Government of Pakistan
Ministry of National Health Services, Regulation & Coordination
Drug Regulatory Authority of Pakistan
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DECISIONS OF THE 35TH MEETING OF THE MEDICAL DEVICE BOARD (MDB) HELD ON 14-07-2021

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

S.#	Name of Establishment	Director/Proprietor/partners	Cold Chain (Yes/No)	Decision
1.	M/s Shafia Enterprises 2nd floor, Nigar Center, Patiala Ground link Mcleod Road, Lahore	Mr. Shahzad Ahmed	No	**Approved** for storage of non cold chain medical devices.
2.	M/s Maven Healthcare House no. 11, Canel Park Gulberg II, Lahore.	Mr. Ayaz Ahemd	No	**Approved** for storage of non cold chain medical devices.
3.	M/s Biliness (SMC) Private Limited, Ground Floor Hameed Building, Bakkar Mandi, Band Road Lahore.	Muhammad Usama	No	**Approved** for storage of non cold chain medical devices.
4.	M/s Zhong Pak Facilitators, KandiArbab Sikandar Khan Khalil,Tehkal Bala, Peshawar.	Arbab Shafiq Ahmed Khan Arbab Daud Khan	No	**Approved** for storage of non cold chain medical devices.
5.	M/s. ZH Traders, House no. 16, Street No. 03, Sharif Park Begum Pura Lahore.	Mirza Maqbool Baig	No	**Approved** for storage of non cold chain medical devices.

6.	M/s Digitronics, 17, 7th Floor, Rimpa Plaza, M.A. Jinnah Road, Karachi.	Ahmed Iltemas Usmani	No	**Rejected.** The firm has storage facility on 7th Floor. Storage facility consists of 10' x 10' room, also office sitting arrangementat same room. No any appropriate ventilation and exit/ entrance.
7.	M/s Imco Technologist, Plot No. 155, Sector 31/C1 Korangi Indutrial Area, Karachi.	Mr. Aleem Ahmed	No	**Approved** for storage of non cold chain medical devices.
8.	M/s T.K. Medical Instruments Company Plot No. C/2, Punjabi Colony, Federal Capital Area, Liaqatabad No. 4, Karachi.	Nirmila Namwer Lal	No	**Approved** for storage of room temperature medical devices
9.	M/s. 3C International 1620, Main Doubel Road, Sector I-10/1, Islamabad.	Mr. Sharafat Ali Muhammad Waqas	No	**Approved** for storage of warm range ofmedical devices
10.	M/s Hanson International, Office No.57-D, , Block DHA, EME Multan Road, Lahore.	Muhammad Shafiq	No	**Approved** for storage of room temperature medical devices
11.	M/s Techsource Enterprises B-36, Karachi University Employees Co-operative Housing Society, Madras Chowk, Gulzar-e-Hijri, Karachi.	Shariq Hassan	No	**Rejected,** the firm have valid DSL, however firm requested 15 days time to improve documentation and to arrange dedicated storage facility for room temperature and temperature sensitive medical devices as per GDPMD checklist. Still no compliance shown by the firm till date 26-06-2021 even after several reminders.
12.	M/s. Koncept Technologies	Mr. Adnan Kamil	No	**Approved** for storage of room temperature and temperature

	A1-198, Block 13A, Railway Society, Gulshan-E-Iqbal, Karachi.	Mirbaz Khan		sensitive medical devices
13.	M/s Asfand Traders 402, 4th floor, Marium Heights, K.C.H.S, Block 7&8, CCA Area Near Baloch Colony Flyover, Shahrah-e-Faisal, Karachi.	Asfand Yar Wali	No	**Rejected,** the firm has requested to shift the premises for storage of medical devices for suitable area as current storage facility is located on 4th floor of building having no passenger /cargo lift not commence to lift the medical equipment at that place, for this firm required 15 days time but no compliance shown by the firm after 15 days.
14.	M/s. Sanabal Ventures (Pvt) Ltd, 13-L, Model Town Lahor	Mr. Ikram ul Haq Qureshi Mr. Umiar Ikram Mr. Mohammad Ali Qureshi Mr. Uzair Ikram Qureshi Mr. Osama Ikram Qureshi	No.	**Approved** for storage of room temperature medical devices.

Item No.II. <u>POST LICENSE VARIATIONS.</u>

<u>Case No.1.</u>

M/s Meritorius Business Solutions (Pvt) Ltd, Office 202, 2nd Floor, 153-D,Civic Center, Phase-4, Bahria Town,Rawalpinndi has requested for approval of change of their qualified technical person in their ELI-00208 issued on 18-10-2018 as per detail given below:-

Existing Qualified Technical Person	**Proposed Qualified Technical Person**
Mr.Nazeer-ud-din Ahsan, House No. 609, StreetNo.4, Setor I-9/4, Islamabad. CNIC No.61101-8131531-7	Muhammad Haris Muteeb Baig, House No.31/CA, Mohallah Chihtian Abad Pindora, Rawalpindi. CNIC No.37405-7830700-7 B.Sc BiomedicalEngineering.

Decision: The Board acceded to the request of the firm /company and approved the change of qualified technical person as follows:-

Previous Qualified Technical Person	New Approved Qualified Technical Person
Mr.Nazeer-ud-din Ahsan, House No. 609, StreetNo.4, Setor I-9/4, Islamabad. CNIC No.61101-8131531-7	Muhammad Haris Muteeb Baig, House No.31/CA, Mohallah Chihtian Abad Pindora, Rawalpindi. CNIC No.37405-7830700-7 B.Sc Biomedical Engineering.

Case No.2.

M/s Bain Medical (SMC-Pvt) Ltd, Shop No.2,Ground Floor, Plot 58-C, Street No.24, Touheed Commerial Area, Phase-5, DHA, Karachi has requested for approval of change of establishment name in their ELI-00614 issued on 03-12-2020, as per detail given below:-

Existing name and address of Etablishment	Proposed name and address of Etablishment
M/s Bain Medical (SMC-Pvt) Ltd, Shop No.2,Ground Floor, Plot -58-C, Street No.24, Touheed Commerial Area, Phase-5, DHA, Karachi	M/s Bain Medical Private Limited, Ground Floor with Mezzanine, Plot -58-C, Street No.24, Touheed Commerial Area, Phase-5, DHA, Karachi

Decision: The Board acceded to the request of the firm /company and approved the change of title of the firm as mentioned below:-

Previous name and address of Etablishment	New Approved name and address of Etablishment
M/s Bain Medical (SMC-Pvt) Ltd, Shop No.2,Ground Floor, Plot -58-C, Street No.24, Touheed Commerial Area, Phase-5, DHA, Karachi	M/s Bain Medical Private Limited, Ground Floor with Mezzanine, Plot -58-C, Street No.24, Touheed Commerial Area, Phase-5, DHA, Karachi

Case No.3.

M/s Mars Enterprises, Office No.4, Jason Center,2nd Floor, BC-8, Block-9,Clifton, Karachi has requested for approval of change of office address in their ELI-00097, issued on 03-08-2018, as per detail given below. There is no change in godown address:-

Existing office address of Etablishment	Proposed office address of Etablishment
M/s Mars Enterprises, Office No.4, Jason Center,2nd Floor, BC-8, Block-9,Clifton, Karachi	Office No.S-43, GlassTower, 2nd Floor, Block-8, Frere Tower, Clifton,Saddar Town, Karachi-South.

Decision: The Board acceded to the request of the firm /company and approved the change of office address as mentioned below:-

Existing office address of Etablishment	Proposed office address of Etablishment
M/s Mars Enterprises, Office No.4, Jason Center,2nd Floor, BC-8, Block-9,Clifton, Karachi	Office No.S-43, GlassTower, 2nd Floor, Block-8, Frere Tower, Clifton,Saddar Town, Karachi-South.

Item No.III. POST REGISTRATION VARIATIONS

Case No.01.

M/s B.Braun Pakistan (Pvt) Ltd, The Forum, Shite 216, Khayaban-e-Jami, Clifton Block-9, Karachi has stated with reference to renewalletter dated 10th March, 2021 for products category (IVC's), as stipulated in the Medical Devices Rule, 2017, clause 19 sub clause (4) which states that labeling information has to include license number, registration number, maximumretail price, as approved for the purpose of enlistment or registration of medical device shall be clearly specified in the labeling.

They have further stated that renewal of registration of below mentioned products, they have communicated to their Global Production /Site that registration numbers have to be changed after renewal of products under Medical Devices Rules, 2017:-

S.No.	Prouct Name	Old Regn. Number	New Regn. Number
1.	Introcan	062281	MDIR-0002279
2.	Introcan Safety	062280	MDIR-0002276
3.	Introcan -W with In-Stopper	062282	MDIR-0002278
4.	Vasofix Braunule	062283	MDIR-0002277
5.	Vasofix Safety	062284	MDIR-0002275

Furthermore, according to their Company's Global SOP,the process of updating labels is a lengthy and time-consuming process as one product label is used in different countries. Moreover, several delays are caused by the pandemic.

Therefore, we M/s B. Braun Pakistan (Pvt) Ltd, Karachi have no choice but to continue to use previous registration number on the labels during the transition phase of label change. Once the labels are updated, they will inform MDMC Division for availability of new updated labels for their above mentioned products.

Decision: The Board after deliberation deferred the case and asked the firm to indicate the time line for which they want to have a waiver from labelling rules and what sort of waiver they would like to have.

Case No.02.

M/s Popular International, 141 Justice Inamullah Road, Block 7 & 8, KMCHS, Karachi., has requested for addition of new manufacturing site and additional sizes of their already registered medical devices as per detail mentioned below: -

Regn. No.	**Name of Medical Devices.**	**Existing Manufacturing Site**	**Proposed Additional Manufacturing Site.**	**Demanded Additional Sizes/Codes**
MDIR-0000852	SOFSILK (Wax Coated Braided Silk Silicone Coated Braided Silk)	M/s Coviden LLC, 15 Hampshire Street Mansfield, MA 02048, USA **Manufacturing Site:** M/s Coviden, 60 Middletown Ave North Haven, CT 06473, USA M/s Coviden, Zona Franca DE San Isidro Carretera San Isidaro, Km 17, Santo Domingo Dominican Republic	M/s Polysuture Industria e Comercio Ltda., Av. Vereador Gabriel Ramos da Silva, 1245-Sao Sebastiao do Paraiso-MG- Brazil	SP15430, SP11440 SP12450, SP13440 SP15401, SP15410 SP15420, SP15430 SP21460, SP23440 SP23450, SP24410 SP24420, SP24430 SP24440, SP24450 SP25410, SP25420 SP26401, SP26410 SP401, SP401E SP402, SP410 SP410E, SP41460 SP420, SP420E SP42430, SP42440 SP430, SP430E SP43420, SP43430 SP43440, SP43450 SP43460, SP440 SP44410, SP44420 SP44430, SP45401 SP45410, SP46401 SP46402, SP48440 SP53430, SP53430E SP6060, SP6070 SP6080, SP6580 SP82430, SP82430E SP82440, SP82440E SP82460, SP86420 SVB6580,SP23440D, SP24410D, SP24420D, SP24430D, SP26401D, SP41460D, SP86420D, SP401ED, SP410ED SP420ED, SP430ED
MDIR-0000849	Ticron Coated Braided Polyester	-do-	-do-	3PLB750, PL15720, PL24710, PL24720, PL24730, PL27702, PL58701, PL710, PL720, PL730, PL740, PL7940,

				PL7950, PL7960, PL8750, PL88705, PL91750, PL92750, PL98705, PLN92720V, PLSK1720, PLSK2620, PL24720D, PL27702D
MDIR-0000858	Surgipro (Monofilament Polypropylene)	-do-	-do-	2PN81680, PP12650, PP13620, PP15620, PP15630, PP22630, PP22640, PP23620, PP23630, PP23640, PP24610, PP24620, PP24630, PP24640, PP25610, PP26601, PP26610, PP26620, PP27601, PP27610, PP43640, PP43640E, PP44620, PP44630, PP45601, PP45610, PP48602, PP48602E, PP6510, PP7510, PP83650, PP84610, PP84620, PP8510, PP87601, PP87610, PP9510, PP24610D, PP24620D, PP26601D, PP43640D, PP44620D, PP44630D, 2PPN12660V
MDIR-0001200	Monosof Monofilament Nyon	-do-	-do-	2NP22340, 2NP22360, 3NP44340, 3NP45320, 3NP45330, 3NP47320, 3NP69330, 3NP69340, 3NP84330, 3NP84340, NB43340, NB43340E, NB52340, NB52350, NB83330, NB83340, NBXF52340, NBXF52350, NBXF81360, NBXF83340, NBXF83350, NP11350, NP12340, NP12350, NP13320, NP13330, NP13340, NP15010, NP15020, NP15030, NP15040, NP21350, NP22340, NP23320, NP23330, NP23340,

				NP23350, NP24301, NP24310, NP25010, NP25020, NP25030, NP25040, NP27310, NP27320, NP43310, NP43320, NP43320E, NP43330, NP43330E, NP43340, NP43340E, NP43350, NP43350E, NP43360, NP43360E, NP44320, NP44320E, NP44330, NP44330E, NP44340, NP44340E, NP45301, NP45310, NP45310E, NP45320, NP45320E, NP45330, NP45330E, NP45340, NP45350, NP46320, NP47310, NP47320, NP52330, NP52340, NP52350, NP52350E, NP52360, NP52360E, NP53320, NP53330, NP53340, NP5410, NP54320, NP54330, NP54340, NP54340E, NP54350, NP5510, NP55330, NP5610, NP5710, NP6580, NP6590, NP6710, NP69320, NP69320E, NP69330, NP69330E, NP69340, NP69340E, NP82350, NP82360, NP83340, NP83350, NP83360, NP84310, NP84330, NP84340, NP85320, NP85330, NP86301, NP86310, NP87310, NP89320, NPK42350V,NPK54320V, NPK5550D, NPM4090, NPM5010, NPM5090E, NPM6580, NPM6590, NPM7010, NPN44350V, NPN45340T, NPXF52330, NPXF52340, NPXF52350, NPXF52360, NPXF81350,

				NPXF81360, NPXF82350, NPXF82360, NPXF83340, NPXF83350, NPXF83360, NPXF84330, NPXF84340, NP57301, NP86330, NBK83330V, NPK81360V, NPB10310D, 2NPG10390D, NPXF81350D, NPXF81360D, NP43320D, NP84330D, NP83340D, NP82350D, NP43330D

Decision: The Board approved the additional manufacturing site and sizes of above mentioned medical devices as mentioned against each.

Item No.IV. EXEMPTION FROM LABELLING REQUIREMENT UNDER MDR, 2017

Case No.01.

M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio PakitanTransmission Center, Hyderabad Road, Landhi, Karachi has requested to consider exemption of additional label requirements for their following registered medical devices: -

S.No.	Name of Medical Device	Registration No.
1.	PanbioCOVID-10 Ag Rapid Test Deice (Nasopharyngeal)	MDIR-0001928
2.	Panbio COVID-19 IgG/IgM Rapid Test Device (FingerstickcWholecBlood/Venous Whole Blood/ serum/plasma)	MDIR-0002494
3.	Panbio COVID-19 Ag Rapid Test Device (Nasal)	MDIR-0002495

They have further stated that due to fact that the Legal manufacturer names as Abbott Rapid Diagnostic Jena GmbH of Germany is unable to fulfil additional labelling requirements until December, 2022 due to heavy workload to manage COVID-19 related need throughout the globe.

Decision: The Board after deliberation deferred the case and asked the firm to specify the waivers from labelling rules they would like to have and to further clarify whether they had got any waivers from labelling in other counties or not?

Item No.V. PRODUCT SPECIFIC INSPECTION TO CHECK THE FACILITY FOR REGISTRATION OF LOCALLY MANUFACTURED VENTILATOR

Decision: The Board after deliberation approved already licensed facility of M/s Alsons Industries (Pvt) Limited, Karachi for manufacture of ICU ventilators.

Item No.VI. REQUIREMENTS FOR MANUFACTURING OF NON-STERILE PPEs INTENDED FOR MEDICAL USE.

Following requirements for manufacturing of non-sterile PPEs has been drafted and reproduced below for consideration of MDB please.

REQUIREMENTS FOR MANUFACTURING OF NON-STERILE PPEs INTENDED FOR MEDICAL USE

General Part

Sr. #	**Description**	
1	Name of manufacturing unit	
2	Address of manufacturing unit	
3	Name of owner / partner / CEO /MD. Copy of CNIC is also required	
4	Name of person in-charge of production. Copy of CNIC is also required	
5	Name of person in-charge of Quality Control. Copy of CNIC is also required	
6	Name of facilities to be inspected	
7	Drug Manufacturing License #, if applicable	

Technical Part

Sr.#	**Description**
1	**Location and surroundings**
	Area: It shall be appropriate for the intended product **Location**: Site to be verified.

	Requirements for site verification:application on cover letter,Fee of Rs. 5,000/-, land and ownership documents.Note: a) It shall preferably be in industrial area (no site verification inspection required). b) It shall not be in residential or commercial area c) In case of unclassified area, then site verification inspection will be performed.
2	**Building design and construction**
	a) Adequate size and suitable design in accordance with manufacturing process flow. b) Fire alarm system to signal evacuation. c) Fire extinguishers, hoses and/or hydrants d) First aid kits e) Emergency exits f) Acceptable Quality of ventilation in the facility
3	**Services**
	Electrical supply, lighting, pest control arrangements, temperature and humidity controls. HVAC not mandatory for non-sterile PPEs, however, manufacturing shall be carried out in hygienic environment and cleanliness is to be ensured by the manufacturer.
4	**Storage areas (raw material store, in-process store and finished goods store)**
	Maintain appropriate storage conditions as per requirement of the material and product
5	**Production**
	Manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications. Manufacturer shall conform to the following international standards for development and production of medical devices: - a. ISO-13485 (Quality management system for the manufacturing of medical devices). b. ISO-14971 (Risk management for processing and development of medical devices). **Personnel:** Production in charge a) Qualification: as determined by MDB (The amendment in MDR, 2017 has been approved by the Authority and is under the process of approval from Federal Government) b) Experience: as determined by MDB as determined by MDB (The amendment in MDR, 2017 has been approved by the Authority and is under the process of approval from Federal Government) **Equipment**: As per the PPE intended to be manufactured. The identity of individual major equipment items and lines must be identified
6	**Quality Control Department**
	Personnel: Quality control in charge a) Qualification: as determined by MDB (The amendment in MDR, 2017 has been approved by the Authority and is under the process of approval from Federal Government) b) Experience: as determined by MDB as determined by MDB (The amendment in MDR, 2017 has been approved by the Authority and is under the process of

	approval from Federal Government) **Equipment**: As per the PPE intended to be manufactured. **Testing**: As per applicable International standards of the PPE intended to be manufactured
7	**Labelling**
	Labelling shall be in accordance with Chapter VI of the Medical Devices Rules, 2017.
8	**Documentation**
	a) Written standard operating procedures of each step from the procurement of raw material till the final dispatch and the associated records of actions taken shall be available. b) Manufacturer shall clearly document the responsibility and authority of all personnel involved in the process and maintain training record c) Written procedures/SOPs for emergency exits and alarms d) Accurate evacuation plan posted on each floor e) Employees medical record keeping
9	**Health and safety**
	a) Electrical cables properly covered b) Electrical outlets and switches properly installed
10	**Environmental**
	a) Waste manage system to dispose of hazardous wastes. b) Waste water treatment facility
11	**Trainings**
	a) ISO13485 b) ISO14971 c) Batch processing d) Emergency evacuation drills and on usage on firefighting equipment e) Disposal, storage and handling of wastes

Decision: The Board approved the above mentioned requirements for manufacture of non-sterile PPEs intended for medical use.

Item No.VIII. <u>REGISTRATION OF MEDICAL DEVICES FOR IMPORT (FORM-7A).</u>

S.#	Name of Firm (s)	Name of Manufacturer	Name of Medical Devices.	Brief Description	Decision
1.	**M/s. Tech Zone,** Ground Floor Weal House, 8 Faiz Road, **Lahore.**	Legal Manufacturer: Dort-A Tip Malzemeleri Sanayi Ithalat Ihracat Ticaret	DORT-A Medical (Hemo-vac Drain) Claimed Shelf life:	Hemovac Drain is used to remove any fluid from body after surgery. It	**Deferred** for provision of original agency agreement

	ELI-00040.	Limited Sirketi, Balikhisar Mah, Cad. Koy Ici Serpmeleri Sk No: 795/Akyurat Ankar/Turkey FSC: Turkey Date of issue: 15.03.2021	03-years. Class: B	consists of perforated tubing connected to a portable vacuum unit called reservoir.	and FSC of any reference country or CE mark documents.
2.	-do-	Legal Manufacturer: Dort-A Tip Malzemeleri Sanayi Ithalat Ihracat Ticaret Limited Sirketi, Balikhisar Mah, Cad. Koy Ici Serpmeleri Sk No: 795/Akyurat Ankar/Turkey FSC: Turkey Date of issue: 15.03.2021	DORT-A Medical (Drain with Resevoir) Claimed Shelf life: 03-years. Class: B	Hemovac Drain is used to remove any fluid from body after surgery. It consists of perforated tubing connected to a portable vacuum unit called reservoir.	**Deferred** for provision of original agency agreement and FSC of any reference country or CE mark documents.
3.	-do-	Legal Manufacturer: Dort-A Tip Malzemeleri Sanayi Ithalat Ihracat Ticaret Limited Sirketi, Balikhisar Mah, Cad. Koy Ici Serpmeleri Sk No: 795/Akyurat Ankar/Turkey FSC: Turkey Date of issue: 15.03.2021	DORT-A Medical (Chest Drainage Device) Claimed Shelf life: 03-years. Class: B	Chest Drainage Device.	**Deferred** for provision of valid certificates of ISO-13485, FQA, QC details and CoA of the subject product and FSC of any reference country or CE mark documents.
4.	-do-	Legal Manufacturer: Dort-A Tip	DORT-A Medical (Thoracic Drain Catheter)	Drain catheter is used to remove any	**Deferred** for provision of original and

		Malzemeleri Sanayi Ithalat Ihracat Ticaret Limited Sirketi, Balikhisar Mah, Cad. Koy Ici Serpmeleri Sk No: 795/Akyurat Ankar/Turkey FSC: Turkey Date of issue: 15.03.2021	Claimed Shelf life: 03-years. Class: B	fluid from body after surgery. It consists of perforated tubing connected to a portable vaccum unit called reservoir.	valid agency agreement, valid ISO-13485 and FQA and FSC of any reference country or CE mark documents.
5.	-do-	Legal Manufacturer: Dort-A Tip Malzemeleri Sanayi Ithalat Ihracat Ticaret Limited Sirketi, Balikhisar Mah, Cad. Koy Ici Serpmeleri Sk No: 795/Akyurat Ankar/Turkey FSC: Turkey Date of issue: 15.03.2021	4-A Medikal (YANKUER Set) Claimed Shelf life: 03-years. Class: B	Yankuer set is a suction Catheter used to prevent aspiration.	**Deferred** for provision following documents:- Original & valid agency agreement. Registration status or free sale certificate of any SRA. Provide technical details of QC along with CoA of respective product(s, Provide the justifiable stability study data and protocols that suffice the claim of shelf life. Provide

					complete EPSPs of subject products and label duly approved in the country of origin or any stringent regulatory authority (SRA)
6.	-do-	Legal Manufacturer: M/s Jiangsu weikang Jiejing Medical Apparatus Co., Ltd 18 # Wenzhou Rd. Economical Development District, Shuyang 223600, China FSC: China Valid Till: 2023.03.22	WERACON (Nasogastric Tube) Claimed Shelf life: 03-years. Class: B	A Nasogastric tube (NG Tube) is a special tube that carries food and medicine to the stomach through the nose.	**Deferred** for provision following documents:- Original & valid agency agreement. Registration status or free sale certificate of any SRA. Provide technical details of QC along with CoA of respective product(s, Provide the justifiable stability study data and protocols that suffice the claim of shelf life.

					Provide complete EPSPs of subject products and label duly approved in the country of origin or any stringent regulatory authority (SRA).
7.	-do-	Legal Manufacturer: M/s Jiangsu weikang Jiejing Medical Apparatus Co., Ltd 18 # Wenzhou Rd. Economical Development District, Shuyang 223600, China FSC: China Valid Till: 2023.03.22	WERACON (Foley Catheter) Claimed Shelf life: 03-years. Class: B	Foley catheter.	**Deferred** for provision following documents:- Original & valid agency agreement. Registration status or free sale certificate of any SRA. Provide technical details of QC along with CoA of respective product(s, Provide the justifiable stability study data and protocols that suffice

					the claim of shelf life. Provide complete EPSPs of subject products and label duly approved in the country of origin or any stringent regulatory authority (SRA).
8.	M/s Nipro Medical Private Limited, Building No. 24 Central Commercial Area, DHA Phase 8, Ex-Park View, Lahore. ELI-00530	Manufacturer: M/s Shunmei Medical Co. Ltd, R401 of Building B, No. 8 of 1st Jinlong Road, Baolong Industrial Zone, Longgang District, Shenzhen city, Guangdong, 518116, China FSC China valid till: 02.03.2022 FSC UK MHRA valid till 26-05-2025	Shunmei Hemodialysis Catheter Kit (Double lumen) Codes & Sizes: As per FSC UK MHRA dated 15-01-2021 Class B Shelf Life: 3 years	These kits provide temporary vascular access for hemodialysis until a permanent access is available or until another type of dialysis therapy is substituted. Sterile, single use	**Approved.** Firm shall submit original and Embassy attested FSC of MHRA.
9.	M/s Digital Imaging Systems, 121 Habitat Apartments, Shadman II, Ghaus-Ul-Azam Road, Lahore ELI-00094	Legal Manufacturer: M/s Abbott Medical, 5050 Nathan Lane North, Plymouth, MN 55442, USA Manufacturing Site: St. Jude Medical,	Amplatzer™ Amulet™ Left Atrial Appendage Occluder Codes as per FSC Belgium dated 14-09-2020	A percutaneous transcatheter device intended to prevent thrombus embolization from the left atrial appendage	**Approved**. Firm shall submit revised Letter of Autorization with product name, MRP and valid ISO13485.

		Costa Rica Ltda. Edificio # 44, Calle 0, Avenida 2, Zona Franca Coyol, EI Coyol, Alajuela, Costa Rica FSC Belgium issued on 14.09.2020 FSC US FDA not available	Class D Shelf Life: 5 years	(LAA) in patients who have nonvalvular atrial fibrillation. Sterile, single use	
10.	-do-	Legal Manufacturer: M/s Abbott Medical, 5050 Nathan Lane North, Plymouth, MN 55442, USA Manufacturing Site: M/s Abbott Medical, 5050 Nathan Lane North, Plymouth, MN 55442, USA FSC Belgium issued on 17.09.2020 FSC US FDA not available	Amplatzer™ Trevisio™ Intravascular Delivery System Codes as per FSC Belgium dated 17-09-2020 Class D Shelf Life: 3 years	Intended to facilitate the attachment, loading, delivery and deployment of the Amplatzer ™ Occluder devices. Sterile, single use	**Approved**. Firm shall submit revised Letter of Autorization with product name, MRP and valid ISO13485.
11.	M/s Iqbal and Company Alfalah Manzil Opp. National Police Foundation, Street No. 26, Sector, E-11/4, Islamabad, Pakistan. ELI-00117	**Legal Manufacturer:** Medical Components, Inc. dba Medcomp 1499 Delp Drive Harleysville PA 19438 USA **Manufacturing site:** MARTECH MEDICAL	Medcomp® Single lumen Vascu-PICC® set (peripherally inserted central catheter) Class D Codes: MR17011101 MR17011121	Peripherally inserted central vein access catheter are indicated for short or long term access to the central venous system via peripheral	**Approved.** Firm shall submit valid Free Sale Certificate.

		PRODUCTS Calle Mercurio N 46 Parque Industrial Mexicali 1 Mexicali, Baja California MEXICO 21210 FSC US FDA valid till 22-01-2021	VP1.9S20-NS VP1.9S50-NS Shelf Life: 3 years	insertion in neonates, infants and children. It may be used for administration of fluids, medication and nutritional therapy. Sterile, single use	
12.	M/s Ferozsons Laboratories Limited. P.O. Ferozsons, Amangarh, Nowshera, KPK ELI-00120	Legal Manufacturer: M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, MA USA 01752 Manufacturing site: M/s Boston Scientific Corporation, 4100 Hamline Ave N Saint Paul, MN USA 55112 FSC US FDA valid till 28-8-2020	EASYTRAK 2 IS-1 Lead (Implantable cardiac pacing lead) Class D Codes: 4542 4543 4544 Shelf Life: 2 years	It is a coronary venous, steroid-eluting, dual electrode pacing/sensing lead intended for chronic implantation as an integral part of a cardiac pulse generator. Sterile, single use	**Approved.** Firm shall submit valid Free Sale Certificate.
13.	-do-	Legal Manufacturer: M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, MA USA 01752 Manufacturing site:	ENDOTAK RELIANCE 4-SITE implantable Defibrillator Lead Class D Codes: 0265 0266	It is a bipolar, transvenous, endocardial, steroid-eluting lead intended for chronic implantation as an integral part of an automatic	**Approved.** Firm shall submit separate application for other types.

		M/s Boston Scientific Corporation, 4100 Hamline Ave N Saint Paul, MN USA 55112 FSC US FDA valid till 29-8-2021	0275 0276 Shelf Life: 2 years	implantable cardioverter/ defibrillator (AICD) or cardiac Resynchronization Therapy with Defibrillation (CRT-D) lead system. Sterile, single use	
14.	-do-	Legal Manufacturer: M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, MA USA 01752 Manufacturing site: M/s Boston Scientific Corporation, 4100 Hamline Ave N Saint Paul, MN USA 55112 FSC US FDA valid till 28-8-2020	SUPPORTRAK Finishing Wire IS-1 Class D Codes: 6667 6668 6669 Shelf Life: 2 years	Intended to aid in the placement of a Boston Scientific implantable coronary venous lead in the coronary venous vasculature. Sterile, single use	**Approved.** Firm shall submit valid Free Sale Certificate.
15.	-do-	Legal Manufacturer: M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, MA USA 01752 Manufacturing site: M/s Lake Region Medical, 340 Lake	Stingray™ Guidewire with hydrophilic coating Class D Sizes and Codes as per US FDA FSC No. 1325-11-2019 Shelf Life: 2	Intended to facilitate placement of balloon dilatation catheters or other intravascular devices during percutaneous transluminal coronary angioplasty	**Approved.**

		Hazeltine Dr, Chaska, MN USA 55318 FSC US FDA valid till 3-11-2021	years	(PTCA) and percutaneous transluminal angioplasty (PTA). Not to be used in cerebral blood vessels. Sterile, single use	
16.	-do-	Legal Manufacturer: M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, MA USA 01752 Manufacturing site: M/s Boston Scientific Corporation, 301 Parkway, Global Park, La Aurora, Heredia Costa Rica FSC US FDA valid till 7-3-2021	ACUITY Whisper View™ Guidewire Class D Codes: 4640 4641 4642 4643 4647 4648 Shelf Life: 2 years	Intended to facilitate placement of Boston Scientific or Guidant Left Ventricular leads within the coronary venous vasculature Sterile, single use	**Approved.** Firm shall submit valid Design Examination Certificate, Free Sale Certificate and ISO13485.
17.	-do-	Legal Manufacturer: M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, MA USA 01752 Manufacturing site: M/s Boston Scientific Limited, Business and Technology Park. Model Farm Road,	CRE Pro Wireguided Esophageal/Pyloric/Colonic/Biliary Balloon Dilatation Catheter Class D Sizes and Codes as per FSC US FDA No. 8332-4-2019	Indicated for use in adult and adolescent populations to endoscopically dilate strictures of the alimentary tract. Also indicated in adults for endoscopic dilatation of	**Approved.** Firm shall submit valid Free Sale Certificate and ISO13485.

		Cork, Ireland FSC US FDA valid till 21-4-2021	Shelf Life: 36 months	the Sphincter of Oddi with or without sphincterotomy. Sterile, single use	
18.	-do-	Legal Manufacturer: M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, MA USA 01752 **Manufacturing site:** M/s Boston Scientific Corporation, 780 Brookside drive spencer, IN USA 47460 FSC US FDA valid till 2-4-2021	Amplatz type renal sheath Class B Sizes and Codes as per FSC US FDA No.3985-1-2019 Shelf Life: 4 years	Used to maintain the nephrostomy tract opening, allowing smooth passage of surgical instrumentation through the nephrostomy tract. Sterile, single use	**Approved.** Firm shall submit valid Free Sale Certificate and ISO13485.
19.	-do-	Legal Manufacturer: M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, MA USA 01752 **Manufacturing site**: Boston Scientific Corporation, Two Scimed Place, Maple Grove, MN USA 55311 FSC US FDA valid till 7-3-2021	ACUITY™ Pro Guide Catheter Class D Sizes and Codes as per FSC US FDA No.6175-3-2019 Shelf Life: 24 months	Intended to access the coronary venous system and serves as a conduit for the delivery of contrast medium and devices, including implantable coronary venous leads, introduced into the coronary venous system.	**Approved.** Firm shall submit valid Free Sale Certificate and ISO13485.

				Sterile, single use	
20.	-do-	Legal Manufacturer: M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, MA USA 01752 **Manufacturing site:** M/s Boston Scientific Corporation, 2546 First Street Propark, EI Coyol Alajuela, COSTA RICA 20904 FSC US FDA valid till 7-2-2021	Percuflex™ Plus Ureteral Stent Sizes and Codes as per FSC US FDA No.3462-1-2019 Class C Shelf Life: 36months	Intended to facilitate drainage from the kidney to the bladder via placement endoscopically or fluoroscopically by a trained physician. Sterile, single use	**Approved.** Firm shall submit valid Free Sale Certificate and ISO13485.
21.	-do-	Legal Manufacturer: M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, MA USA 01752 Manufacturing site: M/s Boston Scientific Corporation, 780 Brookside drive spencer, IN USA 47460 FSC US FDA valid till 27-01-2022	SpyScope™ DS II Access and Delivery Catheter Class B Codes: M00546610 Shelf Life: 24 months	Intended to provide direct visualization and to guide both optical and accessory devices for diagnostic and therapeutic applications during endoscopic procedures in the pancreaticobiliary system including hepatic ducts. For use with the	**Approved.** Firm shall submit original and Embassy attested Free Sale Certificate and valid ISO13485.

				Spyglass DS Digital Controller. Sterile, single use	
22.	-do-	**Legal Manufacturer:** M/s. Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA **Manufacturing Site:** Boston Scientific Corporation 2546 First Street, Propark El Coyol, Alajuela COSTA RICA 20904 FSC US FDA Valid till 15-04-2021	Hydra Jagwire Single-Use High Performance Guidewire Class: B Shelf Life: 3 years Codes as per FSC	The Hydra Jagwire Guidewire is indicated for use in selective cannulation of the biliary ducts including the common bile, pancreatic, cystic, right and left hepatic ducts and to aid in the placement of diagnostic and therapeutic devices during bronchoscopy procedures	**Approved.** Firm shall submit valid Free Sale Certificate and ISO:13485.
23.	-do-	**Legal Manufacturer:** Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA **Manufacturing Site:** Boston Scientific Corporation Two Scimed Place, Maple Grove MN 55311 USA FSC Ireland	AngioJet ™ Solent™ Omni OVER-THE-WIRE Thrombectomy Set Class-C Shelf life: 2 years Codes as per FSC	The device is intended for use with AngioJet Ultra console to break apart and remove thrombus from: Upper and lower extremity peripheral arteries, Upper extremity	**Approved.** Firm shall submit valid ISO:13485.

		Valid till: 05-03-2023		peripheral veins, Iliofemoral and other lower extremity veins, A-V access conduits, For use with AngioJet power plus techniques for control and selective infusion of physician specified fluids, including thrombolytic agents, into the peripheral vascular system.	
24.	-do-	Legal Manufacturer: M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, MA USA 01752 Manufacturing Site: M/s Boston Scientific Corporation, 2546 First Street Propark, EI Coyol Alajuela, COSTA RICA 20904	Jagwire™ High Performance Guidewire Sizes and Codes: as per FSC US FDA dated 8156-4-2019 Class B Shelf Life: 3 years	Indicated for use in selective cannulation of the biliary ducts including, but not limited to the common bile, cystic, right and left hepatic ducts. Designed to be used during endoscopic biliary procedures for catheter	**Approved.** Firm shall submit valid Free Sale Certificate and ISO13485.

		FSC US FDA valid till 15-04-2021		introduction and exchanges. Sterile, single use	
25.	-do-	Legal Manufacturer: M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, MA USA 01752 Manufacturing site: M/s Boston Scientific Corporation, 780 Brookside drive spencer, IN USA 47460 FSC US FDA valid till 25-06-2020	SpyScope™ DS Access and Delivery Catheter Class B Codes: M00546600 Shelf Life: 24 months	Intended to provide direct visualization and to guide both optical and accessory devices for diagnostic and therapeutic applications during endoscopic procedures in the pancreaticobiliary system including hepatic ducts. For use with the Spyglass DS Digital Controller. It is part of SpyGlass DS Direct Visualization System Sterile, single use	**Approved.** Firm shall submit valid Free Sale Certificate and ISO13485.
26.	M/s Krestacorp, 76-C, 3rd Floor, Suit No.2, Khayaban-e-Jami, Street No.9, DHA Phase 7, Karachi (ELI-00258)	**Legal Manufacturer/ Manufacturing Site:** M/s Karex Industries SDN BHD PTD. 7906 & 7907 Taman Pontian Jaya, Bt. 34, Jalan Johor,	**Klimax XXL** Condoms Class: C. Claimed Shelf Life: 05 Years.	Klimax XXL Condoms. Natural Rubber Latex Male Condoms with 8.5% benzocaine gel.	**Deferred** for provision of original FSC of country or origin and FSC of any reference country or

		82000, Pontian Johor Darul Takzim, Malaysia. (FSC Malaysia)			CE mark documents
27.	**M/s Anwar & Sons;** Apartment-10, Safari Villas-2, Commercial complex, Bahria Town, Phase07, Rawalpindi ELI-00017.	Legal Manufacturer: M/s SMI AG, Steinerberg 8 4780 St.Vith Belgium. FSC of Belgium.	**SURGICAL STEEL** (Monofilament Stainless steel Sutures). Claimed Shelf life: 05-years. Class: C	Stainless steel sutures are intended to be mainly used for suturing and ligation of human bone tissues.	**Approved.** Firm shall submit original Agency Agreement.
28.	Tramax Health, A-337, Block-D, North Nazimabad, Karachi (ELI-00026)	**Legal Manufacturer:** M/s Jeil Medical Corporation, 702-703-704-705-706-805-807-812-ho, 55, Digital-ro-gil, Guro-gu, Seoul, Korea. FSC Korea Issuance Date11-05-2017 FSC Netherland valid till Sep, 2024	Leforte Neuro System (Bone Plate and Bone Screw) Class-C Shelf life: Codes as per FSC	Craniofacial bone fixation, non-bioabsorbable.	**Approved.**
29.	-do-	**Legal Manufacturer:** M/s Jeil Medical Corporation, 702-703-704-705-706-805-807-812-ho, 55, Digital-ro-gil, Guro-gu, Seoul, Korea. FSC Korea Issuance Date11-05-2017 FSC Netherland valid till Sep, 2024	Leforte System (Bone Plate and Bone Screw) Class-C Shelf life: Codes as per FSC	Craniofacial bone fixation, non-bioabsorbable.	**Approved.**
30.	M/s Hakimsos (Pvt) Ltd.,	**Legal Manufacturer:**	Alsavin One Injection 2%	Each Product consists of	**Approved.**

	Hakimsons House, A-58/B SITE, Manghopir Road, Karachi (ELI-00396)	Alsanza Medizintechnik und Pharma GmbH Hermann-Burkhardt-Strabe 3 72793 Pfullingen Germany **<u>Manufacturing site:</u>** M/s VSY biotechnology Istanbul Tuzla organize sanayi Bolgesi 3. Cadde 3. Cadde No. Tepeoren (FSC Germany issuance 02-06-2021)	Intra-articular Viscosupplement / Injections of sodium hyaluronate Class D Shelf Life: 24 Months Model: MV062	2.4 ml of viscoelastic solution in a single use glass syringe for intraarticular use.	
31.	Life Cares, M-20, Mezzanine Floor Falaknaz Plaza Natha Khan Bridge, Shahra-e-Faisal, Karachi (ELI-00077)	**<u>Legal Manufacturer:</u>** M/s URO Technology SDN BHD Lot 2491, Batu 39 1/2, Pontain Besar, 82000 Pontaian Johor, Malaysia. FSC Malaysia Valid Till (15-05-2020)	Chroma Urethral Catheter Class-B Shelf life: 5 years Codes: 211XXYY/212XXYY 511XXYY/512XXYY 311XXYY/312XXYY 221XXYY 217XXYY		**Deferred** for provision of FSC of any reference country or CE mark documents.
32.	M/s. Freesia Enterprises House No. First Floor, 104, Dawn Plaza, bank Road, saddar, Rawalpindi. ELI-00201	**<u>Legal Manufacturer:</u>** M/s. Ningbo Luke Medical Devices Co., Ltd Gujiayan Yangming Road 315400 Yuyao City, Zhejiang province China	Canack Single Kit Anesthesia Kit Class: B Shelf Life :05 years	The device is intended for general anesthesia surgeries.	**Approved.** Firm shall submit valid ISO:13485.

		FSC Germany Date of Issue: 23.06.2019	Codes: AMP01 AMP02 AMP03		
33.	M/s Medequips SMC (Pvt) Ltd 30, -Shahrah-E-Quaid-E-Azam, Lahore ELI- 00362	**<u>Legal Manufacturer</u>** CANON MEDICAL Systems Corporation, 1385 SHIMOISHIGAMI, OTWARA SHI TOCHIHI 324-8550 JAPAN FSC: Japan Date of Issue: 7th August,2018	**Viamo system** Diagnostic ultrasound system Class: B Service life: 4 years Models: TUS-VC100	Viamo is diagnostic ultrasound system /echocardiography equipment used for the diagnosis of general abdomen, obstetrics, and vascular superficial parts.	**Approved.** Firm shall submit valid Letter of Authorization.
34.	M/s A.S Enterprises, 03 Mozang Road, Lahore House No. 29-A Lytton Road, Lahore ELI. 00190	**<u>Legal Manufacturer:</u>** SuZhou Laishi Transfusion Equipment Co., Ltd Changsheng Road, Tongli Town Wujiang District Suzhou City Jiangsu Province China FSC: China Valid till: 2020.10.09 FSC Germany issuance: 26-06-2017	Laishi Triple Blood Bag Class-D Shelf life 3 years Codes/ sizes: 350/300*2 450/400*2 500/300*2	Disposable Plastic Blood Bag with CPDA-1 for Whole Blood (Human). with 16/17 G needle for Single Use.	**Approved.** Firm shall submit valid FSC, ISO 13485 & Design examination certificates.
35.	-do-	**<u>Legal Manufacturer:</u>** SuZhou Laishi Transfusion Equipment Co., Ltd Changsheng Road, Tongli Town Wujiang District Suzhou	Laishi Disposable double Blood Bag Class-D Shelf life 3 years Codes/ sizes:	Disposable Plastic Blood Bag with CPDA-1 for Whole Blood (Human). with 16/17 G needle for Single Use.	**Approved.** Firm shall submit valid FSC, ISO 13485 & Design examination certificates.

		City Jiangsu Province China FSC: China Valid till: 2020.10.09 FSC Germany issuance: 26-06-2017	350/300 450/400 500/300		
36.	M/s Global Health Care Midway Commercial Plaz No. 20, Back Side of Prism Arcade 2, Phase 7, Bahria Town, Rawalpindi. ELI: 00086	**Legal Manufacturer:** Troge Medical Milchstrasse 19, 20148 Hamburg Germany FSC: Germany issuance: 19th September, 2018	Tro-Microcut (Surgical Blades) Class: B Shelf Life: 5 years Code: MD0106	TRO-MICROCUT Surgical Blades are used during surgical procedures. Sterile non-pyrogenic and a toxin.	**Approved.**
37.	Kantech Medical System, Office No. R-820 Ground Floor, Block-01, Federal B Area, Karachi (ELI-00460)	**Legal Manufacturer:** M/s TMT Tibbi Medikal Malzemeleri San. VE. TIC. Ltd. Sti, Faith Mahallesi 1188 Sokak No. 14 Sarnic-Gaziemir Izmir, Turkey FSC Turkey Valid Till (31-10-2020)	Egemen International Spinal Needle (Quincke) Class-D Shelf life: 5 years Codes & Sizes as per FSC	Uses for regional anesthesia for collection of CSF from spinal fluid without any loss with safety.	**Deferred** for provision of valid FSC of country of origin and FSC of any reference country or CE mark documents.
38.	-do-	**Legal Manufacturer:** M/s TMT Tibbi Medikal Malzemeleri San. VE. TIC. Ltd. Sti, Faith Mahallesi 1188 Sokak No. 14 Sarnic-Gaziemir Izmir, Turkey FSC Turkey Valid Till (31-10-2020)	Egemen International Bone Marrow Biopsy Needle Class-B Shelf life: 5 years Codes & Sizes as per FSC	Bone Marrow Biopsy Needle uses for Diagnosis blood disease Diagnosis, staging and therapeutic monitoring for lymph proliferative disorders.	**Deferred** for provision of valid FSC of country of origin and FSC of any reference country or CE mark documents.

39.	-do-	**Legal Manufacturer:** M/s TMT Tibbi Medikal Malzemeleri San. VE. TIC. Ltd. Sti, Faith Mahallesi 1188 Sokak No. 14 Sarnic-Gaziemir Izmir, Turkey FSC Turkey Valid Till (31-10-2020)	Egemen International Epidural Set Class-D Shelf life: 5 years Codes & Sizes as per FSC	Hernia repairs. Genitourinary procedures. Lower extremity orthopedic procedures.	**Deferred** for provision of valid FSC of country of origin and FSC of any reference country or CE mark documents.
40.	-do-	**Legal Manufacturer:** M/s TMT Tibbi Medikal Malzemeleri San. VE. TIC. Ltd. Sti, Faith Mahallesi 1188 Sokak No. 14 Sarnic-Gaziemir Izmir, Turkey FSC Turkey Valid Till (31-10-2020)	Egemen International Semi-Automatic Biopsy 14G, 16G, 18G, 20G Class-D Shelf life: 5 years Codes & Sizes as per FSC	Uses for regional anesthesia for collection of CSF from spinal fluid without any loss with safety.	**Deferred** for provision of valid FSC of country of origin and FSC of any reference country or CE mark documents.
41.	M/s Health Care Internatinal, 1st Floor 210/J-2, Johar Town Lahore ELI00141	**Legal Manufacturer:** M/s Teleflex medical 3015 Carrington Mill Blvd Morrisville, NC USA 27560 **Manufacturing site:** Symmetry surgical Vesocculaude, LLC 7429 ACC Blvd. Suite 101 Raleigh North Carolina 27617 USA. FSC US FDA valid till 20-05-2022	Vesocclude Ligating Clip Hemostatic Clip, Ligating Clip Class C Shelf Life: 3 years Codes as per FSC	intended for marking and ligating of any linear tissue structure or vessels during an operation for homeostasis or marking purpose where use of non-absorbable clips is required	**Approved.** Firm shall submit Embassy attested FSC.

<table>
<tr>
<td>42.</td>
<td>M/s Global Marketing Services, 111, Hali Road Westridge1, Rawalpindi, Pakistan
ELI-00109</td>
<td><u>Legal Manufacturer:</u>
SEBIA 27 rue Leonard de Vinci, Parc Technologique Léonard de Vinci, CP 8010 LISSES, 91008 EVRY Cedex, France

FSC France issuance: 13-02-2019</td>
<td>CAPILLARYS 3

Class-B

<table>
<tr><th>Name as per label</th><th>identifier</th><th>Shelf life</th></tr>
<tr><td>CAPI 3 HEMOGLOBIN(E)</td><td>2507</td><td>3 years</td></tr>
<tr><td>HbAFCONTROL</td><td>4777</td><td>4 years</td></tr>
<tr><td>NORMAL HbA2 CONTROL (5)</td><td>4778</td><td>4 years</td></tr>
<tr><td>PATHOLOGICAL HbA2 CONTROL</td><td>4779</td><td>4 years</td></tr>
<tr><td>HbAF</td><td>4792</td><td>4 ye</td></tr>
</table>
</td>
<td>For the separation of the normal hemoglobin’s (A, A2 and F) in human blood samples, and for the detection of the major hemoglobin variants (S, C, E and D) by capillary electrophoresis in alkaline buffer (pH 9.4) with the SEBIA CAPILLARYS <u>3 instruments.</u></td>
<td>Approved.</td>
</tr>
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<tr><td>43.</td><td>-do-</td><td><u>Legal Manufacturer:</u>
SEBIA 27 rue Leonard de Vinci, Parc Technologique Léonard de Vinci, CP 8010 LISSES, 91008 EVRY Cedex, France

FSC France issuance: 13-02-2019</td><td>CAPILLARYS 3 – CDT Kit:

Class-B
<table><tr><th>Name as per label</th><th>identifier</th><th>Shelf life</th></tr><tr><td>CAPI 3 CDT</td><td>2509</td><td>2 years</td></tr><tr><td>CDT SAMPLES TREATMENT SOLUTION</td><td>2054</td><td>2 years</td></tr><tr><td>TETRAVALENT CDT / IS</td><td>2057</td><td>3 years</td></tr><tr><td>CDT CAPILLARYS CALIBRATORS (2 levels)</td><td>4760</td><td>5 years</td></tr></table></td><td>The CAPI 3 CDT kit is designed for the separation of the transferrin isoforms in human serum and the quantification of the CDT (carbohydrate deficient transferrin) by capillary electrophoresis in alkaline buffer (pH 8.8) with the CAPILLARYS 3 instrument</td><td>Approved.</td></tr>
</table>

			HIGH CDT CONTROL: 4772, 3 years INTERMEDIATE CDT CONTROL: 4773, 3 years NORMAL CDT CONTROL (5): 4795, 3 years		
44.	-do-	**Legal Manufacturer:** SEBIA 27 rue Leonard de Vinci, Parc Technologique Léonard de Vinci, CP 8010 LISSES, 91008 EVRY Cedex, France FSC France issuance: 13-02-2019	CAPILLARYS 3 - Hb A1c Kit Class-B **Name as per medical device label** / **Identifier** / **Shelf life** CAPI 3 Hb A1c: 2515, 3 years CAPILLARYS 3 & MC SWITCH RAC: 1383, n/a	The CAPI 3 Hb A1c kit is designed for separation and quantification of the HbA1c glycated fraction of hemoglobin in human blood, by capillary electrophoresis in alkaline buffer (pH 9.4) with the CAPILLARYS 3 instrument.	**Approved.**

			K FOR HbA 1c (1)					
			Hb A1c CAPILLARY CALIBRATORS (2)	4755	5 years			
			MULTI-SYSTEM Hb A1c CAPILLARY CONTROLS (2)	4768	3 years			
45.	-do-	**Legal Manufacturer:** SEBIA 27 rue Leonard de Vinci, Parc Technologique Léonard de Vinci, CP 8010 LISSES, 91008 EVRY Cedex, France FSC France issuance: 13-02-2019	CAPI 3 IMMUNOTYPING Kit Class-B **Name as per medical device label** / **Identifier** / **Shelf life** CAPI 3 IMMUNOTYPING / 2600 / 2 years			The CAPI 3 IMMUNOTYPING kit is designed for the detection and the characterization of monoclonal proteins (immunotyping) in human urine and serum with the CAPILLARYS 3 instrument, SEBIA, for capillary electrophoresis	**Approved.**	

			IT / IF CONTROL | 4788 | 4 years		
46.	-do-	**Legal Manufacturer:** SEBIA 27 rue Leonard de Vinci, Parc Technologique Léonard de Vinci, CP 8010 LISSES, 91008 EVRY Cedex, France FSC France issuance: 13-02-2019	CAPI 3 PROTEIN(E) Kit Class-B Shelf life: 3 years Code: 2503	The CAPI 3 PROTEIN(E) 6 kit is designed for the separation of human serum proteins by capillary electrophoresis in alkaline buffer (pH 9.9) with the CAPILLARYS 3 instrument.	**Approved.**
47.	-do-	**Legal Manufacturer:** SEBIA 27 rue Leonard de Vinci, Parc Technologique Léonard de Vinci, CP 8010 LISSES, 91008 EVRY Cedex, France FSC France issuance: 13-02-2019	CAPI 3 URINE Kit Class-B Shelf life: 3 years Code: 2513	The CAPI 3 URINE kit is designed for the preparation of human urine samples for analysis with the CAPI 3 URINE procedure with the CAPI 3 PROTEIN(E) 6 kit. The CAPI 3 URINE procedure on the CAPILLARYS 3 automated instrument is intended for	**Approved.**

				the qualitative analysis of urinary protein profile to detect abnormalities.	
48.	-do-	**<u>Legal Manufacturer:</u>** SEBIA 27 rue Leonard de Vinci, Parc Technologique Léonard de Vinci, CP 8010 LISSES, 91008 EVRY Cedex, France FSC France issuance: 13-02-2019	Capillarys 3 OCTA Instrument Class-A Shelf life: N/A Code: 1245	The CAPILLARYS 3 OCTA instrument provides fully automated electrophoresis sequencing, from the primary sample tube, with cap for hemoglobin analyses and without cap for other analyses, right through to the final electrophoretic pattern: sample identification, sample dilution, capillary washing, sample injection into the capillaries, migration, detection, results processing and transfer	**Approved.**

				over a computer network.	
49.	-do-	**<u>Legal Manufacturer:</u>** SEBIA 27 rue Leonard de Vinci, Parc Technologique Léonard de Vinci, CP 8010 LISSES, 91008 EVRY Cedex, France FSC France issuance: 13-02-2019	CAPILLARYS 3 TERA Instrument and Accessories Class-A Shelf life: N/A Codes: 1246, 1248	The CAPILLARYS 3 instrument provides fully automated electrophoresis sequencing, from the primary sample tube, with cap for hemoglobin analyses and without cap for other analyses, right through to the final electrophoretic pattern: sample identification, sample dilution, capillary washing, sample injection into the capillaries, migration, detection, results processing and transfer over a computer network.	**Approved.**

50.	-do-	**Legal Manufacturer:** M/s. Adaltis S.r.l. Via Durini, 27 – 20122 Milano – Italy **Manufacturing Site:** M/s. Adaltis S.r.l. Via Luigi Einaudi, 7 – 00012 Guidonia Montecelio (Roma) – Italy FSC Italy Issued on 13th March, 2018	EIAgen HBsAg Kit EIAgen Detect HIV 4 total Screening Kit Class-D Shelf Life: 15 months Codes: 071011 (Kit of 96 tests) 071012 (Kit of 192 tests) 071015 (Kit of 480 tests)	The EIAgen Detect HIV 4 Total Screening assay is a 4th generation solid phase Enzyme-linked immunosorbent assay using a mixture of a antigens and antibodies for the in vitro diagnostic screening in human serum or plasma (EDTA, Heparin and Citrate) of antibodies to HIV-1, HIV-2 and HIV-1 p24 antigen. This kit is a combined Ag/Ab assay and is not to be used for the detection of HIV-1 p24 antigen alone.	**Approved.**
51.	M/s OPTISURG 17/c-1, Valancia Town, Lahore Pakistan (ELI-00305)	**Legal Manufacturer:** MORIA SA (Private limited) 15 Rue George Besse 92160Antony-France FSC: France Date of Issue: 9th	ONE USE PLUS SBK HEAD (One Use plus SBK Head Microkeratome) Class: B Shelf Life: 59 months	The OUP LASIK microkeratome system is intended for use in the making of a corneal flap in patients undergoing Lasik surgery	**Approved**. Firm shall submit notarized LOA, ISO 13485 & EC certificate.

		November, 2018	Code: 19393/90 19393/130	or other treatment requiring initial lamellar resection of the cornea	
52.	-do-	**Legal Manufacturer:** MORIA SA (Private limited) 15 Rue George Besse 92160Antony-France FSC: France Date of Issue: 9th November, 2018	OUP USE PLUS MOTOR Class: B Shelf Life: 5 years Code: 19345	The OUP LASIK microkeratome system is intended for use in the making of a corneal flap in patients undergoing Lasik surgery or other treatment requiring initial lamellar resection of the cornea	**Approved.**
53.	-do-	**Legal Manufacturer:** MORIA SA (Private limited) 15 Rue George Besse 92160Antony-France FSC: France Date of Issue: 9th November, 2018	M2SU HEAD (M2SU Head of Microkeratome System) Class: B Shelf Life: 59 months Code: 19334/90 19334/130	The LASIK M2-M2SU microkeratome system is intended for use in the making of a corneal flap in patients undergoing Lasik surgery or other treatment requiring initial lamellar resection of the cornea.	**Approved.**
54.	-do-	**Legal Manufacturer:** MORIA SA (Private limited)	OUP REUSABLE SUCTION RING	The OUP LASIK microkeratome system is	**Approved.**

		15 Rue George Besse 92160Antony-France FSC: France Date of Issue: 9th November, 2018	(Oup reusable Suction ring of microkeratome system) Class: B Shelf Life: 59 months Code: 19391/-1 19391/0 19391/1 19391/2 19391/3	intended for use in the making of a corneal flap in patients undergoing Lasik surgery or other treatment requiring initial lamellar resection of the cornea	
55.	-do-	**Legal Manufacturer:** MORIA SA (Private limited) 15 Rue George Besse 92160Antony-France FSC: France Date of Issue: 9th November, 2018	ONE-BUSIN GLIDES Class: B Shelf Life: 59 months Code: ONE-BUSIN GLIDES 17300×5	The OUP LASIK microkeratome system is intended for use in the making of a corneal flap in patients undergoing Lasik surgery or other treatment requiring initial lamellar resection of the cornea	**Approved.**
56.	M/s Meher Traders, Office A21-22 First Floor, Zeenat Medicine Market, North Napier Road, Karachi (ELI-00128)	**Legal Manufacture:** M/s Huaian Pingan Medical Instrument Co. Ltd, No.128, West Meigao Road, Huaian, Jiangsu, China. FSC China Valid Till 10-04-2021	PASILK Silk Braided Sutures Class-D Shelf life: 5 years Codes as per FSC	Silk sutures are widely used as ligature and are also used for other applications like skin, ophthalmic, GI tract, etc	**Approved.**

		FSC Spain issuance 10-05-2021			
57.	-do-	**Legal Manufacture:** M/s Huaian Pingan Medical Instrument Co. Ltd, No.128, West Meigao Road, Huaian, Jiangsu, China. FSC China Valid Till 10-04-2021 FSC Spain issuance 10-05-2021	PACRYL Polyglactin 910 Sutures Class-D Shelf life: 3 years Codes as per FSC	Polyglactin 910 Surgical Sutures are indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures; but not for use in cardiovascular or neurological tissues.	**Approved.**
58.	-do-	**Legal Manufacture:** M/s Huaian Pingan Medical Instrument Co. Ltd, No.128, West Meigao Road, Huaian, Jiangsu, China. FSC China Valid Till 10-04-2021 FSC Spain issuance 10-05-2021	PASORB Polyglycolic Acid Sutures Class-D Shelf life: 5 years Codes as per FSC	The Polyglycolic Acid surgical suture is indicated for use in general surgery, plastic surgery, ophthalmic surgery, gynecology and obstetrics, episiotomy, urology, orthopedics, gastroenterology, general closure, ligatures, pediatrics and cuticular.	**Approved.**

59.	-do-	**<u>Legal Manufacture:</u>** M/s Huaian Pingan Medical Instrument Co. Ltd, No.128, West Meigao Road, Huaian, Jiangsu, China. FSC China Valid Till 10-04-2021	PACHROM Chromic Catgut Class-D Shelf life: 5 years Codes as per FSC	Catgut chrome sutures are intended for use in general soft tissue closing and/or ligation; in particular in general surgery, gastrointestinal surgery, gynecology, obstetrics, urology, ophthalmic surgery	**Deferred** for provision FQA, Design EXamination and FSC of any reference country or CE marked documents.
60.	-do-	**<u>Legal Manufacture:</u>** M/s Huaian Pingan Medical Instrument Co. Ltd, No.128, West Meigao Road, Huaian, Jiangsu, China. FSC China Valid Till 10-04-2021 FSC Spain issuance 10-05-2021	PALENE Polypropylene Sutures Class-D Shelf life: 5 years Codes as per FSC	A polypropylene suture is a synthetic monofilament plastic thread used for wound closure in many surgical procedures.	**Approved.**
61.	M/s Bain Medical Private Limited, Ground Floor with Mezzanine, Plot -58-C, Street No.24, Touheed Commerial Area, Phase-5, DHA, Karachi	**Manufacturer:** M/s Bain Medical Equipment (Guangzhou) Co., Ltd. No. 10, Juncheng Road, Eastern Area, Economic & Technological Development District,	Bain Disposable A.V. Fistula Needle Sets Class B Shelf Life: 3 Years Codes: BAIN-A.V.F-	Intended to be used as vein puncture for the hemodialysis treatment. Sterile, singleuse	**Approved.** Firm shall submit valid FSC of China.

	(ELI-00614)	Guangzhou 510760, China (FSC China valid till 26-5-2021) (FSC Germany valid till 22-2-2022)	001S BAIN-A.V.F-002S BAIN-A.V.F-003S BAIN-A.V.F-004S BAIN-A.V.F-005S BAIN-A.V.F-006S BAIN-A.V.F-007S BAIN-A.V.F-008S		
62.	-do-	**Manufacturer:** M/s Bain Medical Equipment (Guangzhou) Co., Ltd. No. 10, Juncheng Road, Eastern Area, Economic & Technological Development District, Guangzhou 510760, China (FSC China valid till 02-9-2021) (FSC Germany valid till 22-2-2022)	Bain Tubing Sets for Hemodialysis Class B Shelf Life: 3 Years Codes: BAIN-BL-009 BAIN-BL-010 BAIN-BL-011 BAIN-BL-012	Intended to connect with the dialyzer to the patient in dialysis treatment. Sterile, single use	**Approved.**
63.	-do-	**Manufacturer:** M/s Bain Medical Equipment (Guangzhou) Co., Ltd. No. 10, Juncheng Road, Eastern Area, Economic & Technological Development District, Guangzhou	Bain Hollow Fiber Dialyzer Class C Shelf Life: 3 Years Codes:	Used for the hemodialysis treatment of acute and chronic renal failure. Sterile, single use	**Approved.** Firm shall submit valid FSC of China.

		510760, China (FSC China valid till 04-7-2021) (FSC Germany valid till 22-2-2022)	B-16HF, B- 18HF, B-20HF		

Item No.IX. <u>ENLISTMENT OF MEDICAL DEVICES FOR IMPORT (FORM-6A).</u>

The following applications for grant of enlistment of medical devices for import on prescribed form 6-A Under Medical Devices Rules, 2017 were received in the Division and are submitted for consideration of MDB:-

Decision: TheBoard discussed and decided as mentioned against each.

S.#	Name of Firm (s)	Name of Manufacturer	Name of Medical Devices.	Brief Description	Decision
1.	**M/s. Tech Zone,** Ground Floor Weal House, 8 Faiz Road, **Lahore.** **ELI-00040.**	M/s PIKDARE Manufacturer Via Saldarini Catelli 10, 22070 Casnate Con Bernate COMO, Italy FSC: Italy (copy)	SOFFIX MED (PIC SOLUTION) Post-Operation Dressing. Claimed Shelf life: 03-years. Class: A	A post OP dressing is an adhesive dressing with sterile pad applied to a wound to promote healing and protect the wound from further harm	**Deferred.** The firm shall provide the following documents:- • Original and valid agency agreement • Valid certificate of ISO-13485/ Latest GMP. • Technical details of mfg. details along with CoA of

					respective product. • Original registration status or free sale certificate in any SRA. • The data provided for claimed shelf life is not Satisfactory, provide the justifiable stability study data and protocols that suffice the claim of shelf life. • Complete EPSPs of subject products and label duly approved in the country of origin or any stringent regulatory authority (SRA).
2.	-do-	M/s PIKDARE Manufacturer Via Saldarini Catelli 10, 22070 Casnate Con Bernate COMO, Italy	AQUA-BLOC (PIC Solution) Water Proof Post-Operation Dressing. Claimed Shelf life: 03-years. Class: A	A WATER PROOF POST OP DRESSING IS AN ADHESIVE DRESSING WITH STERILE PAD APPLIED TO	**Deferred.** The shall provide the following documents:- • Original

		FSC: Italy (copy)		A WOUND TO PROMOTE HEALING AND PROTECT THE WOUND FROM FURTHER HARM	and valid agency agreement • Valid certificate of ISO-13485/ Latest GMP. • Technical details of mfg. details along with CoA of respective product. • Original registration status or free sale certificate in any SRA. • The data provided for claimed shelf life is not Satisfactory , provide the justifiable stability study data and protocols that suffice the claim of shelf life. • Complete EPSPs of subject products and label duly approved in the country of origin or

					any stringent regulatory authority (SRA).
3.	-do-	M/s PIKDARE Manufacturer Via Saldarini Catelli 10, 22070 Casnate Con Bernate COMO, Italy FSC: Italy (copy)	SOFFIX STRETCH (PIC SOLUTION) (Adhesive Role Dressing) Claimed Shelf life: 03-years. Class: A	Adhesive Role Dressing	**Deferred.** The shall provide the following documents:- • Original and valid agency agreement • Valid certificate of ISO-13485/ Latest GMP. • Technical details of mfg. details along with CoA of respective product. • Original registration status or free sale certificate in any SRA. • The data provided for claimed shelf life is not Satisfactory, provide the justifiable stability study data

					and protocols that suffice the claim of shelf life. • Complete EPSPs of subject products and label duly approved in the country of origin or any stringent regulatory authority (SRA).
4.	-do-	M/s PIKDARE Manufacturer Via Saldarini Catelli 10, 22070 Casnate Con Bernate COMO, Italy FSC: Italy (copy)	SECURFIX PLUS (Transparent dressing for cannula) Claimed Shelf life: 03-years. Class: A	A Cannulla Dressing is an Adhesive Dressing used to Control Intravenous (IV) Catheter Insertion Sites.	**Deferred.** The shall provide the following documents:- • Original and valid agency agreement • Valid certificate of ISO-13485/ Latest GMP. • Technical details of mfg. details along with CoA of respective product. • Original registration status or free sale

					certificate in any SRA. • The data provided for claimed shelf life is not Satisfactory, provide the justifiable stability study data and protocols that suffice the claim of shelf life. • Complete EPSPs of subject products and label duly approved in the country of origin or any stringent regulatory authority (SRA).
5.	-do-	Legal Manufacturer: M/s Pikdare S.p.A Via Saldarini Cateli 10, 22070 Casnate con Bernate Como, Italy Manufacturing Site: Zhejiang	MIRAGE (Scalp Vein Set) Claimed Shelf life: 03-years. Class: B	The Scalp vein set is used for blood Smapling and injection of small amounts of Infusion solutions.	**Deferred.** The shall provide the following documents:- • Original and valid agency agreement • Valid certificate of ISO-

		Kindly Medical Devices Co., Ltd no 758 5th Binhai Road Binhai Industrial Park, Longwan Province PRC FSC: China Date of Issue: 12.03.2018			13485/ Latest GMP. • Technical details of mfg. details along with CoA of respective product. • Original registration status or free sale certificate in any SRA. • The data provided for claimed shelf life is not Satisfactory , provide the justifiable stability study data and protocols that suffice the claim of shelf life. • Complete EPSPs of subject products and label duly approved in the country of origin or any stringent regulatory authority (SRA).

6.	-do-	Legal Manufacturer: BUCA 058 MAH, DOGUS CAD. 3/19 SOK. NO. 6, OSB 1, BOLGE, BUCA, IZMIR, TURKEY FSC: TURKEY Date of issue: 27.09.2019	MIRAGE SMART-SAFE (Scalp Vein Set with safety) Claimed Shelf life: 03-years. Class: B	The Scalp vein set is used for blood Smapling and injection of small amounts of Infusion solutions.	**Deferred.** The shall provide the following documents:- • Original and valid agency agreement • Valid certificate of ISO-13485/ Latest GMP. • Technical details of mfg. details along with CoA of respective product. • Original registration status or free sale certificate in any SRA. • The data provided for claimed shelf life is not Satisfactory, provide the justifiable stability study data and protocols that suffice the claim of shelf life.

					• Complete EPSPs of subject products and label duly approved in the country of origin or any stringent regulatory authority (SRA).
7.	-do-	Legal Manufacturer: M/s Pikdare S.p.A Viz Saldarini Catelli 10, 22070 Casnate con Bernate COMO , Italy **Manufacturing Site:** Zhejiang Kindly Medical Device Co., Ltd No. 758, 5th Binhai road, Binhai Industrial Park, Longwan District 325025 Wenshou, Zhejiang Province PRC FSC: CHINA Date of issue: 16-03-2018	GRUPA (Disposable Camera Cover) Claimed Shelf life: 03-years. Class: A	A sterile disposable Endoscopy Camera Cover is a Sheath that is used to protect the endoscopy camera.	**Approved.** The shall provide the following documents:- • Original and valid agency agreement •

8.	-do-	Legal Manufacturer: JIANGSU WEILKANG JIEJING MEDICAL APPARATUS CO., LTD 18 # WENZHOU RD ECONOMICAL DEVELOPMENT DISRICT SHURANT 223600 CHINA FSC: China valid till: 20 Sep.2021	GRUPA (Disposable Surgical Drape Sets) Claimed Shelf life: 03-years. Class: A	Disposable Surgical Drape Sets	**Approved.** The shall provide the following documents:- • Original and valid agency agreement • Valid certificate of ISO-13485/ Latest GMP. • Technical details of mfg. details along with CoA of respective product. • Original registration status or free sale certificate in any SRA. • The data provided for claimed shelf life is not Satisfactory, provide the justifiable stability study data and protocols that suffice the claim of shelf life. • Complete

					EPSPs of subject products and label duly approved in the country of origin or any stringent regulatory authority (SRA).
9.	M/s Ferozsons Laboratories Limited. P.O. Ferozsons, Amangarh, Nowshera, KPK ELI-00120	Legal Manufacturer: M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, MA USA 01752 Manufacturing Site: ENERCON TECHNOLOGIES 25 NORTHBROOK DR. P.O. BOX 665 GRAY, ME USA 04039 FSC US FDA valid till 08-09-2021	SpyGlass DS™ Digital Controller Code: M00546650 Shelf Life: N/A Class A Rs. 5000/-	Endoscopic video imaging system that receives video signals from the Scope, processes the video signals and outputs video images to an attached monitor. It is part of SpyGlass DS Direct Visualization System	**Approved.** Firm shall submit Embassy attested FSC and valid ISO13485.

Item No.X. <u>DEFERRED CASES OF REGISTRATION OF MEDICAL DEVICES FOR IMPORT.</u>

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

S.#	Name of Firm (s)/Importer	Name of Manufacturer	Name of Medical Device	Brief Desciption	Decision
1.	M/s Otsuka Pakistan Limited, 30-B, SMCHS, Karachi (ELI-00243)	**Manufacturer:** Shanghai Microport EP MedTech Co., Ltd. Building 23 & 28, Lane 588, Tianxiong Road, Pudong New District 201318 Shanghai, China. (FSC China valid till 25-2-2021) (FSC Netherlands valid till 17-09-2023)	Fire Magic™ Cardiac RF Ablation Catheter Class D Shelf Life: 3 Years Codes: As Per Netherlands FSC Fee submitted: Rs. 50,000/- As drug on Form-5A (Product approved in 256th meeting of Reg Board. Registration letter was not issued)	Indicated for use in cardiac electrophysiological mapping, simulation and ablation to treat the arrhythmia when used in conjunction with a radiofrequency generator. Sterile, single-use	**Approved.**
2.	**M/s. Moon enterprises**, 5/6 Rabani Road Old Anarkali Lahore **ELI-00356.**	**Legal Manufacturer & mfg. site:** Antitoxin GmBH Industries 88 69245 Bammental Germany FSC: Germany Date of Issue 18.09.2018.	**ImuMed** (ABO-SYSTEM) Anti-A monoclonal IgM Anti-A monoclonal IgM Code 01.001-01.003 Class- D. Shelf Life: 05-Years.	ABO-SYSTEM) Anti-A monoclonal IgM Anti-A monoclonal IgM	**Approved.**
3.	M/s. Mian Scientific Corporation (Pvt) Ltd 534-Jinnah Colony Faisalabad ELI: 00442	**Legal Manufacturer** Wuxi Bio Hermes and Bio-medical technology Co. Ltd, No 136 Mashan	Bio HermesGLYCO HEMOGLOBIN ANALYZER Class: C	In vitro diagnostic test used for quantitative analysis of A1c Glycohemoglobin or A1c glycohemogli	**Approved.** Firm shall submit valid FSC of China.

		Meiliang Road Binhu wuxi Jiangsu 214092, China **Manufacturing Sites:** No. 88 Mashan Meiliang road, Binhu, Wuxi 214092, Jiangsu, China No. 136 Mashan Meiliang road, Binhu, Wuxi 214092, Jiangsu, China 11th Floor, 530 Mansion, #18 Qingyuan Road, Xinwu distict, Wuxi 214135, Jiangsu, China FSC: China Valid till 17.07.2021	Service Life: 5 years Model: A1C-M21	bin fraction in whole venous blood.	

Item No.XI. <u>REGISTRATION OF MEDICAL DEVICES FOR LOCAL MANUFACTURE (Form 7).</u>

Sr. No.	Name & Address of Establishment	Name of Medical Devices With Size	Brief Description	Decision
1.	M/s Crespak Medical Industries, 8Km Manga raiwind Road, Lahore (ELM-0004)	Engel Plus Auto Discard Syringe (2ml, 2.5ml, 3ml, 5ml) (22G, 23G, 24G) Class B	It is a sterile single-use plastic syringe or medical device intended for immediate use for the administration of	**Approved.**

		Shelf Life: 03 Years	injectable preparation.	
2.	M/s Lahore Medical Instruments (Pvt) Ltd., 48Km Lahore-Kasur Road, Lahore (ELM- Not Issued)	Injekt Auto Disable Syringe (3ml, 5ml) Class B Shelf Life: 02 Years	It is a sterile single-use plastic syringe or medical device intended for immediate use for the administration of injectable preparation.	**Approved.**
3.	M/s Smile Surgicals (Pvt) Ltd., HO: Plot No.06, Abbpara Housing Society Canal Road, Lahore 296-L, Street No.13, Industrial Estate, Gadoon Amazi, Dist Swabi (KPK) (ELM-0022)	Smile Auto disable Syringes Class B Shelf Life: 05 Years Sizes: 3ml & 5ml Rs.20,000/-	Autodisable Syringes	**Approved.** Firm shall provide stability data for claimed shelf life.
4.	M/s Unisa (Pvt) Ltd., Main GT Road, Adamzai, Akora Khattak, District Nowshera (ELM-0002)	UNILOCK Auto disable Sterile Single Use Plastic Syringes Class B Shelf Life: 05 Years SIZES: 1ml, 2.5ml, 3ml,5ml, 10ml & 20ml Rs. 20,000/-	Auto disable Sterile Single Use Plastic Syringes	**Approved.** Firm shall provide stability data for claimed shelf life.

Item No.XII. **RENEWAL OF REGISTRATION OF MEDICAL DEVICES FOR LOCAL MANUFACTURE (Form 7).**

Sr. No.	Name & Address of Establishment	Name of Medical Devices With Size	Brief Description	Decision
1.	M/s Injection Systems (Pvt) Ltd., Plot No.271, Main Road, Industrial Estate, Gadoon Amazai. (ELM-0034)	BIOSAFE Disposable Syringe Propylene syringe with gasket as SS needle. (1ml, 3ml, 5ml, 10ml) Class B Shelf Life: 05 Years Previous Registration # 064426 29-09-2020 to 28-09-2025	Biosafe Syringe is used in clinical medicine to administer drug subcutaneously, intramuscularly and intravenously.	**Approved the renewal of 1ml and 10ml only**. Firm shall submit stability data of claimed shelf life.
2.	-do-	BIOSAFE Disposable Syringe Propylene syringe with gasket without needle. (2ml, 3ml, 5ml, 10ml) Class B Shelf Life: 05 Years Previous Registration # 064427 29-09-2020 to 28-09-2025	Biosafe Syringe is used in clinical medicine to administer drug subcutaneously, intramuscularly and intravenously.	**Approved the renewal of 10ml only**. Firm shall submit stability data of claimed shelf life.

Item No.XV. **APPLICATION FOR GRANT OF ESTABLISHMENT LICENSE TO MANUFACTURE MEDICAL DEVICES.**

The below mentioned firm has applied for grant of Establishment License to manufacture medical devices under MDR, 2017 for which inspection panel was constituted for

inspection of their establishment. The information about the firm/company and recommendations of the panel are submitted for consideration of MDB please: -

S.No	Name of Establishment	Address	Name of Qualified Person	Name of QC Incharge
1.	M/s Samad Rubber Works (Pvt) Ltd., Apparel Division	Plot No. 02, Faizi street, 23-Km, Ferozepur Road, Lahore	Ms. Rahat Kanwal Pharmacist (Production Incharge)	

Decision: The Board discussed and approved the grant of Establishment License to M/s Samad Rubber Works (Pvt) Ltd., Apparel Division, Plot No. 02, Faizi street, 23-Km, Ferozepur Road, Lahore for manufacturing of medical devices i.e. PPEs (Gowns, Coveralls and Shoe Cover).

Item No.XVI. <u>REQUEST FOR GRANT OF ADDITIONAL SIZES OF REGISTERED MEDICAL DEVICES FOR IMPORT</u>

M/s Nisa Impex (Pvt) Ltd, Maxim Arcade, Plot No.13-14, Usman Block, Jeddah Town, Phase-1, Opp. DHA-II, G.T. Road, Islamabad, has requested for grant of approval of additional sizes of their following registered medical device for import as per detail mentioned below: -

S.No	Regn.No.	Name of Medical Device	Name of Manufacturer	Existing Approved Sizes/ Codes	Demanded Additional Sizes/ Codes.
2.	MDIR-0001282	Nisa Auto Disable Syringe (Self Destructive Disposable Syringe with Needle)	M/s Chengdu Xinjin Shifeng Medical Apoparatus & Instrument Co. Ltd, No.46, 7th Group, Wanjie Village, Xinping Town, Xinjin County, Chengdu-City, P.R. China.	1ml, 2ml, 5ml, 10ml Needle Size: 0.4. 0.45, 0.5, 0.55. 0.6, 0.7, 0.8, 0.9.	0.05ml, 0.5ml, 2.5ml and 3ml.

Decision: The Board discussed and approved the aditional sizes as per detail mentioned below:-

S.#	Regn.No.	Name of Medical Device	Name of Manufacturer	Existing Approved Sizes/ Codes	New Approved Additional Sizes/ Codes.
1.	**MDIR-0001282**	**Nisa Auto Disable Syringe (Self Destructive Disposable Syringe with Needle)**	**M/s Chengdu Xinjin Shifeng Medical Apoparatus & Instrument Co. Ltd, No.46, 7th Group, Wanjie Village, Xinping Town, Xinjin County, Chengdu-City, P.R. China.**	**1ml, 2ml, 5ml, 10ml Needle Size: 0.4. 0.45, 0.5, 0.55. 0.6, 0.7, 0.8, 0.9.**	**0.05ml, 0.5ml, 2.5ml and 3ml.**

Item No. XVII. **GUIDELINES TO MANUFACTURE MEDICAL DEVICES BY THE DRUG MANUFACTURING LICENCE HOLDERS.**

Guidelines for manufacturing of medical devices by the Drug Manufacturing License (DML) holders has been drafted and placed at Annex-II for consideration of MDB please.

Decision:The Board after deliberations approved the folloing Guidelines (Annex-II) for the Drug Manufacturing License (DML) holders.

Annex-II

GUIDELINES TO MANUFACTURE MEDICAL DEVICES BY THE DRUG MANUFACTURING LICENCE HOLDERS

INTRODUCTION

Drug Regulatory Authority of Pakistan Act, 2012)DRAP Act, 2012(was enacted on 13th November, 2012**.** The objective of DRAP Act is to regulate, manufacture, import, export, storage, distribution and sale of therapeutic goods including medical devicesto ensure quality, safety and efficacy of these therapeutic goods in larger public interest**.**

Under the DRAP Act 2012,medical devices for human and animal usewere brought under the regulations.Under the said Act, Medical Devices Rules, 2015 were promulgated which were subsequently replaced by Medical DevicesRules 2017notifiedon 16th Jan, 2018for the regulation

of all types of medical devices. The said Act and rules can be downloadedfrom official website of the DRAP.

Before the promulgation of Medical Devices Rules, 2015, a number of medical devices were defined as drugs under the Drugs Act, 1976 and few others were declared as drugs through various SROs. Medical devices covered under the said Act were excluded from the definition of drug in Schedule-1 of DRAP Act, 2012 vide SRO.824(I)/2018 dated 26th June, 2018. Further, various SROs declaring medical devices as drugs were repealed vide SRO.167(I)/2017 dated 15th March, 2017 and were required to be registered as medical devices under Medical Devices Rules, 2015. These products which were with either defined as drugs or declared as drugs have now been made part of Schedule E of SRO 526(I)/2021 dated 30th April, 2021. The manufacturing of the abovementioned medical devices and dialysis solutions were carried out in the same premises as that of drugs under Drug Manufacturing License (DML).

Devices other than those defined as drugs or declared as drugs came into regulation for the first time upon promulgation of Medical Devices Rules, 2015 and subsequently Medical Devices Rules, 2017.

The DRAP Act 2012 and the rules framed thereunder do not restrict the manufacturing of medical devices and pharmaceuticals in the same plot.Furthermore, there is no specific requirement of plot size in the Medical Devices Rules, 2017. This is in line with international practices where vertical constructions/expansions are taking place. Moreover, internationally, ISO 13485 in EU, Medical Device Directives or In Vitro Devices Regulations in UK and 21 CFR part 820 Quality System Regulations in USA are followed. All these regulations describe similar manufacturing requirements for pharmaceutical and medical devices with more strict regulations for pharmaceuticals than medical devices.

The purpose of these guidelines is to facilitate the local manufacturing of medical devices, provideease in doing business, promote exportsand outline steps which should be taken, as necessary and appropriate, by manufacturers of medical devices with the objective of ensuring that their products are of the intended quality and nature.

CHAPTER 1

Manufacture of Schedule E medical devices and Dialysis Solutions

The DML holders will be allowed to manufacture Schedule E medical devices and Dialysis Solution in the same building as that of pharmaceutical products by following the below mentioned procedure:-

1. **Application of Building Layout Plan:**
   The applicant will apply to the Division of Licensing for the approval of building lay out. Triplicate copies with duly marked section of medical devices along with the HVAC drawings, personnel and material flow needs to be submitted along with prescribed fee. The building layout plan will be approved by the said Division as per its SOPs for the approval of building

layouts. Quality control lab of pharmaceuticals may also be utilized for the testing of medical devices

2. **Application for the grant of Establishment License to Manufacture Medical Devices:**
   The applicant will apply to the Medical Devices& Medicated Cosmetics (MDMC) Division on FORM 1 along with all the annexures as per the checklist posted on the DRAP official website www.dra.gov.pk under the Division of Medical Devices including the approved building layout and the prescribed fee. The MDMC Division will proceed the application as per the approved SOPs for the grant of License to Manufacture Medical Devices (FORM 3)
3. **Application for the grant of Medical DeviceEnlistment/Registration**:
   The FORM 3 holder will apply to the MDMC Division on the FORM-6 or FORM-7 (as the case may be) along with all the annexures as per the checklist posted on the DRAP official website www.dra.gov.pk under the MDMC Division and the prescribed fee.

CHAPTER 2

Manufacture of Medical Devices other than Schedule E and Dialysis Solutions.

The DML holders intending to manufacture medical devices other than Schedule E and Dialysis Solution will be allowed to manufacture their said medical device on the same plot in separate building by following the below mentioned procedure:-

1. **Application of Building Layout Plan:**
   The applicant will apply to the MDMC Division for the approval of building lay out. Application shall be submitted on cover letter along with prescribed fee and Triplicate copies of duly marked facilities along with the HVAC drawings (where applicable), personnel and material flow. The building layout plan will be approved by the said Division as per its SOPs for the approval of building layout. Quality control lab of pharmaceuticals may also be utilized for the testing of medical devices

2. **Application for the grant of Establishment License to Manufacture Medical Devices:**
   The applicant will apply to the MDMC Division on FORM 1 along with all the annexures as per the checklist posted on the DRAP official website www.dra.gov.pk under the Division of MDMC including the approved building layout and the prescribed fee. The MDMC Division will proceed the application as per the approved SOPs for the grant of License to Manufacture Medical Devices (FORM 3)

3. **Application for the grant of Medical DeviceEnlistment/Registration**:
   The FORM 3 holder will apply to the MDMC Division on the FORM-6 or FORM-7 (as the case may be) along with all the annexures as per the checklist posted on the DRAP official website www.dra.gov.pk under the MDMC Division and the prescribed fee.