator & Controls 12 Months Codes & sizes as per FSC The Alinityi TSH Assay is a Chemiluminescent microparticle immunoassay (CMIA) used for the quantitative determination of human thyroid Stimulating Hormone (TSH) in human serum and plasma on the Alinity I Analyzer.	
4.	-do-	**Legal Manufacturer:** Abbott GmbH & Co, Kg Max-Planck-Ring 2 65205 Wiesbaden Germany. (FSC Germany issue 19-07-2018)	Alinity c Cholestrol Alinity c Triglyceride Alinity c Ultra HDL Alinity c Direct LDL Alinity c Lipid Multiconstituent Calibrator Class- B Shelf Life: Alinity c Cholestrol 18 Months Alinity c Triglyceride 09 Months Alinity c Ultra HDL 17 Months Sizes/Codes as Per FSC Alinity c Cholestrol assay is used for the quantitation of cholesterol in human serum or plasma on the Alinity c Analzyer	**Approved.**
5.	-do-	Abbott Park, Illinois 60064	Glucose Creatinine	**Approved.**

		VALID FSC OF USA VALID FROM 04thMARCH 2019 TO 03rd MARCH	Urea Nitrogen Uric Acid Multiconstituent Calibrator Class-B Shelf life: Glucose 13 months Creatinine 18 months Urea Nitrogen 13 months Uric Acid 24 Months Multiconstituent Calibrator 20 months Codes/sizes Glucose 3L82-21 Glucose 3L82-41 Creatinine 3L81-22 Creatinine 3L81-32 Creatinine 3L81-41 Urea Nitrogen 7D75-21 Urea Nitrogen 7D75-31 Urea Nitrogen 7D75-31 Uric Acid 3P39-21 Uric Acid 3P39-41 Multiconstituent Calibrator 1E65-05 The Creatinine assay is used for quantitation of creatinine in human serum, plasma or urine. The Glucose assay is used for quantitation of glucose in human serum, plasma, urine or CSF. The Multiconstituent calibrator is used in calibration of Albumin, Calcium, Cholestrol, Creatinine, Glucose, Iron, Lactic acid, Megnesium, Phosphorus, Total Protein, Triglyceride, Urea Nitrogen and Uric acid assays. The Urea nitrogen assay is used for the quantitation of urea	

			nitrogen in human serum, plasma or urine. The Uric Acid assay is used for the quantitation of uric acid in human serum, plasma or urine.	
6.	-do-	**Legal Manufacturer:** M/s. Abbott GmbH & Co, Kg Max-Planck-Ring 2 65205 Wiesbaden Germany. (FSC Germany Issuance 14-10-2016)	Architect Active-B12 (Holotranscobalamin)reagent kit (100 test) Code:3P24-25 Architect Active-B12 (Holotranscobalamin)reagent kit (500 test) Code:3P24-35 Architect Active-B12 (Holotranscobalamin)Calibrator kit Code:3P24-01 Architect Active-B12 (Holotranscobalamin)Control kit Code:3P24-10 Class B Shelf Life:18 months (2ºC -8ºC) The Architect Active-B12 (Holotranscobalamin) assay is a chemiluminescentmicro particle immunoassay (CIMA) for the quantitative determination of Holotranscobalamin in human serum on the Architect I System and is used as an aid in the diagnosis and treatment of vitamin deficiency.	**Approved.**
7.	-do-	**Manufacturer:** Microgenics Corporation 46500 Kato Road, Fremont, CA USA 94538 (FSC US FDA	Digoxin (kit) Class C Digoxin Code: 1E06-21 Shelf Life: 24 Months	**Approved.**

		Valid till 06-11-2020)	Fee submitted: Rs. 50,000/- Used for the quantitative in vitro measurement of digoxin in human serum or plasma.	
8.	-do-	**Manufacturer:** M/s. Abbott GmbH & Co, KG Max-Planck-Ring 265205, Wiesbaden, Germany. (FSC Germany Issued on 22-06-2017)	Alinity i HE4 Kit Class C Alinity i HE4 Reagent Kit Code: 08P5022 Shelf life 12 Months Alinity i HE4 Calibrators Code: 08P5001 Shelf life 12 Months Alinity i HE4 Controls Code: 08P5010 Shelf life 12 Months Fee submitted: Rs. 50,000/- CMIA used for the quantitative determination of HE4 antigen in human serum on the Alinity I analyzer.	**Approved.**
9.	M/s United Healthcare, Plot No. 330, 2nd Floor, DMCH, Bahadurabad, Karachi	**Legal Manufacturer:** M/s HuaianMedicom Medical Technology Co. Ltd., N0123 Meicheng west road, Qingpu industry park, huaian city, Jiangsu, China FSC China valid till	Safety-Heparin Cap (Infusion Connector) Heparin Cap or Infusion Connector (Heparin Cap) Class B Shelf Life: 05 Years Red, Blue, White, Yellow, Transparent To provide a port for	**Approved.**

		30-01-2021	Drug administration into the catheter without unscrew it	
10.	-do-	**Legal Manufacturer:** M/s HuaianMedicom Medical Technology Co. Ltd., N0123 Meicheng west road, Qingpu industry park, huaian city, Jiangsu, China FSC China valid till 30-01-2021	Star-Urine Drainage Bag Class A Shelf Life: 05 Years 100ml, 200ml, 750ml, 1000ml, 1500ml, 2000ml Collection and temporary storage of uringe	**Approved.**

20. <u>CASES WHICH WERE APPROVED IN PREVIOUS MDB MEETINGS SUBJECT TO PROVISION OF DOCUMENTS.</u>

Following applications for enlistment/registration were approved in previous MDB meetings (Meeting No. tabulated below) for want a certain document/information on part of the applicant firms. The desire information has been provided by the firms as detail below and submitted for information of MDB before issuance of enlistment/registration letter to the applicant firms.

Decision: The Board discussed and decided as mentioned against each:-

Sr.#	Name and Addresses of Applicant.	Manufacture Details	Name of Medical Device with sizes /Class/Shelf Life, Description	Decisions
1.	M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi (ELI-00019)	**Legal Manufacturer:** Abbot GmbH & Co, Kg Max-Planck-Ring 2 65205 Wiesbaden Germany. (FSC Germany Issuance 23-07-2017)	Alinity I 2nd Generation Testosterone, Alinity i SHBG, Alinityi DHEA-S Class- B Shelf Life: Alinity I 2nd Generation Testosterone Reagent: 2nd Generation 9 months Calibrator 12 Months Control: 11 M, Alinity I SHBG Reagent: 10 Months	**Approved.**

			Clibrators: 9 Months Controls: 15 Months Alinityi DHEA-S Reagent: 9 Months, Calibrator: 8 Months, Calibrator: 8 Months, Controls: 15 Months (Sizes & Codes as Per FSC) Alinityi 2nd Generation Testosterone, Reagent Kit (2x 100 Test) 07P6822 Alinityi 2nd Generation Testosterone, Reagent Kit (2x 400 Test) 07P6832 Alinityi 2nd Generation Testosterone, Calibrator 07P6801 Alinityi 2nd Generation Testosterone, Controls 077P6810. The Alinity i 2ndGenertaion Testosterone assay is used for the quantitative determination of testosterone in human serum and plasma. The Alinity i SHBG assay is used for the Quantitative determination of sex human serum and plasma. The Alinityi DHEA-S assay is used for the quantitative determination of dehydroepiandrosterone sulfate (DHEA-S) in Human serum.	
2.	-do-	**Abbott** Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.	ARCHITECT Urine NGAL Calibrator 1P37-01 Controls 1P37-10 Reagent Kit 1P37-25 Reagent Kit 1P37-35	**Approved.**

		VALID FSC OF IRELAND EXPIRED ON 03rdSEPTEMBER 2023.	Class-B Shelf Life: 18 Months ARCHITECT Urine NGAL consists of Calibrator, Controls, Reagent Kit and Reagent Kit. The device may be used for the in-vitro determination of human NGAL in urine as an indication of kidney injury	
3.	-do-	**Legal Manufacturer:** Abbott Laboratories Abbott Diagnostic Division 100 Abbott Park Road Abbott Park, IL 60064, USA. (FSC USFDA Valid Till 25-04-2020)	Architect Stat CK-MB Class C Shelf Life: Reagent & Calibrator 18 Months Controls 36 Months Codes/sizes: 2K42-28, 2K42-38, 2K42-01, 2K42-10. Assay for the quantitative determination of the MB isoenzyme of creatine kinase (CK-MB) in human serum and plasma	**Approved.**
4.	-do-	**Manufacturer:** Axis-Shield Diagnostics Ltd, Luna Place, The Technology Park, Dundee, DD2 1XA, United Kingdom. (FSC UK issuance 12-12-2018)	Alere NT-proBNP for Alinityi Reagent Kit, Calibrators & Controls Class C Shelf Life: Alere NT-proBNP for Alinityi Reagent Kit, Calibrators 10 Months & Controls 11 Months Sizes & Codes as Per FSC 04S7920 (2x100 Test Reagent), 04S7930 (2x500 Test Reagent), 04S7901 (Calibrator) & 04s7910 (Controls) The Alere NT-proBNP	**Approved.**

			for Alinity i assay is a chemiluminesent microparticle immunoassay used for the in vitro quantitative determination of N-terminal pro B-type natriuretic peptide in human serum and olasma on Alinity i analyzer.	
5.	-do-	**Manufacturer:** Abbott Ireland Diagnostic Division Lisnamuck Longford Co. Longford Ireland. (FSC valid 03-09-2023)	Alinityi LH Alinityi FSH Alinityi Estrdiol Alinityi Prolactin Alinityi Progesterone Class B Shelf Life: Alinity i LH 15 Months, Cal: 12 Months Alinityi FSH 18 Months, Cal & Control: 15 Months AlinityiEstrdiol 8 Months, Cal & Control 10 Months Alinityi Prolactin 12 Months Alinityi Progesterone 9 Months, Cal & Control 12 Months Sizes & Codes As Per FSC	**Approved.**

21. REGISTRATION OF MEDICAL DEVICES FOR LOCAL MANUFACTURER (Form 7)

Sr No.	Name and Address of Firm	Name of Medical Device/ Shelf Life/ Class of MD	Brief Description	Decisions
1.	M/s Silver Surgical Complex (Pvt) Ltd. C-40/41, Scheme 33, SITE, Super Highway, Industrial Area, Karachi (ELM-0007)	Sterile Hypodermic Needle 23,24 and 21 Gauge Class B Shelf Life: 05 Years Rs.20,000/-	The hypodermic needle is a device used by medical professionals to transfer liquids into or out of the body. Used after attaching it with syringe	**Approved.**

2.	M/s 3N-Lifemed Pharmaceuticals, 45 SB Abdullah Colony, Sargodha (ELM-0026)	Lifemed BiBag Concentrate Powder (3NLBB) Class B Shelf Life: 03 Years Rs. 20,000/- Sizes/Pack as mentioned/ applied in Form	Sodium Bicarbonate Haemodialysis Concentrate Part-B: Powder	**Approved.**
3.	-do-	Lifemed Tricarb Dry Powder (3NLDP) Class B Shelf Life: 03 Years Rs. 20,000/- Sizes/Pack as mentioned/ applied in Form	Haemodialysis Concentrate Part-A Powder Part-B Powder Part-C Liquid	**Approved.**
4.	-do-	Lifemed Citrate Bicarb Concentrate (3NLCPSV) Class B Shelf Life: 03 Years Rs. 20,000/- Sizes/Pack as mentioned/ applied in Form	Haemodialysis Concentrate Part-A Solution Part-B Powder	**Approved.**
5.	-do-	Lifemed Bicart (3NLBC) Class B Shelf Life: 03 Years Rs. 20,000/- Sizes/Pack as mentioned/ applied in Form	Sodium Bicarbonate Haemodialysis Concentrate Part-B: Powder	**Approved.**
6.	M/s Whitesun Pharma, Marri Road, Tehsil Kamoke, Distt Gujranwala (ELM-0016)	Nexcare Gauze Swab Class B Shelf Life: 03 Years Rs. 20,000/-	Non Extensible	**Approved.**

		Sizes/Pack as mentioned/ applied in Form		

22. ENLISTMENT OF MEDICAL DEVICES FOR LOCAL MANUFACTURER (Form 6)

Sr No.	Name and Address of Firm	Name of Medical Device/ Shelf Life/ Class of MD	Brief Description	Decisions
1.	M/s Essity Pakistan Limited, A/69, SITE Manghopir Road, P O Box 3659, Karahi (ELM-00008)	Gypsona (Plaster of Paris Bandage) Class A Shelf Life: 05 Years Rs.5,000/- Sizes/Pack as mentioned/applied in Form	Plaster of Paris Bandage	**Approved.**
2.	-do-	Elastocrepe (Cotton Crepe Bandage) Class A Shelf Life: 05 Years Rs.5,000/- Sizes/Pack as mentioned/ applied in Form	Cotton Crepe Bandage	**Approved.**
3.	-do-	Coverplast E (First Aid Dressing) Class A Shelf Life: 05 Years Rs. 5,000/- Sizes/Pack as mentioned/applied in Form	First Aid Dressing	**Approved.**
4.	M/s Silver Surgical Complex (Pvt) Ltd. C-40/41, Scheme 33, SITE, Super Highway, Industrial Area, Karachi (ELM-0007)	Heparin Cap Class A Shelf Life: 05 Years Rs. 5,000/- Sizes/Pack as mentioned/applied in Form	Injection Stopper/ Luer Cap	**Approved.**

5.	M/s Lab Diagnostic Systems (SMC) Pvt Ltd., 111, Hali Road, Westridge 1, Rawalpindi	Viral Transport Media Class A Shelf Life: 12 Months from the manufacture date when stored at +2C to +8C. 3 Months from the manufacture date when stored at +15C to +25C Rs. 5,000/- Sizes/Pack as mentioned/applied in Form	Viral Specimen transfer solution/medium **Source:** M/s Capricon Scientific GmbH Auf der Lette 13 A 35085 Ebsdorfergrund, Germany **Formulation:** The Viral Transport Medium is based on Hanks Balanced Salt Solution (HBSS) with Calcium and Magnesium and contains heat-inactivated Fetal Bovine Serum, Gentamicin and Amphotericin B.	**Approved.**

23. RENEWAL OF MEDICAL DEVICES FOR LOCAL MANUFACTURER (FORM 6).

Sr No.	Name and Address of Firm	Name of Medical Device/ Shelf Life/ Class of MD	Brief Description	Decisions
1.	M/s Asian Fiber, Plot No. 41-42, Sector 25, KIA, Karachi (DML-000668)	Ortho Band Bandage Previous Reg. No. 061279 Class A Shelf Life: 02 Years Rs. 5,000/- Sizes/Pack as mentioned/ applied in Form	Ortho Band Bandage	**Approved.**
2.	-do-	Absorbent Cotton Wool Previous Reg. No. 061281 Class A Shelf Life: 02 Years Rs. 5,000/- Sizes/Pack as mentioned/ applied in Form	Absorbent Cotton Wool	**Approved.**
3.	-do-	Wave Cot	Wave Cot	**Approved.**

		Previous Reg. No. 061277 Class A Shelf Life: 02 Years Rs. 5,000/- Sizes/Pack as mentioned/ applied in Form		
4.	-do-	Ascrepe Crope Bandage Previous Reg. No. 061278 Class A Shelf Life: 02 Years Rs. 5,000/- Sizes/Pack as mentioned/ applied in Form	Ascrepe Crope Bandage	**Approved.**
5.	-do-	Chlore Tulle Previous Reg. No. 061280 Class A Shelf Life: 02 Years Rs. 5,000/- Sizes/Pack as mentioned/ applied in Form	Chlore Tulle	**Approved** as Class-C medical device subject to submission of differential fee.