



No.F.4-13/2023-MD (M-63)
Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
Drug Regulatory Authority of Pakistan

Islamabad the 20th December, 2023

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 63rd meeting held on 22nd November, 2023 and Board deferred these applications being deficient of the information/documents as specified in last column (V) of the Table below:-

Sr No	Firm Details	Manufacturer Details	Name of Medical Device/ Class / Shelf life / Codes etc	Decision
(I)	(II)	(III)	(IV)	(V)
1.	Shirazi Trading Company Private Limited 114-C, Al Murtaza Commercial Lane 3, Khayaban-e-Iqbal, Phase 8, D.H.A., Karachi. Establishment Licence No.: ELI-000263	Legal manufacturer GE Medical Systems Information Technologies Inc. 8200 West Tower Avenue, Milwaukee, WI 53223 U.S.A. Manufacturing Site: Critikon de Mexico S.de R.L. de C.V. Calle Valle del Cedro 1551, Juarez 32575, Chihuahua, Mexico Legalized FSC issued F.D.A. (U.S.A.) Certificate No. 14586-9-2019, Valid until: 16.09.2021. Notarized copy of ISO valid till 29-11-2023 Notarized copy of FQA/CE valid till 26-05-2024	Carescape Central Station Patient Monitoring System Central Station Monitor Class C Shelf Life: Expected Service Life: 7 Years Code:- 38470 Fee submitted: Rs. 50,000/- Date of submission: 26.09.2022	Deferred for submission of valid legalized Free Sale Certificate of country of origin or from any reference regulatory authority.
2.	M/s. Care and Cure International. 65-B, Satellite Town Rahim Yar Khan. ELI-00192	Legal Manufacturer & Site: AnHui AnYu Latex Products Co., Ltd No.95, YuHe, road Bengbu, AnHui, China. Copy of FSC issued by China valid upto 19/12/2020 Notarized copy of FQA/EC valid upto 14-05-2024	Cure (Latex Surgical Gloves Powdered) Codes & Sizes: 6, 6.5, 7, 7.5, 8, 8.5 (2 Pcs or 1 pair per pack) Class-B Shelf Life :5 years Fee:25,000 Date of Application: 22-02-2021	Deferred for submission of valid legalized FSC & ISO 13485.

3.	M/s Ali Gohar & Company (Pvt) Ltd., State Life Building 1-B, I.I. Chundrigar Road, Karachi. (ELI-00004) 4638 30-06-2022	Legal Manufacturer: Zimmer Trabecular Metal Technology inc. 10 Pomeroy Road, Parsippany, New Jersey 07054 USA. FSC US FDA validity 04-03-2022	Trabecular Metal Revision Acetabular System (Hip implants, Trabecular Metal Acetabular Augment) Class-C Shelf life: 5 years Codes as per FSC	Deferred for the provision of following: - • Original, valid and Embassy attested FSC of US FDA. • Valid and notarized ISO 13485 certificate. • Apply separately for Buttress and Restrictor.
4.	M/s V care International 8C ,6 sunset commercial Lane Phase 2 Extension Defense housing authority Karachi ELI: 00433 33-C 05-11-2022	Legal Manufacturer: YASEE Biomedical Inc. NO.9, Xiuyuan Rd, High-Tech Development Zone, Qingdao City, China. FSC China valid till 16-05-2023 FSC MHRA, UK Issuance 01-12-2018	BeneSense PLUS (Blood Glucose Meter System) Class-C Shelf life: 24 Months (strips) Model: AC-305	Deferred for provision of following: - Original and valid LOA, FSC of China, FSC of MHRA UK, ISO 13485, FQA certificates duly notarized/ attested.
5.	M/s V care International 8C ,6 sunset commercial Lane Phase 2 Extension Defense housing authority Karachi ELI: 00433 607-C-C 30-11-2022	Legal Manufacturer: General Life Biotechnology Co., Ltd 5F, No. 240, Shinshu Road, Shin Juang Dist, New Taipei City, 242, Taiwan. FSC Taiwan issued on 19-09-2022	Benecheck (Multi-Monitoring System) Class-C Shelf life: Meter (5 years) Glucose Test Strip (24 Months) Total Cholesterol Strip (18 Months) Uric Acid Strip (20 Months) Models as per FSC	Deferred for provision of following: - Original and valid LOA, FSC of China, FSC of MHRA UK, ISO 13485, FQA certificates duly notarized/ attested.
6.	M/s Roys & Roys International, 1st Floor Rehman Centre-2, Service Lane Ring Road, Near Askari-11, Gate-3, Lahore ELI: 00708 4255-P 24-10-2023	Legal Manufacturer: M/s Suzhou Laishi Transfusion Equipment Co. Ltd Changshen Road, Tongli Town, Wujian City, Jiangsu Province- 215217, China FSC: China Valid Till: 2024/04/22	MEDIGAR Single Blood Bags (Plastic Blood Bag) Class-D Shelf Life: 2 years Sizes: 100ml, 150ml, 200ml, 250ml, 300ml, 350ml, 400ml, 450ml, 500ml	Deferred for the provision of following: - • Credential of manufacturer. • Manufacturing and QC details. • Shelf life studies for the claimed shelf life. • Validation data. • DoC for the models as per FSC of China. • FSC of any SRA as the device is from non-reference country or CE mark certificate.
7.	M/s Mais Medical Products (Pvt) Ltd, Office No. 8 Second Floor Qartaba	Legal Manufacturer: Saudi Mais Co. for Medical Products, Third Industrial Area, Al Kharj Road, Street No.	Maicath I.V Cannula (I.V. Cannula with injection Port Catheter) Class-B	Deferred for the following reason: Both the firms M/S Pharma Supply Corporation, Karachi and M/S Mais Medical, Lahore are directed to clarify and verify their position

	center 7/8 Jail Road Muzung Chungi, District, Lahore. ELI-00693 3064-P 18-02-2022	256, Riyadh Saudi Arabia FSC: Saudi Arabia Date of issue: 09.11.2021 FSC Spain issuance 29-06-2023	Shelf Life 5 year Sizes: 14G, 16G, 18G, 20G, 22G, 24G	through substantial evidence that the applied product is granted to him by the legal manufacturer as same device with the same brand name is applied by both of the firms.
8.	M/s SIND MEDICAL STORES, 13-B, Block 6, PECHS, Shahrah e Faisal, Karachi – 75400, PAKISTAN Lic. No.ELI-00010 R&I 7-3-22	BIO-RAD MEDICAL DIAGNOSTICS GmbH Industriestrasse.1, 63303 Dreieich, Germany. FSC Germany issued on (14.05.2021)	MULTIPLE BLOOD GROUPING IVD – ANTIBODY (IVD GROUPING - Family Of 02 Products) Seraclone Anti-A1 (ABO4) (Product Ref. Nos. 801136) Shelf Life = 18 Months Storage Condition: (2-8 °C and do not freeze) Seraclone Anti-H (H1) (Product Ref. Nos. 801165) Shelf Life = 12 Months Storage Condition: (2-8 °C and do not freeze) Class – C	Deferred for provision of valid LOA & Clarification required regarding grouping of 2 products in family as per Medical Devices Raules, 2017 or apply separately.
9.	M/s Allmed Solutions, A-21/3, KDA Scheme No.1 (ext) Stadium Road, Karachi (ELI-00029) D.O.S. 27-06-2022	KARL STORZ SE & CO. KG Address: Dr.-Karl-Storz- StraBe 34 78532 Tuttlingen, Germany FSC: US FDA Valid Till: 22-5-2024. Copy provided FSC Germany copy issue date 12.10.2022	KARL STORZ Optical Biopsy Forceps Class C Shelf Life: N/A Fees Rs. 50,000/- Challan no. 9057074718	Deferred for clarification of brand name as per FSC and submit embassy attested valid FSC of Germany or USFDA. Submit notarized and valid, ISO and FQA. Provide DOC. And apply as per Family of Medical Devices Raules, 2017 or justify.
10.	M/s Allmed Solutions, A-21/3, KDA Scheme No.1 (ext) Stadium Road, Karachi (ELI-00029) D.O.S. 27-06-2022	KARL STORZ SE & CO. KG Address: Dr.-Karl-Storz- StraBe 34 78532 Tuttlingen, Germany FSC: US FDA Valid Till: 22-5-2024 . Copy provided FSC Germany copy issue date 12.10.2022	KARL STORZ Insert Grasping Forceps and Forceps Inserts Class C Shelf Life: N/A Fees Rs. 50,000/- Challan no. 41388607578	Deferred for the provision of following. • Embassy attested valid FSC of Germany or USFDA notarized and valid ISO 13485, FQA and DOC.
11.	M/s Allmed Solutions, A-21/3, KDA Scheme No.1 (ext) Stadium Road, Karachi	KARL STORZ SE & CO. KG Address: Dr.-Karl-Storz- StraBe 34 78532 Tuttlingen, Germany FSC: US FDA Valid	KARL STORZ CLICKLINE Outer Sheath/Forceps Insert (Surgical Biopsy Forceps) And CLICKLINE Forceps Insert with Movable Jaws (Grasping	The board deferred the case and decided that the firm shall clarify/ justify the family/ system applied under the MDR 2017 and Submit embassy attested valid FSC of

	(ELI-00029) D.O.S. 27-09-2022	Till: 22-5-2024 . Copy provided FSC Germany copy issue date 12.10.2022	Forceps) Class C Shelf Life: N/A Fees Rs. 50,000/- challan no. 190710892	Germany or USFDA Submit notarized and valid , ISO 13485, FQA and DOC.
12.	M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi (ELI00019) Dossier Submission date: 9-May-2023	Manufacturer: Abbott Molecular Inc. 1300 East Touhy Avenue Des Plaines, IL 60018 USA (embassy attested original FSC Issuance: 19.10. 2021, Germany)	Vysis 13q34 Spectrum Green FISH Probe Kit 05N34-020 Shelf Life: 24 Months -15°C- -25°C Class: C Rs.50,000/-	Deferred for clarification of the brand name in the LOA .
13.	M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi (ELI00019)	Manufacturer: Abbott Molecular Inc. 1300 East Touhy Avenue Des Plaines, IL 60018 USA (embassy attested original FSC Issuance: 19.10. 2021, Germany)	Vysis D13s319/13q34 FISH Probe Kit 05N37-020 Shelf Life: 24 Months -15°C- -25°C Class: C Rs.50,000/-	Deferred for clarification of the brand name in the LOA .
14.	M/s Hoora Pharma (Pvt.) Ltd. Address: WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi. Establishment License no: ELI-00037 Slip No: 9247526297 Date: 22-11-2022	LEGAL MANUFACTURE: Name: FUJIFILM Healthcare Corporation Medical System Operations Group, Kashiwa. Address: -1, Shintoyofuta, Kashiwa-shi, Chiba, 277-0804 Japan. MANUFACTURING SITE: Name: FUJIFILM Healthcare Manufacturing Corporation, Kashiwa Factory Address: 2-1, Shintoyofuta, Kashiwa-shi, Chiba 3-1, Shintoyofuta, Kashiwa-shi, Chiba	SCENARIO VIEW (CT SCAN) Class-C Service Life: 10 years Size: 1 unit	Deferred for clarification of the brand name as per FSC / or revise Form 7A. Clarify the number of slabs in the CT scan.



		<p>FSC: MHLW Japan Certificate no: Fhc-22-0093 Valid Till: 14-11-2024</p> <p>LOA Valid Till: 10-11-2024</p> <p>EC Certificate: Certificate no: HD-2251444-1 Valid Till: 10-01-2024</p> <p>ISO 13485:2016 SX-2251441 Valid Till :26-12-2022</p> <p>DOC Date of Issue: 01-07-2021</p> <p>Remarks: Original FSC, DOC, FQA, LOA & ISO Attached in Aperto Lucent Dossier.</p>		
15.	<p>M/s Hoora Pharma (Pvt.) Ltd. Address: WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi. Establishment License no: ELI-00037</p> <p>Slip nbr: 25408938985 Date: 06-11-2022</p>	<p>Name: FUJIFILM Healthcare Corporation Medical System Operations Group, Kashiwa. Address: -1, Shintoyofuta, Kashiwa-shi, Chiba, 277-0804 Japan. MANUFACTURING SITE: Name: FUJIFILM Healthcare Manufacturing Corporation, Kashiwa Factory</p> <p>Address: 2-1, Shintoyofuta, Kashiwa-shi, Chiba 3-1, Shintoyofuta, Kashiwa-shi, Chiba</p> <p>FSC Issued by: MHLW Japan. Certificate no: Fhc-22-0093 Expiry Date: 14-11-2024</p> <p>LOA Valid Till: 10-11-2024</p> <p>EC Certificate: Certificate no: HD 2251444-1</p>	<p>SUPRIA (CT SCAN)</p> <p>Service Life: 10 years</p> <p>Size: 1 unit/pack</p>	<p>Deferred for clarification of the brand name as per FSC / or revise Form 7A.</p> <p>Clarify the no. of slabs in the CT scan.</p>

		<p>Date of Expiry:10-01-2024</p> <p>ISO 13485:2016 SX-2251441 Date of Expiry:26-12-2022</p> <p>DOC Date of Issue: 01-07-2021</p> <p>Remarks: Original FSC, DOC, FQA, LOA & ISO Attached in Aperto Lucent Dossier</p>		
16.	<p>M/s Hoora Pharma (Pvt.) Ltd.</p> <p>Address: WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi.</p> <p>Establishment License no: ELI-00037 03/08/2018 03/08/2023</p> <p>Slip nbr: 846780079 Date: 02-12-2022</p>	<p>Name: FUJIFILM Healthcare Corporation Medical System Operations Group, Kashiwa.</p> <p>Address: -1, Shintoyofuta, Kashiwa-shi, Chiba, 277-0804 Japan.</p> <p>MANUFACTURING SITE: Name: FUJIFILM Healthcare Manufacturing Corporation, Kashiwa Factory Address: 2-1, Shintoyofuta, Kashiwa-shi, Chiba 3-1, Shintoyofuta, Kashiwa-shi, Chiba</p> <p>FSC Issued by: MHLW Japan. Certificate no: Fhc-22-0093 Expiry Date: 14-11-2024</p> <p>LOA Date of Validity: 10-11-2025</p> <p>EC Certificate: Certificate no: HD 2251444-1 Date of Expiry:10-01-2024</p> <p>ISO 13485:2016 SX-2251441 Date of Expiry:26-12-2022</p> <p>DOC Date of Validity: 01-07-2023</p>	<p>Echelon Smart (MRI)</p> <p>Service Life: 10 years</p> <p>Size: 1 unit/pack</p>	<p>Deferred for clarification of the brand name as per FSC / or revise Form 7A.</p> <ul style="list-style-type: none"> Clarify the no. of slabs in the MRI. Submit Embassy attested valid FSC in the country of origin. Since the already submitted FSC does not confirm the Free sale of the product in the country of origin. The firm has applied in Class C however the DOC submitted reflect the class as class B. Clarify.

		Remarks: Original FSC, DOC, FQA, LOA & ISO Attached in Aperto Lucent Dossier		
17.	M/s Hoora Pharma (Pvt.) Ltd. Address: WH-01-20-A7- A8, Korangi Creek Industrial Park, Karachi. Establishment License no: ELI-00037 03/08/2018 03/08/2023 Slip nbr: 660223680411 Date: 02-12-2022	Name: FUJIFILM Healthcare Corporation Medical System Operations Group, Kashiwa. Address: -1, Shintoyofuta, Kashiwa- shi, Chiba, 277-0804 Japan. MANUFACTURING SITE: Name: FUJIFILM Healthcare Manufacturing Corporation, Kashiwa Factory Address: 2-1, Shintoyofuta, Kashiwa- shi, Chiba 3-1, Shintoyofuta, Kashiwa-shi, Chiba FSC MHLW Japan Certificate no: 3834 Expiry Date: 17-11- 2027	Aris Vento (MRI) Service Life: 10 years Size: 1 unit/pack	Deferred for clarification of the brand name as per FSC / or revise Form 7A. <ul style="list-style-type: none"> Clarify the no. of slabs in the MRI. Submit Embassy attested valid FSC in the country of origin. Since the already submitted FSC does not confirm the Free sale of the product in the country of origin. The firm has applied in Class C however the DOC submitted reflect the class as B; Clarify.
18.	M/s Hoora Pharma (Pvt.) Ltd. Address: WH-01-20-A7- A8, Korangi Creek Industrial Park, Karachi. Establishment License no: ELI-00037 03/08/2018 03/08/2023 Slip nbr: 660223680411 Date :Nov 2022	Name: FUJIFILM Healthcare Corporation Medical System Operations Group, Kashiwa. Address: -1, Shintoyofuta, Kashiwa- shi, Chiba, 277-0804 Japan. MANUFACTURING SITE: Name: FUJIFILM Healthcare Manufacturing Corporation, Kashiwa Factory Address: 2-1, Shintoyofuta, Kashiwa- shi, Chiba 3-1, Shintoyofuta, Kashiwa-shi, Chiba FSC Certificate no:3838 CS106/2 Date of issue:26-12-	Aperto Lucent (MRI) Service Life: 10 years Size: 1 unit/pack	Deferred for clarification of the brand name as per FSC / or revise Form 7A. <ul style="list-style-type: none"> Clarify the no. of slabs in the MRI. Submit Embassy attested valid FSC in the country of origin. Since the already submitted FSC does not confirm the Free sale of the product in the country of origin. The firm has applied in Class C however the DOC submitted reflect the class as B; Clarify.

		2022 Expiry Date: 26-12-2024		
19.	M/s Bio Medics Medical System, F-597, F. Block, Satellite Town, Rawalpindi ELI: 00022 Dossier# 1812 (P) Submission date: 19/10/2020 Fee submitted: 50,000/- Challan No. 2036506	Legal Manufacturer: Fengh Medical Co., Ltd D3 No. 6, Dongsheng West Road, Jiangyin National High-tech Zone, 214437, China FSC: MHRA Date of issue: 24.10.2019	FENGH (Disposable Linear Cutter Stapler & Reloads (All models) Class-C Shelf life: 36 months	Deferred for the provision of following: <ul style="list-style-type: none">• Submit original & valid LOA.• Submit valid ISO certificate.• Submit valid CE certificate.
20.	M/s Bio Medics Medical System, F-597, F. Block, Satellite Town, Rawalpindi ELI: 00022 Dossier# 1813 (P) Submission date: 19/10/2020 Fee submitted: 50,000/- Challan No. 2036505	Legal Manufacturer: Fengh Medical Co., Ltd D3 No. 6, Dongsheng West Road, Jiangyin National High-tech Zone, 214437, China FSC: MHRA Date of issue: 24.10.2019	FENGH (Disposable Powered Articulating Endoscopic Linear Cutter Stapler & Reloads) Class-C Shelf life: 36 months	Deferred for the provision of following: <ul style="list-style-type: none">• Submit original & valid LOA.• Submit valid ISO certificate.• Submit valid CE certificate.
21.	M/s Ferozs Laboratories Limited P.O. Ferozs, Amangarh, Nowshera, KPK (ELI-00120) Dossier# 1056c/7A Submission date: 21/12/2022 Fee submitted: 50,000/- Challan No. 018349554948	Legal Manufacturer: Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA Manufacturing site: Statice SA 9 rue Thomas Edison Besancon, Franche-Comte France 25000 FSC :MHRA valid till 27-10-2022	Habib EndoHPB Bipolar Radiofrequency Catheter and adaptor cable bipolar Codes & Sizes: 8F/180cm in length Class-C Shelf Life: 03 years	Deferred for the provision of following: <ul style="list-style-type: none">• Submit original, valid & embassy attested FSC (USA) as the submitted one was expired (on 27-10-2022) at the time of submission of dossier.• Submit separate fee for adapter cable bipolar as classified as a class I non-sterile.• There are three different adapter cables specify which one is connected to Habib EndoHPB Catheter.
22.	M/s SM Impex Office No. B-309 3rd Floor, New Chali Trade Centre, Shahrah-e-Liaquat, Karachi, Pakistan (ELI-00473)	Legal Manufacturer: Geotek Medikal Ve Saglik Hiz.Tic. San Ltd Sti. Lvedik OSB Agac Metal Sitesi 1436 Sk No. 12, Yenimahalle Ankara, Turkey	Maxicore Biopsy Needle Class-B Shelf life: 5 years	Deferred for the provision of following documents: <ul style="list-style-type: none">• Notarized letter of authorization.• Instructions for Use for the applied product.• Original, legalized and valid Free Sale certificate mentioning relevant details (codes/sizes) of

	8569-R&I 16.03.2020	FSC: Turkey, valid till 3 rd December, 2023.		<p>the applied product.</p> <ul style="list-style-type: none"> • Detail of quality control procedures along with the established protocol of testing for the applied product. • Submission of notarized and valid full quality assurance certificate, ISO-13485 and Declaration of Conformity (mentioning the class of medical device) is required. • Stability studies for the applied product supporting claimed shelf life. <p>Apply separately for Biopsy Gun</p>
23.	<p>M/s SM Impex Office No. B-309 3rd Floor, New Chali Trade Centre, Shahrah- e-Liaquat, Karachi, Pakistan (ELI-00473)</p> <p>3601 16.03.2021</p>	<p>Legal Manufacturer: Geotek Medikal Ve Saglik Hiz.Tic. San Ltd Sti. Lvedik OSB Agac Metal Sitesi 1436 Sk No. 12, Yenimahalle Ankara, Turkey</p> <p>FSC: Turkey, valid till 3rd December, 2023.</p>	<p>Geotek (Bone Marrow Biopsy Needle)</p> <p>Class D</p> <p>Shelf life: 5 years</p>	<p>Deferred for the provision of following documents:</p> <ul style="list-style-type: none"> • FSC of any RRA country as the device is from non-reference country • FSC submitted is missing the device annexure, submit the FSC having the relevant device applied. • Detail of quality control procedures along with the established protocol of testing for the applied product. • Valid ISO 13485 certificate. • Updated LOA and FSC. • Apply separately for Aspiration and Semi-Automatic Biopsy needles. • Provide MRP of the device.
24.	<p>M/s SM Impex Office No. B-309 3rd Floor, New Chali Trade Centre, Shahrah- e-Liaquat, Karachi, Pakistan (ELI-00473)</p> <p>16.03.2021 (Duplicate Dossier) (13-10-2023)</p>	<p>Legal Manufacturer: Geotek Medikal Ve Saglik Hiz.Tic. San Ltd Sti. Lvedik OSB Agac Metal Sitesi 1436 Sk No. 12, Yenimahalle Ankara, Turkey</p> <p>FSC: Turkey, valid till 3rd December, 2023.</p>	<p>Geotek (Double J Ureteral Stent, One End Close with Guide wire and Clamp)</p> <p>Class-C</p> <p>Shelf life: 5 years</p>	<p>Deferred for the provision of following documents:</p> <ul style="list-style-type: none"> • FSC of any RRA country as the device is from non-reference country • FSC submitted is missing the device annexure, submit the FSC having the relevant device applied. • Detail of quality control procedures along with the established protocol of testing for the applied product. • Valid ISO 13485 certificate. • Updated LOA and FSC. • Apply separately for Aspiration and Semi-Automatic Biopsy

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				<p>needles.</p> <ul style="list-style-type: none"> MRP of the device.
25.	<p>M/s Quintex Medicals, Office No. 1, 1st Floor, Latif Manzil, 100-B, Main Lyton Road, Data Gunj Bukhsh Town, Lahore.</p> <p>ELI: 00823 4211-P 02-10-2023</p>	<p>Legal Manufacturer: M/s FAZZINI S.r.l, vimodrone (MI) S.S. Padana Superior n.317, Italy.</p> <p>Original FSC: Italy Date of Issue: 11/02/2021</p>	<p>Infant Radiant warmer/baby warmer (Infant radiant warmer/baby warmer)</p> <p>Class-C</p> <p>Shelf Life: 5 years</p>	<p>Deferred for the provision of following documents:</p> <ul style="list-style-type: none"> Stability studies for the claimed shelf life. Credentials of manufacturer abroad as per format approved in 3rd meeting of MDB. Manufacturing and Quality control tests protocols in detail. FSC having the applied device.
26.	<p>M/s New Pakistan Traders, Office No. 306/I, Trade Tower, Altaf Hussain Road, New Challi, Karachi.</p> <p>(ELI-00161) 4469-P 16-05-2022</p>	<p>Legal Manufacturer: M/s Shanghai Kinmed Import & Export Co. Ltd, Suit L, 12th Floor, No.588 Yingkou Road, Shanghai, China</p> <p>FSC China Date of Issuance 06-12-2021 valid for 2 years</p>	<p>KBM Auto-Disable Syringe</p> <p>Class B</p> <p>Shelf life: 05 Years</p> <p>Sizes: 3ml, 5ml</p>	<p>Deferred for the provision of following documents:</p> <ul style="list-style-type: none"> Credentials, LOA, FSC of China, ISO 13485, FQA certificates are copies and without notarization/ attestation. Submit all the documents in original and notarized/attested as per requirement of the Form-7A. FSC of reference country or CE marked document. Stability studies for the claimed shelf life.
27.	<p>M/s K.S. Agencies, Office NO. 210, 2nd floor, Business Arcade, Main University Road, Karachi</p> <p>ELI-00382 824-C 19-01-2023</p>	<p>Legal Manufacturer: Micro-Tech (Nanjing Co., Ltd) No. 10 Gaoke Third Road, Nanjing National High-tech, Industrial Development Zone, Nanjing 210032, Jiangsu Province, P.R. China.</p> <p>FSC China expired on 15-12-2022 FSC Germany issuance 13-10-2021</p>	<p>Micro-Tech Esophageal Stent (Esophageal Stent)</p> <p>Class-C</p> <p>Shelf life: 3 years</p> <p>Codes are not mentioned on FSC of China and Germany</p>	<p>Deferred for the provision of following documents:</p> <ul style="list-style-type: none"> Updated and original LOA. Credentials of manufacturer's abroad. Updated and notarized ISO 13485 certificate Declaration of Conformity. Manufacturing & QC details Stability studies Product details Essential requirements checklist FSC of China is expired before the submission of application and is copy without attestation; submit valid & notarized. FSC of Germany provided missing the codes of applied device; submit valid & notarized.
28.	<p>M/s K.S. Agencies, Office NO. 210, 2nd floor, Business Arcade, Main University Road, Karachi</p>	<p>Legal Manufacturer: Micro-Tech (Nanjing Co., Ltd) No. 10 Gaoke Third Road, Nanjing National High-tech, Industrial Development Zone, Nanjing 210032,</p>	<p>Micro-Tech Duodenal Stent (Duodenal Stent)</p> <p>Class-C</p> <p>Shelf life: 3 years</p>	<p>Deferred for the provision of following documents:</p> <ul style="list-style-type: none"> Updated and original LOA. Credentials of manufacturer's abroad.

	ELI-00382 827-C 19-01-2023	Jiangsu Province, P.R. China. FSC China expired on 15-12-2022 FSC Germany issuance 13-10-2021	Codes are not mentioned on FSC of China and Germany	<ul style="list-style-type: none"> Updated and notarized ISO 13485 certificate Declaration of Conformity. Manufacturing & QC details Stability studies Product details Essential requirements checklist FSC of China is expired before the submission of application and is copy without attestation; submit valid & notarized. FSC of Germany provided missing the codes of applied device; submit valid & notarized.
29.	M/s Universal Enterprises 29 Block 3, Overseas Cooperative Housing Society, Stadium Road, Karachi. (ELI-00079) 5128 18-08-2022	Legal Manufacturer: Gentherm Medical LLC. Located at 12011 Mosteller Road Cincinnati Oh 45241 United State of America. FSC US FDA validity 06-09-2023	Hemotherm (Dual Reservoir Cooler/ Heater System) Class-C Shelf life: 3 years Model: 400CE	Deferred for the provision of following documents: Updated and original FSC, ISO 13485 and FQA. Clarification is required as the same device with same Brand and model manufactured by M/s Cincinnati Sub-Zero Products, LLC 12011 Mosteller Road Cincinnati, OH 45241, USA is registered for M/s Hospicare, Lahore. The address of the both manufacturers are same only the Company name is different, clarification is required by both the firms.
30.	M/s Ferozsos Laboratories Limited, P.O Ferozsos, Amangarh, Nowshera (KPK) ELI: 00120	Legal Manufacturer: Xeridiem Medical Devices 4700 S Overland Dr. Tucson, AZ, USA, 85714 Manufacturing Site: Xeridiem Medical Devices 7700 S Overland Dr. Tucson, AZ, USA 85714 FSC: U.S.A Valid till: 04.01.2024	ENDOVIVE Gastrostomy Tube, Straight, with Enfit Connector (Gastrostomy Feeding Tubes) Codes & Sizes: As per FSC Class-C Shelf life: 03- years	Deferred with final opportunity for the provision of following: <ul style="list-style-type: none"> Provide the Original and Valid LoA containing the address as per ELI, original fee submission challan slips (DRAP Copy), clarify about grouping with application form
31.	M/s Vertex Medical (Pvt) Ltd, 70-B-1, Gulberg-III, Lahore ELI-00150 3152-P 22-07-2022	Legal Manufacturer: LivaNova Deutschland GmbH Lindberghstr.25 80939 Munich-Germany FSC: Germany Date of Issue: 23/02/2022	XTRA Auto Transfusion Cell Separator (XTRA Auto Transfusion Cell Separator) Class-C Shelf Life: 7 years Codes & Sizes: As per FSC	The Board deferred the case and decided to give personal hearing to both of the firms i.e Vertex Medical (Pvt) Ltd and Pharma Consultant, Lahore to clarify the current scenario of agreement between the importers and the manufacturer.
32.	Noor international, 29-D, Block 6, PECHS, Karachi	Legal Manufacturer: Radiometer Medical ApS Akandevej 21	AQT 90 Flex Analyser with reagents and samplers	Deferred with final opportunity to provide evidence for change of class or apply separately or justify clustering of reagents samplers and

	(ELI-00061), 03-08-2018 3187 Date (R&I) 23-9-2020	2700 Bronshoj-Denmark Manufacturing site: Assays and consumables Radiometer Turku , Oy Biolinja12, 2075 turku, Finland Radiometer Solutions Sp. Zo.o Stalowa 6, Stargard 73-110, Poland Ivd FSC of Denmark expired on 5-12-2021, valid upon submission	9027.8000 AQT flex analyser 9018.3120 Samplers (IVDD) Class C Code 393-899 Shelf Life: N/A Fee: 50,000/-	analyser
33.	M/s Noor International, 29-D, Block 6, PECHS, Karachi (ELI-00061) 2987 Date (R&I) 31-8-2020	Legal Manufacturer: Radiometer Medical ApS Akandevej 21 2700 Bronshoj-Denmark Manufacturing site: SenDx Medical Inc. 1945 Palomar Oaks Way Carlsbad, CA92011 USA FSC Denmark Valid till 3-1-2021	ABL9 Blood gas electrolyte and metabolite analyzer Class C Code 393-899 Shelf Life: N/A Fee: 50,000/-	Deferred with final opportunity to provide original FSC of country of origin

2. In the light of decision of MDB in its 37th meeting wherein Board in order to make quick disposal of cases decided for the firms who have submitted original, valid and Notarized/Embassy attested documents at the time of submission of application for registration/enlistment and is expired during the processing of applications, such firms shall only submit valid and original (where applicable) documents.

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



No.F.4-13/2023-MD (M-63)
Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
Drug Regulatory Authority of Pakistan

Islamabad the 20th December, 2023

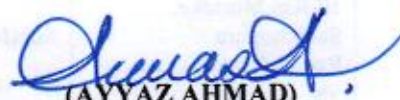
Subject:- **DEFERRED CASES OF ENLISTMENT/REGISTRATION OF MEDICAL DEVICES TO LOCAL MANUFACTURE – SUBMISSION OF DEFICIENT INFORMATION/ DOCUMENTS THEREOF**

The applications of following applicants were considered by Medical Device Board (MDB) in its 63rd meeting held on 22nd November, 2023 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	Decision
(I)	(II)	(III)	(IV)
1.	M/s Surgiplast. Plot No 78, Road No L-4, Industrial Estate Gadoon Amazai, Swabi ELM No 0030 Sections: 1. Syringe Section 2. IV sets section	Clinic Disposable Butterfly Scalp Vein Set Codes and Sizes: 16G/18G/21G/22G/23G/24G/26G Class.B Shelf life:05 Years Fee Challan: Rs.20,000	Deferred for confirmation of manufacturing facility for the applied product.
2.	M/s NISA.SF Private Limited. 10-Km, Muridke, Sheikhpura Road, Muridke, Distt. Sheikhpura ELM-0001 Sections: 1. Disposable Syringe Section 2. IV canula section 3. I.V Products	Injectocan Auto Disable syringe Class:B Shelf-life:5Years Sizes: 3ml syringe, 5ml syringe, 10ml syringe Needle sizes: 3ml Auto disable syringe Needle sizes: 21G x 1" (0.8mm x 25mm) 21 G x 1 1/2" (0.8mm x 38mm) 21G x 1 1/4" (0.8mm x 32mm) 22G (0.7mm x 30mm) 22G x 1 1/4" (0.7mm x 32mm) 22G x 1 1/2" (0.7mm x 38mm) 22G (0.7mm x 40mm) 23G x 1" (0.6mm x 25mm) 23G x 1 1/4" (0.6mm x 32mm) 23G x 1 1/2" (0.6mm x 38mm) 24G x 1" (0.55mm x 25mm) 24G x 1 1/4" (0.55mm x 32mm) 25G x 1/2" (0.5mm x 13mm) 25G x 1" (0.5mm x 0.25mm) 5ml Auto disable syringe Needle sizes: 21G x 1" (0.8mm x 25mm) 21 G x 1 1/2" (0.8mm x 38mm)	Deferred for confirmation of manufacturing facility for the applied product.

	21G x 1 ¼" (0.8mm x 32mm) 22G (0.7mm x 30mm) 22G x 1 ¼" (0.7mm x 32mm) 22G x 1 ½" (0.7mm x 38mm) 22G (0.7mm x 40mm) 23G x 1" (0.6mm x 25mm) 23G x 1 ¼" (0.6mm x 32mm) 23G x 1 ½" (0.6mm x 38mm) 24G x 1" (0.55mm x 25mm) 24G x 1 ¼" (0.55mm x 32mm) 25G x ½" (0.5mm x 13mm) 25G x 1" (0.5mm x 25mm)	
	10ml Auto disable syringe Needle sizes: 21G x 1 ½" (0.80mm x 38mm) 21G x 1" (0.80mm x 25mm) 21G x 1 ¼" (0.80mm x 32mm) 22G (0.7mm x 30mm) 22G (0.7mm x 40mm) 23G x 1" (0.6mm x 25mm) 23G x 1 ¼" (0.6mm x 32mm) 24G x 1" (0.55mm x 25mm) 25G x 1/2" (0.5mm x 13mm) 25G x 1" (0.5mm x 25mm)	
	Fee Challan No	

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