

DECISIONS OF THE 29th MEETING OF THE MEDICAL DEVICE BOARD (MDB)
HELD ON 03-02-2021

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 S.U. Enterprises, 3-Edward Road, First Floor, Near A.G. Office, Lahore. Godown Address; 4-Lake Road, Near Highway Office, Lahore.	Shafi Ullah Sheikh Muhammad Imran Safi Irfan Shafi AsimShafi Abid Shafi	No	Approved for storage of medical devices except medical devices which require cold storage/specialized storage.
2.	M/s Shah Surgical Suppliers, Room No.213, Makkah Tower, 2 nd Floor, Namak Mandi, Peshawar. Godown Address: Same as above.	Mr. Mudassir Shah	No	Approved for storage of non-cold chain medical devices.
3.	M/s SZ Surgical Supplier, Office No.S-12, 2 nd Floor, Ghulam Said Medicine Market, Namak Mandi Peshawar. Godown Address: Same as above.	Shakir Ullah	No	Approved for storage of non-cold chain medical devices.

2. CORRECTION IN MINUTES OF 26TH MEETING OF MDB HELD ON 06-01-2021.

It is submitted that that case of M/s Reckitt Benckiser Pakistan Limited, Karachi for grant of establishment license to import medical devices was discussed in 26th meeting of MDB.

Decision: The Board discussed and decided to correct the earlier decision as "Deferred to verify the warehousing facility from connect logistics".

3. POST LICENSE VARIATIONS.

3.1.

M/s Chemical House, 6-C, Sikandar Malhi Road Canal Park, Gulbeg-II, Lahore has requested for approval of change of qualified/technical person in their ELI-00156 issued on 17-10-2018 as per detail given below:-

Existing Technical Person	Proposed Technical Person
Sayeda Rubba Kazmi, House # 136, Street No.2, Sector-D, Askari-X, Lahore Cantt. CNIC # 35200-5732381-4	Ms. Beenish Pervaiz, Permanent Address: House No.360, Block-@, Mohallah Sector C-1, Township, Lahore. Present Address: 51-A2, PGECHS Near Wapda Town, Lahore CNIC # 35202-91900922-1 (Pharm-D)

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

Previous Technical Person	New Approved Technical Person
SayedaRubba Kazmi, House # 136, Street No.2, Sector-D, Askari-X, Lahore Cantt. CNIC # 35200-5732381-4	Ms. Beenish Pervaiz, Permanent Address: House No.360, Block-@, Mohallah Sector C-1, Township, Lahore. Present Address: 51-A2, PGECHS Near Wapda Town, Lahore CNIC # 35202-91900922-1

3.2.

M/s Grace Pharmaceutical, Karachi has requested for approval of change of Establishment address in their ELI-00254 issued on 19-10-2018 as per detail given below:-

Existing Address	Proposed Address
102, 1 st Floor, Block-9, Clifton, Karachi.	Office No.503, 5 th Floor, Plot No.42C/2, Lane-8 Bukhari Commercial DHA Phase-6, Karachi.

Decision: The Board acceded to the request of the firm/company and approved the change of address as per detail given below:-

Previous Address	New Approved Address
102, 1 st Floor, Block-9, Clifton, Karachi.	Office No.503, 5 th Floor, Plot No.42C/2, Lane-8 Bukhari Commercial DHA Phase-6, Karachi.

4. CANCELLATION OF SOLE AGENCY AGREEMENT.

It is submitted that the principal manufacturer M/s International Company for Medical Necessities, Industrial Zone, Block No.19 & 67, El-Zarby, Abu-Tig, Assiut, Egypt has informed the DRAP on 4th January, 2021 that they have cancelled the Distribution Authorization of M/s Tech Zone, Lahore. They have stated that earlier dossiers/ applications submitted by M/s Tech Zone, Lahore stands cancel for all range of their product including disposable syringes, Auto-Disable Syringes, Safety Syringes, Insulin Syringes, as this distributor is no more authorized to submit any dossier for their company products.

Decision: The Board discussed the matter at length and decided to issue show cause notice and giving an opportunity of hearing to M/s Tech Zone, Lahore as to why not their product, namely, I.CO Safety Syringe Auto-Disable (0.5, 3, 5 and 10ml) (Reg.No. MDIR-0001938) manufactured by M/s International Company for Medical Necessities, Industrial Zone, Block No.19 & 67, El-Zarby, Abu-Tig, Assiut, Egypt registered on 11th November, 2020 be cancelled as the manufacturer had cancelled their Agency Agreement / contract/Authorization for the said product.

5. REGISTRATION OF MEDICAL DEVICES FOR IMPORT (AUTO DISABLE SYRINGES).

S. #	Name and Addresses of Establishment	Manufacture Details	Name of Medical Device with sizes/ Class/Shelf Life	Brief Description	Decision
1.	M/s Pharma Life, Distributors, Office No. CB-94/1 Cobline, Near Askari-11, Sajid Bukhari Road, Afshan Colony, Rawalpindi ELI-00606	Manufactured For: M/s Sunsoars Co., Ltd, 3F, 3, LN260 SEC4, XINHAI RD, Wenshan , TAIPEI 11692, Taiwan Manufactured by: Yangzhou Medline Industry Co. Ltd No. 108 Jinshan Road, Economic Development Zone, Yangzhou 225009 Jiangsu, China	Apex Life Auto Disable Syringe Codes & Sizes: As per FSC Class B Shelf Life: Not mentioned on form Fee submitted: Rs. 25,000/-	Sterile, single-use auto-disable syringes	Rejected as the Auto disable syringe of this manufacturer has already been registered in the name of M/s Zenith International, Karachi.
2.	M/s Mehran International, 498/C Feroz Shah Mehta Road Karachi ELI: 00351	Legal Manufacturer: M/s Hunan Pingan Medical Device Technology Co., Ltd Economic Development Zone, LI country, Human	RELATION Sterile Auto Disable syringes (3ml, 5ml, 10 ml) Codes As per FSC. Class-B	Relation Sterile Auto Disable syringes 3ml, 5ml, 10 ml	Approved subject to provision of following documents: - • Original &

		Province, P.R China.	Claimed Shelf Life: 5 years		<p>valid FSC of SRA OR WHO Pre-qualification OR CE certifications from the notified body of NANDOs database.</p> <ul style="list-style-type: none"> GMDN code, MRP, Grouping, ISO-13485, Full QA certificate, EPSPs and shelf-life/ stability studies.
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6. REGISTRATION OF MEDICAL DEVICES FOR IMPORT (FORM-7A).

S.#	Name of Firm (s)	Name of Manufacturer	Name of Medical Devices.	Brief Description	Decision
1.	M/s B.Braun Pakistan (Pvt) Ltd., The Forum, Suite 216, Khayaban-e-Jami, Block No.9, Clifton, Karachi (ELI-00006)	<p>Legal Manufacturer: B. Braun Melsungen AG Carl-Braun-StraBe 1 34212 Melsungen, Germany</p> <p>Production Facility: B. Braun Melsungen AG PfiEFFewiesen 34212 Melsungen Germany</p> <p>(FSC Germany issuance 22-05-2019)</p>	<p>Infusomat®P (volumetric infusion pump)</p> <p>Class C</p> <p>Shelf Life: N/A</p> <p>Code: 8712212, 8700109, 8700150, 8701628, 8701644 ,8707879, 8711661, 8711674, 8711682, 8711747, 8721106</p> <p>Fee submitted:</p>	It is a volumetric infusion pump for application of liquids in infusion and nutritional therapy	Approved.

			Rs. 50,000/-		
2.	M/s. Cor-Med, 2nd Floor 38/62 Rehman Plaza, Bank Road, Saddar, Rawalpindi. (ELI-00226)	Legal Manufacturer/Manufacturing site: Merit Medical systems, Inc. 1600 West Merit Parkway, South Jordan, UT USA 84095 FSC US FDA valid till 27-02-2021	Prelude® Sheath Introducer Class B Shelf Life: 4 years Codes: as per FSC US FDA dated 28-02-2019	Intended to provide access and facilitate the percutaneous introduction of various devices into veins and / or arteries while maintaining hemostasis for a variety of diagnostic and therapeutic procedures. Sterile, single-use	Approved.
3.	M/s. Cardiac Care, 848-C Shadman-I, Lahore. ELI-00070	Manufacturer: HSINER Co. Ltd 312, Jhongshan Rd, ShengangDist, Taichung 429, Taiwan. FSC Germany copy (not notarized and embassy attested) issued for Argentina without codes mentioned in it	HME FILTER Class: B Shelf Life: 3 years Fee submitted: Rs. 25,000/-	Intended to removing microbiological and particulate matter from the gases in the breathing circuit by attaching this device in between the circuit and the patient or between the circuit and the ventilation machine, keep and exchange of breathe heat and moisture.	Rejected the product based on Policy Guidelines on Taiwan sent by Ministry of Foreign Affairs.
4.	-do-	Manufacturer: M/s Vygon 5 rue Adeline-95440 Ecouen- France FSC France issued on 12.10.2016	Vyextractor (Mucus extractor with connector to fibroscopes) Codes: 536.10 536.16 536.20 Class: B Shelf Life: 5	Device for mucus aspiration during fibroscopy/ bronchoscopy. Sterile, single-use	Approved.

			years Fee submitted: Rs. 25,000/-		
5.	M/s Johnson & Johnson Pakistan (Pvt) Ltd., Office No.806, 8th Floor, Horizon Towers, Block 3, Scheme 5, Clifton, Karachi (ELI-00154)	Legal Manufacturer: Ethicon Endo-Surgery, LLC 475 Calle C Guaynabo, PR USA 00969 Manufacturing site: Nypro Healthcare Baja, Inc. (Torres) Ave de Las Torres #7125 Colonia Salvarcar 118 Ciudad Juarez, Chihuahua Mexico 32580 (FSC US FDA valid till 22-12-2022)	Ligaclip® Extra (Ligating Clip Cartridge) Class C Shelf Life: 60 Months Codes: LT100, LT102, LT200, LT202, LT300, LT400 Fee submitted: Rs. 50,000/-	Sterile, single patient use clips produced from titanium designed for the ligation of tubular structures where a non-absorbable ligating device is indicated.	Approved.
6.	M/s Pak Punjab Cardex Medical System, 202, 2 nd Floor, Eden Heights, Jail Road Lahore, ELI: 00174	Manufacturer: M/s Bioteque Corporation 5F-6 No. 23, Sec.1, Chang-An, East Road, Taipei 104, Taiwan. FSC Germany issued on 03.09.2018 2018	Bioteq Sheath Introducer Kit Class: B Shelf Life: 3 years Fee submitted: Rs. 50,000/-	Used to provide access and facilitate the percutaneous introduction of various devices into peripheral veins or arteries while maintaining hemostasis for a variety of diagnostic and the therapeutic procedures. Sterile, single-use	Rejected the product based on Policy Guidelines on Taiwan sent by Ministry of Foreign Affairs.
7.	-do-	Manufacturer: M/s Bioteque Corporation 5F-6 No. 23, Sec.1, Chang-An, East Road, Taipei 104, Taiwan FSC Germany issued on 03.09.2018 2018	Bioteq Angiographic Catheter Class: D Shelf Life: 3 years Fee submitted: Rs. 50,000/-	Angiographic catheter. Sterile, single-use	Rejected the product based on Policy Guidelines on Taiwan sent by Ministry of Foreign Affairs.

8.	M/s Nipro Medical (Pvt) Ltd, Building No. 24, Central Commercial Area, DHA Phase 8, Ex Park View, Lahore ELI: 00530	<p>Manufacturer: Ningbo Tianyi Medical Appliance Co. Ltd No. 788 Mozhi North Road Tourism Resort, Dongqian Lake, 315121 Ningbo, China</p> <p>FSC China valid till 07-05-2022 FSC Germany (not embassy attested) copy issued on 15-1-2021</p>	<p>Nipro Extracorporeal Blood Circuit (Blood Tubing Set)</p> <p>Codes: As per FSC China</p> <p>Class: B</p> <p>Shelf Life: 3 years</p> <p>Fee submitted: Rs. 25,000/-</p>	<p>Extracorporeal blood channel during blood purification treatment. Sterile, single use</p>	<p>Approved.</p> <p>The firm shall submit original and Embassy attested FSC of Germany at the time of issuance of registration letter.</p>
9.	M/s Fresenius Medical Care Pakistan Pvt. Ltd TAMC, First Floor, 27C III, M.M. Alam Road Gulberg III, Lahore 54660, Pakistan ELI-00315	<p>Legal Manufacturer: Fresenius Medical Care AG & Co. KGaA61346 Bad Homburg Germany</p> <p>Manufacturing Site: Fresenius Medical Care Deutschland GmbH, Hafenstrasse 9, 97424 Schweinfurt, Germany</p> <p>FSC: Germany Issue Date 05.4.2016</p>	<p>MultiFiltrate Acute Therapy System</p> <p>Class C</p> <p>Shelf life: (Expected service life: If the Technical Safety Checks are performed to the full extent specified and at the prescribed intervals, the safe operation of the device in the time between these procedures is guaranteed)</p> <p>Codes: M200701</p>	<p>This product is intended for single use only for extracorporeal blood purification</p>	<p>Approved.</p>
10.	-do-	<p>Legal Manufacturer: Fresenius Medical Care AG & Co. KGaA 61346 Bad Homburg Germany</p> <p>Manufacturing Site: Fresenius Medical Care Deutschland GmbH Frankfurter StraÙe 6 – 866606 St.</p>	<p>(Ci-Ca® Dialysate K4)</p> <p>Dialysate for Citrate Continuous Renal Replacement Therapies (CRRT)</p> <p>Class C</p>	<p>Dialysis solution for acute treatment - like the Ci-Ca Dialysate products are used as dialysis solutions within CVVHD (Continuous Venovenous</p>	<p>Approved.</p>

		Wendel Germany FSC: Germany Issue Date 2.3.2018	Shelf life: 2 years Code: F00000431	hemodialysis) treatment. The solutions are non-invasive and are supposed to change the chemical composition of the blood in the filter by removal of exceeding water and metabolic toxins from the blood and by balancing the pH and electrolyte concentrations	
11.	-do-	Legal Manufacturer: Fresenius Medical Care AG & Co. KGaA 61346 Bad Homburg Germany Manufacturing Site Fresenius Medical Care Deutschland GmbH Address: Frankfurter Straße 6 - 8 66606 St. Wendel Germany FSC: Germany Date of issue: 11.06.2019	(FX Paed) (Dialyzers/Filters) Class: C Shelf Life: 3 years Code: 5008221	Dialyzers are applied for single use for extracorporeal blood cleaning during renal replacement therapy (hemodialysis). This may be a transient acute therapy until restoration of renal function or a permanent (chronic) use.	Approved.
12.	-do-	Legal Manufacturer: Fresenius Medical Care AG & Co. KGaA 61346 Bad Homburg Germany Manufacturing Site: Fresenius Medical Care Deutschland GmbH Frankfurter Straße 6 – 8 66606 St. Wendel Germany	(Sodium Citrate 4% w/v (Citrate Solution for Ci-Ca therapy) Class: C Shelf Life 2 years Code: F00008105	Sodium Citrate 4% w/v is applied for regional anticoagulation in Continuous Renal Replacement Therapies (CRRT). It must only be used with Fresenius	Approved.

		FSC: Germany Date of issue: 11.07.2019		Medical Care CRRT devices multiFiltrate and multiFiltrate PRO for the Continuous Venovenous hemodialysis and post dilution Continuous Venovenous hemodiafiltrati on blood processing therapies and having integrated pumps to administer citrate and calcium. The solution is not to be used for direct intravenous infusion.	
13.	M/s. AL YAHYA Enterprises Office 206, Sana Plaza Garrison Golf Club, Bahar Shah Road,Lahore ELI 00111	Legal Manufacturer: Lux-Sutures Ag Located At 22, Gruuss-Stroos 9991 Weiswampach- Luxembourg. FSC Luxembourg Valid Till 30.06.2021	LUXCRYL 910 Sutures Class-D Shelf life 5 years Code: PL01DS40	Luxcry 910 sutures are intended for use in general soft tissues closing and/or ligation, especially in general surgery, skin closure, gastrointestinal surgery, plastic surgery, ophthalmic surgery, gynecology, obstetrics, orthopedics, urology.	Deferred for provision of FSC from a reference country OR valid CE mark documents.
14.	-do-	Legal Manufacturer: Lux-Sutures Ag Located At 22, Gruuss-Stroos 9991	CATGUT CHROM Sutures Code:CC01HR40	Catgut plain sutures are intended for use in general soft tissues	Deferred for provision of FSC from a reference country OR

		Weiswampach-Luxembourg. FSC Luxembourg Valid Till 30.06.2021	Class-D Shelf life 5 years	closing and/or ligation, especially in general surgery, gastrointestinal surgery, gynecology, obstetrics, orthopedics, urology.	valid CE mark documents.
15.	M/s Zenith International, Room # 104, Tahir Plaza, A/20, Block 7&8. K.C.H.S.U Karachi. (ELI-0090)	Legal Manufacturer: Zhejiang Bagli Medical Products Co., Ltd 118 Yuegui South Road City West New District 321300 Yongkang City, Zhejiang Province China. FSC China Validity 24-12-2020	Perfect Disposable Non-Woven I.V. Dressing Sterile. Class A Shelf Life: 5 years Sizes & Codes as per FSC 72x19 mm, 10cmx10m, 6x 8 cm, 9x15cm, 9x20 cm, 9x25 cm, 9x30,	Non-woven IV Dressing is used for fixation of catheter of cannula.	Approved. The firm shall provide valid FSC before issuance of registration letter.
16.	M/s Briogene Private Limited., 196-A, Sindhi Muslim, Cooperative Housing Society, Shahrah-e-Faisal, Karachi (ELI-00015)	Legal Manufacturer: SFRI SAS Lieu ditBerganton 33127 Saint Jean d'Ilac France (FSC France issue 06-03-2019)	Hemix 5-60-part Analyzer Hemix 5-60 Autoloader SFRI Diluent 5.1 SFRI Lyse 5.1 SFRI Quench 5.1 SFRI Clair 5.1 Blood Trol 22 Blood Cal Class B Shelf Life: SFRI Diluent 5.1 36 Months SFRI Lyse 5.1 24 Months SFRI Quench 5.1 24 Months SFRI Clair 5.1 15 Months Blood Trol 22 3 Months	The Hemix 5-60 is fully automated high-quality hematology analyzer for in vitro diagnostic use in clinical laboratories. It provides precise and accurate 5-part differential measurement using a laser based optical measurement technology.	Approved . .

			Blood Cal 45 days Sizes & Codes as Per FSC:		
17.	-do-	<p>Legal Manufacturer: SFRI SAS Lieu ditBerganton 33127 Saint Jean d'Illac France</p> <p>(FSC issue 06-03-2019)</p>	<p>H18 Light 3 Diff Analyzer Diluton H18 Lysoglobine 18 Diluterge H18 Diluclair H18 Hemaclair H18 BloodTrol 16 BloodCal</p> <p>Class B</p> <p>Shelf Life: H18 Light 3 Diff Analyzer 36 Months Diluton H18 24 Months Lysoglobine 18 24 Months Diluterge H18 24 Months Diluclair H18 12 Months Hemaclair H18 12 Months BloodTrol 16 105 days BloodCal 45 days</p> <p>Sizes & Codes as Per FSC</p>	The H18 Light is a hematology blood cell Counter with 3-part differentiation of WBC, 20 parameters & 3 color histograms (WBC, RBC, PLT)	Approved .
18.	M/s JohnsonMathew Pakistan (Pvt) Ltd., Unit C-304, Falak Tower, Frere Town Karachi 75530, Pakistan.	<p>Legal Manufacturer: AliveCor 444 Castro Street, Suite 600 Mountain View, CA USA 94041.</p> <p>Contract Manufacturer: China Turnkey Solutions logistics (Shenzen) Co, Ltd. 9F. Building A, ZTY Logistic Centre Futian Free Trade Zone Shenzen,</p>	<p>KardiaMobile System</p> <p>Class-B</p> <p>Shelf Life: 2 years (life time limiting factor is the battery used in the KardiaMobile hardware, non-rechargeable commonly used in wrist watches</p>	The Kardimobile System is a trans-telephonic (Transmission by telephone) ECG event recorder that records, stores, and transfers and analyzes single channel or two channel ECG rhythm	Approved subject to submission of original and Embassy attested FSC

		Guangdong, Chna 518045. FSC US FDA unattested copy valid till 23-09-2021.	and other electronic equipment. Battery is replaceable. Model: Kardiamobile 1L (single lead)	recordings. The device utilizes the computing power of Apple, Inc., iOS or Google LLC, Android-based smartphones to obtain and analyze single-channel ECG.	
19.	-do-	Legal Manufacturer: AliveCor 444 Castro Street, Suite 600 Mountain View, CA USA 94041. Contract Manufacturer: China Turnkey Solutions logistics (Shenzen) Co, Ltd. 9F. Building A, ZTY Logistic Centre Futian Free Trade Zone Shenzen, Guangdong, Chna 518045. FSC US FDA unattested copy valid till 23-09-2021.	Kardiamobile System Class-B Shelf Life: 2 years (life time limiting factor is the battery used in the Kardiamobile hardware, non-rechargeable commonly used in wrist watches and other electronic equipment. Battery is replaceable. Model: Kardiamobile 6L (Six Leads)	The Kardiamobile System is a trans-telephonic (Transmission by telephone) ECG event recorder that records, stores, and analyzes single channel or two channel ECG rhythm recordings. The device utilizes the computing power of Apple, Inc., iOS or Google LLC, Android-based smartphones to obtain and analyze single-channel ECG.	Approved subject to submission of original and Embassy attested FSC
20.	M/s IBL HealthCare Limited, 2nd Floor, One IBL Centre, Plot No.1, Block 7 & 8 Dehli Mercantile Muslim Cooperative Housing Society (DMCHS), Tipu Sultan Road, Off. Shahrah-e-Faisal, Karachi (ELI-00119)	Legal Manufacturer: M/s Kawasumi Laboratories, Inc. Shinagawa Intercity Tower B, 2-15-2, Konan, Minato-ku, Tokyo 108-6109, Japan Manufacturing Site: M/s Kawasumi Laboratories	Karmi Blood Bag Single 250ml, 500ml, single 250ml with safety accessories, single 500ml with safety accessories Class-D Shelf Life: 03	Blood Bags are used for storing and transfusion of whole blood and blood components.	Approved subject to submission of labels of all applied codes.

		(Thailand) Co., Ltd., 48 MU 8 Rachasima-Chok Chai Road, TambonTha Ang, AmphoeChok Chai, Changwat Nakhon Rachasima 30190, Thailand. FSC Thailand valid till (15-02-2022)	Years Codes as per FSC		
21.	-do-	Legal Manufacturer: M/s Kawasumi Laboratories, Inc. Shinagawa Intercity Tower B, 2-15-2, Konan, Minato-ku, Tokyo 108-6109, Japan Manufacturing Site: M/s Kawasumi Laboratories (Thailand) Co., Ltd., 48 MU 8 Rachasima-Chok Chai Road, TambonTha Ang, AmphoeChok Chai, Changwat Nakhon Rachasima 30190, Thailand. FSC Thailand valid till (15-02-2022)	Karmi Blood Bag Quadruple 500ml, Quadruple 500ml with safety accessories Class-D Shelf Life: 03 Years Codes as per FSC	Blood Bags are used for storing and transfusion of whole blood and blood components.	Approved subject to submission of labels of all applied codes.
22.	-do-	Legal Manufacturer: M/s Kawasumi Laboratories, Inc. Shinagawa Intercity Tower B, 2-15-2, Konan, Minato-ku, Tokyo 108-6109, Japan Manufacturing Site: M/s Kawasumi Laboratories (Thailand) Co., Ltd.,	Karmi Blood Bag Triple 500ml, Triple 500ml with safety accessories Class-D Shelf Life: 03 Years Codes as per FSC	Blood Bags are used for storing and transfusion of whole blood and blood components.	Approved subject to submission of labels of all applied codes.

		48 MU 8 Ratchasima-Chok Chai Road, TambonTha Ang, AmphoeChok Chai, Changwat Nakhon Ratchasima 30190, Thailand. FSC Thailand valid till (15-02-2022)			
23.	-do-	Legal Manufacturer: M/s Kawasumi Laboratories, Inc. Shinagawa Intercity Tower B, 2-15-2, Konan, Minato-ku, Tokyo 108-6109, Japan Manufacturing Site: M/s Kawasumi Laboratories (Thailand) Co., Ltd., 48 MU 8 Ratchasima-Chok Chai Road, TambonTha Ang, AmphoeChok Chai, Changwat Nakhon Ratchasima 30190, Thailand. FSC Thailand valid till (15-02-2022)	Karmi Blood Bag Double 500ml, Triple 500ml with safety accessories Class-D Shelf Life: 03 Years Codes as per FSC	Blood Bags are used for storing and transfusion of whole blood and blood components.	Approved subject to submission of labels of all applied codes.
24.	M/s Global Marketing Services,111, Hali Road Westridge 1, Rawalpindi, Pakistan. ELI-00109.	Legal Manufacturer: Sacace Biotechnologies s.r.l. via Scalabrini, 44 - 22100 Como, Italy, 22100 Como, Italy	SACYCLER-96 sc 96I, sc 96R Class-B Shelf life.....	A new instrument for Real time amplification and melting analysis suitable both for research studies as well as for diagnostic applications	Deferred for the provision of following documents:- Provide the original & valid agency agreement and FSC. GMDN code, MRP and stability/ service life

					studies not provided.
25.	M/s Mehran International, 498/C Feroz Shah Mehta Road Karachi ELI: 00351	Legal Manufacturer: M/s Shandong Qinkal Medical Industry Co., Ltd the Southern Tip of Quancheng Road in Industrial Park) Medical Equipment Industrial Park, Chengwu, County, Heze City, Shandong Province P.R China.	RELATION Burette Infusion Set 100 ML Class-B. Claimed Shelf Life: 5 years	Relation Burette Infusion Set 100 ML	Deferred for provision of following documents:- <ul style="list-style-type: none"> • Provide the original & valid FSC of country of origin and FSC of SRA OR WHO Pre-qualification OR CE certifications from the notified body of NANDOs database. • GMDN code, MRP, Grouping, ISO-13485, Full QA certificate, EPSPs and shelf-life/ stability studies not provided.
26.	-do-	Legal Manufacturer: M/s Changshu Taining Medical Equipment Co., Ltd Nan Shou, Town, Changshu City Jiangsu Province P.R China. FSC: China	Suction Connecting Tube. Codes & Sizes: As per FSC Class-B Claimed Shelf Life: 5 years	Suction Connecting Tube	Deferred for provision of following documents:- <ul style="list-style-type: none"> • Provide the original & valid FSC of country of origin • GMDN code, MRP, Grouping, ISO-13485,

					Full QA certificate, EPSPs and shelf-life/ stability studies not provided.
27.	-do-	Legal Manufacturer: M/s Jiangxi Glance Medical Equipmetn Co., Ltd Jinxian Medical Device Industrial Area Nanchang City, Jiangxi Province P.R China. FSC: China.	Endotracheal Tube Cuffed. Codes & Sizes: As per FSC Class-B. Claimed Shelf Life: 5 years	Endotracheal Tube Cuffed	Approved subject to provision of following documents:- • GMDN code, MRP, Grouping, Full QA certificate, and shelf-life/ stability studies. Uncuffed tubes to be applied separately
28.	-do-	Legal Manufacturer: M/s Changshu Taining Medical Equipment Co., Ltd Nan Shou, Town, Changshu City Jiangsu Province P.R China FSC: China.	Nasal Oxygen Cannula. Codes & Sizes: As per FSC Class-B Claimed Shelf Life: 5 years	Nasal Oxygen Cannula	Deferred for provision of following documents:- • Provide the original & valid FSC of country of origin issued by Chinese Health Authority. • GMDN code, MRP, Grouping, ISO-13485, Full QA certificate,

					EPSPs and shelf-life/ stability studies.
29.	-do-	Legal Manufacturer: M/s Changshu Taining Medical Equipment Co., Ltd Nan Shou, Town, Changshu City Jiangsu Province P.R China FSC: China	RELATION Oxygen Mask with Reservoir Bag Codes &Size: As per FSC Class-B. Claimed Shelf Life: 5 years	Relation Oxygen Mask with Reservoir Bag	Deferred for provision of following documents:- <ul style="list-style-type: none"> • Provide the original & valid FSC of country of origin issued by Chinese Health Authority. • GMDN code, MRP, Grouping, ISO-13485, Full QA certificate, EPSPs and shelf-life/ stability studies.
30.	-do-	Legal Manufacturer: M/s Changshu Taining Medical Equipment Co., Ltd Nan Shou, Town, Changshu City Jiangsu Province P.R China. FSC: China	Suction Catheter Cap Cone connector. Codes &Size: As per FSC Class-B. Claimed Shelf Life: 5 years	Suction Catheter Cap Cone connector	Deferred for provision of following documents:- <ul style="list-style-type: none"> • Provide the original & valid FSC of country of origin issued by Chinese Health Authority. • GMDN code, MRP, Grouping, ISO-13485, Full QA certificate, EPSPs and

					shelf-life/ stability studies.
31.	-do-	Legal Manufacturer: M/s Hunan Pingan Medical Device Technology Co., Ltd Economic Development Zone, LI country, Human Province, P.R China FSC: China.	M.I. Sterile Safety Syringes (Needle Retractable 3ml, 5ml, 10ml) Codes &Size: As per FSC Class-B. Claimed Shelf Life: 5 years	M.I Sterile Safety Syringes (Needle Retractable 3ml, 5ml, 10 ml)	Rejected , as the same product from same manufacture has been approved in this meeting with brand name RELATION Sterile Auto Disable syringes (3ml, 5ml, 10 ml).
32.	-do-	Legal Manufacturer: M/s Hunan Pingan Medical Device Technology Co., Ltd Economic Development Zone, LI country, Human Province, P.R China FSC:China	M.I Sterile Hydrodermic Disposable Syringes. (1 ml Insulin) Codes &Size: As per FSC Class-B. Claimed Shelf Life: 5 years	M.I Sterile Hydrodermic Disposable Syringes 1 ml Insulin)	Deferred for provision of following documents:- • FSC of contry of origin as the provided FSC does not mention the product name as insuolin syringe. • Provide the original & valid FSC of SRA OR WHO Pre- qualification OR CE certifications from the notified body of

					<p>NANDOs database.</p> <ul style="list-style-type: none"> • GMDN code, MRP, Grouping, ISO-13485, Full QA certificate, EPSPs and shelf-life/ stability studies not provided.
33.	-do-	<p>Legal Manufacturer: Human Pingan Medical Device Technology Co., Ltd Economic Development Zone, LI country, Human Province, P.R China FSC: China.</p>	<p>M.I.Hydrodermic Disposable Syringes. (1 ml)</p> <p>Codes &Size: As per FSC</p> <p>Class-B Claimed Shelf Life: 5 years</p>	<p>M.I Hydrodermic Disposable Syringes 1 ml</p>	<p>Deferred for provision of following documents:-</p> <ul style="list-style-type: none"> • Provide the original & valid FSC of SRA OR WHO Pre-qualification OR CE certifications from the notified body of NANDOs database. • GMDN code, MRP, Grouping, ISO-13485, Full QA certificate, EPSPs and shelf-life/ stability studies not provided.
34.	Genix Pharma, 44-45B, Korangi Creek Road, Karachi (ELI-00590)	<p>Legal Manufacturer: M/s FeelLife Health Inc, Room No. 1903. Building A, No.9,</p>	<p>Air Q+ (Portable mesh nebulizer)</p>	<p>Ultrasonic Portable mesh Nebulizer</p>	<p>Approved subject to provision of notarized legal documents</p>

		Furong Road, Tantou Community Songgang Subdistrict, Street Baoan District Shenzhen 518104, Guandong, China. FSC China copy unattested Valid Till (16-05-2021) FSC Netherlands issued for India valid till 26-05-2024	Class-B Service life: 5 years Codes & Sizes as per FSC		and provision of original, valid, embassy attested free sale certificate of Netherlands issued for Pakistan.
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7. ENLISTMENT OF MEDICAL DEVICES FOR IMPORT (FORM-6A).

S.#	Name of Firm (s)	Name of Manufacturer	Name of Medical Devices.	Brief Description	Decision
1.	M/s. Cardiac Care, 848-C Shadman-I, Lahore. ELI-00070	Manufacturer: M/s Vygon 5 rue Adeline-95440 Ecouen- France FSC France issued on 12.10.2016	BO ₂ ugie Boussignac (Oro-tracheal tubing for difficult intubations) Codes: 5576.01,5576.02, 5576.03 Class A Shelf Life: 5 years Fee submitted: Rs. 5,000/-	Gum elastic bougie for difficult endotracheal intubation. Sterile, single- use	Approved.

8. DEFERRED CASES OF REGISTRATION OF MEDICAL DEVICES FOR IMPORT.

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 Description	Decision
1.	M/s Intra Health, 56-A Unit No.1, Justice Inamullah Road,	Legal Manufacturer: M/s Flexicare Medical Limited, Cynon Valley	Flexicare Adult Parallel Circuit with Y-piece Codes & Sizes:	Non-sterile, single use adult anaesthesia breathing circuit	Approved. The firm shall provide notarized

	Block 7/8, KCHS, Karachi (ELI-00049)	Business Park, Mountain Ash, CF45 4ER, UK Manufacturing Site: M/s Flexicare Medical (Dongguan) Limited, No. B-15, District I, Xi Cheng Industrial Zone, Hengli Town, Dongguan City, Guangdong Province, 523460, PR China. FSC UK Issuance Date 15-02-2019	Class B Shelf Life: 05 Years Fee submitted: Rs.25,000/-		Letter of Authorization (LOA) at the time of issuance of registration letter . Other types shall be applied separately.
2.	-do-	Legal Manufacturer: M/s Flexicare Medical Limited, Cynon Valley Business Park, Mountain Ash, CF45 4ER, UK Manufacturing Site: M/s Flexicare Medical (Dongguan) Limited, No. B-15, District I, Xi Cheng Industrial Zone, Hengli Town, Dongguan City, Guangdong Province, 523460, PR China. FSC UK Issuance Date 15-02-2019	Flexicare Paediatric Parallel Circuit 1.6 m with Y-piece Codes & Sizes: 038-02-110 038-02-165 Class B Shelf Life: 05 Years Fee submitted: Rs.25,000/-	Single use paediatric anesthesia breathing circuit	Approved. The firm shall provide notarized Letter of Authorization (LOA) at the time of issuance of registration letter Other types shall be applied separately.
3.	M/s Intra Health, 56-A Unit No.1, Justice	Legal Manufacturer: M/s Flexicare Medical Limited,	Flexicare Nasal Cannula Codes & Sizes: As	Non-sterile, single-use nasal oxygen cannula	Approved. The firm shall provide

	Inamullah Road, Block 7/8, KCHS, Karachi (ELI-00049)	Cynon Valley Business Park, Mountain Ash, CF45 4ER, UK Manufacturing Site: M/s Flexicare Medical (Dongguan) Limited, No. B- 15, District I, Xi Cheng Industrial Zone, Hengli Town, Dongguan City, Guangdong Province, 523460, PR China. FSC UK Issuance Date 15-02-2019	per FSC UK issued on 15-02-2019 Class B Shelf Life: 05 Years Fee submitted: Rs.25,000/-		notarized Letter of Authorization (LOA) at the time of issuance of registration letter . Other types shall be applied separately.
4.	-do-	Legal Manufacturer: M/s Flexicare Medical Limited, Cynon Valley Business Park, Mountain Ash, CF45 4ER, UK Manufacturing Site: M/s Flexicare Medical (Dongguan) Limited, No. B- 15, District I, Xi Cheng Industrial Zone, Hengli Town, Dongguan City, Guangdong Province, 523460, PR China. FSC UK Issuance Date 15-02-2019	Flexicare T-piece (Anaesthesia Components) Codes: 010-630 010-631 Class B Shelf Life: 05 Years Fee submitted: Rs.25,000/-	Breathing circuit connector. Single-use, non-sterile	Approved. The firm shall provide notarized Letter of Authorization (LOA) at the time of issuance of registration letter Washington T-piece to be applied separately
5.	-do-	Legal Manufacturer: M/s Flexicare Medical Limited, Cynon Valley	Flexicare Anaesthes ia Face Mask (Inflatable, Scented)	Non-sterile, single use anaesthesia face mask	Approved. The firm shall provide notarized

		<p>Business Park, Mountain Ash, CF45 4ER, UK</p> <p>Manufacturing Site: M/s Flexicare Medical (Dongguan) Limited, No. B-15, District I, Xi Cheng Industrial Zone, Hengli Town, Dongguan City, Guangdong Province, 523460, PR China.</p> <p>FSC UK Issuance Date 15-02-2019</p>	<p>Codes & Sizes: As per FSC UK issued on 15-02-2019</p> <p>Class B</p> <p>Shelf Life: 05 Years</p> <p>Fee submitted: Rs.25,000/-</p>		<p>Letter of Authorization (LOA) at the time of issuance of registration letter</p> <p>Other types shall be applied separately.</p>
6.	-do-	<p>Legal Manufacturer: M/s Flexicare Medical Limited, Cynon Valley Business Park, Mountain Ash, CF45 4ER, UK</p> <p>Manufacturing Site: M/s Flexicare Medical (Dongguan) Limited, No. B-15, District I, Xi Cheng Industrial Zone, Hengli Town, Dongguan City, Guangdong Province, 523460, PR China.</p> <p>FSC UK Issuance Date 15-02-2019</p>	<p>Flexicare Catheter Mount Standard (Corrugated)</p> <p>Codes & Sizes: 038-61-301 038-61-301A 038-61-307</p> <p>Class B</p> <p>Shelf Life: 05 Years</p> <p>Fee submitted: Rs.25,000/-</p>	<p>Non-sterile, single-use catheter mount</p>	<p>Approved.</p> <p>The firm shall provide notarized Letter of Authorization (LOA) at the time of issuance of registration letter</p> <p>Other types to be applied separately</p>
7.	-do-	<p>Legal Manufacturer: M/s Flexicare Medical Limited, Cynon Valley Business Park,</p>	<p>Flexicare Plain Oral/Nasal Uncuffed Endotracheal Tube</p> <p>Codes & Sizes: As</p>	<p>Sterile, single use endotracheal tube</p>	<p>Approved.</p> <p>The firm shall provide notarized Letter of</p>

		<p>Mountain Ash, CF45 4ER, UK</p> <p>Manufacturing Site: M/s Flexicare Medical (Dongguan) Limited, No. B-15, District I, Xi Cheng Industrial Zone, Hengli Town, Dongguan City, Guangdong Province, 523460, PR China.</p> <p>FSC UK Issuance Date: 15-02-2019</p>	<p>per FSC UK issued on 15-02-2019</p> <p>Class B</p> <p>Shelf Life: 05 Years</p> <p>Fee submitted: Rs.25,000/-</p>		<p>Authorization (LOA) at the time of issuance of registration letter</p> <p>Other types to be applied separately</p>
8.	-do-	<p>Legal Manufacturer: M/s Flexicare Medical Limited, Cynon Valley Business Park, Mountain Ash, CF45 4ER, UK</p> <p>Manufacturing Site: M/s Flexicare Medical (Dongguan) Limited, No. B-15, District I, Xi Cheng Industrial Zone, Hengli Town, Dongguan City, Guangdong Province, 523460, PR China.</p> <p>FSC UK Issuance Date 15-02-2019</p>	<p>FlexicareLarySeal Clear Laryngeal Mask Airway</p> <p>Codes & Sizes: As per FSC UK issued on 15-02-2019</p> <p>Class B</p> <p>Shelf Life: 05 Years</p> <p>Fee submitted: Rs.25,000/-</p>	<p>Curved tube used in inhalational anaesthesia and resuscitation to facilitate and secure airway patency for the delivery and exchange of gases in spontaneously breathing and ventilated patients. Sterile, single use</p>	<p>Approved. The firm shall provide notarized Letter of Authorization (LOA) at the time of issuance of registration letter</p> <p>Other types to be applied separately.</p>
9.	-do-	<p>Legal Manufacturer: M/s Flexicare Medical Limited, Cynon Valley Business Park, Mountain Ash, CF45 4ER, UK</p>	<p>FlexicareVentiShield adult bacterial/viral filter</p> <p>Code: 038-41-360</p> <p>Class B</p>	<p>Non-sterile, single-use breathing filter</p>	<p>Approved. The firm shall provide notarized Letter of Authorization (LOA) at the</p>

		<p>Manufacturing Site: M/s Flexicare Medical (Dongguan) Limited, No. B-15, District I, Xi Cheng Industrial Zone, Hengli Town, Dongguan City, Guangdong Province, 523460, PR China.</p> <p>FSC UK Issuance Date 15-02-2019</p>	<p>Shelf Life: 05 Years</p> <p>Fee submitted: Rs.25,000/-</p>		<p>time of issuance of registration letter</p> <p>Other types to be applied separately</p>
10.	<p>M/s Vertex Medical Pvt Ltd, 70-B-1, Gulberg III, Lahore</p> <p>ELI: 00150.</p>	<p>Legal Manufacturer</p> <p>M/s Dragerwerk AG &CO, KGaA Moislinger Allee 53-55 23542 Lubeck Germany</p> <p>Manufacturing Site: DragerwerkAG& Co. KgaA RevalstrBe 1 23560, Lubeck, Germany.</p> <p>FSC: Germany Date of issue: 15.10.19</p>	<p>DRAGER DISPOSABLE Anesthesia Masks COMFORT-STAR (Disposable Anesthesia Masks) Codes as per FSC: Class-B Shelf Life: Rs.25,000/-</p>	<p>Disposable Anesthesia Masks.</p>	<p>Approved.</p>

9. CASES OF REGISTRATION OF MEDICAL DEVICES FOR IMPORT (COVID RELATED).

S.#	Name of Firm (s)/Importer	Name of Manufacturer	Name of Medical Device	Brief Description	Decision
1.	<p>M/s A.S. Enterprises, 3-Mozang, Lahore.</p> <p>ELI: 00190</p>	<p>Manufacturer: M/s SD Biosensor Inc. C-4th&5th, 16, Deogyong-daero, 1556 beon-gil, Yeongtong-gu, Suwon-si-</p>	<p>Standard™ Q COVID-19 Ag Test (Device)</p> <p>Ref No: Q-NCOV-01G</p>	<p>Rapid chromatographic immunoassay for the qualitative detection of specific antigen</p>	<p>Approved subject to provision of original valid Embassy attested</p>

		<p>Gyenggi-do, 16690, Republic of Korea</p> <p>Manufacturing Site: 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Republic of Korea</p> <p>FSC Korea issued on 12-11-2020 FSC Germany copy (Not Embassy attested) valid till 31.12.2021</p>	<p>Class-C</p> <p>Shelf Life: 24 months (Accelerated stability studies of 19 weeks provided)</p> <p>Fee submitted: Rs. 50,000/-</p>	<p>to SARS-CoV-2 present in human nasopharynx. It is for professional use only and is intended to be used as an aid in the early diagnosis of SARS-CoV-2 infection in patient with clinical symptoms. The result on this test should not be the sole basis for the diagnosis.</p>	<p>FSC of Germany.</p>
2.	<p>M/s Chemical House, 6-C Sikander Malhi Road, Canal Park, Gulberg II, Lahore Pakistan.</p> <p>ELI: 00156</p>	<p>Legal Manufacturer: 3 Boulevard Raymond Poincare, 92430 Marnes-la-Conquette, France.</p> <p>FSC: France</p>	<p>Platelia SARS-CoV-2 Total Ab Assay (Imunoassay Kit to screen for total anti-nucleocapsid antibodies (1gM, 1gA, 1gG) to coronavirus SARS-Cov-2 Class-C Shelf Life: 12 months</p>	<p>Imunoassay Kit to screen for total anti-nucleocapsid antibodies (1gM, 1gA, 1gG) to coronavirus SARS-Cov-2</p>	<p>Deferred for provision of following documents:</p> <ul style="list-style-type: none"> • Provided free sale certificate (FSC) doesn't contain the name or annex. of the product applied. • Provide the original & valid agency agreement with all coded particulars as per MDB-06. (Copy provided)

3.	M/s Global Marketing Services, 111, Hali Road Westridge-1, Rawalpindi ELI: 00109	Legal Manufacturer: BioMerieux SA 376 Chemin de l'Orme 69280 Marcy, l'Etoile France. Physical Manufacturer: BioMerieux SA 138 rue Louis Pasteur, Parc Technologique Delta Sud, 09340 Verniolle France. FSC:France Date of Issue: 2020.04.10	ARGENE SARS-COV-2-GENE (Real Time Amplification and Detection Kit) Class-C Claimed Shelf Life: 24 months.	The SARS-Cov-2-GENE ® kit allows a quantitative detection of severe acute respiratory syndrome coronavirus 2 (SARS-Cov-2) in nasopharyngeal swabs .	Approved subject to provision of original and valid agency agreement, FSC and MRP.
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10. REGISTRATION OF DISPOSABLE SYRINGES.

M/s Grace Pharmaceuticals office # 102, First floor, The plaza, Block-9 Clifton, Karachi.	Legal Manufacturer: JianxiHongda Medical Equipment Group Ltd. No. 39 South sehngli Road, JinxianCountry , Nanchang City , Jangixi Province, China. (FSC China Valid Till 26-11-2021)	ALPHA Disposable Syringes (3ml, 5ml, 10ml and 20ml) Class B Codes & Sizes as per FSC.	Approved only 10ml & 20ml on the basis of CE marked submitted documents.
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Decision: The Board discussed and approved the renewal of ALPHA Disposable Syringes 3ml and 5ml till 31st March, 2021.

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