

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:-

<u>DEFERRED CASES OF ENLISTMENT/REGISTRATION OF MEDICAL DEVICES TO LOCAL MANUFACTURE – SUBMISSION OF DEFICIENT INFORMATION/DOCUMENTS THEREOF</u>

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.	Name & Address of Establishment	Name of Medical Devices with	Decision
No.		sizes	
(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.

Additional Director (MDMC)/ Secretary MDB



No.F.4-11/2023-MD (M-61) Government of Pakistan try of National Health Sorvings Regulations 8

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 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	Name of	Name of Medical Devices	Decision
<u>(I)</u>	Importer	Manufacturer (III)	/ ** **	
	(II)	(III)	(IV)	(V)
	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.

Deferred Letters of 61st Meeting of MDB (26-09-2023)

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		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	manufacturer site (as per FSC) Xiamen Biotime Biotechnology Co., Ltd.	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. 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 (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.

	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.

International, Gulf House 10&11-B/2, Satellite Town Abdullah Jan Masjid Street Near Kali Tanki Said Pur Road, Rawalpindi ELI-00194 Gulf Marketing International, Gulf House	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. Legal manufacturer &	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.
International, Gulf House	Legal manufacturer &	DIOTIME	Deferred for submission of
Abdullah Jan Masjid Street Near Kali Tanki Said Pur Road, Rawalpindi ELI-00194	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.	(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	following documents: (i) Valid Legalized Free Sale Certificate. (ii) Valid notarized ISO13485. (iii) Valid Legalized FSC from reference country/CE Certificate & FQA.
International, Gulf House 10&11-B/2, Satellite Town Abdullah Jan Masjid Street Near Kali Tanki Said Pur Road,	Legal manufacturer & manufacturer site (as per FSC) Xiamen Biotime Biotechnology Co., Ltd. 3rd 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	Date of Application:11-04-2022	
		Legalized Free Sale Certificate (FSC) No.20200013 valid upto 24-02-2022.		
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	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.202000013 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.
eferred	Letters of 61st N	Meeting of MDB (26-0)	9-2023) Sunas	Page 6 of 24

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. 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 (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. 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 (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. 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 (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	Deffered for the provision of following documents: (i) FSC of country of origin (Kenya) is expired. (ii) ISO 13485 certificate is expired.

19.	Allmed Solutions, A-21/3, KDA Scheme No.1 (ext) Stadium	M/s Nanjing Shouliang- Med Technology Co. Ltd. China Address: Zhongshan Science Park D9 block,	ELECT	IG NON-STERI ROSURGICAL R/DIVIDER 0.	Deferred for submession of the following documents: (i) The product is from non-reference country and the firm has not provided FSC o	
	Road, Karachi (ELI-00029)	No. 9 Kechuang Avenue, Jiangbei new area, Nanjing city, Jiangsu, China	S. N	Details	Article no.	any reference country, therefore, the firm need to submit Embassy attested valid FSC of China.
	Date of submission:02.0	Copy of FSC: China, Valid Till: 20-04-2024	1	Electrosurgic al Generator Sterile Vessel	SL100	(ii) Notarsed and valid CE mark certicfate from notified body mentioned in nando data
	6.2022		2	Sealer / divider Sterile Vessel	SL1120A	base or embassy attested FSo of any rerefrence Regulatory authority.
			3	Sealer / divider Sterile Vessel	SL1137A	(iii) Submit Notarsied and valid ISO 13485 and FQA and DOC.
			4	Sealer / divider Sterile Vessel	SL1120S	(iv) Notarised and valid Letter of
			5	Sterile Vessel Sealer / divider Sterile Vessel	SL1137S	(v) Clarification of codes and brand names as per FSC required
			6	Sterile Vessel Sealer / divider Sterile Vessel	SL5137S	(vi) and clarify whether it's a system or family as per MDR 2017.
			7	Sterile Vessel Sealer / divider Sterile Vessel	SL5137A	(vii) Submit complete stability studies
			8	Sterne Vessel Sealer / divider Sterile Vessel	SL5120S	
			9	Sterile Vessel Sealer / divider Sterile Vessel	SL5300S	
			10	Sealer / divider	SL0837	
			11	Sterile Vessel Sealer / divider	SL0823	
			Class C Shelf Lif	e: 2 years		N. Carlotte
20.	M/s Medtronic Pakistan Private Limited	Invatec SpA-Via Martiri della Liberta 7, Roncadelle, 25030	Hippocar	mpus-Renal Stent	Deferred fro submession of the following Documents:-	
	Date of submission 2020	(BS), Italy. FSC itally 25.05.2018 ISO 13485 15.02.2022	Shelf life	e: 3 years	(i) Valid and Notarsied FSC in the country of origin with clear brand name.	
						 (ii) Valid and notarised letter of Authorization. (iii) Valid ISO 13485 certificate (iv) Complete Stability studies (v) R&I recivings.
21.	CSM Pakistan (Guarantee)	Innolatex (Thailand) Limited F1-6 Export Processing		– Ultrathin		Deferred for submession of the following documents:-
	Ltd., 23-C, Old Sunset Boulevard, Phase 2, DHA, Karachi E1-6, Export Process Zone, Southern Industrial Estate, Village 4, Chalung, Hatyai, Songkhla,		Class C Shelf life 5 Years Fee 50000/-			(i) Embassy attested valid FSC with clearity for free sale in the country of origin, since in the current FSC the

	(ELI-00418) Date of submission 03.06.2021	90110, Thailand Embassy attested FSC Thailand valid till 15.03.2023				following is written. The product has the same standard as the product sold in the country and exported without restriction (ii) Valid and notarised letter of Authorization letter. (iii) Valid ISO 13485 certificate (iv) Complete Stability (v) Valid and notarsied CE certificate from Nando Data base or FSC of RRA.
22.	Johnson & Johnson Pakistan (Pvt)	Legal Manufacturer: Synthes GmbH 3 Eimattstrasse, 4436	Cable Impl Class C	ants		Deferred for the provision of justification grouping of subject device in Family since there are
	Ltd., Office No.506, 5th	Oberdorf, CH	l	Description	Shelf-life	positioning pins, wires, plates, screw and cable included. Justify
	Floor, Horizon	FSC # 00015771 valid	Codes	Description	i i	how all these implants will work
	Tower, Block 3,	until 29-Sep-2025	Codes	S Carelage Five	(years)	together. There are also some
	Scheme 5,	FSC # 00015773 valid] 201 004	CerclageFix	N/A	implants of sterile nature having
	Clifton, Karachi	until 24-Oct-2025	281.001	Insert	11/2	shelf life of 10 years whereas other
	,	(submitted in Response		CerclageFix	N/A	have no shelf life.
	(ELI-00154)	to 48th MDB Decision		f/LCP		
	[2966]	Letter)	281.002	4.5/5.0		
	25-08-2020	FSC # 00015778 valid		Coil	N/A	
		until 24-Oct-2025		w/Cerclage		
		į	11	Wire Ø		
-			 	0.4mm, L 8		
1			291.044	m		
			1	Coil	N/A	
				w/Cerclage		
				Wire Ø		
]]	1.0mm, L]	
			291.050	10 m		
				Coil	N/A	
				w/Cerclage	'',''	
				Wire Ø		
				1.25mm, L	:	
			291.060	10 m		
	*		231.000	Coil	N/A	
				w/Cerclage	'''	
				Wire Ø		
				0.6mm, L 8		
			291.070	m		
1			231.070	Coil	N/A	
				w/Cerclage	''/^	
1			[]	Wire Ø		
				0.8mm, L]	
			291.090	10 m		
			251.030	Coil	N/A	
				w/Cerclage	IN/A	
				Wire Ø		
] 201 120	1.5mm, L		
			291.130	10 m	10/0	
				Cerclage	N/A	
1			11	Positioning		
				Pin f/LCP		
				3.5 + LC-]	
			298.837	DCP* 3.5		
				Cerclage	N/A	
		1	298.839	Positioning		(\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \

Deferred Letters of 61st Meeting of MDB (26-09-2023)

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 		11	a. (/)	r	T
			Pin f/LCP		
			4.5 + LC-		
	-		DCP® 4.5		
			CerclageFix	N/A	
			f/LCP		
		481.002	4.5/5.0		
			TRD -	N/A	
:			Trochanter		
		[]	Reattachm		
			ent Device,		
		498.806	small		
	1		TRD -	N/A	
			Trochanter	'''	
			Reattachm		
			ent Device,		
		498.807		1	
		498.807	large	81/8	
			Cerclage	N/A	
			Positioning		
			Pin f/LCP		
			3.5 + LC-		
		498.837	DCP® 3.5		
1			Cerclage	N/A	
		11	Positioning		
			Pin f/LCP		
		11	4.5 + LC-		1
		498.839	DCP® 4.5		
			Cerclage	N/A	
		11	Eye	'''	
		02.221.0	f/Screws Ø		
		02.05	3.5mm		
		02.03	Cerclage	10	:
			Eye	10	
		02.221.0	f/Screws Ø		
		025	3.5mm	11/4	
			Cerclage	N/A	
•			Eye	1	
		02.221.0	f/Screws Ø		
		03.05	4.5mm		
			Cerclage	10	
			Eye		
		02.221.0	f/Screws Ø		
		035	4.5mm		
			Cerclage	N/A	
			Eye		
			f/Hexagona		
		02.221.0	l Socket, Ø		
		04.05	4.0mm	1	
		11	Cerclage	10	
[Eye	10	
			f/Hexagona		
		02.221.0			
			I Socket, Ø		
		04S	4.0mm	1111	
		11	Positioning	N/A	
		11	Pin f/VA		
		02.231.0	5.0,		
}		22	cruciform		
]			Positioning	10	*
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		02.231.0	5.0,		
	i e				
		225	cruciform	Seud	(y /

Wire-Cable 10 0.0mm		 	T	r	····	
OSS W/Crimp N/A Eye			1		10	
OSS W/Crimp N/A Eye			02.401.0	Ø 1.0mm,		
Cerclage OA 221.0 f/Screws Ø O2.05 S.5mm Cerclage Fee Fee Fee Fee Fee OA 221.0 f/Screws Ø O2.5 S.5mm O2.5 S.5mm O2.5 S.5mm O2.5 S.5mm O2.5 S.5mm O2.5 O3.5		i i				
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22			04.231.0	5.0,		
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225			ļ			
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CerclageFix f/LCP S 4.5/5.0			1		10	
CerclageFix f/LCP S 4.5/5.0		[S	Insert		
281.002 f/LCP S	1				10	
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Cerclage Wire Ø 1.0mm 291.010.		į į				
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Wire ∅ 1.0mm 291.010. w/Eye, L 01 280mm		[Cerclage	N/A	
1.0mm 291.010. w/Eye, L 280mm N/A Wire Ø 1.0mm 291.010. w/Eye, L 10 280mm N/A Wire Ø 1.25mm 291.020. w/Eye, L 01 280mm Cerclage N/A Wire Ø 1.25mm 291.020. w/Eye, L 01 280mm N/A Wire Ø 1.25mm Cerclage N/A Wire Ø 10 1.25mm O O O O O O O O O		[
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Cerclage Wire Ø 1.0mm 291.010.						
Cerclage Wire Ø 1.0mm 291.010.			01	280mm		
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291.010.						
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291.020. Wire Ø 1.25mm				w/Lye, L		
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291.020. Wire Ø 1.25mm	i				N/A	
10 1.25mm			291.020.			
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					11/11/06	

	l .		Wire Ø	1 1	
		10	600mm Cerclage	N/A	
		291.120.	1.5mm w/Eye, L		
			Cerclage Wire Ø	N/A	
		291.120. 01	600mm		
			Wire Ø 1.5mm		
		10	280mm Cerclage	N/A	
		291.110.	1.5mm		
			Cerclage	N/A	
		291.110. 01	w/Eye, L		
			Wire Ø		
:		10	280mm	N/A	
		291.080.	w/Eye, L		
			Wire Ø	N/A	
		291.080. 01	280mm		
		204 000	0.8mm		
		10	Cerclage	N/A	
		291.040.	w/Eye, L		
			Wire Ø	1377	
		01	600mm	N/A	
		291.040.	1.25mm		
			Cerclage	N/A	
		291.030. 10	w/Eye, L 600mm		
			1.0mm		
			Cerclage	N/A	
		291.030.	w/Eye, L		
			Wire Ø		
	•		280mm Cerclage	N/A	
			291.030. 10 291.040. 01 291.080. 01 291.110. 01 291.110. 10 291.120. 01	Wire Ø 1.0mm w/Eye, L 01 600mm 291.030. w/Eye, L 10 600mm 291.030. w/Eye, L 10 600mm 291.040. w/Eye, L 10 600mm 291.040. w/Eye, L 01 600mm 291.040. w/Eye, L 10 600mm 291.040. w/Eye, L 10 600mm 291.040. w/Eye, L 10 600mm 291.080. w/Eye, L 10 280mm 291.080. w/Eye, L 10 280mm 291.110. w/Eye, L 10 600mm 291.120. 280mm 291.030. N/A W/Eye, L 01 600mm 291.030. 0.0mm 291.030. 0.0mm	
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		11		Cerclage	N/A
		11		Wire Ø	
			291.240.	0. 6mm, L	
			01	17 5mm	
		11	· · ·	Cerclage	N/A
				Wire Ø	''/^
			204 240		
			291.240.	0.6mm, L	
			10	17 5mm	
		1 (Cerclage	N/A
				Wire Ø	
1			291.260.	0.8mm, L	
			01	20 0mm	
				Cerclage	N/A
				Wire Ø	'''^
		11	204 250		
			291.260.	0.8mm, L	
			10	20 0mm	
				Cerclage	N/A
				Wire Ø	
			291.270.	1.0mm, L	
			01	250mm	
] -			N/A
				Cerclage	IN/A
				Wire Ø	
			291.270.	1.0mm, L	
			10	25 0mm	
		11		Cerclage	N/A
		11		Wire Ø	
			291.280.	1.25mm, L	
			01	30 0mm	
		11		Cerclage	N/A
		-			IN/A
		11		Wire Ø	
		11	29 1.280.	1 .25mm, L	
		1 _	10	3 00mm	
] [Cerclage	N/A
		11		Cable	
			298.800.	w/Crimp Ø	
			01	1.0mm	
ł		 		Cerclage	10
					10
				Cable	
			298. 800 .	w/Crimp Ø	
			01S	1.0mm	
				Cerclage	N/A
				Cable	
			298.801.	w/Crimp Ø	
			01	1. 7mm	
		1		Cerclage	10
				Cable	10
			200.004		
			298.801.	w/Crimp Ø	
			01S	1.7mm	
				Position ing	N/A
			298. 803 .	Pin 4.5	
			01	w/thread	
		11		Positioning	10
				Pin 4.5	
			200.002		
		11	298. 803 .	w/thread,	
] [015	f/LCP	
				Cerclage	10
				Positioning	ļ l
				Pin	
			298. 837	f/LCP+LC-	_ ,,
1			S	DCP® 3.5	/ X
Ь		. 1 4		20. 0.0	Juno

			Positioning	N/A	
		298.838.	Pin 3.5		
	÷	01	w/thread		
			Positioning	10	
- [200 000	Pin 3.5		
		298.838.	w/thread,		
- 1		015	f/LCP		
			Cerclage	10	
			Positioning		
			Pin]	
		298.839	f/LCP+LC-		
		S	DCP® 4.5		
			Cerclage	N/A	
١			Cable	1	
		498.800.	w/Crimp Ø	1	
1		01	1.0mm		
			Cable	10	
- 1		498.800.	w/Crimp Ø		
		01\$	1.0mm		
			Positio ning	N/A	
			Pin 4.5		
		498.803.	w/thread,		
		01	f/LCP		
			Positioning	10	
			Pin 4.5		
- 1		498.803.	w/thread,		
		015	f/LCP		
			TRD-Troch.	10	
ŀ			Reattachm.		
			Device,		
			small,		
- 1		498.806	f/Cable		
		S	Syst.		
-			TRD-Troch.	10	
			Reattachm.		
			Device,		
			large,		
Í		498.807	f/Cable		
		S	Syst.		
			Cerclage	10	
		l i	Positioning]	
		11	Pin		
		498.837	f/LCP+LC-		
		S	DCP® 3.5		
			Positioning	N/A	
			Pin 3.5		
		498.838.	w/thread,		
		01	f/LCP	<u> </u>	
			Positioning	10	
			Pin 3.5		
		498.838.	w/thread,		
		015	f/LCP		
-			Cerclage	10	
			Positioning		
			Pin	[
		498.839	f/LCP+LC-		
		S	DCP® 4.5		
			Cerclage	N/A	
			Cable		
		611.105.	w/Crimp Ø	•	
		01	1.7mm /		
		 		Lucias	

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

		Date of Issue: 14.04.2021		
27.	Shams Scientific Traders, 22-Y-J	Legal Manufacturer: Healgen Scientific LLC,	Healgen Dengue IgM/1gG Antibody Test Cassette	Deferred for the provision of following documents:
	Madina Town, Faisalabad	3818 Fuqua Street, Houston, TX 77047, USA.	Class-C	(i) Manufacturing site is no mentioned on FSC of Belgium.
	ELI: 00459 3563-P	Manufacturing site: M/s Zhejiang Orient	Shelf Life: 24 months	(ii) Linkup letter between th
	11-05-2022	Gene Biotech Co., Ltd., 3787, east Yangguang Avenue, Dipu street Anji 313300 Huzhou, Zhejiang, China	Codes & Sizes: As per FSC	Legal manufacturer and th physical manufacturer i required.
		FSC Belgium: Date of Issue: 14.04.2021		
28.	Shams Scientific Traders, 22-Y-J Madina Town,	Legal Manufacturer: Healgen Scientific LLC, 3818 Fuqua Street,	Healgen Corona Virus Ag Rapid Test Cassette (Swab)	Deferred for the provision of following documents: -
	Faisalabad ELI: 00459	Houston, TX 77047, USA. Manufacturing site:	Class-C	(i) Manufacturing site is no mentioned on FSC o Belgium.
	3562-P 11-05-2022	M/s Zhejiang Orient Gene Biotech Co., Ltd., 3787, east Yangguang	Shelf Life: 24 months Codes & Sizes: As per FSC	(ii) Linkup letter between th Legal manufacturer and th
		Avenue, Dipu street Anji 313300 Huzhou, Zhejiang, China		physical manufacturer i
		FSC Belgium: Date of Issue: 14.04.2021		(iii) The device is not mentione on provided FSC of Belgium
29.	Shams Scientific Traders, 22-Y-J Madina Town,	Legal Manufacturer: Healgen Scientific LLC, 3818 Fuqua Street,	Healgen HbsAg Hepatitis B Envelop Antigen Test	Deferred for the provision of following documents: -
	Faisalabad ELI: 00459	Houston, TX 77047, USA. Manufacturing site:	Class-D Shelf Life: 2 years	(i) Manufacturing site is no mentioned on FSC of Belgium.
	3566-P 11-05-2022	M/s Zhejiang Orient Gene Biotech Co., Ltd., 3787, east Yangguang Avenue, Dipu street Anji 313300 Huzhou, Zhejiang, China	Codes & Sizes: As per FSC	(ii) Linkup letter between th Legal manufacturer and th physical manufacturer i required.
		FSC Belgium: Date of Issue: 14.04.2021		(iii) The device is not mentione on provided FSC of Belgium
3	Shams Scientific Traders, 22-Y-J Madina Town,	Legal Manufacturer: Healgen Scientific LLC, 3818 Fuqua Street,	Healgen HBV COMBO TEST	Deferred for the provision of following documents: -
	Faisalabad	Houston, TX 77047, USA.	Class-B	(i) Manufacturing site is no mentioned on FSC co
	ELI: 00459 3565-P 11-05-2022	Manufacturing site: M/s Zhejiang Orient Gene Biotech Co., Ltd., 3787, east Yangguang Avenue, Dipu street Anji 313300 Huzhou,	Shelf Life: 24 months Codes & Sizes: As per FSC	Belgium. (ii) Linkup letter between th Legal manufacturer and th physical manufacturer i required.
		Zhejiang, China FSC Belgium:	~ 1	(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 1348 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 Applicance Co., Ltd,Fulin Road, Fuzhou Ciity , 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	Deffered 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
33.	A&E Medical 323-ATA Turk	Legal Manufacturer Sunny Medical Device	Pressure Lines (Angiographic Guide wire)	mentioned on DOC. (vii) Clarify the type of I cannula Deffered for the provision of following documents:
	Block New Garden Town Lahore ELI:00023 Dossier# 1610-P Submission date: 13/08/2020	(Shenzhen) Co., Ltd 1/F and 401, Zhongtianxin B, Longgang District, Shenzhen, Guangdong, China FSC: china Valid till: 14.05.2020	Class-B Shelf Life: 3 years	 (i) LOA, ISO 13485 certificate & (ii) CE certificate are expired. (iii) FSC of country of origin is provided which was expire 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	Deffered for the provision of following documents: (i) LOA, ISO 13485 certificates the control of the provision of following documents:

	ELI:00023 Dossier# 1588-P	Shenzhen, Guangdong, China		(ii) CE certificate are expired.
	Submission date: 14/07/2020	FSC: china Valid till: 14.05.2020		(iii) FSC of country of origin i provided which was expire 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 establishmen 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 or FSC and all other document while it's Cooper Vision ® on applied form-7A. (iv) Declaration on stamp paper
26	Missi	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	MIGDOGAG	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 MicroC3F8P MicroC3F8M) Class: C Shelf Life: 5 years	Deffered for the provision of following documents: (i) Credentials of manufacture 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 at the time of submission.
				provided. (v) Stability data for the claime shelf life is not provided
37.	Mian Enterprises, Office No. UG- 400 Deans Trade Center, Peshawar Cantt 25000, Pakistan ELI: 00507	Legal Manufacturer: M/s Micromed Srl Via Val Padana n. 126 B/2- 00141, Roma (RM), Italy Manufacturing site Address: Via Guglielmo Oberdan,	(PDMS (Silicon Oil) Codes & Sizes: As per FSC Class: C Shelf Life: 5 years	Deffered for the provision of following documents: (i) Credentials of manufacture duly notarized from countr of origin is not provided. (ii) Notarized LOA, FQA & ISO
	Dossier# 3696- KP Submission date: 19/01/2023	21-00013-Fonte Nuova (RM), Italy FSC: not provided	Quias	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
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	Deffered for the provision of following documents: (i) FSC of reference country and FSC of country of origin are not provided. (ii) Stability data is not provided for the claimed shelf life.
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, hydrophilicgel) Codes & Sizes: As per FSC Class-C Shelf Life: 05 years	Deffered 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 Alginate rope.
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	Deffered 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) Submit revised form-7A incorrect MD comentioned on it i.e., class while product falls in Cla
F N 5 n N E I	Healthcare Enterprises Makkah tower th floor office to. 507, Namak Mandi Peshawar ELI No. 00931 Dossier# 357-c Submission date: 13/11/2022	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	Deffered for the provision following documents: (i) Provide original, valid notarized LOA. (ii) Credentials of manufacted duly notarized from cour of origin is not provided. (iii) Product label is not provided. (iv) Provide product catalowith complete description (v) Declaration on stamp paper not provided. (vi) Stability data of claimed silife is not provided. (vii) Design examinate certificate is not provided.
F N 5 n N E C	Healthcare Enterprises Makkah tower th floor office o. 507, Namak Mandi Peshawar ELI No. 00931 Possier# 358-c ubmission date: 3/11/2022	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	Deffered for the provision following documents: (i) Provide original, valid notarized LOA. (ii) Credentials of manufacted duly notarized from cours of origin is not provided. (iii) Product label is not provided. (iv) Provide product catalowith complete description (v) Declaration on stamp paper not provided. (vi) Stability data of claimed slife is not provided. (vii) Apply separate case we separate fee for Activity Hydrocollide foam Backet
C C C III C C S K K Jii K K	amzco Trading company, office No. 501,, mperial Optical lenter, Masjid treet, Ghari hatta M. A nnah Road, arachi 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	Deffered for the provision following documents: (i) LOA is not notarized. (ii) ISO certificate is expirate upon submission. (iii) FSC of country of original Reference country are provided.

		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,	Legal Manufacturer: Wohlk Contactlinsen GMBH	Zeiss Contact Day 30 (Contact Lenses)	Deffered for the provision of following documents:
		Imperial Optical Center, Masjid Street, Ghari Khatta M. A	BurgerMeister-Schade- Str.12-6 24232 Schon kirchen, Germany	Codes & Sizes: As per FSC Class-C	(i) LOA is not notarized. (ii) ISO certificate is expired upon submission.
		Jinnah Road, Karachi (ELI-00685)	FSC: not provided.	Shelf Life: 05 years	(iii) FSC of country of origin/ Reference country are not provided.
		Dossier#4877- 7A Date:07-07-22			(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,	Legal Manufacturer: UTAS technologies	UTAS (Patient Monitor UM-300S)	Deffered for the provision of following documents:
		Bangalow No. A-86, block C, Gulshan-e-	S.R.O., 1, Stavitelska st., Bratislava,83104, Slovakia	Codes & Sizes: As per FSC	(i) Photocopies of all relevant documents are provided.
		Jamal, Karachi, 75360, Pakistan. (ELI-00495) Dossier#1448-C	FSC: Slovakia Issued: 26-04-2021	Class-C Shelf Life: 05 years	(ii) Submit Original, embassy attested FSC, notarized LOA, Credentials of manufacturer, ISO certificate & FQA certificate.
		Date:04-04-23			(iii) ISO certificate is expired.
	46.	Technology Links (Pvt) Ltd Office # 4/18	Legal Manufacturer: Enraf Nonius B.V. Vareseweg 127, 3047	Eltrac 471 (Traction Therapy Device)	Deffered for the provision of following documents:
			Rotterdam, Netherland	Codes & Sizes: As per FSC	(i) LOA is expired on 31/12/2022.
		Jinnah Road, Karachi Pakistan (ELI-00427)	FSC: Netherland (Original) Valid Till: 26-5-2024	Class-C Shelf Life:	(ii) ISO certificate is expired.(iii) Stability data is not provided
		Dossier#4802- 7A Date:30-09-22	Vand 1111, 20-5-2024	Not provided.	for the shelf life.
-	47				
	47.	Universal Enterprise, Karachi (ELI-00079)	Legal Manufacturer: M/S Terumo Corporation, Japan.	Terufusion Syringe Pump Software (TE-SS830) (TE-SS730) N Standard Rack System (TE-RS800) N	Deferred for provision of following documents (i) Valid & notarized FSC of
		3183	Manufacturing site: M/S Ashitaka factory of terumo Corporation 150	Communication Rack system (Extension)(TE-RS800) No3	country of origin, Letter of authorization & ISO 13485, Form-7A not signed stamped,
		Date (R&I) 05-11-2020	Maimaigi-Cho, Fujinomiya-Shi, Shizuoka 418-0015, Japan.	Class C HS Code 9018.9090	Credential of manufacturer abroad, Clarification required regarding stability/service life of product,
			M/S Terumo	GMDN code 13217	(ii) Grouping of medical device
ef	erred l	Letters of 61st M	Meeting of MDB (26-09	9-2023) Acuras	Page 22 of 24

		Corporation ME center	Fee: 50,000/-	
	·	M/S OKI Electric industry CO. Ltd Corporation ME center	166. 30,000/-	
		FSC of Japan(copy) Date of issuance 19-01- 2018, valid upon submission. (software Model not found in FSC)		
48.	M/s. United Healthcare Plot No. 330/B	M/s Huaian Medicom Medical Technology Co. Ltd.,	Star IV Catheter with Injection Port Plus Heparin Cap	Deferred for Clarification and submission of CE marking certificate, FSC of Country o
	Second Floor, DMCHS, Bahadurabad,	N0123 Meicheng west road, Qingpu industry	Class B Shelf Life: 05 Years	origin for combination as applied.
	Karachi. ELI 00293	park, huaian city, Jiangsu, China	Codes & Sizes: As per FSC	
		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		
		FSC provided is not for relevant product		:
49.	M/s Otsuka Pakistan ltdNo.	Legal Manufacturer:	Euca VI	Deferred for Clarification and submission of valid& notorised
	F/4-9, Hub Industrial Trading Estate, Distt. Lasbella, Balochistan, Pakistan	M/s Eucatech AG, Rebgertenweg 27, 79576 weil am Rhein/ Germany	Generic Name: PTCA ballon Catheter Codes as per FSC: Class: D Family	FSC, LOA, Stability data.
		notorised) of Germany		*
	(ELI-00053)	DOI 05-04-2022	Codes and sizes	
	(ELI-00053) 14204 Date (R&I) 27-03-2022	DOI 05-04-2022	Codes and sizes. GMDN 47732 UMDNS 17-184	
50.	14204 Date (R&I)	Legal Manufacturer: Radiometer Medical ApS Akandevej 21 2700 Bronshoj- Denmark Manufacturing site: Assays and consumables Radiometer Turku, Oy Biolinja12, 2075 turku, Finland	GMDN 47732	Deferred for clarification Th firm has applied clustering of class C products which is not consister with MDR 2017 which allow Clustering of class A/B product only therefore justify clustering a per MDR 2017 and revise form 7A or clarify. Complete stability study required

		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 I Guoxiang RD Wujin Economic Development Zone 213149 Changhzhou 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 submession 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.

Additional Director (MDMC)/ Secretary MDB