



No.F.4-2/2024-MD (M-66)
Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
Drug Regulatory Authority of Pakistan

Islamabad the 19th April 2024

Subject:- DEFERRED CASES OF ENLISTMENT/REGISTRATION OF MEDICAL DEVICES TO IMPORT – SUBMISSION OF DEFICIENT INFORMATION/DOCUMENTS THEREOF.

The applications of following applicants were considered by Medical Device Board (MDB) in its 66th meeting held on 26th February, 2024 and Board deferred these applications being deficient of the information/documents as specified in last column (V) of the Table below:-

S#	Name of Importer	Name of Manufacturer	Name of Medical Devices	Decision of MDB
(i)	(II)	(III)	(IV)	(V)
1.	M/s FDS (Pvt) Ltd., Lahore. ELI-00475	Legal Manufacturer & Site: LIMACORPORATE S.p.A., Via Nazionale 52, 33038 Villanova di San Daniele (UD) Italy. Copy of FSC issued by Italy on 28-10- 2019. Copy of ISO 13485 valid upto 11-12- 2021 Copy of EC/FQA Certificate valid upto 26-05-2024. Copy of Design Examination Certificate valid upto 26-05-2024 LOA valid upto 29- 07-2023	Lima Multigen Knee System Total Knee Replacement Codes & Sizes: As per Class-C Shelf Life :5 years Fee: 50,000/-	Deferred for the provision of valid notorized letter of Authorization (LOA) & valid ISO 13485.
2.	M/s. Seico Scientific Traders, 1st Floor, 104, Muhammadia Plaza, Gordon College Road, Rawalpindi. ELI-00205 60-P 30-10-2019	Legal Manufacturer: M/s. Ortho-Clinical Diagnostics, 100 Indigo Creek Drive Rochester New York 14626, USA. Manufacturing Site: NPA de Mexico S. de C.V., Sor Juana Ines de la Cruz, # 20150, Industrial Tijuana,	Vitros ECIQ Immunodiagnostic System Class-A Self-life: N/A Code: 1922814	Deferred for the clarification since the Legal Manufacturer M/s. Ortho-Clinical Diagnostics has terminated the agreement with M/s. Seico Scientific Traders and entered into new agreement with M/s Martin Dow. The Board decided to give personal hearing to M/s Seico Scientific to clarify their position regarding the Agency agreement.

Signature

		Baja California, CP 22444, Mexico. FSC UK valid till 31-11-2023		
3.	M/s. Seico Scientific Traders, 1st Floor, 104, Muhammadia Plaza, Gordon College Road, Rawalpindi. ELI-00205 57-P 30-10-2019	Legal Manufacturer: M/s. Ortho-Clinical Diagnostics, 100 Indigo Creek Drive Rochester New York 14626, USA. Manufacturing Site: NPA de Mexico S. de C.V., Sor Juana Ines de la Cruz, # 20150, Industrial Tijuana, Baja California, CP 22444, Mexico. FSC UK valid till 31-11-2023	Vitros 5600 Immunodiagnostic System Class-A Self-life: N/A Code: 6802413	Deferred for the clarification since the Legal Manufacturer M/s. Ortho-Clinical Diagnostics has terminated the agreement with M/s. Seico Scientific Traders and entered into new agreement with M/s Martin Dow. The Board decided to give personal hearing to M/s Seico Scientific to clarify their position regarding the Agency agreement.
4.	M/s. Seico Scientific Traders, 1st Floor, 104, Muhammadia Plaza, Gordon College Road, Rawalpindi. ELI-00205 59-P 30-10-2019	Legal Manufacturer: M/s. Ortho-Clinical Diagnostics, 100 Indigo Creek Drive Rochester New York 14626, USA. FSC UK valid till 31-11-2023	Ortho Workstation Class-A Self-life: N/A Code: 6904629	Deferred for the clarification since the Legal Manufacturer M/s. Ortho-Clinical Diagnostics has terminated the agreement with M/s. Seico Scientific Traders and entered into new agreement with M/s Martin Dow. The Board decided to give personal hearing to M/s Seico Scientific to clarify their position regarding the Agency agreement.
5.	M/s. Seico Scientific Traders, 1st Floor, 104, Muhammadia Plaza, Gordon College Road, Rawalpindi. ELI-00205 58-P 30-10-2019	Legal Manufacturer: M/s. Ortho-Clinical Diagnostics, 100 Indigo Creek Drive Rochester New York 14626, USA. Manufacturing Site: NPA de Mexico S. de C.V., Sor Juana Ines de la Cruz, # 20150, Industrial Tijuana, Baja California, CP 22444, Mexico. FSC UK valid till 31-11-2023	Vitros 3600 Immunodiagnostic Class-A Self-life: N/A Code: 682783	Deferred for the clarification since the Legal Manufacturer M/s. Ortho-Clinical Diagnostics has terminated the agreement with M/s. Seico Scientific Traders and entered into new agreement with M/s Martin Dow. The Board decided to give personal hearing to M/s Seico Scientific to clarify their position regarding the Agency agreement.
6.	Humed Mfg Co., 78/6 Khalid Road Link Quaid E Azam Road Sialkot, Cantt ELI: 1746-P	Legal Manufacturer Shenzhen Fitconn Technology Co., Ltd No, 1605, building A Bantian International Center No. 5, Huancheng South	Compressor Nebulizer Class-B Shelf Life: N/A Codes as per FSC	Deferred for the provision of following: <ul style="list-style-type: none">• Copy of Establishment license.• Credentials of manufacturer

Decided 19/04/24

	18-09-2020	Road Bantian Shenzhen, Guangdong, China FSC China validity 04-11-2020		abroad, duly notarized. <ul style="list-style-type: none"> • Original, valid and notarized LOA. • Original and valid FSC in the country of origin, duly attested. • FSC of reference country duly attested. • Valid and notarized ISO 13485 and FQA certificate. • Shelf life and Stability studies. • Declaration of Conformity. • Provide codes and Labels of applied models as per FSC.
7.	Vertex Medical Pvt Ltd, 70-B-1, Gulberg III, Lahore ELI-00150	<u>Legal</u> <u>Manufacturer:</u> SRA Developments Ltd., (trading as Bowa Medical UK) Bremridge Ashburton Devon Tq13 7Jx, UK. FSC MHRA issued on 15-06-2022	Lotus (Ultrasonic Surgical Generator & Accessories) Class-C Shelf life: 3 years Codes as per FSC	Deferred for the provision of following: Valid original notarized LOA; Clarify grouping of the applied product.
8.	Lab Medikal Solutions Pvt.Ltd Office No 14/1-A Main Harley Street Rawalpindi. ELI-00694 1121-C 23-12-2022	<u>Legal</u> <u>Manufacturer:</u> Guangzhou Wondfo Biotech Co, Ltd. No.8 Lizhishan Road, Science City, Luogang District 510663, Guangzhou P.R China.	Wondfo (Blood Gas analyzer, reagent pack, Test card and Control) Class-B Shelf life: not provided Codes: FSC is not provided	Deferred for the provision of following: Original, valid and notarized LOA. Original, valid and attested FSC in the country of origin. Original, valid and attested FSC in any reference country. Valid and notarized ISO 13485 and FQA certificate. Declaration of conformity.
9.	Lab Medikal Solutions Pvt.Ltd Office No 14/1-A Main Harley Street Rawalpindi. ELI-00694 1688-C 23-12-2022	<u>Legal</u> <u>Manufacturer:</u> Guangzhou Wondfo Biotech Co, Ltd. No.8 Lizhishan Road, Science City, Luogang District 510663, Guangzhou P.R China.	Wondfo Optical coagulation Analyzer Prothrombin Time kit Activated Partial Thrombin Time Reagent kit Fibrinogen Reagent kit Activated Clotting Time Reagent kit	Deferred for the provision of following: Original, valid and notarized LOA. Original, valid and attested FSC in the country of origin. Original, valid and attested FSC in any reference country.

Handwritten signature and date: 19/4/24

			Thrombin Time Reagent kit Class-C Shelf life: Codes: FSC is not provided	Valid and notarized ISO 13485 and FQA certificate. Declaration of conformity.
10.	Opti med, 6-A Hassan Plaza 2nd Floor behind lucky Centre Jail Road, Lahore ELI: 00501 4342-P 26-10-2023	<u>Legal</u> <u>Manufacturer:</u> <u>Medical Instrument</u> Development Laboratories, Inc. 557 McCormick St SAN LEANDRO, CA USA 9477 Original FSC: U.S Valid Till: 06/06/2025	Bi-Blade ® Cutter with Tubing Set, Vitreous Cutter with Tubing Set Class-B Shelf Life: 3 years Codes & Sizes: 2820BB, 2840BB, 2320BB, 2340BB	Deferred for the provision of following: Stability studies for the claimed shelf life
11.	Opti med, 6-A Hassan Plaza 2nd Floor behind lucky Centre Jail Road, Lahore ELI: 00501 637-P 04-10-2021	<u>Legal</u> <u>Manufacturer:</u> CSO Via degli Staggmacchi 12/E-Badia a Settimo-Firenze (Italy) FSC: Italy Date of Issue: 14.05.2019	C-eye (UV-A light emitter con corneal cross linking) Class-A Shelf Life: Codes & Sizes: As per FSC	Deferred for the provision/clarification of following: Class clarification, in DoC it is mentioned as IIb. Brand name clarification. Device name is not mentioned in FSC. Shelf life/ service life is not provided.
12.	Opti med, 6-A Hassan Plaza 2nd Floor behind lucky Centre Jail Road, Lahore ELI: 00501 2849-P 04-10-2021	<u>Legal</u> <u>Manufacturer:</u> Unique Technologies Inc. Iii Chestnut St. Mohnton. Pennsylvania 19540 United States Original FSC: U.S Valid till: 27.02.2022	UniqueEdge Microsurgical Knives (Clear Corneal Knife) Class-B Shelf Life: 5 years Codes & Sizes: As per FSC	Deferred for the provision of following: Stability studies for the claimed shelf life Manufacturing and QC details valid FSC of US FDA and ISO 13485 certificate.
13.	Hanson International Office No. 57 3rd Floor Block DHA, EME, Multan Road, Lahore. ELI: 00773 4056-P 23-06-2023	<u>Legal</u> <u>Manufacturer:</u> Vansun Medimal equipment (Fujian) Co., located at Li Dun Industrial Zone, Lidun District Zhouning, 355402 Ningde City, Fujian People Republic of China Original FSC: China Valid till: 2024/06/12	HMD (IV Set) (IV set) Class-B Shelf life: 5 Years Codes: KN-01, KN-02, KN-03, KN-04	Deferred for the provision of following: Manufacturing and QC details. Stability studies of the claimed shelf life. Information on Validation of medical device. Credentials of manufacturer's abroad.

14.	<p>M/s UNIPLAN Trade International 132/2 Quaid-e- Azam Industrial Estate, Kot Lakhpat, Lahore</p> <p>ELI: 00132 843-P 30-10-2019</p>	<p>Legal Manufacturer: Heinrich Hertz StraBe 3, 63303 Dreieich Dreieichenhain, Germany</p> <p>FSC: Germany Date of issue: 19.10.2019</p>	<p>Lumenis Pulse 30H Holmium Laser System</p> <p>Class: B</p> <p>Shelf Life: 07 years</p> <p>Model: GA-2006098GR</p>	<p>Deferred for the provision of following:</p> <p>The applied product falls in class C medical device. Submit differential fee of Rs. 25,000/-</p> <p>Letter of Authorization expired. Provide original Letter of Authorization or Agency agreement with manufacturer abroad, duly notarized in the country of origin. Letter of Authorization or agreement shall be original, signed & stamped, having validity, names and addresses of both manufacturer and importer and having NAME of medical devices for which SOLE/EXCLUSIVE authorization is given to importer. Multiple products applied on one application. Lumenis pulse 30H will be considered on this application. Submit separate applications for others and disposable accessories are also to be applied separately.</p> <p>Copy of free sale certificate is provided which is not Embassy attested. Provide original, valid Free sale certificate duly attested by Embassy of Pakistan in country of origin.</p> <p>QC tests not provided for the applied product. Provide product verification report or details of Quality Control for the applied product.</p> <p>Provide MRP for Lumenis pulse 30H ISO13485 expired even on submission. Provide valid ISO13485 certificate duly notarized (original notarization) in the country of origin.</p> <p>Provide copy of Establishment License to import medical device.</p> <p>Provide label of Lumenis pulse 30H.</p> <p>Provide essential principles of safety and performance or essential checklist or essential</p>
-----	--	--	--	--

Handwritten signature and date: 19/04/24

				<p>requirements for Lumenis pulse 30H</p> <p>Credentials not provided.</p> <p>Provide credentials on format approved by Medical Device Board in its 3rd meeting. Provide on the prescribed format duly notarized from country of origin.</p> <p>Provide Declaration on stamp paper as mentioned on Form 7A.</p>
15.	<p>Haji S. Ameer Din and Sons, 305-A Upper Mall Lahore.</p> <p>ELI: 00059 1567-P 10-07-2020</p>	<p>Legal Manufacturer: HAAG-STREIT AG 10 Gartenstadtstrasse, 3098 Koeniz Switzerland</p> <p>FSC: Switzerland Valid till: 14.06.2022</p>	<p>HAAG-STREIT Diagnostic (Perimeter Octopus 600)</p> <p>Class-B</p> <p>Shelf life: not mentioned</p> <p>Models: Perimeter Octopus 600 Basic (7220354/180600) Perimeter Octopus 600 Pro (7220355/180600)</p>	<p>Deferred for the provision of following:</p> <p>Shelf life/Service life and stability studies.</p> <p>Valid FSC and ISO 13485 certificate.</p> <p>Apply separately for the Octopus 900.</p>
16.	<p>Haji S. Ameer Din and Sons, 305-A Upper Mall Lahore.</p> <p>ELI: 00059 1566-P 10-07-2020</p>	<p>Legal Manufacturer: HAAG-STREIT AG 10 Gartenstadtstrasse, 3098 Koeniz Switzerland</p> <p>FSC: Switzerland Valid till: 14.06.2022</p>	<p>HAAG-STREIT Diagnostic (Biometer Lenstar LS 900)</p> <p>Class-B</p> <p>Shelf life: not mentioned</p> <p>Models: LENSTAR LS 900 Pro (7220096/1009000) LENSTAR LS 900 Pro T-Cone (7220400/1009000)</p>	<p>Deferred for the provision of following:</p> <p>Shelf life/Service life and stability studies.</p> <p>Valid FSC and ISO 13485 certificate.</p> <p>Apply separately for other models.</p>
17.	<p>OPTI Med, 2nd Floor Hassan Plaza Behind Lucky Centre 6A Jail road Lahore</p> <p>ELI: 00501 2852-P 22-10-2021</p>	<p>Legal Manufacturer: New World Medical Inc. 10763 Edison Ct, Rancho Cucamonga, CA 91730, United States</p> <p>FSC: U.S Valid till: 11.07.2023</p>	<p>Kahook Dual Blade Glide (Ophthalmic knife)</p> <p>Class-B</p> <p>Shelf Life: not mentioned</p> <p>Codes: (10-0065 as mentioned on label) Not mentioned on FSC and DoC</p>	<p>Deferred for the provision of following:</p> <p>Shelf life and shelf life studies.</p> <p>Valid FSC and ISO 13485 certificate.</p>
18.	<p>OPTI Med, 2nd Floor Hassan Plaza Behind Lucky Centre 6A Jail road Lahore</p> <p>ELI: 00501</p>	<p>Legal Manufacturer: Medicel AG Dornierstrasse 11 CH-9423 Altenrhein Switzerland</p>	<p>Phaco Accessories Set (Phaco Accessories Set)</p> <p>Class-B</p> <p>Shelf Life: 5 years</p>	<p>Deferred for the provision of following:</p> <p>Stability studies of the product.</p> <p>Valid FSC and ISO 13485 and</p>

m/16/1612

Duan

	2083-P 14-01-2021	FSC: Switzerland Validity 10-08-2023	Codes: PA603019FKRU PA603020FKRU PA603021FKRU PA603023FKRU PA603500RU PA603510RU	EC declaration certificate.
19.	M/S A&E Medical 323-ATA Turk Block New garden Town, Lahore ELI: 00023 1171-P 13-20-2020	Legal Manufacturer: Shenzhen for U Meditech Co., Ltd located at R4 Bld, 2C, Kunda Industrial Park No.9, Baolong 1 st Rd, Long Gang Shenzhen, Guangdong, China. FSC: Spain Date of issue: 13 august,2019	Angiographic Guide Wires (Catheter Guide Wire, PTFE Coated) Class-B Shelf Life: 3 years Codes: As per FSC	Deferred for the provision of following: Valid original notarized LOA; Valid ISO 13485 & FQA. Clarification is required as the applied product Angiographic Guidewires falls in Class-D medical device moreover no description and intended purpose of the applied product is provided which can specify its class. So provide the intended use of the applied device. Apply separately for the hydrophilic coated type.
20.	M/s. Physiomed Pvt Ltd, 268/3, Kamal Road, Saddar, Rawalpindi ELI-00199	Legal Manufacturer: ST. JUDE Medical 5050 Nathan Lane North Plymouth, MN USA. FSC – Belgium DATE OF ISSUE 01.03.2018	Advisor TM HD Grid, Sensor Enabled (High Density Mapping Catheter) Class-D Shelf Life: 3 years Code: D-AVHD-DF16	Deferred for the provision of following: Valid and notarized Letter of Authorization. Valid and attested Free Sale Certificate, valid and notarized ISO 13485, Full QA and Design- Examination certificates. Labels etc from the legal manufacturer In STED, the shelf life studies provided are of 18 months and the claimed shelf life is 3 years. Clearly state the shelf life of this product supported by the stability studies with clear conclusion of the shelf life.
21.	Reckitt Benckiser Pakistan Limited, Plot no. 73 B, C & D, K-28, Phase-II, Lyari Quarters, Hawaks Bay road, Karachi ELI- 01031 Date of Dossier submission 20 December 2023	Reckitt Benckiser UK M/s SSL International plc and Qingdao London Durex co. Ltd., no. 1- 13Shangma part, Adong road, High – tech industrial development zone, Qingdao city, Shandong Province, located at P.R. China.	Durex Invisible Condoms Class – C Shelf Life: 5 Years As per attached stability study Annex-IV Amount and Fee Rs. 50,000/ through slip no. 59599870, dated 30.11.2023	Deferred. Firm is advised to provide FSC of Durex Invisible Condoms manufactured from M/s SSL International plc and Qingdao London Durex co. Ltd., no. 1- 13Shangma part, Adong road, High – tech industrial development zone, Qingdao city, Shandong Province, located at P.R. China.

m/19/16/2023
Dr. Anwar

		www.reckitt.com FSC MHRA UK Issuance date: 26.10 2023 Validity Up to: 25.05.2025	Storage Temperature and condition. Store in cool and dry place away from direct sunlight Annex-V	
22.	M/s Sultan Sons, 133, Kutchi Gali No.1, Marriot Road, Karachi. (ELI-00051) R&I 19-05-21	M/s Zhanjiang Star Enterprise Co., Ltd., No.1 West Jinhua Road, Mazhang District, 524049 Zhanjiang and People's Republic of China FSC China Valid Till 22-03-2024	ST Classic Disposable Silicone Foley Catheter Sterile 2-way Class B Shelf life: 05 Years Codes & Sizes as per FSC 8FR, 10FR, 12FR, 14 FR, 16 FR, 18 FR, 20 FR, 22 FR, 24 FR Fee Rs. 25,000/- Schedule E	Deferred for submission of: Remaining fees i.e Rs. 25000/- as the DOC is for class C. Revised form 7A is required. Original Valid LOA required. Firm is advised to apply separately for the product in 3- way size.
23.	M/s: Medichem Enterprise, Address: 331/C, Block no. 3, DMCHS Society, Alamgir road, Karachi ELI-00252 DATE OF SUBMISSION: 04- 11-2022	Legal manufacturer: TSK Laboratory Japan Address: 1510-1 Soja-Machi, Tochigi- Shi, Tochigi Ken, Japan 328-0002 Manufacturing Facility: TSK Laboratory, Japan soja no.1 factory 1485-11, soja Machi, Tochigi- shi, Tochigi-ken, 328- 0002 JAPAN. Original Legalized Free Sale Certificate (FSC) of JAPAN Issue date: 13-01- 2023 Expiry not mentioned.	Brand Name: TSK Starcut Biopsy Needles (Generic Name: semi- automatic biopsy needle) Class: Class-B Shelf Life: 5 years Fee: Rs 25000/-	Deferred for submission of the stability studies testing methods, brochure and label of the product.
24.	M/s: Medichem Enterprise, Address: 331/C, Block no. 3, DMCHS Society Alamgir Road, Karachi. ELI-00252 DATE OF	Legal manufacturer: TSK Laboratory Japan Address: 1510-1 Soja-Machi, Tochigi- Shi, Tochigi Ken, Japan 328-0002 Manufacturing Facility: TSK Laboratory, Japan soja no.1 factory 1485-11, soja	Brand Name: TSK Acecut Biopsy Needle (Generic Name: biopsy needle) Class: B Shelf Life: 5 years Fee: Rs...25000/-	Deferred for submission of the stability studies testing methods, brochure and label of the product.

Demand 19/04/24

	SUBMISSION: 04-11-2022	Machi, Tochigi-shi, Tochigi-ken, 328-0002 JAPAN. Original Legalized Free Sale Certificate (FSC) of JAPAN Issue date: 13-01-2023 Expiry not mentioned.		
25.	M/s: Medichem Enterprise, Address: 331/C, Block no. 3, DMCHS Society Alamgir Road, Karachi. ELI-00252 DATE OF SUBMISSION: 04-11-2022	Legal manufacturer: TSK Laboratory Japan Address: 1510-1 Soja-Machi, Tochigi-Shi, Tochigi Ken, Japan 328-0002 Manufacturing Facility: TSK Laboratory, Japan soja no.1 factory 1485-11, soja Machi, Tochigi-shi, Tochigi-ken, 328-0002 JAPAN. Original Legalized Free Sale Certificate (FSC) of JAPAN Issue date: 13-01-2023 Expiry not mentioned.	Brand Name: TSK Surelock BMB (Needle) (Generic Name: bone marrow biopsy needle) Code as per DOC: BTS-08100 BTS-08150 BTS-11100 BTS-11150 BTS-13065 BTS-13100 Class: B Shelf Life: 5 years Fee: Rs 25000/-	Deferred for submission of the stability studies testing methods, brochure and label of the product.
26.	M/s: Medichem Enterprise Address: 331/C, Block no. 3, DMCHS Society Alamgir Road, Karachi. ELI-00252 DATE OF SUBMISSION: 10-11-2022	Legal manufacturer: TSK Laboratory Japan Address: 1510-1 Soja-Machi, Tochigi-Shi, Tochigi Ken, Japan 328-0002 Manufacturing Facility: TSK Laboratory, Japan soja no.1 factory 1485-11, soja Machi, Tochigi-shi, Tochigi-ken, 328-0002 JAPAN. Original Legalized Free Sale Certificate (FSC) of JAPAN Issue date: 13-01-2023 Expiry not mentioned.	Brand Name: TSK SURECUT Biopsy needle (Generic Name: biopsy needle) Class: B Shelf Life: 5 years Fee: Rs 25000/-	Deferred for submission of the stability studies testing methods, brochure and label of the product.

Handwritten signature and date: 19/04/24

27.	<p>M/s: Medichem Enterprise</p> <p>Address: 331/C, Block no. 3, DMCHS Society Alamgir Road, Karachi.</p> <p>ELI-00252</p> <p>DATE OF SUBMISSION: 10-11-2022</p>	<p>Legal manufacturer: TSK Laboratory Japan</p> <p>Address: 1510-1 Soja-Machi, Tochigi-Shi, Tochigi Ken, Japan 328-0002</p> <p>Manufacturing Facility: TSK Laboratory, Japan soja no.1 factory 1485-11, soja Machi, Tochigi-shi, Tochigi-ken, 328-0002 JAPAN.</p> <p>Original Legalized Free Sale Certificate (FSC) of JAPAN Issue date: 13-01-2023 Expiry not mentioned.</p>	<p>Brand Name: TSK Co-axial Guide needle</p> <p>(Generic Name: biopsy needle)</p> <p>Class: B</p> <p>Shelf Life: 5 years</p> <p>Fee: Rs 25000/-</p>	<p>Deferred for submission of the stability studies testing methods, brochure and label of the product.</p>
28.	<p>M/s Medzntech (Pvt.) Ltd.</p> <p>D-21, Sector 16-A, Govt. Teachers' Co-operative Housing Society, K.D.A Scheme-33, Karachi</p> <p>(ELI-00657)</p> <p>Date of Submission: 19th Jan 2024</p>	<p>Legal Manufacturer Alcon Laboratories Inc. 6201 South Freeway Fort Worth, Texas USA 76134-2099 United States</p> <p>Manufacturing Site Alcon Singapore Manufacturing Pte. Ltd. 19 Tuas, South Avenue 4, Singapore 637313</p> <p>FSC Health Sciences Authority (HSA) Republic of Singapore: Apostilled from the Singapore Academy of Law (Singapore).</p> <p>Date of Issuance: 13-09-2023 FSC valid till: N/A</p>	<p>Systane Ultra Lubricant Eye Drops (10ml) Propylene glycol 400 0.4 % Propylene glycol 0.3 %</p> <p>Shelf Life: 24 months</p> <p>Class: C</p> <p>Fee Challan No. 487656149 Rs. 50,000/-</p>	<p>Deferred for personal hearing notice to M/S Ali Gohar & Company (Pvt) Ltd. for confirmation of NOC to M/S Medzntech as the Board observed that the same product (Systane Ultra Lubricant Eye Drops (10ml) Lubricant Eye Drops is registered in MD&MC Division in the name of M/s Ali Gohar & Company (Private) Limited (MDIR-0001889) and they have provided NOC for transfer of the registration of said product of principal manufacturer M/S Alcon pharmaceutical Ltd in the name of Medzntech.</p>
29.	<p>Vertex Medical (Pvt) Ltd, 70-B-1, Gulberg III, Lahore. ELI: 00150 3252-P 21-06-2022</p>	<p>Legal Manufacturer: LivaNova USA, Inc. 100 Cyberonics Boulevard, Houston, TX-77058 USA Original FSC: U.S.A Valid till: 12/05/2024</p>	<p>VNS Therapy ® (VNS Therapy ® AspireSR ®)</p> <p>Class-D</p> <p>Shelf Life: 2 years</p> <p>Model: 106 Generator</p>	<p>Deferred for personal hearing to M/s Pharma Consultant for deregistration of the subject device since the registration is still in the name of Pharma Consultant while the legal manufacturer has terminated its contract with the firm and has issued market authorization in the name of M/S Vertex Medical</p>

m/ha/612
19/04/24
Dewan

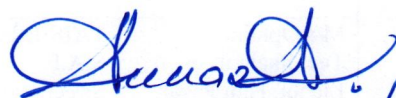
				(Pvt) Ltd, 70-B-1, Gulberg III, Lahore.
30.	M/s Ophthalmotec, Shahrah-e-Liaqut, Haji Fazal Ellahi Building, opposite Women College, Karachi.	TAISIER-MED S.A.E Street 100, Building No. 8, 1st Industrial Zone, El- Obour City 11828, CAIRO Egypt	EGYSORB Dyed Class D Shelf Life 5 year	Deferred with final opportunity to provide Fsc notorised from country of origin
31.	M/s Ophthalmotec, Shahrah-e-Liaqut, Haji Fazal Ellahi Building, opposite Women College, Karachi	TAISIER-MED S.A.E Street 100, Building No. 8, 1st Industrial Zone, El- Obour City 11828, CAIRO Egypt	EGYSILK (Black braided silk) Class D Shelf life 05 years File no 3568	Deferred with final opportunity to provide Fsc notorised from country of origin
32.	M/s Ophthalmotec, Shahrah-e-Liaqut, Haji Fazal Ellahi Building, opposite Women College, Karachi	TAISIER-MED S.A.E Street 100, Building No. 8, 1st Industrial Zone, El- Obour City 11828, CAIRO Egypt	EGYCRYLIC FAST' Class D Shelf Life 5 year 3570	Deferred with final opportunity to provide Fsc notorised from country of origin
33.	M/s Ophthalmotec, Shahrah-e-Liaqut, Haji Fazal Ellahi Building, opposite Women College, Karachi	TAISIER-MED S.A.E Street 100, Building No. 8, 1st Industrial Zone, El- Obour City 11828, CAIRO Egypt	EGYCRYLIC Dyed and undyed Class D Shelf Life 5 years	Deferred with final opportunity to provide Fsc notorised from country of origin
34.	M/s Ophthalmotec, Shahrah-e-Liaqut, Haji Fazal Ellahi Building,	TAISIER-MED S.A.E Street 100, Building No. 8, 1st Industrial Zone, El- Obour	EGYPROLENE (Polypropylene monofilament) Class D Shelf life 05years	Deferred with final opportunity to provide Fsc notorised from country of origin.
35.	M/s New Pakistan Traders, Office No. 306/I, Trade Tower, Altaf Hussain Road, New Challi, Karachi. (ELI-00161) 4469-P 16-05-2022	Legal Manufacturer: M/s Shanghai Kinmed Import & Export Co. Ltd, Suit L, 12th Floor, No.588 Yingkou Road, Shanghai, China FSC China Date of Issuance 06-12-2021 valid for 2 years	KBM Auto-Disable Syringe Class B Shelf life: 05 Years Sizes: 3ml, 5ml	Deferred with final opportunity to provide evidence of original documents submitted as previous claim of the firm was not verified.
36.	CSM Pakistan (Guarantee) Ltd., 23-C, Old Sunset Boulevard, Phase 2, DHA, Karachi (ELI-00418) Date of submission 03.06.2021	Innolates (Thailand) Limited E1-6, Export Processing Zone, Southern Industrial Estate, Village 4, Chalung, Hatyai, Songkhla, 90110, Thailand Embassy attested	FLAME – Ultrathin Class C Shelf life 5 Years Fee 50000/-	Deferred for submission of the following with the final opportunity to submit FSC in the country of origin or RRA mentioning the name of the product on Free sale certificate since the firm has submitted FSC with the following sentence written on it, "The product has the same standard as the product

19/04/24
Dewas

		FSC Thailand valid till 15.03.2023		<i>sold in the country and exported without restriction."</i> Submit stability study of the product.
--	--	------------------------------------	--	---

2. In the light of decision of MDB in its 37th meeting wherein Board decided that once the firm has submitted original, valid and notarized/Embassy attested documents at the time of submission of application for registration/enlistment and the same are expired during the processing of application, the firm shall only submit valid and original (where applicable) documents without notarization/Embassy attestation.

3. It is requested to furnish the requisite information/documents mentioned in last column against each within 30 days after uploading of this letter on official website of DRAP.


(AYYAZ AHMAD)
Additional Director (MDMC)/
Secretary MDB

19/04/24



No.F.4-2/2024-MD (M-66)
Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
Drug Regulatory Authority of Pakistan


Islamabad the 19th April, 2024

Subject:- **DEFERRED CASES OF ENLISTMENT/REGISTRATION OF MEDICAL DEVICES TO LOCAL MANUFACTURE – SUBMISSION OF DEFICIENT INFORMATION/ DOCUMENTS THEREOF**

The applications of following applicants were considered by Medical Device Board (MDB) in its 65th meeting held on 25th and 26th January, 2024 and Board deferred these applications being deficient of the information/documents as specified in last column (IV) of the Table below: -

Sr. No.	Name & Address of Establishment	Name of Medical Devices with Size	
1.	M/s Kamion Pharma Plot No. G/4-C, SITE, Super Highway, Phase-II, Karachi [ELM-0070] Sections: i. Adhesive Section ii. Plaster/Patches Section iii. Sterile Dressing / Wound Dress Section iv. Gauze/Sponge Section v. Bandage Section vi. Surgical Tape Section	Kamigauze X-Ray Detectable Abdominal Sponges BPC Sponge Class: A Shelf-life: 03 Years Sizes: 5cm x 5cm (4 ply) 7.5cm x 7.5cm (4 ply) 10cm x 10cm (4 ply) 15cm x 15cm (4 ply) 5cm x 5cm (8 ply) 7.5cm x 7.5cm (8 ply) 10cm x 10cm (8 ply) 15cm x 15cm (8 ply) Fee: Rs. 5,000/-	Deferred for provision of clarification regarding the class of the product and accordingly for submission of the balance fee of the relevant class i.e. Rs. 15,000/-
2.	M/s Kamion Pharma Plot No. G/4-C, SITE, Super Highway, Phase-II, Karachi [ELM-0070] Sections: i. Adhesive Section ii. Plaster/Patches Section iii. Sterile Dressing / Wound Dress Section iv. Gauze/Sponge Section v. Bandage Section vi. Surgical Tape Section	Kamistat Heamostatic Rapid Clot Heamostatic Gauze Class: C Shelf-life: three year Sizes: 5cm x 5cm 10cm x 10cm 15cm x 15cm 10cm x 100cm Z Fold 10cm x 150cm Z Fold 15cm x 100cm Z Fold Fee: Rs. 20,000/-	Deferred for the provision of the safety and the stability data of the product alongwith the source of the chitosan which is being used in manufacturing of the product.

2. It is requested to furnish the requisite information/documents within 30 days after uploading of this letter on official website of DRAP.


(AYYAZ AHMAD)
Additional Director (MDMC)/
Secretary MDB