



No.F.4-11/2023-MD (M-61)
Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
Drug Regulatory Authority of Pakistan


Islamabad the 12th October, 2023

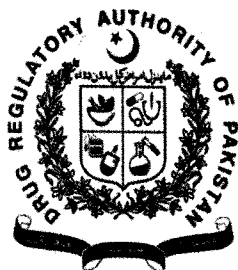
Subject:- **DEFERRED CASES OF ENLISTMENT/REGISTRATION OF MEDICAL DEVICES TO LOCAL MANUFACTURE – SUBMISSION OF DEFICIENT INFORMATION/ DOCUMENTS THEREOF**

The applications of following applicants were considered by Medical Device Board (MDB) in its 61st meeting held on 26th September, 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 sizes	Decision
(I)	(II)	(III)	(IV)
1	M/s Medipak Limited 132/1 Quaid-e-Azam Industrial Estate KotLakhpat Lahore . [ELM No.0048] Sections as ELM: 1. Hemodialysis Section. 2. Disposable IV Set Section	Intra Flow IV Cannula (IV Cannula) Class: B Shelf-life: 5 years Fee Challan No. 0830437336 Rs. 5,000 dated 02-05-2023 & 7467025708 Rs. 15,000 dated 22-06-2023	Deferred for verification of manufacturing facility for the applied product

2. It is requested to furnish the requisite information/documents within 20 days after uploading of this letter on official website of DRAP.


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



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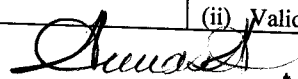
Islamabad the 12th October, 2023

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 61st meeting held on 26th September, 2023 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
(I)	(II)	(III)	(IV)	(V)
1.	Gulf Marketing International, Gulf House 10&11-B/2, Satellite Town Abdullah Jan Masjid Street Near Kali Tanki Said Pur Road, Rawalpindi ELI-00194	Legal manufacturer & manufacturer site (as per FSC) Xiamen Biotime Biotechnology Co., Ltd. 3rd Floor , No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 3610326, P>R. China. Legal manufacturer (as per Form-7: Xiamen Biotime Biotechnology Co., Ltd 2F/3F/4F , No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 36103 Legalized Free Sale Certificate (FSC) No.20200013 valid upto 24-02-2022.	BIOTIME (E2 Rapid Quantitative Test) Code: BT2212 Class-C Shelf Life: 02- years Fee: Rs=50,000/- dated 07-04-2022 Date of Application: 11-04-2022	Deferred for submission of following documents: (i) Valid Legalized Free Sale Certificate. (ii) Valid notarized ISO13485. (iii) Valid Legalized FSC from reference country/CE Certificate & FQA.
2.	Gulf Marketing International, Gulf House 10&11-B/2, Satellite Town Abdullah Jan Masjid Street Near Kali Tanki Said Pur Road, Rawalpindi ELI-00194	Legal manufacturer & manufacturer site (as per FSC) Xiamen Biotime Biotechnology Co., Ltd. 3rd Floor , No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 3610326, P>R. China. Legal manufacturer (as per Form-7: Xiamen Biotime Biotechnology Co., Ltd	BIOTIME (AFP Rapid Quantitative Test) BT2402 Class-C Shelf Life: 02- years Fee: Rs=50,000/- dated 07-04-2022 Date of Application: 11-04-2022	Deferred for submission of following documents: (i) Valid Legalized Free Sale Certificate. (ii) Valid notarized ISO13485. (iii) Valid Legalized FSC from reference country/CE Certificate & FQA.

		2F/3F/4F, No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 36103 Legalized Free Sale Certificate (FSC) No.20200013 valid upto 24-02-2022.		
3.	Gulf Marketing International, Gulf House 10&11-B/2, Satellite Town Abdullah Jan Masjid Street Near Kali Tanki Said Pur Road, Rawalpindi ELI-00194	Legal manufacturer & manufacturer site (as per FSC) Xiamen Biotime Biotechnology Co., Ltd. 3 rd Floor, No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 3610326, P>R. China. Legal manufacturer (as per Form-7: Xiamen Biotime Biotechnology Co., Ltd 2F/3F/4F, No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 36103 Legalized Free Sale Certificate (FSC) No.20200013 valid upto 24-02-2022.	BIOTIME (cTnI/CK-MB/Myo Rapid Quantitative Test) BT2104 Class-C Shelf Life: 02- years Fee: Rs=50,000/- dated 07-04- 2022 Date of Application:11-04-2022	Deferred for submission of following documents: (i) Valid Legalized Free Sale Certificate. (ii) Valid notarized ISO13485. (iii) Valid Legalized FSC from reference country/CE Certificate & FQA.
4.	Gulf Marketing International, Gulf House 10&11-B/2, Satellite Town Abdullah Jan Masjid Street Near Kali Tanki Said Pur Road, Rawalpindi ELI-00194	Legal manufacturer & manufacturer site (as per FSC) Xiamen Biotime Biotechnology Co., Ltd. 3 rd Floor, No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 3610326, P>R. China. Legal manufacturer (as per Form-7: Xiamen Biotime Biotechnology Co., Ltd 2F/3F/4F, No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 36103 Legalized Free Sale Certificate (FSC) No.20200013 valid upto 24-02-2022.	BIOTIME (tPSA Rapid Quantitative Test) BT2404 Class-C Shelf Life: 02- years Fee: Rs=50,000/- dated 07-04- 2022 Date of Application:11-04-2022	Deferred for submission of following documents: (i) Valid Legalized Free Sale Certificate. (ii) Valid notarized ISO13485. (iii) Valid Legalized FSC from reference country/CE Certificate & FQA.
5.	Gulf Marketing International, Gulf House 10&11-B/2, Satellite Town	Legal manufacturer & manufacturer site (as per FSC) Xiamen Biotime	BIOTIME (PCT Rapid Quantitative Test) BT2301	Deferred for submission of following documents: (i) Valid Legalized Free Sale Certificate. (ii) Valid notarized ISO13485.



	Abdullah Jan Masjid Street Near Kali Tanki Said Pur Road, Rawalpindi ELI-00194	Biotechnology Co., Ltd. 3rd Floor , No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 3610326, P>R. China. Legal manufacturer (as per Form-7: Xiamen Biotime Biotechnology Co., Ltd 2F/3F/4F , No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 36103 Legalized Free Sale Certificate (FSC) No.20200013 valid upto 24-02-2022.	Class-C Shelf Life: 02- years Fee: Rs=50,000/- dated 07-04-2022 Date of Application: 11-04-2022	(iii) Valid Legalized FSC from reference country/CE Certificate & FQA.
6.	Gulf Marketing International, Gulf House 10&11-B/2, Satellite Town Abdullah Jan Masjid Street Near Kali Tanki Said Pur Road, Rawalpindi ELI-00194	Legal manufacturer & manufacturer site (as per FSC) Xiamen Biotime Biotechnology Co., Ltd. 3rd Floor , No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 3610326, P>R. China. Legal manufacturer (as per Form-7: Xiamen Biotime Biotechnology Co., Ltd 2F/3F/4F , No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 36103 Legalized Free Sale Certificate (FSC) No.20200013 valid upto 24-02-2022.	BIOTIME (CRP Rapid Quantitative Test) BT2302 Class-C Shelf Life: 02- years Fee: Rs=50,000/- dated 07-04-2022 Date of Application: 11-04-2022	Deferred for submission of following documents: (i) Valid Legalized Free Sale Certificate. (ii) Valid notarized ISO13485. (iii) Valid Legalized FSC from reference country/CE Certificate & FQA.
7.	Gulf Marketing International, Gulf House 10&11-B/2, Satellite Town Abdullah Jan Masjid Street Near Kali Tanki Said Pur Road, Rawalpindi ELI-00194	Legal manufacturer & manufacturer site (as per FSC) Xiamen Biotime Biotechnology Co., Ltd. 3rd Floor , No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 3610326, P>R. China. Legal manufacturer (as per Form-7: Xiamen Biotime Biotechnology Co., Ltd 2F/3F/4F , No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 36103	BIOTIME (HbA1c Rapid Quantitative Test) BT2501 Class-B Shelf Life: 02- years Fee: Rs=25,000/- dated 07-04-2022 Date of Application: 11-04-2022	Deferred for submission of following documents: (i) Valid Legalized Free Sale Certificate. (ii) Valid notarized ISO13485. (iii) Valid Legalized FSC from reference country/CE Certificate & FQA.

		Legalized Free Sale Certificate (FSC) No.20200013 valid upto 24-02-2022.		
8.	Gulf Marketing International, Gulf House 10&11-B/2, Satellite Town Abdullah Jan Masjid Street Near Kali Tanki Said Pur Road, Rawalpindi ELI-00194	Legal manufacturer & manufacturer site (as per FSC) Xiamen Biotime Biotechnology Co., Ltd. 3 rd Floor, No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 3610326, P>R. China. Legal manufacturer (as per Form-7: Xiamen Biotime Biotechnology Co., Ltd 2F/3F/4F, No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 36103 Legalized Free Sale Certificate (FSC) No.20200013 valid upto 24-02-2022.	BIOTIME (25(OH)-D Rapid Quantitative Test) BT2801 Class-B Shelf Life: 02- years Fee: Rs=25,000/- dated 07-04-2022 Date of Application:11-04-2022	Deferred for submission of following documents: (i) Valid Legalized Free Sale Certificate. (ii) Valid notarized ISO13485. (iii) Valid Legalized FSC from reference country/CE Certificate & FQA.
9.	Gulf Marketing International, Gulf House 10&11-B/2, Satellite Town Abdullah Jan Masjid Street Near Kali Tanki Said Pur Road, Rawalpindi ELI-00194	Legal manufacturer & manufacturer site (as per FSC) Xiamen Biotime Biotechnology Co., Ltd. 3 rd Floor, No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 3610326, P>R. China. Legal manufacturer (as per Form-7: Xiamen Biotime Biotechnology Co., Ltd 2F/3F/4F, No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 36103 Legalized Free Sale Certificate (FSC) No.20200013 valid upto 24-02-2022.	BIOTIME (Thyroid Profile : TSH/TT4/TT3Rapid Quantitative Test) BT2209, BT2210, BT2204 Class-B Shelf Life: 02- years Fee: Rs=25,000/- dated 07-04-2022 Date of Application:11-04-2022	Deferred for submission of following documents: (i) Valid Legalized Free Sale Certificate. (ii) Valid notarized ISO13485. (iii) Valid Legalized FSC from reference country/CE Certificate & FQA.
10.	Gulf Marketing International, Gulf House 10&11-B/2, Satellite Town Abdullah Jan Masjid Street Near Kali Tanki Said Pur Road, Rawalpindi	Legal manufacturer & manufacturer site (as per FSC) Xiamen Biotime Biotechnology Co., Ltd. 3 rd Floor, No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian	BIOTIME (Rapid Quantitative Tests for Renal Function Cys-C , NGAL , MAU) BT2601, BT2602, BT2603 Class-B Shelf Life: 02- years Fee: Rs=25,000/- dated 07-04-2022	Deferred for submission of following documents: (i) Valid Legalized Free Sale Certificate. (ii) Valid notarized ISO13485. (iii) Valid Legalized FSC from reference country/CE Certificate & FQA.

	ELI-00194	3610326, P>R. China. Legal manufacturer (as per Form-7: Xiamen Biotime Biotechnology Co., Ltd 2F/3F/4F, No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 36103 Legalized Free Sale Certificate (FSC) No.20200013 valid upto 24-02-2022.	Date of Application: 11-04-2022	
11.	Gulf Marketing International, Gulf House 10&11-B/2, Satellite Town Abdullah Jan Masjid Street Near Kali Tanki Said Pur Road, Rawalpindi ELI-00194	Legal manufacturer & manufacturer site (as per FSC) Xiamen Biotime Biotechnology Co., Ltd. 3rd Floor, No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 3610326, P>R. China. Legal manufacturer (as per Form-7: Xiamen Biotime Biotechnology Co., Ltd 2F/3F/4F, No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 36103 Legalized Free Sale Certificate (FSC) No.20200013 valid upto 24-02-2022.	BIOTIME (β-HCG PROG Rapid Quantitative Test) BT2202, BT2203 Class-B Shelf Life: 02- years Fee: Rs=25,000/- dated 07-04-2022 Date of Application: 11-04-2022	Deferred for submission of following documents: (i) Valid Legalized Free Sale Certificate. (ii) Valid notarized ISO13485. (iii) Valid Legalized FSC from reference country/CE Certificate & FQA.
12.	Gulf Marketing International, Gulf House 10&11-B/2, Satellite Town Abdullah Jan Masjid Street Near Kali Tanki Said Pur Road, Rawalpindi ELI-00194	Legal manufacturer & manufacturer site (as per FSC) Xiamen Biotime Biotechnology Co., Ltd. 3rd Floor, No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 3610326, P>R. China. Legal manufacturer (as per Form-7: Xiamen Biotime Biotechnology Co., Ltd 2F/3F/4F, No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 36103 Legalized Free Sale Certificate (FSC) No.20200013 valid upto 24-02-2022.	BIOTIME (Total IgE Rapid Quantitative Test) BT2901 Class-B Shelf Life: 02- years Fee: Rs=25,000/- dated 07-04-2022 Date of Application: 11-04-2022	Deferred for submission of following documents: (i) Valid Legalized Free Sale Certificate. (ii) Valid notarized ISO13485. (iii) Valid Legalized FSC from reference country/CE Certificate & FQA.

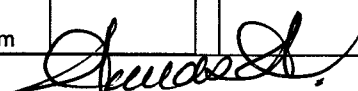
13.	Gulf Marketing International, Gulf House 10&11-B/2, Satellite Town Abdullah Jan Masjid Street Near Kali Tanki Said Pur Road, Rawalpindi ELI-00194	Legal manufacturer & manufacturer site (as per FSC) Xiamen Biotime Biotechnology Co., Ltd. 3 rd Floor, No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 3610326, P>R. China. Legal manufacturer (as per Form-7: Xiamen Biotime Biotechnology Co., Ltd 2F/3F/4F, No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 36103 Legalized Free Sale Certificate (FSC) No.20200013 valid upto 24-02-2022.	BIOTIME (FSH , LH , PRL ,TESTOSTERONE Rapid Quantitative Test) BT2211, BT2205 , BT 2006 , BT 2007 , BT 2208 Class-B Shelf Life: 02- years Fee: Rs=25,000/- dated 07-04-2022 Date of Application:11-04-2022	Deferred for submission of following documents: (i) Valid Legalized Free Sale Certificate. (ii) Valid notarized ISO13485. (iii) Valid Legalized FSC from reference country/CE Certificate & FQA.
14.	Gulf Marketing International, Gulf House 10&11-B/2, Satellite Town Abdullah Jan Masjid Street Near Kali Tanki Said Pur Road, Rawalpindi ELI-00194	Legal manufacturer & manufacturer site (as per FSC) Xiamen Biotime Biotechnology Co., Ltd. 3 rd Floor, No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 3610326, P>R. China. Legal manufacturer (as per Form-7: Xiamen Biotime Biotechnology Co., Ltd 2F/3F/4F, No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 36103 Legalized Free Sale Certificate (FSC) No.20200013 valid upto 24-02-2022.	BIOTIME (Ferritin Rapid Quantitative Test) BT 22701 Class-B Shelf Life: 02- years Fee: Rs=25,000/- dated 07-04-2022 Date of Application:11-04-2022	Deferred for submission of following documents: (i) Valid Legalized Free Sale Certificate. (ii) Valid notarized ISO13485. (iii) Valid Legalized FSC from reference country/CE Certificate & FQA.
15.	Gulf Marketing International, Gulf House 10&11-B/2, Satellite Town Abdullah Jan Masjid Street Near Kali Tanki Said Pur Road, Rawalpindi ELI-00194	Legal manufacturer & manufacturer site (as per FSC) Xiamen Biotime Biotechnology Co., Ltd. 3 rd Floor, No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 3610326, P>R. China. Legal manufacturer (as per Form-7: Xiamen Biotime Biotechnology Co., Ltd 2F/3F/4F, No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 36103 Legalized Free Sale Certificate (FSC) No.20200013 valid upto 24-02-2022.	BIOTIME (BIOT-YG-I FIA Analyzer) Class-B Shelf Life: 02- years Fee: Rs=25,000/- dated 07-04-2022 Date of Application:11-04-2022	Deferred for submission of following documents: (i) Valid Legalized Free Sale Certificate. (ii) Valid notarized ISO13485. (iii) Valid Legalized FSC from reference country/CE Certificate & FQA.

		2F/3F/4F, No.188, Pingcheng South Road, Haicang District, Xiamen, Fujian 36103 Legalized Free Sale Certificate (FSC) No.20200013 valid upto 24-02-2022.		
16.	M/s Qadri Health Co., Head Office, 4- A Mozang Road, Lahore ELI: 00372 (1399) Evaluator: DD-1	Legal manufacturer & manufacturer (as per FSC): M/s Croma Pharma GmbH Industriezeile 6 2100 Leobendorf Austria. Legal manufacturer & manufacturer (as per Form-7A): M/s Croma Industriezeile 6,A-2100 Leobendorf Austria. FSC: Austria Valid till: 23.01.2021	Saypha Filler (Hyaluronic Acid(HA) derma Filler) Size: One ml viscoelastic gel Class: C Shelf Life: Fee: Rs=50,000/- dated 13-02-2020 Date of application: 25-02-2020	Deferred for provision of followings: (i) Authorization letter. (ii) Valid Legalized Free Sale Certificate. (iii) Valid notarized ISO13485.
17.	Crystal Healthcare 10- A, Main Market, Samanabad, Lahore ELI:00166 (3068-P) Evaluator-DD-I	Legal Manufacturer: Fanem LTDA." Rua Arthur Carl Schmidt.186 Cumbica 07222-050-Guarulhos- SP-Brazil FSC: Brazil Valid till: 25/07/2021 FQA submitted & verified by Nando database.	Ampla (Infant Radiant Warmer) Codes & Sizes: As per FSC Class-C Shelf Life: 7 years (No Stability study available) Fee : 50,000/- dated 23-05-2022	Deferred for submission of the following: (i) Valid Legalized Free Sale Certificate. (ii) Stability study data up to the claimed shelf life
18.	Hashir Surgical Services, Office No 16 , Street 1, F-2, Phase 6, Hayatabad, Peshawar Godowns: • Office No, 05, 2nd Floor, Syed 's Tower, University Road, Peshawar •House No. 2 Street No. 1m Gulshan Colony, GT Road, Peshawar ELI: 00075 Dossier# 1982- KP Submission date: 10/12/2020	Legal Manufacturer: Revital healthcare (EPZ) limited LR No. 5025/1239 Msumarini-Mombasa- Malindi Rd, P.O Box 80713-80100 Mombasa- Kenya. FSC: Kenya Valid till: 31.12.2020	Revital Infusion Set (Infusion Set) Codes & Sizes: As per FSC Class-B Shelf Life: 5 years	Deferred for the provision of following documents: (i) FSC of country of origin (Kenya) is expired. (ii) ISO 13485 certificate is expired.

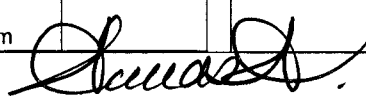
19.	<p>Allmed Solutions, A-21/3, KDA Scheme No.1 (ext) Stadium Road, Karachi (ELI-00029)</p> <p>Date of submission:02.06.2022</p>	<p>M/s Nanjing Shouliang-Med Technology Co. Ltd. China Address: Zhongshan Science Park D9 block, No. 9 Kechuang Avenue, Jiangbei new area, Nanjing city, Jiangsu, China Copy of FSC: China, Valid Till: 20-04-2024</p>	<p>SOLIANG NON-STERILE ELECTROSURGICAL VESSEL SEALER/DIVIDER</p> <p>Article no.</p> <table><tr><th>S. N o.</th><th>Details</th><th>Article no.</th></tr><tr><td>1</td><td>Electrosurgical Generator</td><td>SL100</td></tr><tr><td>2</td><td>Sterile Vessel Sealer / divider</td><td>SL1120A</td></tr><tr><td>3</td><td>Sterile Vessel Sealer / divider</td><td>SL1137A</td></tr><tr><td>4</td><td>Sterile Vessel Sealer / divider</td><td>SL1120S</td></tr><tr><td>5</td><td>Sterile Vessel Sealer / divider</td><td>SL1137S</td></tr><tr><td>6</td><td>Sterile Vessel Sealer / divider</td><td>SL5137S</td></tr><tr><td>7</td><td>Sterile Vessel Sealer / divider</td><td>SL5137A</td></tr><tr><td>8</td><td>Sterile Vessel Sealer / divider</td><td>SL5120S</td></tr><tr><td>9</td><td>Sterile Vessel Sealer / divider</td><td>SL5300S</td></tr><tr><td>10</td><td>Sterile Vessel Sealer / divider</td><td>SL0837</td></tr><tr><td>11</td><td>Sterile Vessel Sealer / divider</td><td>SL0823</td></tr></table> <p>Class C Shelf Life: 2 years</p>	S. N o.	Details	Article no.	1	Electrosurgical Generator	SL100	2	Sterile Vessel Sealer / divider	SL1120A	3	Sterile Vessel Sealer / divider	SL1137A	4	Sterile Vessel Sealer / divider	SL1120S	5	Sterile Vessel Sealer / divider	SL1137S	6	Sterile Vessel Sealer / divider	SL5137S	7	Sterile Vessel Sealer / divider	SL5137A	8	Sterile Vessel Sealer / divider	SL5120S	9	Sterile Vessel Sealer / divider	SL5300S	10	Sterile Vessel Sealer / divider	SL0837	11	Sterile Vessel Sealer / divider	SL0823	<p>Deferred for submission of the following documents:</p> <p>(i) The product is from non-reference country and the firm has not provided FSC of any reference country, therefore, the firm need to submit Embassy attested valid FSC of China.</p> <p>(ii) Notarised and valid CE mark certificate from notified body mentioned in nando data base or embassy attested FSC of any rereference Regulatory authority.</p> <p>(iii) Submit Notarsied and valid ISO 13485 and FQA and DOC.</p> <p>(iv) Notarised and valid Letter of Authorization</p> <p>(v) Clarification of codes and brand names as per FSC required</p> <p>(vi) and clarify whether it's a system or family as per MDR 2017.</p> <p>(vii) Submit complete stability studies</p>
S. N o.	Details	Article no.																																						
1	Electrosurgical Generator	SL100																																						
2	Sterile Vessel Sealer / divider	SL1120A																																						
3	Sterile Vessel Sealer / divider	SL1137A																																						
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10	Sterile Vessel Sealer / divider	SL0837																																						
11	Sterile Vessel Sealer / divider	SL0823																																						
20.	<p>M/s Medtronic Pakistan Private Limited Date of submission 2020</p>	<p>Invatec SpA-Via Martiri della Liberta 7, Roncadelle, 25030 (BS), Italy. FSC itally 25.05.2018 ISO 13485 15.02.2022</p>	<p>Hippocampus-Renal Stent System</p> <p>Class: C</p> <p>Shelf life: 3 years</p>	<p>Deferred fro submission of the following Documents:-</p> <p>(i) Valid and Notarsied FSC in the country of origin with clear brand name.</p> <p>(ii) Valid and notarised letter of Authorization.</p> <p>(iii) Valid ISO 13485 certificate</p> <p>(iv) Complete Stability studies</p> <p>(v) R&I recivings.</p>																																				
21.	<p>CSM Pakistan (Guarantee) Ltd., 23-C, Old Sunset Boulevard, Phase 2, DHA, Karachi</p>	<p>Innolates (Thailand) Limited E1-6, Export Processing Zone, Southern Industrial Estate, Village 4, Chalung, Hatyai, Songkhla,</p>	<p>FLAME – Ultrathin</p> <p>Class C Shelf life 5 Years Fee 50000/-</p>	<p>Deferred for submission of the following documents:-</p> <p>(i) Embassy attested valid FSC wuth clarity for free sale in the country of origin. since in the current FSC the</p>																																				

	(ELI-00418) Date of submission 03.06.2021	90110, Thailand Embassy attested FSC Thailand valid till 15.03.2023		<p>following is written. The product has the same standard as the product sold in the country and exported without restriction</p> <p>(ii) Valid and notarised letter of Authorization letter.</p> <p>(iii) Valid ISO 13485 certificate</p> <p>(iv) Complete Stability</p> <p>(v) Valid and notarised CE certificate from Nando Data base or FSC of RRA.</p>																																	
22.	<p>Johnson & Johnson Pakistan (Pvt) Ltd., Office No.506, 5th Floor, Horizon Tower, Block 3, Scheme 5, Clifton, Karachi</p> <p>(ELI-00154) [2966] 25-08-2020</p>	<p>Legal Manufacturer: Synthes GmbH 3 Eimattstrasse, 4436 Oberdorf, CH</p> <p>FSC # 00015771 valid until 29-Sep-2025 FSC # 00015773 valid until 24-Oct-2025 (submitted in Response to 48th MDB Decision Letter) FSC # 00015778 valid until 24-Oct-2025</p>	<p>Cable Implants</p> <p>Class C</p> <table><tr><th>Codes</th><th>Description s</th><th>Shelf-life (years)</th></tr><tr><td>281.001</td><td>CerclageFix Insert</td><td>N/A</td></tr><tr><td>281.002</td><td>CerclageFix f/LCP 4.5/5.0</td><td>N/A</td></tr><tr><td>291.044</td><td>Coil w/Cerclage Wire Ø 0.4mm, L 8 m</td><td>N/A</td></tr><tr><td>291.050</td><td>Coil w/Cerclage Wire Ø 1.0mm, L 10 m</td><td>N/A</td></tr><tr><td>291.060</td><td>Coil w/Cerclage Wire Ø 1.25mm, L 10 m</td><td>N/A</td></tr><tr><td>291.070</td><td>Coil w/Cerclage Wire Ø 0.6mm, L 8 m</td><td>N/A</td></tr><tr><td>291.090</td><td>Coil w/Cerclage Wire Ø 0.8mm, L 10 m</td><td>N/A</td></tr><tr><td>291.130</td><td>Coil w/Cerclage Wire Ø 1.5mm, L 10 m</td><td>N/A</td></tr><tr><td>298.837</td><td>Cerclage Positioning Pin f/LCP 3.5 + LC-DCP® 3.5</td><td>N/A</td></tr><tr><td>298.839</td><td>Cerclage Positioning</td><td>N/A</td></tr></table>	Codes	Description s	Shelf-life (years)	281.001	CerclageFix Insert	N/A	281.002	CerclageFix f/LCP 4.5/5.0	N/A	291.044	Coil w/Cerclage Wire Ø 0.4mm, L 8 m	N/A	291.050	Coil w/Cerclage Wire Ø 1.0mm, L 10 m	N/A	291.060	Coil w/Cerclage Wire Ø 1.25mm, L 10 m	N/A	291.070	Coil w/Cerclage Wire Ø 0.6mm, L 8 m	N/A	291.090	Coil w/Cerclage Wire Ø 0.8mm, L 10 m	N/A	291.130	Coil w/Cerclage Wire Ø 1.5mm, L 10 m	N/A	298.837	Cerclage Positioning Pin f/LCP 3.5 + LC-DCP® 3.5	N/A	298.839	Cerclage Positioning	N/A	<p>Deferred for the provision of justification grouping of subject device in Family since there are positioning pins, wires, plates, screw and cable included. Justify how all these implants will work together. There are also some implants of sterile nature having shelf life of 10 years whereas other have no shelf life.</p>
Codes	Description s	Shelf-life (years)																																			
281.001	CerclageFix Insert	N/A																																			
281.002	CerclageFix f/LCP 4.5/5.0	N/A																																			
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298.837	Cerclage Positioning Pin f/LCP 3.5 + LC-DCP® 3.5	N/A																																			
298.839	Cerclage Positioning	N/A																																			

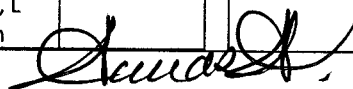
				Pin f/LCP 4.5 + LC- DCP® 4.5	
			481.002	CerclageFix f/LCP 4.5/5.0	N/A
			498.806	TRD - Trochanter Reattachm ent Device, small	N/A
			498.807	TRD - Trochanter Reattachm ent Device, large	N/A
			498.837	Cerclage Positioning Pin f/LCP 3.5 + LC- DCP® 3.5	N/A
			498.839	Cerclage Positioning Pin f/LCP 4.5 + LC- DCP® 4.5	N/A
			02.221.0 02.05	Cerclage Eye f/Screws Ø 3.5mm	N/A
			02.221.0 02S	Cerclage Eye f/Screws Ø 3.5mm	10
			02.221.0 03.05	Cerclage Eye f/Screws Ø 4.5mm	N/A
			02.221.0 03S	Cerclage Eye f/Screws Ø 4.5mm	10
			02.221.0 04.05	Cerclage Eye f/Hexagona l Socket, Ø 4.0mm	N/A
			02.221.0 04S	Cerclage Eye f/Hexagona l Socket, Ø 4.0mm	10
			02.231.0 22	Positioning Pin f/VA 5.0, cruciform	N/A
			02.231.0 22S	Positioning Pin f/VA 5.0, cruciform	10



			02.401.0 00S	Wire-Cable Ø 1.0mm, w/Crimp	10
			04.221.0 02.05	Cerclage Eye f/Screws Ø 3.5mm	N/A
			04.221.0 02S	Cerclage Eye f/Screws Ø 3.5mm	10
			04.221.0 03.05	Cerclage Eye f/Screws Ø 4.5mm	N/A
			04.221.0 03S	Cerclage Eye f/Screws Ø 4.5mm	10
			04.221.0 04.05	Cerclage Eye f/Hexagona l Socket, Ø 4.0mm	N/A
			04.221.0 04S	Cerclage Eye f/Hexagona l Socket, Ø 4.0mm	10
			04.231.0 22	Positioning Pin f/VA 5.0, cruciform	N/A
			04.231.0 22S	Positioning Pin f/VA 5.0, cruciform	10
			281.001 S	CerclageFix Insert	10
			281.002 S	CerclageFix f/LCP 4.5/5.0	10
			291.010. 01	Cerclage Wire Ø 1.0mm w/Eye, L 280mm	N/A
			291.010. 10	Cerclage Wire Ø 1.0mm w/Eye, L 280mm	N/A
			291.020. 01	Cerclage Wire Ø 1.25mm w/Eye, L 280mm	N/A
			291.020. 10	Cerclage Wire Ø 1.25mm	N/A



				w/Eye, L 280mm	
			291.030. 01	Cerclage Wire Ø 1.0mm w/Eye, L 600mm	N/A
			291.030. 10	Cerclage Wire Ø 1.0mm w/Eye, L 600mm	N/A
			291.040. 01	Cerclage Wire Ø 1.25mm w/Eye, L 600mm	N/A
			291.040. 10	Cerclage Wire Ø 1.25mm w/Eye, L 600mm	N/A
			291.080. 01	Cerclage Wire Ø 0.8mm w/Eye, L 280mm	N/A
			291.080. 10	Cerclage Wire Ø 0.8mm w/Eye, L 280mm	N/A
			291.110. 01	Cerclage Wire Ø 1.5mm w/Eye, L 280mm	N/A
			291.110. 10	Cerclage Wire Ø 1.5mm w/Eye, L 280mm	N/A
			291.120. 01	Cerclage Wire Ø 1.5mm w/Eye, L 600mm	N/A
			291.120. 10	Cerclage Wire Ø 1.5mm w/Eye, L 600mm	N/A
			291.220. 01	Cerclage Wire Ø 0.4mm, L 150mm	N/A
			291.220. 10	Cerclage Wire Ø 0.4mm, L 150mm	N/A



			291.240.01	Cerclage Wire Ø 0.6mm, L 175mm	N/A
			291.240.10	Cerclage Wire Ø 0.6mm, L 175mm	N/A
			291.260.01	Cerclage Wire Ø 0.8mm, L 200mm	N/A
			291.260.10	Cerclage Wire Ø 0.8mm, L 200mm	N/A
			291.270.01	Cerclage Wire Ø 1.0mm, L 250mm	N/A
			291.270.10	Cerclage Wire Ø 1.0mm, L 250mm	N/A
			291.280.01	Cerclage Wire Ø 1.25mm, L 300mm	N/A
			291.280.10	Cerclage Wire Ø 1.25mm, L 300mm	N/A
			298.800.01	Cerclage Cable w/Crimp Ø 1.0mm	N/A
			298.800.01S	Cerclage Cable w/Crimp Ø 1.0mm	10
			298.801.01	Cerclage Cable w/Crimp Ø 1.7mm	N/A
			298.801.01S	Cerclage Cable w/Crimp Ø 1.7mm	10
			298.803.01	Positioning Pin 4.5 w/thread	N/A
			298.803.01S	Positioning Pin 4.5 w/thread, f/LCP	10
			298.837S	Cerclage Positioning Pin f/LCP+LC-DCP® 3.5	10



			298.838.01	Positioning Pin 3.5 w/thread	N/A
			298.838.01S	Positioning Pin 3.5 w/thread, f/LCP	10
			298.839S	Cerclage Positioning Pin f/LCP+LC-DCP® 4.5	10
			498.800.01	Cerclage Cable w/Crimp Ø 1.0mm	N/A
			498.800.01S	Cable w/Crimp Ø 1.0mm	10
			498.803.01	Positioning Pin 4.5 w/thread, f/LCP	N/A
			498.803.01S	Positioning Pin 4.5 w/thread, f/LCP	10
			498.806S	TRD-Troch. Reattachm. Device, small, f/Cable Syst.	10
			498.807S	TRD-Troch. Reattachm. Device, large, f/Cable Syst.	10
			498.837S	Cerclage Positioning Pin f/LCP+LC-DCP® 3.5	10
			498.838.01	Positioning Pin 3.5 w/thread, f/LCP	N/A
			498.838.01S	Positioning Pin 3.5 w/thread, f/LCP	10
			498.839S	Cerclage Positioning Pin f/LCP+LC-DCP® 4.5	10
			611.105.01	Cerclage Cable w/Crimp Ø 1.7mm	N/A

			<table><tr><td>611.105.01S</td><td>Cerclage Cable w/Crimp Ø 1.7mm</td><td>10</td></tr><tr><td>9014-6/50</td><td>Tubercable Ø 1.0mm, w/Crimp</td><td>10</td></tr></table> <p>Fee Deposited: PKR 50,000/-</p> <p>Submission Date: 25-Aug-20</p>	611.105.01S	Cerclage Cable w/Crimp Ø 1.7mm	10	9014-6/50	Tubercable Ø 1.0mm, w/Crimp	10	
611.105.01S	Cerclage Cable w/Crimp Ø 1.7mm	10								
9014-6/50	Tubercable Ø 1.0mm, w/Crimp	10								
23.	Raffay Associates Office No. 04, 2nd Floor Ahmed Plaza Range Road, Rawal+B2555: M2555pidni ELI: 00021 3980-P 11-07-2023	<p>Legal Manufacturer Sewoon Medical Co., Ltd, 60 Dorim-gil, Ipjang-myeon, Seobuk-gu, Cheonan-si, Chungcheongnamdo, Korea</p> <p>FSC: Korea Date of Issue: 2016/05/16</p> <p>FSC UK Date of Issue: 17/05/2018</p>	BONASTENT ® (Partially Covered) (Self-Expandable Metallic (Partially Covered)) Class-C Shelf Life: 3 years Codes & Sizes: As per FSC	<p>Deferred for the provision of following documents: -</p> <p>(i) Valid and original LOA, duly notarized.</p> <p>(ii) Original and attested FSC of Korea.</p> <p>(iii) Original and attested FSC of MHRA, UK.</p> <p>(iv) Valid and notarized ISO 13485 certificate.</p>						
24.	Medical Devices Specialty, Office # 1-2, First Floor, Al-Riaz Plaza, Bank Road Saddar, Rawalpindi. ELI: 00919 3958-P 12-06-2023	<p>Legal Manufacturer: M/s Eyekon Medical Inc. 2451 Enterprises Road Clearwater, Florida, USA 33763</p> <p>Certificate of Exportability USA Valid till: 26/05/2023</p>	Acuity Hydroflex II Advance Series (Hydrophilic Foldable IOL) Class-C Shelf Life: 5 Years Code: FS25B-UV	<p>Deferred for the provision of following documents: -</p> <p>(i) Original and legalized documents as the submitted documents are copies.</p> <p>(ii) FSC in the country of origin.</p>						
25.	Vertex Medical (Pvt) Ltd, 70-B-1, Gulberg-III, Lahore ELI-00150 3153-P	<p>Legal Manufacturer: LivaNova Deutschland GmbH Lindberghstr.25 80939 Munich-Germany</p> <p>FSC: Germany Date of Issue: 23/02/2022</p>	Stockert 3T Heater Cooler System (Heater Cooler System) Class-C Service Life: 10 years Model: 16-02-80	<p>Deferred for clarification as same product from the same manufacturer having same Brand name and Model is registered with Pharma consultant, Lahore.</p>						
26.	Shams Scientific Traders, 22-Y-J Madina Town, Faisalabad ELI: 00459 3567-P 11-05-2022	<p>Legal Manufacturer: Healgen Scientific LLC, 3818 Fuqua Street, Houston, TX 77047, USA.</p> <p>Manufacturing site: M/s Zhejiang Orient Gene Biotech Co., Ltd., 3787, east Yangguang Avenue, Dipu street Anji 313300 Huzhou, Zhejiang, China</p> <p>FSC Belgium:</p>	Healgen Typhoid Ag Rapid Test Cassette (Serum/Plasma) Class-C Shelf Life: 24 Months Codes & Sizes: As per FSC	<p>Deferred for the provision of following documents: -</p> <p>(i) Manufacturing site is not mentioned on FSC of Belgium.</p> <p>(ii) Linkup letter between the Legal manufacturer and the physical manufacturer is required.</p> <p>(iii) The device is not mentioned on provided FSC of Belgium.</p>						



		Date of Issue: 14.04.2021		
27.	Shams Scientific Traders, 22-Y-J Madina Town, Faisalabad ELI: 00459 3563-P 11-05-2022	<u>Legal Manufacturer:</u> Healgen Scientific LLC, 3818 Fuqua Street, Houston, TX 77047, USA. <u>Manufacturing site:</u> M/s Zhejiang Orient Gene Biotech Co., Ltd., 3787, east Yangguang Avenue, Dipu street Anji 313300 Huzhou, Zhejiang, China FSC Belgium: Date of Issue: 14.04.2021	Healgen Dengue IgM/IgG Antibody Test Cassette Class-C Shelf Life: 24 months Codes & Sizes: As per FSC	Deferred for the provision of following documents: - (i) Manufacturing site is not mentioned on FSC of Belgium. (ii) Linkup letter between the Legal manufacturer and the physical manufacturer is required.
28.	Shams Scientific Traders, 22-Y-J Madina Town, Faisalabad ELI: 00459 3562-P 11-05-2022	<u>Legal Manufacturer:</u> Healgen Scientific LLC, 3818 Fuqua Street, Houston, TX 77047, USA. <u>Manufacturing site:</u> M/s Zhejiang Orient Gene Biotech Co., Ltd., 3787, east Yangguang Avenue, Dipu street Anji 313300 Huzhou, Zhejiang, China FSC Belgium: Date of Issue: 14.04.2021	Healgen Corona Virus Ag Rapid Test Cassette (Swab) Class-C Shelf Life: 24 months Codes & Sizes: As per FSC	Deferred for the provision of following documents: - (i) Manufacturing site is not mentioned on FSC of Belgium. (ii) Linkup letter between the Legal manufacturer and the physical manufacturer is required. (iii) The device is not mentioned on provided FSC of Belgium.
29.	Shams Scientific Traders, 22-Y-J Madina Town, Faisalabad ELI: 00459 3566-P 11-05-2022	<u>Legal Manufacturer:</u> Healgen Scientific LLC, 3818 Fuqua Street, Houston, TX 77047, USA. <u>Manufacturing site:</u> M/s Zhejiang Orient Gene Biotech Co., Ltd., 3787, east Yangguang Avenue, Dipu street Anji 313300 Huzhou, Zhejiang, China FSC Belgium: Date of Issue: 14.04.2021	Healgen HbsAg Hepatitis B Envelop Antigen Test Class-D Shelf Life: 2 years Codes & Sizes: As per FSC	Deferred for the provision of following documents: - (i) Manufacturing site is not mentioned on FSC of Belgium. (ii) Linkup letter between the Legal manufacturer and the physical manufacturer is required. (iii) The device is not mentioned on provided FSC of Belgium.
30.	Shams Scientific Traders, 22-Y-J Madina Town, Faisalabad ELI: 00459 3565-P 11-05-2022	<u>Legal Manufacturer:</u> Healgen Scientific LLC, 3818 Fuqua Street, Houston, TX 77047, USA. <u>Manufacturing site:</u> M/s Zhejiang Orient Gene Biotech Co., Ltd., 3787, east Yangguang Avenue, Dipu street Anji 313300 Huzhou, Zhejiang, China FSC Belgium:	Healgen HBV COMBO TEST Class-B Shelf Life: 24 months Codes & Sizes: As per FSC	Deferred for the provision of following documents: - (i) Manufacturing site is not mentioned on FSC of Belgium. (ii) Linkup letter between the Legal manufacturer and the physical manufacturer is required. (iii) The device is not mentioned on provided FSC of Belgium.

		Date of Issue: 14.04.2021		
31.	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	Deferred for the provision of following documents: - (i) Original and valid LOA, FSC, Credentials, ISO 13485 and FQA certificates.
32.	AMB HK Enterprises (Pvt) Ltd, 2nd Floor Plaza 60, Commercial Block-K, Phase-1, DHA, Lahore ELI: 00863 Dossier# 3675-P Submission date: 14/02/2023	Legal Manufacturer: M/s Jiangxi Fenglin Medical Appliance Co., Ltd, Fulin Road, Fuzhou City, Jiangxi Province, China FSC: CHINA Valid till: 10/03/2022	IV CANNULA (With injection valve) Codes & Sizes: As per FSC Class-B Shelf Life: not provided Storage Temperature: +5 to +25°C	Deferred for the provision of following documents: (i) Photocopied FSC of country of origin is provided which was expired at the time of submission. (ii) Brand name is not provided. (iii) Stability data is not provided. (iv) Essential principle of safety & performance is not provided. (v) Declaration on stamp paper as per form-7 A is not provided. (vi) Medical device class is not mentioned on DOC. (vii) Clarify the type of IV cannula
33.	A&E Medical 323-ATA Turk Block New Garden Town Lahore ELI:00023 Dossier# 1610-P Submission date: 13/08/2020	Legal Manufacturer Sunny Medical Device (Shenzhen) Co., Ltd 1/F and 401, Zhongtianxin B, Longgang District, Shenzhen, Guangdong, China FSC: china Valid till: 14.05.2020	Pressure Lines (Angiographic Guide wire) Class-B Shelf Life: 3 years	Deferred for the provision of following documents: (i) LOA, ISO 13485 certificate & (ii) CE certificate are expired. (iii) FSC of country of origin is provided which was expired at the time of submission. (iv) Credentials of manufacturer duly notarized from country of origin is not provided. (v) Stability data for the claimed shelf life is not provided. (vi) Copy of valid establishment license is not provided.
34.	A&E Medical 323-ATA Turk Block New Garden Town Lahore	Legal Manufacturer Sunny Medical Device (Shenzhen) Co., Ltd 1/F and 401, Zhongtianxin B, Longgang District,	Pressure Lines (Extension Tubes) Class-B Shelf Life: 3 years	Deferred for the provision of following documents: (i) LOA, ISO 13485 certificate &

	ELI:00023 Dossier# 1588-P Submission date: 14/07/2020	Shenzhen, Guangdong, China FSC: china Valid till: 14.05.2020		(ii) CE certificate are expired. (iii) FSC of country of origin is provided which was expired at the time of submission. (iv) Credentials of manufacturer duly notarized from country of origin is not provided. (v) Stability data for the claimed shelf life is not provided. (vi) Copy of valid establishment license is not provided.
35.	Ameer Din and Sons, 305-A, Upper Mall, Lahore ELI: 00058 Dossier# 2419-P Submission date: 27/04/2021	Legal Manufacturer Cooper Vision Manufacturing Ltd, South Point Hamble Southampton SO31 4RF UK FSC: UK Date of Issue. 14.10.2020	Cooper Vision ® Biomedics 1 Day Extra (Soft Contact Lens) Codes & Sizes: As per FSC Class-B Shelf Life: 7 year	Deffered for the provision of following documents: (i) LOA, ISO 13485 certificate & (ii) CE certificate are expired. (iii) Clarify the brand name as it is Biomedics 1 Day Extra on FSC and all other documents while it's Cooper Vision ® on applied form-7A. (iv) Declaration on stamp paper as per form-7 A is not provided.
36.	Mian Enterprises, Office No. UG-400 Deans Trade Center, Peshawar Cantt 25000, Pakistan ELI: 00507 Dossier# 3699-KP Submission date: 19/01/2023	Legal Manufacturer: M/s Micromed Srl Via Val Padana n. 126 B/2-00141, Roma (RM), Italy Manufacturing site Address: Via Guglielmo Oberdan, 21-00013-Fonte Nuova (RM), Italy FSC: not provided	MICROGAS (Eye implants) (MicroSF6P MicroSF6M MicroC2F6P MicroC2F6PM MicroC3F8P MicroC3F8M) Class: C Shelf Life: 5 years	Deffered for the provision of following documents: (i) Credentials of manufacturer duly notarized from country of origin is not provided. (ii) Notarized LOA, FQA & ISO certificates are not provided. (iii) FQA is expired at the time of submission. (iv) FSC of reference country and country of origin are not provided. (v) Stability data for the claimed shelf life is not provided
37.	Mian Enterprises, Office No. UG-400 Deans Trade Center, Peshawar Cantt 25000, Pakistan ELI: 00507 Dossier# 3696-KP Submission date: 19/01/2023	Legal Manufacturer: M/s Micromed Srl Via Val Padana n. 126 B/2-00141, Roma (RM), Italy Manufacturing site Address: Via Guglielmo Oberdan, 21-00013-Fonte Nuova (RM), Italy FSC: not provided	(PDMS (Silicon Oil) Codes & Sizes: As per FSC Class: C Shelf Life: 5 years	Deffered for the provision of following documents: (i) Credentials of manufacturer duly notarized from country of origin is not provided. (ii) Notarized LOA, FQA & ISO certificates are not provided. (iii) FQA is expired at the time of submission.

				<p>(iv) FSC of reference country and country of origin are not provided.</p> <p>(v) Stability data for the claimed shelf life is not provided</p>
38.	MR Medical Pakistan Private Limited, Office No. 1101, 11th Floor, ISE Tower, Jinnah Avenue, Blue Area Islamabad. ELI-01008 Dossier# 3297-P Submission date: 01/08/2022	Legal Manufacturer: Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, People's Republic of China FSC: Germany Issue date: 02/02/2021	MINDRAY (Medical Supply Unit) Codes & Sizes: As per FSC Class-C Shelf Life: 10 years	Deferred for the provision of following documents: <p>(i) FSC of reference country and FSC of country of origin are not provided.</p> <p>(ii) Stability data is not provided for the claimed shelf life.</p>
39.	Healthcare Enterprises Makkah tower 5th floor office no. 507, Namak Mandi Peshawar ELI No. 00931 Dossier# 355-c Submission date: 03/11/2022	Legal Manufacturer: Advanced Medical Solutions Limited Premier Park 33 Road one Winsford Industrial Estate Winsford Cheshire, CW73RT,UK FSC : UK Valid till: 26/05/2025	Activheal Alginate (Exudate-absorbent dressing, hydrophilic-gel) Codes & Sizes: As per FSC Class-C Shelf Life: 05 years	Deferred for the provision of following documents: <p>(i) Provide original, valid & notarized LOA.</p> <p>(ii) Credentials of manufacturer duly notarized from country of origin is not provided.</p> <p>(iii) Product label is not provided.</p> <p>(iv) Provide product catalogue with complete description.</p> <p>(v) Declaration on stamp paper is not provided.</p> <p>(vi) Stability data of claimed shelf life is not provided.</p> <p>(vii) Apply separate case with separate fee for Activheal Alginate rope.</p>
40.	Healthcare Enterprises Makkah tower 5th floor office no. 507, Namak Mandi Peshawar ELI No. 00931 Dossier# 356-c Submission date: 03/11/2022	Legal Manufacturer: Advanced Medical Solutions Limited Premier Park 33 Road one Winsford Industrial Estate Winsford Cheshire, CW73RT,UK FSC : UK Valid till: 26/05/2025	ActivHeal Hydrogel (Hydrogel dressing sterile) Codes & Sizes: As per FSC Class-C Shelf Life: 03 years	Deferred for the provision of following documents: <p>(i) Provide original, valid & notarized LOA.</p> <p>(ii) Credentials of manufacturer duly notarized from country of origin is not provided.</p> <p>(iii) Product label is not provided.</p> <p>(iv) Provide product catalogue with complete description.</p> <p>(v) Declaration on stamp paper is not provided.</p> <p>(vi) Stability data of claimed shelf life is not provided.</p>

				(vii) Submit revised form-7A as incorrect MD class mentioned on it i.e., class D while product falls in Class C
41.	Healthcare Enterprises Makkah tower 5th floor office no. 507, Namak Mandi Peshawar ELI No. 00931 Dossier# 357-c Submission date: 03/11/2022	Legal Manufacturer: Advanced Medical Solutions Limited Premier Park 33 Road one Winsford Industrial Estate Winsford Cheshire, CW73RT,UK FSC : UK Valid till: 26/05/2025	ActivHeal Aquafiber Ag (Exudate-absorbent dressing, hydrophilic gel-forming antimicrobial) Codes & Sizes: As per FSC Class-D Shelf Life: 03 years	Deferred for the provision of following documents: (i) Provide original, valid & notarized LOA. (ii) Credentials of manufacturer duly notarized from country of origin is not provided. (iii) Product label is not provided. (iv) Provide product catalogue with complete description. (v) Declaration on stamp paper is not provided. (vi) Stability data of claimed shelf life is not provided. (vii) Design examination certificate is not provided.
42.	Healthcare Enterprises Makkah tower 5th floor office no. 507, Namak Mandi Peshawar ELI No. 00931 Dossier# 358-c Submission date: 03/11/2022	Legal Manufacturer: Advanced Medical Solutions Limited Premier Park 33 Road one Winsford Industrial Estate Winsford Cheshire, CW73RT,UK FSC : UK Valid till: 26/05/2025	Activheal Hydrocollide film Backed Activheal Hydrocollide foam Backed (Hydrocolloid Dressing/Exudate-absorbent dressing, hydrophilic gel) Codes & Sizes: As per FSC Class-C Shelf Life: 03 years	Deferred for the provision of following documents: (i) Provide original, valid & notarized LOA. (ii) Credentials of manufacturer duly notarized from country of origin is not provided. (iii) Product label is not provided. (iv) Provide product catalogue with complete description. (v) Declaration on stamp paper is not provided. (vi) Stability data of claimed shelf life is not provided. (vii) Apply separate case with separate fee for Activheal Hydrocollide foam Backed.
43.	Samzco Trading Company, Office No. 501,, Imperial Optical Center, Masjid Street, Ghari Khatta M. A Jinnah Road, Karachi (ELI-00685)	Legal Manufacturer: Wohlk Contactlinsen GMBH BurgerMeister-Schade- Str.12, 24232 Schon kirchen, Germany FSC: not provided.	Zeiss Contact Day 1 (Contact Lenses) Codes & Sizes: As per FSC Class-C Shelf Life: 05 years	Deferred for the provision of following documents: (i) LOA is not notarized. (ii) ISO certificate is expired upon submission. (iii) FSC of country of origin/ Reference country are not provided. (iv) Credentials of manufacturer


	Dossier#4646-7A Date:19-07-22			must be in English language and duly notarized from country of origin. (v) Stability studies data must be provided in English language
44.	Samzco Trading Company, Office No. 501,, Imperial Optical Center, Masjid Street, Ghari Khatta M. A Jinnah Road, Karachi (ELI-00685) Dossier#4877-7A Date:07-07-22	Legal Manufacturer: Wohlk Contactlinsen GMBH BurgerMeister-Schade-Str.12-6 24232 Schon kirchen, Germany FSC: not provided.	Zeiss Contact Day 30 (Contact Lenses) Codes & Sizes: As per FSC Class-C Shelf Life: 05 years	Deferred for the provision of following documents: (i) LOA is not notarized. (ii) ISO certificate is expired upon submission. (iii) FSC of country of origin/ Reference country are not provided. (iv) Credentials of manufacturer must be in English language and duly notarized from country of origin. (v) Stability studies data must be provided in English language.
45.	Oasis Medical Systems, Bangalow No. A-86, block C, Gulshan-e-Jamal, Karachi, 75360, Pakistan. (ELI-00495) Dossier#1448-C Date:04-04-23	Legal Manufacturer: UTAS technologies S.R.O., 1, Stavitel'ska st., Bratislava,83104, Slovakia FSC: Slovakia Issued: 26-04-2021	UTAS (Patient Monitor UM-300S) Codes & Sizes: As per FSC Class-C Shelf Life: 05 years	Deferred for the provision of following documents: (i) Photocopies of all relevant documents are provided. (ii) Submit Original, embassy attested FSC, notarized LOA, Credentials of manufacturer, ISO certificate & FQA certificate. (iii) ISO certificate is expired.
46.	Technology Links (Pvt) Ltd Office # 4/18 Rimpa Plaza 4th Floor, M.A. Jinnah Road, Karachi Pakistan (ELI-00427) Dossier#4802-7A Date:30-09-22	Legal Manufacturer: Enraf Nonius B.V. Vareseweg 127, 3047 Rotterdam, Netherland FSC: Netherland (Original) Valid Till: 26-5-2024	Eltrac 471 (Traction Therapy Device) Codes & Sizes: As per FSC Class-C Shelf Life: Not provided.	Deferred for the provision of following documents: (i) LOA is expired on 31/12/2022. (ii) ISO certificate is expired. (iii) Stability data is not provided for the shelf life.
47.	Universal Enterprise, Karachi (ELI-00079) 3183 Date (R&I) 05-11-2020	Legal Manufacturer: M/S Terumo Corporation, Japan. Manufacturing site: M/S Ashitaka factory of terumo Corporation 150 Maimaigi-Cho, Fujinomiya-Shi, Shizuoka 418-0015, Japan. M/S Terumo	Terufusion Syringe Pump Software (TE-SS830) (TE-SS730) N Standard Rack System (TE-RS800) N Communication Rack system (Extension)(TE-RS800) No3 Class C HS Code 9018.9090 GMDN code 13217	Deferred for provision of following documents (i) Valid & notarized FSC of country of origin, Letter of authorization & ISO 13485, Form-7A not signed stamped, Credential of manufacturer abroad, Clarification required regarding stability/service life of product, (ii) Grouping of medical device

		<p>Corporation ME center</p> <p>M/S OKI Electric industry CO. Ltd Corporation ME center</p> <p>FSC of Japan(copy) Date of issuance 19-01-2018, valid upon submission. (software Model not found in FSC)</p>	<p>Fee: 50,000/-</p>	
48.	<p>M/s. United Healthcare Plot No. 330/B Second Floor, DMCHS, Bahadurabad, Karachi. ELI 00293</p>	<p>M/s Huaian Medicom Medical Technology Co. Ltd.,</p> <p>N0123 Meicheng west road, Qingpu industry park, huaian city, Jiangsu, China</p> <p>Sterilization Site: M/s. Changzhou Medical & Health Suppliers Sterilization Co., Ltd. Heping Village Zhenglu Town, Wujin District 213114 Changzhou City China. FSC Germany issued on 10-05-2020</p> <p>FSC provided is not for relevant product</p>	<p>Star IV Catheter with Injection Port Plus Heparin Cap</p> <p>Class B</p> <p>Shelf Life: 05 Years</p> <p>Codes & Sizes: As per FSC</p>	<p>Deferred for Clarification and submission of CE marking certificate, FSC of Country of origin for combination as applied.</p>
49.	<p>M/s Otsuka Pakistan LtdNo. F/4-9, Hub Industrial Trading Estate, Distt. Lasbella, Balochistan , Pakistan (ELI-00053)</p> <p>14204 Date (R&I) 27-03-2022</p>	<p>Legal Manufacturer:</p> <p>M/s Eucatech AG, Rebgertenweg 27, 79576 weil am Rhein/ Germany</p> <p>FSC (Copy not notorised) of Germany DOI 05-04-2022</p>	<p>Euca VI</p> <p>Generic Name: PTCA ballon Catheter Codes as per FSC:</p> <p>Class: D Family</p> <p>Codes and sizes. GMDN 47732 UMDNS 17-184</p>	<p>Deferred for Clarification and submission of valid& notorised FSC, LOA, Stability data.</p>
50.	<p>Noor international, 29-D, Block 6, PECHS, Karachi (ELI-00061), 03-08-2018 3187 Date (R&I) 23-9-2020</p>	<p>Legal Manufacturer:</p> <p>Radiometer Medical ApS Akandevej 21 2700 Bronshoj-Denmark</p> <p>Manufacturing site: Assays and consumables Radiometer Turku , Oy Biolinja12, 2075 turku, Finland Radiometer Solutions Sp. Zo.o</p>	<p>AQT 90 Flex Analyser with reagents and samplers 9027.8000 AQT flex analyser 9018.3120 Samplers (IVDD) Class C Code 393-899 Shelf Life: N/A Fee: 50,000/-</p>	<p>Deferred for clarification The firm has applied clustering of class C products which is not consistent with MDR 2017 which allows Clustering of class A/B products only therefore justify clustering as per MDR 2017 and revise form-7A or clarify.</p> <p>Complete stability study required.</p> <p>Valid & Notorised LOA, ISO</p>

		Stalowa 6, Stargard 73-110, Poland Ivd FSC of Denmark expired on 5-12-2021, valid upon submission		13485, FQAS required.
51.	M/s Tech Zone, 764 Askari 9 Zarar Shaheed Road Cantt Lahore, WH: Ground Floor, Weal House 8 Faiz road, Lahore ELI: 00040 888-C 23-01-2023	Legal Manufacturer: Jiangsu Nanfang Medical Co., Ltd 1 Guoxiang RD Wujin Economic Development Zone 213149 Changzhou city, Jianagsu Province China FSC China validity 19-08-2024	Yashfaeen zinc Oxide Adhesive Plaster Class-A Shelf life: 3 years Codes as per FSC	Deferred as the Device is not mentioned in FSC.
52.	Vertex Medical (Pvt) Ltd, 70-B- 1, Gulberg III, Lahore. ELI: 00150 3154-P 22-07-2022	Legal Manufacturer: LivaNova Deutschland GmbH Lindberghstr.25 80939 Munich- Germany FSC: Germany Date of Issue: 23/02/2022	Stockert S5 (Heart Lung Machine) Class-C Shelf Life: 10 years Code: 45-95-02	Deferred for original LOA and clarification as same product from the same manufacturer having same Brand name and Model is registered with Pharma consultant, Lahore.
53.	Medco Healthcare, 155, Block 3 C.P Barar Society, Alamgir Road Karachi ELI-00072	Manufacturer OBS BAISHENG MEDICAL CO., LTD of No.11 Fusheng Road, Xinhui District, Jiangmen, Guangdong, China. FSC China. 05/12/2023	OBS Diathermy Pencil. Class-B Claimed Shelf life: 5Years Codes: OBS-Db #0039, #1031A. Sizes: Nil	Deferred for submission of the following (i) Clarify the brand name since the firm provided FSC having name electrosurgical Pencil. Furthermore, the company in the FSC is BAISHENG MEDICAL CO., LTD however previous name is OBS BAISHENG MEDICAL CO., LTD need clarification or revise Form7A A as per FSC . (ii) Provide valid LOA

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 20 days after uploading of this letter on official website of DRAP.


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