



No.F.4-12/2023-MD (M-62)
Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
Drug Regulatory Authority of Pakistan

Islamabad the 1st December, 2023

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

The applications of following applicants were considered by Medical Device Board (MDB) in its 62nd meeting held on 6th November, 2023 and Board deferred these applications being deficient of the information/documents as specified in last column (V) of the Table below:-

S#	Firm Details	Manufacturer Details	Name of Medical Device/ Class / Shelf life / Codes etc	Decision
(I)	(II)	(III)	(IV)	(V)
1.	Briogene Pvt Ltd, 196-A, Sindhi Muslim Cooperative Housing Society, Shahrah-e-Faisal, Karachi (ELI-00015)	Legal Manufacture QIAGEN GmbH, Qiagen Strasse 1, 40724 Hilden, Germany Copy of FSC: Germany Issuance DATE: 16-3-2022 ISO 13485 Issuance Date: 19 Aug 2021 Expiry Date: 14 June 2024 FQA Issuance Date: 6 May 2021 Expiry Date: 26 May 2024 (Original submitted with HBV RG PCR Kit) LOA Issuance date: 11 October 2018 Validity: 5 Years (Original submitted with HBV RG PCR Kit)	QIAsat-Dx Respiratory SARS-CoV- 2 Panel Class C Shelf Life: 9 months Codes: 691214 Date of submission: 13 Dec 2022 Fee submitted: PKR 50,000/-	Deferred for submission of valid Letter of Authroization, FSC, ISO 13485 & FQA.
2.	Briogene Pvt Ltd, 196-A, Sindhi Muslim Cooperative Housing Society, Shahrah-e-Faisal, Karachi (ELI-00015)	Legal Manufacture QIAGEN GmbH, Qiagen Strasse 1, 0724 Hilden, Germany FSC: Germany Issuance DATE: 16- 3 - 2022	QIAsTAT-DX® GASTROINTESTINAL PANEL Class C Shelf Life: 9 months Codes: 691411	Deferred for submission of valid Letter of Authroization, FSC, ISO 13485 & FQA.

		<p>ISO Issuance Date: 19 Aug 2021 Expiry Date: 14 June 2024</p> <p>FQA Issuance Date: 6 May 2021 Expiry Date: 26 May 2024 (Original submitted with HBV RG PCR Kit)</p> <p>LOA Issuance date: 11 October 2018 Validity : 5 Years (Original submitted with HBV RG PCR Kit)</p>	<p>Date of submission: 13 Dec 2022</p> <p>Fee submitted: PKR 50,000/-</p>	
3.	<p>Briogene Pvt Ltd, 196-A, Sindhi Muslim Cooperative Housing Society, Shahr-e-Faisal, Karachi</p> <p>(ELI-00015)</p>	<p>Legal Manufacture</p> <p>QIAGEN GmbH, Qiagen Strasse 1, 0724 Hilden, Germany FSC: Germany Issuance DATE: 16-3-2022</p> <p>ISO Issuance Date: 3 May 2022 Expiry Date: 14 June 2024</p> <p>FQA Issuance Date: 6 May 2021 Expiry Date: 26 May 2024 (Original submitted with HBV RG PCR Kit)</p> <p>LOA Issuance date: 11 October 2018 Validity : 5 Years (Original submitted with HBV RG PCR Kit)</p>	<p>QIAstat-Dx® Meningitis/Encephalitis</p> <p>Class C</p> <p>Shelf Life: 9 months</p> <p>Codes: 69161 I</p> <p>Date of submission: 15 Dec 2022</p> <p>Fee submitted: PKR 50,000/-</p>	<p>Deferred for submission of valid Letter of Authorization, FSC, ISO 13485 & FQA.</p>
4.	<p>M/s Maqsood Brothers, Office No 503-B, 5th Floor, Saima Trade Tower, I.I Chandrigar Road, Karachi.</p> <p>ELI-00282</p>	<p>Legal & Physical manufacturer:</p> <p>TaiDoc Technology Corporation Wugu Factory, B1-7F, No. 127, Wugong 2nd Rd., Wugu Dist., 24888 New Taipei city, Taiwan.</p> <p>Certificate issued by Mo Health & Welfare, Republic of China (Taiwan) No. 082573 dated 13-05-2021. FQA/CE certificate, ISO13485 submitted.</p>	<p>Life Check Blood Glucose Monitoring System</p> <p>Class-C</p> <p>Shelf Life: not mentioned however in stability 25 months is mentioned</p> <p>Fee: 50,000/-</p>	<p>Deferred for submission of valid Embassy attested Free Sale Certificate with clear availability of the product in the country of origin.</p>



5.	M/s Maqsood Brothers, Office No 503-B, 5th Floor, Saima Trade Tower, I.I Chandrigar Road, Karachi. ELI-00282	Legal & Physical manufacturer: TaiDoc Technology Corporation Wugu Factory, B1-7F, No. 127, Wugong 2 nd Rd., Wugu Dist., 24888 New Taipei city, Taiwan. Certificate issued by Mo Health & Welfare, Republic of China (Taiwan) No. 082573 dated 13-05-2021. FQA/CE certificate, ISO13485 submitted.	Life Check Blood Glucose Test strip Class-C Shelf Life: not mentioned however in stability 25 months is mentioned Fee:50,000/-	Deferred for submission of valid Embassy attested Free Sale Certificate with clear availability of the product in the country of origin.
6.	M/s Maqsood Brothers, Office No 503-B, 5th Floor, Saima Trade Tower, I.I Chandrigar Road, Karachi. ELI-00282	Legal & Physical manufacturer: TaiDoc Technology Corporation Wugu Factory, B1-7F, No. 127, Wugong 2 nd Rd., Wugu Dist., 24888 New Taipei city, Taiwan. Copy of certificate issued by Mo Health & Welfare, Republic of China (Taiwan) No. 072103 dated 25-05-2018. FQA/CE certificate, ISO13485 submitted.	Atom Medical Blood Glucose Monitoring System Class-C Shelf Life: not mentioned however in stability 25 months is mentioned Fee:50,000/-	Deferred for submission of valid Embassy attested Free Sale Certificate with clear availability of the product in the country of origin.
7.	M/s Maqsood Brothers, Office No 503-B, 5th Floor, Saima Trade Tower, I.I Chandrigar Road, Karachi. ELI-00282	Legal & Physical manufacturer: TaiDoc Technology Corporation Wugu Factory, B1-7F, No. 127, Wugong 2 nd Rd., Wugu Dist., 24888 New Taipei city, Taiwan. Copy of certificate issued by Mo Health & Welfare, Republic of China (Taiwan) No. 072103 dated 25-05-2018. FQA/CE certificate, ISO13485 submitted.	Atom Medical Blood Glucose Testy strip Class-C Shelf Life: not mentioned however in stability 25 months is mentioned Fee:50,000/-	Deferred for submission of valid Embassy attested Free Sale Certificate with clear availability of the product in the country of origin.
8.	M/s Maqsood Brothers, Office No 503-B, 5th Floor, Saima Trade Tower, I.I Chandrigar Road, Karachi. ELI-00282	Legal & Physical manufacturer: TaiDoc Technology Corporation Wugu Factory, B1-7F, No. 127, Wugong 2 nd Rd., Wugu Dist., 24888 New Taipei city, Taiwan. Copy of certificate issued by	U-Check Blood Glucose Monitoring System Class-C Shelf Life: not mentioned Fee:50,000/-	Deferred for submission of valid Embassy attested Free Sale Certificate with clear availability of the product in the country of origin & complete stability study data with claimed shelf life.

Deferred

		Mo Health & Welfare, Republic of China (Taiwan) No. 085483 dated 12-04-2022. FQA/CE certificate, ISO13485 submitted.		
9.	M/s Maqsood Brothers, Office No 503-B, 5th Floor, Saina Trade Tower, I.I Chandrigar Road, Karachi. ELI-00282	Legal & Physical manufacturer: TaiDoc Technology Corporation Wugu Factory, B1-7F, No. 127, Wugong 2 nd Rd., Wugu Dist., 24888 New Taipei city, Taiwan. Copy of certificate issued by Mo Health & Welfare, Republic of China (Taiwan) No. 085483 dated 12-04-2022. FQA/CE certificate, ISO13485 submitted.	U-Check Blood Glucose Tesy strip Class-C Shelf Life: not mentioned Fee: 50,000/-	Deferred for submission of valid Embassy attested Free Sale Certificate with clear availability of the product in the country of origin & complete stability study data with claimed shelf life.
10.	Elate CCPVt Ltd. Suite No. 1, 2, 3, ST-3, Block-3, Gulshan-e-Iqbal, Karachi (ELI-00294)	Manufacturer: ATLAS MEDICAL S.A. 28C, MIAOULI STR. 153 44 GERAKAS ATHENS-GREECE Copy of FSC issued by the company Atlas Medical itself. Valid Till: 26-5-2024 ISO valid till 30-10-2024 FQA/CE valid till 26-05-2024	Premisut Absorbable Surgical Sutures Premisut PGLAR with & without Needle Class D Shelf Life: 5 years Fee submitted: Rs. 50,000/-	Deferred for submission of valid embassy attested Free Sale Certificate issued by the concerned regulatory authority with complete codes and notarized copy of design examination certificate of the product.
11.	Elate CCPVt Ltd. Suite No. 1, 2, 3, ST-3, Block-3, Gulshan-e-Iqbal, Karachi (ELI-00294)	Manufacturer: ATLAS MEDICAL S.A. 28C, MIAOULI STR. 153 44 GERAKAS ATHENS-GREECE Copy of FSC issued by the company Atlas Medical itself. Valid Till: 26-5-2024 ISO valid till 30-10-2024 FQA/CE valid till 26-05-2024	Premisut Absorbable Surgical Sutures Premisut PGLA with & without Needle Class D Shelf Life: 5 years Fee submitted: Rs. 50,000/-	Deferred for submission of valid embassy attested Free Sale Certificate issued by the concerned regulatory authority with complete codes and notarized copy of design examination certificate of the product.
12.	Elate CCPVt Ltd. Suite No. 1, 2, 3, ST-3, Block-3, Gulshan-e-Iqbal, Karachi	Manufacturer: ATLAS MEDICAL S.A. 28C, MIAOULI STR. 153 44 GERAKAS ATHENS-GREECE	Premisut Absorbable Surgical Sutures Premisut Polypropylene with & without Needle	Deferred for submission of valid embassy attested Free Sale Certificate issued by the concerned regulatory authority with complete codes and notarized copy of design

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	(ELI-00294)	Copy of FSC issued by the company Atlas Medical itself. Valid Till: 26-5-2024 ISO valid till 30-10-2024 FQA/CE valid till 26-05-2024	Class D Shelf Life: 5 years Fee submitted: Rs. 50,000/-	examination certificate of the product.
13.	Elate CCPVt Ltd. Suite No. 1, 2, 3, ST-3, Block-3, Gulshan-e-Iqbal, Karachi (ELI-00294)	Manufacturer: ATLAS MEDICAL S.A. 28C, MIAOULI STR. 153 44 GERAKAS ATHENS- GREECE Copy of FSC issued by the company Atlas Medical itself. Valid Till: 26-5-2024 ISO valid till 30-10-2024 FQA/CE valid till 26-05-2024	Premisut Absorbable Surgical Sutures Premisut PGAR with & without Needle Class D Shelf Life: 5 years Fee submitted: Rs. 50,000/-	Deferred for submission of valid embassy attested Free Sale Certificate issued by the concerned regulatory authority with complete codes and notarized copy of design examination certificate of the product.
14.	Elate CCPVt Ltd. Suite No. 1, 2, 3, ST-3, Block-3, Gulshan-e-Iqbal, Karachi (ELI-00294)	Manufacturer: ATLAS MEDICAL S.A. 28C, MIAOULI STR. 153 44 GERAKAS ATHENS- GREECE Copy of FSC issued by the company Atlas Medical itself. Valid Till: 26-5-2024 ISO valid till 30-10-2024 FQA/CE valid till 26-05-2024	Premisut Absorbable Surgical Sutures Premisut PDO with & without Needle Class D Shelf Life: 5 years Fee submitted: Rs. 50,000/-	Deferred for submission of valid embassy attested Free Sale Certificate issued by the concerned regulatory authority with complete codes and notarized copy of design examination certificate of the product.
15.	Elate CCPVt Ltd. Suite No. 1, 2, 3, ST-3, Block-3, Gulshan-e-Iqbal, Karachi (ELI-00294)	Manufacturer: ATLAS MEDICAL S.A. 28C, MIAOULI STR. 153 44 GERAKAS ATHENS- GREECE Copy of FSC issued by the company Atlas Medical itself. Valid Till: 26-5-2024 ISO valid till 30-10-2024 FQA/CE valid till 26-05-2024	Premisut Non-Absorbable Surgical Sutures Premisut SILK with & without Needle Class D Shelf Life: 5 years Fee submitted: Rs. 50,000/-	Deferred for submission of valid embassy attested Free Sale Certificate issued by the concerned regulatory authority with complete codes and notarized copy of design examination certificate of the product.
16.	Life Cares, M-20, Mezzanine Floor Falaknaz Plaza Natha Khan Bridge, Shahra-e-Faisal,	Manufacturer: FORTUNE MEDICAL INSTRUMENT CORP. 6F, NO. 29, SEC.2 JHONGJHENG E RD., DANSHUEI DISTRICT,	FORTUNE Stomach Gastric, Chest Laryngeal Mask Tube Class C Shelf Life: Not provided	Deferred for following: • Embassy Attested Free Sale Certificate along with clear cut import status of the product from Taiwan.

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	Karachi (ELI-00077)	NEW TAIPEI CITY, 251 TAIWAN Copy of FSC issued by Mo Health & Welfare, Republic of China (Taiwan) No. 078737 dated 13-05-2020 ISO valid till 08-08-2022 FQA/CE valid till 04-09- 2023	Code:- Model (Type) : 2020-0003, 2020-0004, 2020-0005, 2020-0006, 2020-0008, 2020-0010, 2020-0012, 2020-0014, 2020-0016, 2020-0018, 2020-0020, 2020-5514, 2020-5516, 2020-6014, 2020-6016, 2020-6514, 2020-6516, 2020-7014, 2020-7016, 2020-7514, 2020-7516, Fee submitted: Rs. 50,000/-	<ul style="list-style-type: none"> Stability Study data along with claimed shelf life. Separate Application & fee for each different types of products.
17.	Life Cares, M- 20, Mezzanine Floor Falaknaz Plaza Natha Khan Bridge, Shahra-e-Faisal, Karachi (ELI-00077)	Manufacturer: FORTUNE MEDICAL INSTRUMENT CORP. 6F, NO. 29, SEC.2 JHONGHENG E RD., DANSHUEI DISTRICT, NEW TAIPEI CITY, 251 TAIWAN Copy of FSC issued by Mo Health & Welfare, Republic of China (Taiwan) No. 078737 dated 13-05-2020 ISO valid till 08-08-2022 FQA/CE valid till 04-09- 2023	FORTUNE Urological Catheters (Family) + Silicone Suprapubic Catheter Class C Shelf Life: Not provided Fee submitted: Rs. 50,000/-	Deferred for following: <ul style="list-style-type: none"> Embassy Attested Free Sale Certificate along with cleat cut import status of the product from Taiwan. Stability Study data along with claimed shelf life. Separate Application & fee for each different types of products.
18.	Life Cares, M- 20, Mezzanine Floor Falaknaz Plaza Natha Khan Bridge, Shahra-e-Faisal, Karachi (ELI-00077)	Manufacturer: Phenox GmbH, Meitner-Allee 31, D-44801 Bochum, Germany FSC: Germany Issued: 1-9-21 ISO valid till 26-06-2022 FQA/CE valid till 26-05- 2024 Deign Examination:26-05- 2024	pNovus 21 Microcatheter Family Microcatheters Code: PNOV-21-155 Class D Shelf Life: 4 years Fee submitted: Rs. 50,000/-	Deferred for submission of valid embassy attested Free Sale Certificate, ISO 13485 & Stability Study data.
19.	Life Cares, M- 20, Mezzanine Floor Falaknaz Plaza Natha Khan Bridge, Shahra-e-Faisal,	Manufacturer: Phenox GmbH, Meitner-Allee 31, D-44801 Bochum, Germany FSC: Germany	pHLO AC Aspiration Catheter Family Intravascular recanalization device.	Deferred for submission of valid embassy attested Free Sale Certificate, ISO 13485 & Stability Study data.

	Karachi (ELI-00077)	Issued: 1-9-21 ISO valid till 26-06-2022 FQA/CE valid till 26-05-2024 Design Examination: 26-05-2024	Code: PHLO-72-115, PHLO-72-125, PHLO-72-135 Class D Shelf Life: 4 years Fee submitted: Rs. 50,000/-	
20.	Life Cares, M-20, Mezzanine Floor Falaknaz Plaza Natha Khan Bridge, Shahr-e-Faisal, Karachi (ELI-00077)	Manufacturer: Ningbo Medical Multi-Way Medical Co., Ltd No. 225, Haiguan N. Rd, Cixi City 315300, Zhejiang Province, P.R. China Copy of Certificate issued by Spanish Agency of Medicines and Medical Devices but product name & free sale status not confirmed. ISO valid till 06-01-2022 Production QA/CE valid till 04-09-2023	MULTI-WAY Guidewires Class C Shelf Life: 4 years Fee submitted: Rs. 50,000/-	Deferred for submission of valid embassy attested Free Sale Certificate of country of origin as well as from reference country, ISO 13485 & Stability Study data.
21.	Bone Solution Plot No. 35-C, Stadium Lane-2, Phase V, D.H.A., Karachi. ELI-00517	Manufacturer: Desu Medikal Urunler Ve Tibbi Cihazlar San. Ve Tic. A.S. Universiteler Mahallesi 1596. Cadde Safir Bloklari E Blok ofis No. 02-03 Zemin Kat Kapl No. 6 Beytepe-Cankaya-Anarka, Turkey Copy of FSC issued by Turkey Dated 08-04-2022 FQA/CE valid till 13-12-2023	Desu Hydrocephalus External Neurological Drainage Sysytem Code: 61796 Class D Shelf Life: 2 years Fee submitted: Rs. 50,000/-	Deferred for submission of valid notarized Design Examination, ISO 13485 & FQA/CE.
22.	Bone Solution Plot No. 35-C, Stadium Lane-2, Phase V, D.H.A., Karachi. ELI-00517	Manufacturer: Desu Medikal Urunler Ve Tibbi Cihazlar San. Ve Tic. A.S. Universiteler Mahallesi 1596. Cadde Safir Bloklari E Blok ofis No. 02-03 Zemin Kat Kapl No. 6 Beytepe-Cankaya-Anarka, Turkey	Desu Hydrocephalus Shunt Systems Code: 45694 Class D Shelf Life: 2 years	Deferred for submission of valid notarized Design Examination, ISO 13485 & FQA/CE.

		Copy of FSC issued by Turkey Dated 08-04-2022 FQA/CE valid till 13-12-2023	Fee submitted: Rs. 50,000/-	
23.	TRI TECH INTERNATIONAL 10-C, 6 TH SUNSET COMMERCIAL LANE, PHASE 2 EXT, DHA, KARACHI, PAKISTAN 75500 ELI-00247 Dossier#4248 Submission date: 03/11/2021	Legal manufacturer ALLIED HEALTH CARE PRODUCTS, Inc. 1720 Sublette Avenue, St. Louis, MO 63110, USA FSC USFDA valid till 28-05-22 (Expired)	Brand Name: ALLIED (Generic Name: EMERGENCY PORTABLE VENTILATOR) Code: EVP200 Class- C Shelf Life: 5 years Fee: Rs50, 000/-	Deffered for provision of <ul style="list-style-type: none"> • Valid notorised LOA. • valid FSC USFDA (with relevant model or clarification) • valid CE/FQAS original notorised • valid ISO 13485
24.	TRI TECH INTERNATIONAL 10-C, 6 TH SUNSET COMMERCIAL LANE, PHASE 2 EXT, DHA, KARACHI, PAKISTAN 75500 ELI-00247 Submission date: 03/11/2021	Legal manufacturer ALLIED HEALTH CARE PRODUCTS, Inc. 1720 Sublette Avenue, St. Louis, MO 63110, USA FSC USFDA valid till 28-05-22 (Expired)	Brand Name: ALLIED (Generic Name: PORTABLE VENTILATOR AHP300) Code: AHP300 Class- C Shelf Life: 5 years Fee: Rs50, 000/-	Deffered for provision of <ul style="list-style-type: none"> • Valid notorised LOA. • valid CE/FQAS original notorised • valid ISO 13485 • Valid FSC
25.	M/s Safe Health Pakistan Bizcon, Office No.25, 2nd Floor, Dilkusha Chamber, Marston Road, Karachi (ELI-00275)	Zhanjiang Star Enterprises Co., Ltd. No. 1, West Jinhua Road, Mazhang District, 524094 Zhanjiang, People's Republic of China. FSC Valid Till: 24-04-2021	Venous FOLEYS CATHETER (Urinary Catheter or Urethral Catheter) Various sizes & Types FDA Re: K170233 Class B(Schedule-E) Shelf life: 05 Years Codes & Sizes as per FSC	Deffered for provision of following documents: - <ul style="list-style-type: none"> • Valid& notorised LOA • Valid & notorised FSC • Firm has applied for 4 different products clarification required.
26.	M/s Safe Health Pakistan Bizcon, Office No.25, 2nd Floor, Dilkusha Chamber, Marston Road,	Zhanjiang Star Enterprises Co., Ltd. No. 1, West Jinhua Road, Mazhang District, 524094 Zhanjiang, People's Republic of China. FSC Valid Till:	Venous Tracheostomy Tubes for Single use Cuffed & Un-Cuffed Various sizes & Types Class B	Deffered for the following reasons: <ul style="list-style-type: none"> • Clarification of the class of the product as in application the product is class B while in DOA class C.

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	Karachi (ELI-00275) Submission date: 06/10/2020 Dossier# 3185	24-04-2021	Shelf life: 05 Years Codes Cuffed 6.5, 7, 7.5, 8, 8.5, 9.0, 10& Sizes as per FSC	<ul style="list-style-type: none"> If class C then submit differential fee. Apply separately for uncuffed product and provide FSC with codes.
27.	M/s Safe Health Pakistan Bizcon, Office No.25, 2nd Floor, Dilkusha Chamber, Marston Road, Karachi (ELI-00275)	M/s Changzhou Major Medical Co., Ltd.No. 1, Beiyang Road, Hexi Village, Zouqu Town, 213144 Changzhou City, Jingsu province, Peoples Republic of China. FSC: China. Valid original Till: 2-12- 2021	Venous Wound Dressing Class B Shelf life: 05 Years Codes Sizes as per FSC	Deferred subject to clarification of dressing material and DOC
28.	M/s Safe Health Pakistan Bizcon, Office No.25, 2nd Floor, Dilkusha Chamber, Marston Road, Karachi (ELI-00275) Schedule D R&I : 14-03-22 Dossier No 4666	Suzhou Leapmed Healthcare Corporation, Wuzhong Science Park, No. 2 & No. 3 Building, 38#, North Guandu Road, Wuzhong District, Suzhou City, 215100 Jiangsu, P.R.China FSC: China. Valid original Till: 27-04- 2023	Venous Disposable Automatic Core Instrument [Biopsy Needle & Needle Set for Soft Tissue Disposable, all types (Manual, Automatic & Semi-Automatic) all sizes] Class B Shelf life: 05 Years Codes & sizes as per FSC	Deferred for provision of following documents. <ul style="list-style-type: none"> Valid Original notorised ISO- 13485 & CE Certificates & DOC & Valid FSC
29.	M/s Safe Health Pakistan Bizcon, Office No.25, 2nd Floor, Dilkusha Chamber, Marston Road, Karachi (ELI-00275) Schedule D R&I : 14-03-22 Dossier No 4667	Suzhou Leapmed Healthcare Corporation, Wuzhong Science Park, No. 2 & No. 3 Building, 38#, North Guandu Road, Wuzhong District, Suzhou City, 215100 Jiangsu, P.R.China FSC: China (Original) Valid Till: 27-4-2023	Venous Disposable Semi- Automatic Instrument Biopsy Needle & Needle Set for Soft Tissue Disposable, all types (Manual, Automatic & Semi-Automatic) all sizes Class B Shelf life: 05 Years Codes & sizes as per FSC	Deferred for provision of following documents:- <ul style="list-style-type: none"> Valid Original notorised ISO- 13485 & CE Certificates & DOC & Valid FSC
30.	M/s Safe Health Pakistan Bizcon, Office No.25, 2nd Floor, Dilkusha Chamber, Marston Road, Karachi	Suzhou Leapmed Healthcare Corporation, Wuzhong Science Park, No. 2 & No. 3 Building, 38#, North Guandu Road, Wuzhong District, Suzhou City, 215100 Jiangsu, P.R.China	Venous Disposable Coaxial Biopsy Needle Class B Shelf life: 05 Years	Deferred for provision of following documents:- <ul style="list-style-type: none"> Valid Original notorised ISO- 13485 & CE Certificates & DOC & Valid FSC

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	(ELI-00275) Schedule D R&I : 14-03-22 Dossier No 4668	FSC: China (Original) Valid Till: 27-4-2023	Codes & sizes as per FSC	
31.	M/s Safe Health Pakistan Bizcon, Office No.25, 2nd Floor, Dilkusha Chamber, Marston Road, Karachi (ELI-00275) Schedule D R&I : 14-03-22 Dossier No 4669	Suzhou Leapmed Healthcare Corporation, Wuzhong Science Park, No. 2 & No. 3 Building, 38#, North Guandu Road, Wuzhong District, Suzhou City, 215100 Jiangsu, P.R.China FSC: China (Original) Valid Till: 27-4-2023	Venous Disposable Puncture Needle Class B Shelf life: 05 Years Codes & sizes as per FSC	Deffered for provision of following documents:- • Valid Original notarised ISO-13485 & CE Certificates & DOC & Valid FSC
32.	Sorabjee Patel & Co, 45-Badri Building, I.I. Chundrigar Road, Karachi-74000, PAKISTAN Lic. No.ELI-00067 Submission Date: 01.11.2022	Rayner Intraocular Lenses limited The Ridley Innovation Centre 10 Dominion Way Worthing West Sussex BN14 8 AQ United Kingdom. FSC MHRA Validity (21.04.2024) United Kingdom(UK)	Ophthalmic Kit for Cataract Surgery Rayone Hydrophobic Aspheric BLF RAO850B Intraocular Acrylic Foldable Lens Class - C Fee 50,000 Shelf Life: Five years	The MDB deferred the case of M/s Sorabjee Patel as the firm was found involved in the illegal manufacturing i.e pasting labels of imported lens on the locally manufactured lenses. The case is pending before appellate board.
33.	Spero Enterprises, Office No. 301, 3rd Floor, Trade Arcade, Plot No. 23/F, Muhammad Ali Society Karachi (ELI-00600) Dossier#4404-7A Date: 04-10-23	Legal Manufacturer: M/S Jiangxi hongda medical equipment group LTD, 39 south shangli rd jinxian county, Nanchang Jiangxi province china FSC: china Valid Till: 05-03-2025	Blood tubing set for hemodialysis Codes & Sizes: As per FSC Class-B Shelf Life: 3 years.	Deferred for provision of fees i.e Rs.25000/- as the firm has not submitted requisite fee.
34.	Spero Enterprises, Office No. 301, 3rd Floor, Trade Arcade, Plot No. 23/F, Muhammad Ali Society Karachi (ELI-00600) Dossier#2-7A Date: 04-10-23	Legal Manufacturer: M/S Jiangxi hongda medical equipment group LTD, 39 south shangli rd jinxian county, Nanchang Jiangxi province china FSC: not provided	Hollow Fiber hemo Dialyser Codes & Sizes: As per FSC Class-B Shelf Life: 3 years.	Deferred for provision of original valid notarised FSC

35.	Seamac (Pvt) Ltd 301 3 rd floor Plot No 186-C Al-Murtaza commercial lane 5 DHA Phase-VIII Karachi. (ELI-00674) Dossier# 06-c/ F.7/A Diary# 28188 Date:04-10-22 Submitted Fee: 50,000/-PKR Challan No.: 242421948944	Legal Manufacturer: Ningbo David Medical Device Co., Ltd. #2 Keyuan Road, Shipu Science And Technology Park, Ningbo, Zhejiang Province, China P.C.: 315040 FSC: China Valid Till: 19-01-2023	Infant Radiant Warmer HKN-9010 (Infant Radiant Warmer) Codes & Sizes: HKN-9010 Class-C Shelf Life: 08 years	Deferred for the provision of following documents: • Provide valid FSC of country of origin (China). • Provide Stability studies of claimed shelf life of 08 years.
36.	Seamac (Pvt) Ltd 301 3 rd floor Plot No 186-C Al-Murtaza commercial lane 5 DHA Phase-VIII Karachi. (ELI-00674) Dossier# 07- c/F.7/A Diary# 28187 Date:04-10-22 Submitted Fee: 50,000/-PKR Challan No.: 5592348294	Legal Manufacturer: Ningbo David Medical Device Co., Ltd. #2 Keyuan Road, Shipu Science And Technology Park, Ningbo, Zhejiang Province, China P.C.: 315040 FSC: China Valid Till: 19-01-2023	Infant Incubator YP90AB (Infant Incubator) Codes & Sizes: YP90AB Class-C Shelf Life: 08 years	Deferred for the provision of following documents: • Provide valid FSC of country of origin (China). • Provide Stability studies of claimed shelf life of 08 years.
37.	Seamac (Pvt) Ltd 301 3 rd floor Plot No 186-C Al-Murtaza commercial lane 5 DHA Phase-VIII Karachi. (ELI-00674) Dossier# 08- c/F.7/A Diary# 28186 Date:04-10-22 Submitted Fee: 50,000/-PKR Challan No.: 8126309219	Legal Manufacturer: Ningbo David Medical Device Co., Ltd. #2 Keyuan Road, Shipu Science And Technology Park, Ningbo, Zhejiang Province, China P.C.: 315040 FSC: China Valid Till: 19-01-2023	Infant Incubator YP100B Codes & Sizes: YP100B Class-C Shelf Life: 08 years	Deferred for the provision of following documents: • Provide valid FSC of country of origin (China). • Provide Stability studies of claimed shelf life of 08 years.
38.	Noor International, Noor House, 29- D, Block 6,	Legal Manufacturer: Precision Medical 300 Held Drive, Northampton Pa 18067	Air-Oxygen Blender PM 5200 (Blender)	Deferred for the provision of following documents:

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	<p>PECHS, Karachi 75400 Pakistan (ELI-00061)</p> <p>Dossier# 4415-7A Date:23-02-22</p> <p>Submitted Fee: 50,000/-PKR</p> <p>Challan No.: 7318054037</p>	<p>USA</p> <p>FSC: USA Valid Till: 14-04-2022</p>	<p>Codes & Sizes:</p> <p>PM 5200</p> <p>Class-C</p> <p>Shelf Life: 08 years</p>	<ul style="list-style-type: none"> • Provide valid FSC of country of origin (USA). • Provide Stability studies of claimed shelf life of 08 years. • Provide valid ISO 13485 certificate.
39.	<p>UDL Distribution (pvt) Ltd.1-D-13, Sector 30, Korangi Industrial Area, Karachi. (ELI-00073)</p> <p>Dossier# 1046-c Date:26-01-23 Submitted Fee: 50,000/-PKR Challan No.: 9691575380</p>	<p>Legal Manufacturer:</p> <p>Karex Industries Sdn. Bhd. PTD, 7906 & 7907 Taman Pontian Jaya BT,34 Jalan Johor,82000 Pontian,Johor, Darul Takzim, Malaysia <i>Manufacturing site:</i> Lot 2244,Batu 39 ½ Pontian Besar, 82000 Pontian,Johor, Darul Takzim, Malaysia FSC: Malaysia Valid till: 16-01-2027</p>	<p>Happy Life- Chahat (Natural Rubber Latex Male Condoms)</p> <p>Code: P53S Red</p> <p>Class-C</p> <p>Shelf Life: 05years</p>	<p>Deferred for the provision of following documents:</p> <ul style="list-style-type: none"> • Provide valid original & embassy attested FSC of country of origin (Malaysia). • Provide valid ISO 13485 certificate.
40.	<p>Moody Consulting Pakistan, Office No. 14, 2nd Floor, Mujahid Plaza, Jinnah Avenue, Blue area Islamabad ELI-00926</p> <p>Dossier# 4010- ISB Date:04-01-23 Submitted Fee: 50,000/-PKR Challan No.: 3342502957</p>	<p>Legal Manufacturer:</p> <p>M/s Daan Gene Co., Ltd. No.19, Xiangshan Road, Science Park, High & New Technology Development District, Guangzhou, Guangdong, P.R. China</p> <p>Original FSC: Netherlands</p> <p>Valid till: 26/05/2025</p>	<p>DAAN GENE (Monkeypox Virus DNA (PCR-Fluorescence Probing)</p> <p>Codes & Sizes: cat#DA1430; DA1431</p> <p>Class-D</p> <p>Shelf Life: 12 Months</p>	<p>Deferred for the provision of following documents:</p> <ul style="list-style-type: none"> • Provide notarized Design examination certificate for class D product.
41.	<p>Zaman Enterprises & Diagnostics Shop No. G-31, Ground Floor, Orison Tower & Shopping Mall, Block 10, KDA Scheme No. 24 Gulshan e Iqbal Karachi (ELI-00465)</p>	<p>Legal Manufacturer:</p> <p>CITEST DIAGNOSTIC INC 170-422 Richards Street Vancouver BC, V6B 2Z4, CANADA</p> <p>FSC: Spain Issued: 07-09-2020</p>	<p>CITEST DENGUE NSI RAPID TEST Kit</p> <p>Codes & Sizes: Ref: IDES-402 Mod: WB/S/P, Cassette</p> <p>Class-C</p> <p>Shelf Life: 27 months</p>	<p>Deferred for the provision of following documents:</p> <ul style="list-style-type: none"> • Provide valid & original LOA • Provide valid ISO 13485 certificate.

	Dossier#4250-7A Date:23-11-21 Submitted Fee: 50,000/-PKR Challan No.: 35080080533			
42.	WIS International (Pvt) Ltd, Office no. 910, 9th Floor, Business Avenue Building, plot No. 26-A, Block 6, P.E.C.H.S, Karachi ELI NO. 00659 Dossier#313-C Date:30-11-22 Submitted Fee: 50,000/-PKR Challan No.: 646878823471	Legal Manufacturer: Suzhou Sunan Zimmered Medical Instrument Co., Ltd South Jiangang Road, Hexing, Jinfeng Town, Zhanjiang, 215626 Jiangsu P.R. China FSC China issued 15-09-2022	ZMD Compression Bone Plates Codes & Sizes: ZSQ01, ZSQ02, ZSQ03, ZSQ04, ZSQ05, ZSQ06, ZSQ07, ZSQ08, ZSQ09, ZSQ10, ZSQ11, ZSQ12, ZSQ13, ZSQ14, ZEQ01, Class-D Shelf Life: 5 years	Deferred for the provision of following documents: <ul style="list-style-type: none"> • Provide notarized Design examination certificate for class D product.
43.	MR Medical Pakistan Pvt, Ltd Office in. 1101, 11th floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad ELI-01008 Dossier# 4130-p Submission date: 22/02/2023 Fee submitted: 50,000/- Challan No. 6488215328	Legal Manufacturer: Shenzhen Mindray Bio- Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, Hig-Tech Industrial Park, Nanshan, 518057, Shenzhen, China. FSC original: Germany Issued on 02-02-2021	MINDRAY (Multi Control Sera P) Codes & Sizes: N/A Class-C Shelf Life: 24 months Storage condition: 2-8°C	Deferred for the provision of following documents: <ul style="list-style-type: none"> • Provide complete stability studies for claimed shelf life of 24 months.
44.	Medi-Serv International GF 28 Jinnah Plaza, Defense Chowk, Main Boulevard, Lahore Cantt ELI: 00171 4194-P 18-09-2023	Legal Manufacturer: M/s Eyekon Medical Inc., 2451 Enterprise Road, Clearwater, FL USA 33763 FSC: USA Valid till: 15/03/2025 FSC issued by Safety Harbor chamber of commerce issuance 31-07-2023 FDA Registration no. 1038833	Eyekon (Posterior Chamber Intraocular Lenses (Hydrophilic Acrylic) Class-C Shelf Life: not provided Codes:	Deferred for the provision of following: <ul style="list-style-type: none"> • Brand name is mentioned on the FSC of US FDA only, codes are not mentioned, Clarification is required. • Updated stability studies. • Difference between the applied models. • Labels of applied models approved in the country of origin.

45.	Medi-Serv International GF 28 Jinnah Plaza, Defense Chowk, Main Boulevard, Lahore Cantt ELI: 00171 4195-P 18-09-2023	<u>Legal Manufacturer:</u> M/s Eyekon Medical Inc., 2451 Enterprise Road, Clearwater, FL USA 33763 FSC: USA Valid till: 15/03/2025 FSC issued by Safety Harbor chamber of commerce issuance 31-07-2023 FDA Registration no. 1038833	Eyekon Viscoelastic Gel (Ophthalmic viscosurgical device) Class-B Shelf Life: 02 Years Model: Eyecoat	Deferred for the provision of following: <ul style="list-style-type: none">• Brand name is mentioned on the FSC of US FDA only, codes are not mentioned, Clarification is required.• Updated stability studies.• Difference between the applied models.• Labels of applied models approved in the country of origin.• Apply separately for other models/ types.
46.	Medi-Serv International GF 28 Jinnah Plaza, Defense Chowk, Main Boulevard, Lahore Cantt ELI: 00171 4196-P 18-09-2023	<u>Legal Manufacturer:</u> M/s Eyekon Medical Inc., 2451 Enterprise Road, Clearwater, FL USA 33763 FSC: USA Valid till: 15/03/2025 FSC issued by Safety Harbor chamber of commerce issuance 31-07-2023 FDA Registration no. 1038833	Eyekon (PMMA Posterior Chamber Intraocular Lens) Class-C Shelf Life: 05 Years Codes as per CFG, US FDA: S-116 S-104	Deferred for the provision of following: <ul style="list-style-type: none">• Brand name is mentioned on the FSC of US FDA only, codes are not mentioned, Clarification is required.• Updated stability studies.• Difference between the applied models.• Labels of applied models approved in the country of origin.• Apply separately for other models/ types.
47.	Verizon, 60-D, FCC, Zahoor Elahi Road, Gulberg IV, Lahore ELI: 00087 2394-P 23-05-2021	<u>Legal Manufacturer:</u> Cook Ireland Limited O'Halloran Road National Technology Park, Limerick, Ireland FSC: Ireland Valid till: 13.08.2023	ECHOTIP PROCORE HD Ultrasound Biopsy Needle (Aspiration Needles) Class-B Shelf Life: 36 Months Codes: ECHO-HD-19-C ECHO-HD-22-C ECHO-HD-25-C ECHO-HD-3-20-C	Deferred for the provision of original and valid LOA, FSC, ISO 13485 and FQA certificates.
48.	Verizon, 60-D, FCC, Zahoor Elahi Road, Gulberg IV, Lahore ELI: 00087 1686-P 07-09-2020	<u>Legal Manufacturer:</u> Cook Inc. 750 Daniels Way, Bloomington, IN USA 47404 FSC: FDA U.S FOOD &DRUG Date of issue: September 18, 2018 Valid till: September 17, 2020	ATB Advance PTA Dilatation Catheters (Angioplasty Balloon Catheters) Class-B Shelf Life: 3 Years Codes as per FSC	Deferred for the provision of original and valid LOA, FSC, ISO 13485 and FQA certificates.

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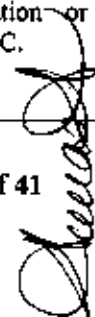
49.	Verizon, 60-D, FCC, Zahoor Elahi Road, Gulgerg IV, Lahore ELI: 00087 1685-P 07-09-2020	Legal Manufacturer: Cook Inc. 750 Daniels Way, Bloomington, IN USA 47404 FSC: FDA U.S FOOD & DRUG Date of issue: September 18, 2018 Valid till: September 17, 2020	Disposable Two-Part Trocar Needle (Introducer/ Access Needle) Class-B Shelf Life: 3 Years Code: 090020 090021, 090020-S1	Deferred for the provision of original and valid LOA, FSC, ISO 13485 and FQA certificates.
50.	M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi (ELI-00019) Dossier Number: 846 Dossier Submission date: 20-Dec-2022	Manufacturer: Abbott Molecular Inc. 1300 East Touhy Avenue Des Plaines, IL 60018 USA (embassy attested original FSC Issuance: 13.09. 2022, Germany) LOA issuance date 28.10.2022	Vysis LSI BCR/ABL ES Dual Color Translocation Probe Set 08L55-020 -15 to -25°C Shelf Life: Months Class: C Rs.50,000/-	Deferred for submission of stability studies and provision of the shelf life.
51.	Hospital Supply Corporation, 42 Darul Aman Housing Society, Block 7& 8, Karachi, Pakistan Lic. No. (ELI-00005)	Infomed Fluids S.r.l, Blvd Theodor Pallady, 50 032266 Sector 3-Bucharest Romania FSC: Romania (EU) Valid till: 26-05-2024	ACD-A Anticoagulant Solution 500ml Class : C, Shelf Life: 24 Months, Sizes and Model as per FSC, Date of submission :07-04-2022	Deferred for submission of the following documents:- <ul style="list-style-type: none">• The firm has provided copy of FSC. Therefore, provide valid and embassy attested FSC of country of origin and reference country.• Provide Notarized LOA• Expired ISO submitted therefore provide valid and notarized ISO 13485• Provide CE certificate or clarify.• Provide stability study
52.	Hospital Supply Corporation, 42 Darul Aman Housing Society, Block 7& 8, Karachi, Pakistan Lic. No. (ELI-00005) Date of submission :19-07-2022	Dornier Medtech GmbH, Argelsrieder Feld 7, 82234 Wessling, Germany Copy of FSC Germany Issued on: 21-03-2022	Dornier Delta III Pro (Extra-Corporeal Shock Wave Lithotripter) with its Accessories. Class :C, Shelf Life: N/A, Sizes and Model as per FSC, Fee Submission : 50000/-	Deferred for submission of the following documents:- <ul style="list-style-type: none">• Two name of the manufacturer is given in the FSC Dornier Medtech GmbH and the other is Dornier Medtech systems GmbH need clarification.• All documents are photocopy, submit original documents.

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				<ul style="list-style-type: none"> The name in the FSC is Dornier Delta III Pro they have applied with Dornier Delta III Pro (Extra-Corporeal Shock Wave Lithotripter) with its Accessories need clarification. Submit embassy attested valid FSC in the country of origin Submit Notarized and valid LOA , ISO 13485 and CE Certificate
53.	<p>Hospital Supply Corporation, 42 Darul Aman Housing Society, Block 7& 8, Karachi, Pakistan Lic. No. (ELI-00005) Date of submission :19-07-2022</p>	<p>Dornier Medtech GmbH, Argelsrieder Feld 7, 82234 Wessling, Germany FSC Germany Issued on: 21-03-2022</p>	<p>Dornier Aries 2 (Extra Corporeal Shock Wave Therapy) with its Accessories. Class :C, Shelf Life: N/A, Sizes and Model as per FSC, Fee Submission 5000/-</p>	<p>Deferred for submission of the following documents:-</p> <ul style="list-style-type: none"> Two name of the manufacturer is given in the FSC Dornier Medtech GmbH and the other is Dornier Medtech systems GmbH need clarification. All documents are photocopy, submit original documents. The name in the FSC is Dornier Aries 2 with cart and accessories while they have applied with Dornier Aries 2 (Extra Corporeal Shock Wave Therapy) with its Accessories need clarification. Also revise Form 7A and write model. Submit embassy attested valid FSC in the country of origin Submit Notarized and valid LOA , ISO 13485 and CE Certificate
54.	<p>Hospital Supply Corporation, 42 Darul Aman Housing Society, Block 7& 8, Karachi, Pakistan Lic. No. (ELI-00005) Date of submission :19-07-2022</p>	<p>Dornier Medtech systems GmbH, Argelsrieder Feld 7, 82234 Wessling, Germany 1) FSC Germany Issued on 21-03-2022 2) FSC USA Validity: 04-04-2024</p>	<p>Dornier Compact Sigma (Extra- Corporeal Shock Wave Lithotripter) with its Accessories. Class :C, Shelf Life: N/A, Sizes and Model as per FSC, Fee Submission Date: 18-07-2022</p>	<p>Deferred for submission of the following documents:-</p> <ul style="list-style-type: none"> All documents are photocopy, submit original documents. The name in the FSC is different than on Form 7A need to revise Form 7A Submit embassy attested valid FSC in the country of origin Submit Notarized and valid LOA , ISO 13485 and CE Certificate

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55.	Hospital Supply Corporation, 42 Darul Aman Housing Society, Block 7& 8, Karachi, Pakistan Lic. No. (ELI-00005) Date of submission :02-09-2022	Dornier Medtech GmbH, Argelsrieder Feld 7, 82234 Wessling, Germany 1) FSC Germany Issued on 21-03-2022	Dornier Medilas H Solvo 35 with Accessories and laser Fibers. LASER FIBER: Dornier SmartFlex Reusable Laser Fibers: i)270 micron Reusable Laser Fiber K2013151 ii)400 micron Reusable Laser Fiber K2013152 iii)600 micron Reusable Laser Fiber K2013153 iv)1000 micron Reusable Laser Fiber K2013154 v)270 micron Reusable Laser Fiber Slim K2013162 Dornier SingleFlex Single Use Laser Fibers i)270 micron Single Use Laser Fiber K2013062 ii)400 micron Single Use Laser Fiber K2013063 iii)600 micron Single Use Laser Fiber K2013064 iv) 1000 micron Single Use Laser Fiber K2013065 v) 270 micron Single Use Laser Fiber Slim K2013161 vi) 400 micron Single Use Laser Fiber 4.5 meter K2013156 Dornier GentleFlex Single Use Ball Tip Laser Fibers 270 micron Single Use Ball Tip Laser Fiber K2014290 Class : C, Shelf Life: N/A Sizes and Model as per FSC, Fee Submission 50000/-	Deferred for submission of the following documents:- <ul style="list-style-type: none"> Two name of the manufacturer is given in the FSC Dornier Medtech GmbH and the other is Dornier Medtech systems GmbH need clarification. All documents are photocopy, submit original documents. The name in the FSC is Dornier Medilas H Solvo 35 while they have applied with Dornier Medilas H Solvo 35 with Accessories and laser Fibers. LASER FIBER: Dornier SmartFlex Reusable Laser Fibers need clarification and justification of Family/system under the MDR 2017. Also revise Form7A and write model. Submit embassy attested valid FSC in the country of origin Submit Notarized and valid LOA , ISO 13485 and CE Certificate
56.	Hakimsons House, A-58/B S.I.T.E Manghopir Road, Karachi- 75700, Pakistan. ELI_00396	TMT Tibbi Medical Malz San. Ve Tic. A.S Add: Faith Mah.1188 Sok. No 14 PK 35414 Sarnic Gaziemirizmir/Turkiye. FSC Country valid until (22-10-2024)	Life Control Disposable Mechanical Ventilator Claimed shelf life: 05 Class: C	Deferred for submission of the following documents:- <ul style="list-style-type: none"> The brand name of the product on the FSC is different than the applied; need clarification or revise form 7A as per FSC. Correct the Model name



		ISO Valid until 09-02-2024 FQA Valid until EC Certificate (12-12-2023) LOA Valid until (22-19-2024)		
57.	Medisurg Innovatives Healthcare 1-6-N, Block-6, PECHS, Main Nursery Shahrah e faisal Karachi. (ELI-00242)	Legal Manufacturer and mfg. site: Optimed medizinische instrumente GmbH, Ferdinand-Porsche-Strasse 11, 76275 Ettlingen Germany. FSC: Germany Issued: 28-9-2020	OptiSoft Ureteral Stents Class: C Shelf Life: Steerable stents: 3 years All other 5 years Following Products are in OptiSoft ureteral stent family: <ul style="list-style-type: none">▪ OptiSoft endoprosthesis▪ OptiSoft Ureteral Stents Intra Operative▪ OptiSoft MultiLength Ureteral Stents▪ OptiSoft Ureteral Stents, MultiLength Steerable▪ OptiSoft Pediatric Ureteral Stents▪ OptiSoft Renal Transplantation Ureteral Stents▪ OptiSoft Steerable Ureteral Stents▪ OptiSoft Ureteral Stents, Standard▪ OptiSoft Ext-Tumor Ureteral Stents▪ OptiSoft Ext-Tumor Ureteral Stents, Steerable Codes & sizes: As per FSC Fee Detail: 50,000/- Submitted on 29-06-2022	Deferred for submission of the following documents:- <ul style="list-style-type: none">• Justify the grouping of applied product in multiple products and codes as per medical device Rules 2017 or Revise Form-7A as per grouping given in MDR 2017.• Provide Stability studies.• Clarify the brand names as per FSC
58.	Medisurg Innovatives Healthcare 1-6-N, Block-6, PECHS, Main	Legal Manufacturer and mfg. site: Optimed medizinische instrumente GmbH,	OptiPur Ureteral Stents Class: C <ul style="list-style-type: none">▪ OptiPur endoprosthesis	Deferred for submission of the following documents:- <ul style="list-style-type: none">• Justify the grouping of applied product in multiple products and

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	Nursery Shahrah e faisal Karachi. (ELI-00242)	Ferdinand-Porsche-Strasse 11, 76275 Ettlingen Germany. FSC: Germany Issued: 28-9-2020	<ul style="list-style-type: none"> OptiPur Ureteral Stents, MultiLength OptiPur Steerable Ureteral Stents, MultiLength OptiPur Steerable Ureteral Stents OptiPur Ureteral Stents, Standard OptiPur Ureteral Stents, Ureterorenoscopic Optipur Probing & Placement Ureteral Stent <p>Steerable stents & Probing & Placement Ureteral Stent: 3 years All other 5 years</p> <p>Codes & sizes: As per FSC</p> <p>Fee Detail: 50,000/- Submitted on 29-06-2022</p>	<p>codes as per medical device Rules 2017 or Revise Form-7A as per grouping given in MDR 2017.</p> <ul style="list-style-type: none"> Provide Stability studies. Clarify the brand names as per FSC
59.	Medisurg Innovatives Healthcare 1-6-N, Block-6, PECHS, Main Nursery Shahrah -e-faisal Karachi. (ELI-00242)	<p>Legal Manufacturer and mfg. site:</p> <p>Optimed medizinische instrumente GmbH, Ferdinand-Porsche-Strasse 11, 76275 Ettlingen Germany.</p> <p>FSC: Germany</p> <p>Issued: 28-9-2020</p>	<p>Opti-J Ureteral Stent</p> <ul style="list-style-type: none"> Opti-J Ureteral Stents, MultiLength Opti-J Ureteral Stents, Standard <p>Class: C</p> <p>Shelf Life: 3 Years</p> <p>Codes & sizes: As per FSC</p> <p>Fee Detail: 50,000/- Submitted on 29-06-2022</p>	<p>Deferred for submission of the following documents:-</p> <ul style="list-style-type: none"> Justify the grouping of applied product in multiple products and codes as per medical device Rules 2017 or Revise Form-7A as per grouping given in MDR 2017. Provide Stability studies. Clarify the brand names as per FSC
60.	Medisurg Innovatives Healthcare 1-6-N, Block-6, PECHS, Main Nursery Shahrah -e-faisal Karachi. (ELI-00242)	<p>Legal Manufacturer and mfg. site:</p> <p>Optimed medizinische instrumente GmbH, Ferdinand-Porsche-Strasse 11, 76275 Ettlingen Germany.</p> <p>FSC: Germany</p> <p>Issued: 28--2020</p>	<p>CarboSoft Ureteral Stent (With DLC Coating)</p> <p>Class: C</p> <p>Shelf Life: 3 years</p> <p>Codes & sizes: As per FSC</p> <p>Fee Detail: 50,000/- Submitted on 29-06-2022</p> <p>Slip No. 591547947</p>	<p>Deferred for submission of the following:-</p> <ul style="list-style-type: none"> Provide complete Stability studies. Clarify the brand names as per FSC.

61.	Jawad Traders, PS Tower City Mall Godown Road Near Govt. Commerce College Peshawar, KPK, Pakistan ELI: 00532 Dossier# 3921- KP Submission date: 08/05/2023 Fee submitted: 25,000/- Challan No. 891441409	Legal Manufacturer: M/s Beijing Fert Technology Co., Ltd, Room 4196, Building 1, Shixingdong Jie, Badachu High Scientific and Technologic Garden,, Shijingshan District, Beijing China Original FSC: China Valid till: 2024/01/22	Fert (Sterile IV Catheter) Codes & Sizes: As per FSC Class-B Shelf Life: 3 years	Deferred for the provision of following: <ul style="list-style-type: none">• FSC of reference country/ CE mark certificate is not provided.• Stability data of 3years claimed shelf life is not provided.• ISO certificate scope is not covered for the applied MD.• There are two different types of models applied in single application i.e., Y Model & Z Model.• Submit separate fee & form-7A for Sterile IV Catheter Z-Model.
62.	Jawad Traders, PS Tower City Mall Godown Road Near Govt. Commerce College Peshawar, KPK, Pakistan ELI: 00532 Dossier# 3923- KP Submission date: 08/05/2023 Fee submitted: 25,000/- Challan No. 437720164356	Legal Manufacturer: M/s Beijing Fert Technology Co., Ltd, Room 4196, Building 1, Shixingdong Jie, Badachu High Scientific and Technologic Garden,, Shijingshan District, Beijing China FSC: China Valid till: 2024/01/22	Fert (Sterile Safety IV Catheter) Codes & Sizes: As per FSC Class-B Shelf Life: 3 years	Deferred for the provision of following: <ul style="list-style-type: none">• FSC of reference country/ CE mark certificate is not provided.• Stability data of 3years claimed shelf life is not provided.• ISO certificate scope is not covered for the applied MD.• There are four different types of models applied in single application i.e., Y Model Single port, Y Model Dual port, Z Model Pen-like&, Z Model with wings & injection port.• Submit separate fee & form-7A for Sterile Safety IV Catheter Y Model Dual port, Z Model Pen- like &, Z Model with wings & injection port.
63.	Saad enterprises. shop no,03,Basement Mubarak Plaza Balahisar road, Peshawar ELI.00815 Dossier# 3977- KP Submission date: 15/05/2023 Fee submitted: 50,000/- Challan No. 19875604914	Legal Manufacturer: BIOVIC Sdn.Bhd. 12A Jalan PJU3/40, Sunway Damansara Technology Park,Petaling Jaya,47810 Malaysia. Original FSC: Malaysia Date of Issue: 30/10/2023 Expiry date: 29/10/2025	AVATOR PTFE VASCULAR GRAFTS (Avator Ptfе vascular grafts) Codes & Sizes: N/A Class-C Shelf Life: 5 years	Deferred for the provision of following: <ul style="list-style-type: none">• Challan form bearing the name of Aortic, single stage venous, Aortic root, two stage venous Cannula & left vent instead of the applied MD (Avator Ptfе vascular grafts); provide challan as per applied product.• Embassy attested FSC is not submitted.

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64.	<p>Bajwa Sons, House # 03, 1st and 2nd Floor, 13 Muslim street, Mayo Hospital Road, Lahore ELI: 00314</p> <p>Submission date: 21/02/2022</p> <p>Fee submitted: 20,000/- Challan No. 7272023977</p> <p>Fee submitted: 5,000/- Challan No. 932080436</p>	<p>Legal Manufacturer: Winner Medical (Hunan) Co, Ltd, Address: No. 8 industry AVE, Economic development zone, Li county, 415500 changde, Hunan province, P.R, China. FSC: China Valid till: 2024/09/27</p>	<p>Blood transfusion set for single use (Disposable transfusion set) Codes & Sizes: As per FSC Class-B Shelf Life: 03 years</p>	<p>Deferred for the provision of following:</p> <ul style="list-style-type: none"> • ISO 13485 certificate is expired, provide valid certificate. • CE certificate//FSC of reference country is not provided, • Stability studies of claimed shelf life of 3years is not provided. • Credentials of manufacturer is not duly notarized from country of origin; provide the original notarized copies.
65.	<p>Bajwa Sons, House # 03, 1st and 2nd Floor, 13 Muslim street, Mayo Hospital Road, Lahore ELI: 00314</p> <p>Submission date: 21/02/2022</p> <p>Fee submitted: 25,000/- Challan No. 2102877</p>	<p>Legal Manufacturer: Winner Medical (Hunan) Co, Ltd, Address: No. 8 industry AVE, Economic development zone, Li county, 415500 changde, Hunan province, P.R, China. FSC: China Valid till: 2024/09/27</p>	<p>IV Infusion set (Infusion set with needle for single use) Codes & Sizes: As per FSC Class-B Shelf Life: 03 years</p>	<p>Deferred for the provision of following:</p> <ul style="list-style-type: none"> • ISO 13485 certificate is expired, provide valid certificate. • CE certificate//FSC of reference country is not provided. • Stability studies of claimed shelf life of 3years is not provided. • Credentials of manufacturer is not duly notarized from country of origin; provide the original notarized copies.
66.	<p>Bajwa Sons, House # 03, 1st and 2nd Floor, 13 Muslim street, Mayo Hospital Road, Lahore ELI: 00314</p> <p>Submission date: 21/02/2022</p> <p>Fee submitted: Not provided Challan No. Not provided.</p>	<p>Legal Manufacturer: Winner Medical (Hunan) Co, Ltd, Address: No. 8 industry AVE, Economic development zone, Li county, 415500 changde, Hunan province, P.R, China. FSC: China Valid till: 2024/09/27</p>	<p>IV Cannula / Catheter Codes & Sizes: As per FSC Class-B Shelf Life: 03 years</p>	<p>Deferred for the provision of following:</p> <ul style="list-style-type: none"> • ISO 13485 certificate is expired, provide valid certificate. • CE certificate//FSC of reference country is not provided. • Stability studies of claimed shelf life of 3years is not provided. • Credentials of manufacturer is not duly notarized from country of origin; provide the original notarized copies.
67.	<p>AK Traders 123- Canal Bank Housing Scheme, Harbanspura, Lahore. ELI: 01035</p>	<p>Legal Manufacturer: Hingzhou Rejoin Mastin Medical Co., Ltd, Floors 1st and 2nd, 101B No. 22 xiyan Road Yuhang Economic & technological</p>	<p>Rejoin Codes & Sizes: not provided Class-C Shelf Life: not provided</p>	<p>Deferred for the provision of following:</p> <ul style="list-style-type: none"> • LOA is expired upon submission i.e., on 30-04-2023. • No generic name is provided.

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	<p>Dossier# 3989-P Submission date: 06/07/2023 Fee submitted: 50,000/- Challan No. 472968130532</p>	<p>Development Zone, Linping district, 311100 Hangzhou Zhejiang, People's Republic of China</p> <p>FSC: China Valid till: 204/01/08</p>		<ul style="list-style-type: none"> • Provide Credentials of manufacturer abroad duly notarized from country of origin. • Provide ISO 13485 certificate duly notarized from country of origin. • Provide Stability studies for the claimed shelf life. • Incomplete information is provided on form-7A. Kindly submit revised form-7A with all relevant & required information. • Multiple orthopedic devices are applied in single application. Apply separate case for each MD.
68.	<p>S. Ejazuddin & Co., P O Box 5629, Zia Plaza, Altaf Hussain Road, Karachi</p> <p>[ELI-00078]</p> <p>Dossier#4780-7A Date:05-07-22</p> <p>Submitted Fee: 50,000/-PKR</p> <p>Challan No.: 8205341568</p>	<p>Legal Manufacturer: HYPHEN BIOMED 155 rue d'Eragny, 9500 Neuville-sur-Oise, France</p> <p>FSC: France</p> <p>Issued on: 02/06/2021</p>	<p>BIOPHEN LMWH Control Low CI</p> <p>Codes & Sizes: 224301</p> <p>Class-C</p> <p>Shelf Life: 36 Months at 2-8 °c</p>	<p>Deferred for the provision of following:</p> <ul style="list-style-type: none"> • Photocopies FSC is submitted. Provide Valid, Original & embassy attested FSC of country of origin. • Provide notarized credentials of manufacturer, LOA, ISO 13485 certificate & FQA certificate. • Provide valid ISO 13485 certificate • The stability studies for claimed shelf life of 36 months are not provided; provide the same.
69.	<p>S. Ejazuddin & Co., P O Box 5629, Zia Plaza, Altaf Hussain Road, Karachi</p> <p>[ELI-00078]</p> <p>Dossier#4781-7A Date:05-07-22</p> <p>Submitted Fee: 50,000/-PKR</p> <p>Challan No.: 9127638365</p>	<p>Legal Manufacturer: HYPHEN BIOMED 155 rue d'Eragny, 9500 Neuville-sur-Oise, France</p> <p>FSC: France</p> <p>Issued on: 02/06/2021</p>	<p>BIOPHEN DiXal</p> <p>Codes & Sizes: 221030</p> <p>Class-C</p> <p>Shelf Life: 36 Months at 2-8 °c</p>	<p>Deferred for the provision of following:</p> <ul style="list-style-type: none"> • Photocopied FSC is submitted. Provide Valid, Original & embassy attested FSC of country of origin. • Provide notarized credentials of manufacturer, LOA, ISO 13485 certificate & FQA certificate. • Provide valid ISO 13485 certificate • The stability studies for claimed shelf life of 36 months are not provided; provide the same.
70.	<p>S. Ejazuddin & Co., P O Box 5629, Zia Plaza, Altaf Hussain Road, Karachi</p>	<p>Legal Manufacturer: HYPHEN BIOMED 155 rue d'Eragny, 9500 Neuville-sur-Oise, France</p>	<p>BIOPHEN Heparin Calibrator</p> <p>Codes & Sizes: 222001</p> <p>Class-C</p>	<p>Deferred for the provision of following:-</p> <ul style="list-style-type: none"> • The name of product on fee challan, FSC and all other documents is <i>Biophen Heparin Calibrator</i> while it's <i>Biophen Heparin LRT</i> on form-

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	<p>[ELI-00078]</p> <p>Dossier#4782-7A Date:05-07-22</p> <p>Submitted Fee: 50,000/-PKR</p> <p>Challan No.: 64844926</p>	<p>FSC: France</p> <p>Issued on: 02/06/2021</p>	<p>Shelf Life: 30 Months at 2-8 °c</p>	<p>7A. Give proper justification.</p> <ul style="list-style-type: none"> • Photocopied FSC is submitted. Provide Valid, Original & embassy attested FSC of country of origin. • Provide notarized credentials of manufacturer, LOA, ISO 13485 certificate & FQA certificate. • Provide valid ISO 13485 certificate. • The stability studies for claimed shelf life of 30 months are not provided; provide the same.
71.	<p>S. Ejazuddin & Co., P O Box 5629, Zia Plaza, Altaf Hussain Road, Karachi</p> <p>[ELI-00078]</p> <p>Dossier#4783-7A Date:05-07-22</p> <p>Submitted Fee: 50,000/-PKR</p> <p>Challan No.: 1956491227</p>	<p>Legal Manufacturer: HYPHEN BIOMED 155 rue d'Eragny, 9500 Neuville-sur-Oise, France</p> <p>FSC: France</p> <p>Issued on: 02/06/2021</p>	<p>BIOPHEN LMWH Control C4</p> <p>Codes & Sizes: 224201</p> <p>Class-C</p> <p>Shelf Life: 36 Months at 2-8 °c</p>	<p>Deferred for the provision of following:</p> <ul style="list-style-type: none"> • Photocopied FSC is submitted. Provide Valid, Original & embassy attested FSC of country of origin. • Provide notarized credentials of manufacturer, LOA, ISO 13485 certificate & FQA certificate. • Provide valid ISO 13485 certificate • The stability studies for claimed shelf life of 36 months are not provided; provide the same.
72.	<p>S. Ejazuddin & Co., P O Box 5629, Zia Plaza, Altaf Hussain Road, Karachi</p> <p>[ELI-00078]</p> <p>Dossier#4784-7A Date:05-07-22</p> <p>Submitted Fee: 50,000/-PKR</p> <p>Challan No.: 83636347200</p>	<p>Legal Manufacturer: HYPHEN BIOMED 155 rue d'Eragny, 9500 Neuville-sur-Oise, France</p> <p>FSC: France</p> <p>Issued on: 02/06/2021</p>	<p>BIOPHEN Rivaroxaban Plasma Calibrator</p> <p>Codes & Sizes: 222701</p> <p>Class-C</p> <p>Shelf Life: 36 Months at 2-8 °c</p>	<p>Deferred for the provision of following:</p> <ul style="list-style-type: none"> • Photocopied FSC is submitted. Provide Valid, Original & embassy attested FSC of country of origin. • Provide notarized credentials of manufacturer, LOA, ISO 13485 certificate & FQA certificate. • Provide valid ISO 13485 certificate • The stability studies for claimed shelf life of 36 months are not provided; provide the same.
73.	<p>S. Ejazuddin & Co., P O Box 5629, Zia Plaza, Altaf Hussain Road, Karachi</p> <p>[ELI-00078]</p> <p>Dossier#4785-7A</p>	<p>Legal Manufacturer: HYPHEN BIOMED 155 rue d'Eragny, 9500 Neuville-sur-Oise, France</p> <p>FSC: France</p> <p>Issued on: 02/06/2021</p>	<p>BIOPHEN Heparin LRT</p> <p>Codes & Sizes: 221011, 221013, 221015</p> <p>Class-C</p>	<p>Deferred for the provision of following:</p> <ul style="list-style-type: none"> • Photocopied FSC is submitted. Provide Valid, Original & embassy attested FSC of country of origin. • Provide notarized credentials of manufacturer, LOA, ISO 13485

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	<p>Date:05-07-22</p> <p>Submitted Fee: 50,000/-PKR</p> <p>Challan No.: 17686978748</p>		<p>Shelf Life: 18 Months at 2-8 °c</p>	<p>certificate & FQA certificate.</p> <ul style="list-style-type: none"> • Provide valid ISO 13485 certificate • The stability studies for claimed shelf life of 36 months are not provided; provide the same.
74.	<p>S. Ejazuddin & Co., P O Box 5629, Zia Plaza, Altaf Hussain Road, Karachi</p> <p>[ELI-00078]</p> <p>Dossier#1059-C Date:26-01-23</p> <p>Submitted Fee: 50,000/-PKR</p> <p>Challan No.: 88736694153</p>	<p>Legal Manufacturer: Arkray industry west, Inc. main Avenue, corner 3rd street, Cavite Economic Zone, Rosario, Cavite, 4106 Philippines.</p> <p>FSC: Philippines Issued on: 27/04/2021</p>	<p>Glucocard Σ (Blood Glucose Meters)</p> <p>Codes & Sizes: Not provided Class-C</p> <p>Shelf Life: 03 years</p>	<p>Deferred for the provision of following:-</p> <ul style="list-style-type: none"> • Apply separate case with separate fee for Glucocard Σ test strips (Blood Glucose test strips).As different manufacturing site on FSC for Blood Glucose test strips from Blood Glucose Meter. • Provide CE mark certificate/ FSC of reference country as product is from non-reference country. • LOA is expired (31-12-2022) upon submission. Submit valid & duly notarized LOA. • Provide notarized credentials of manufacturer, ISO 13485 certificate & FQA certificate. • Code justification is required as no code is mentioned on FSC of country of origin.
75.	<p>S.M Impex office No. B-309,3RD Floor, New chaili trade centre, Shahrah-e-Liaquat, Karachi. (ELI-00473) Dossier# 1107-c/7A Diary# 35479 Date:07-12-22</p> <p>Submitted Fee: 50,000/-PKR</p> <p>Challan No.: 7242163017</p>	<p>Legal Manufacturer: Geotek Medikal Ve Saglik Hiz. Tic. San Ltd Sti. Address: Ivedik OSB Agac Metal Sitesi 1436 Sk No. 12, Yenimahalle Ankara, Turkey</p> <p>FSC: Turkey Issued on: 04/12/2020</p>	<p>Geotek (Breast Localization Needle)</p> <p>Codes & Sizes: Sizes: 20GX10cm, 20GX12cm, 20GX15cm, 20GX5cm, 20GX7cm</p> <p>Codes: GBL2010, GBL2012, GBL2015, GBL2005, GBL2007,</p> <p>Class-D</p> <p>Shelf Life: 05 years</p>	<p>Deferred for the provision of following:-</p> <ul style="list-style-type: none"> • Provide clarification of medical device class as On form-7A class D is mentioned while its class IIA on DOC. • Provide valid ISO 13485 certificate • Provide design examination certificate if MD class is D.
76.	<p>Uniprom Healthcare L-151, 2ND floor, Sehba Akhter Road, block 13-D Gulshan-e-Iqbal Karachi. (ELI-00286)</p>	<p>Legal Manufacturer: Amity international address: Libra house, west street , Worsbrough Dale, Barnsley, S70 5PG, UK</p> <p>FSC: MHRA, UK Valid Till: 14-09-2024</p>	<p>VIRUSOLVE+ EDS (Didecyldimethyl ammonium chloride)</p> <p>Codes & Sizes: J35A, J35AA, J35B, J35C, J35D, J35E, J35F,</p>	<p>Deferred for the provision of following:</p> <ul style="list-style-type: none"> • LOA is expired on 31/12/2022. Provide Valid & Original LOA. • CE mark certificate is expired on 14/09/2023.

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	<p>Dossier# 125-c Date:17-10-22</p> <p>Submitted Fee: 50,000/-PKR</p> <p>Challan No.: 94649183</p>		<p>J35G.</p> <p>Class-C</p> <p>Shelf Life: 03 years</p>	<ul style="list-style-type: none"> • All Photocopied documents are provided. • Provide notarized credentials of manufacturer, LOA, ISO 13485 certificate & FQA certificate. • Provide Valid, Original & embassy attested FSC of country of origin. • The stability studies for claimed shelf life of 03years are not provided; provide the same.
77.	<p>Spero Enterprises, Office No. 301, 3rd Floor, Trade Arcade, Plot No. 23/F, Muhammad Ali Society Karachi (ELI-00600)</p> <p>Dossier#4403-7A Date:18-01-22</p> <p>Submitted Fee: 50,000/-PKR</p> <p>Challan No.: 826181121</p>	<p>Legal Manufacturer: Chengdu Wesley Bioscience Technology Co., Ltd. No. 3F. Block B-6, Tianfu life Science Park, No. 88 South Keyuan Road, High-Tech Zone, Chengdu, China</p> <p>FSC: China Valid Till: 13-6-2022</p>	<p>Wesley Hemodialysis Machine</p> <p>Codes & Sizes: W-T2008-B W-T6008S</p> <p>Class-C</p> <p>Shelf Life/ Service life: 08 years</p>	<p>Deferred for the provision of following:</p> <ul style="list-style-type: none"> • Form-7A is not signed & stamped. • Grouping of medical devices on Form-7A is not provided. • FSC (China) is expired on 13-06-2022. Provide Valid Original FSC of country of origin. • The stability studies for claimed Shelf Life/ service life of 08years are not provided.
78.	<p>National Enterprises, 409, 4th Floor, Al-Sehat Centre Annexe Reagent Plaza, Sharah-e-Faisal Karachi (ELI-00043)</p> <p>Dossier# 662c-F7/A Date:10-01-23</p> <p>Submitted Fee: 50,000/-PKR</p> <p>Challan No.: 19008571657</p>	<p>Legal Manufacturer: M/S Nakanishi Inc., 700 Shimohinata, Kanumashi, Tochigi, 322-8666, Japan</p> <p>FSC: Japan</p> <p>Issued on: 24/03/2021</p>	<p>Primado2 (Total Surgical System)</p> <p>Codes & Sizes: As per FSC</p> <p>Class-C</p> <p>Shelf Life: 05 years</p>	<p>Deferred for the provision of following:</p> <ul style="list-style-type: none"> • Photocopied FSC of country of origin (Japan) is submitted. Provide Valid, Original & embassy attested FSC of country of origin. • Provide valid ISO certificate • Stability studies of claimed shelf life of 05 years are not provided; provide the same. • Credentials of manufacturer, CE mark certificate are not duly notarized from country of origin; provide the notarized copies..
79.	<p>National Enterprises, 409, 4th Floor, Al-Sehat Centre Annexe Reagent Plaza, Sharah-e-Faisal Karachi (ELI-00043)</p>	<p>Legal Manufacturer: M/S Nakanishi Inc., 700 Shimohinata, Kanumashi, Tochigi, 322-8666, Japan</p> <p>FSC: Japan</p> <p>Issued on: 24/03/2021</p>	<p>Primado2 (Total Surgical System cutting Accessories sterile drills, sterile Burs, Saw blades, Resps & files)</p> <p>Codes & Sizes: As per FSC</p>	<p>Deferred for the provision of following:</p> <ul style="list-style-type: none"> • Photocopied FSC of country of origin (Japan) is submitted. Provide Valid, Original & embassy attested FSC of country of origin.

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	<p>Dossier#1238c-7A Date:28-02-23</p> <p>Submitted Fee: 25,000/-PKR</p> <p>Challan No.: 4265344687</p>		<p>Class-C</p> <p>Shelf Life: 05 years</p>	<ul style="list-style-type: none"> • Provide valid ISO certificate • Stability studies of claimed shelf life of 05 years are not provided. • Credentials of manufacturer, CE mark certificate are not duly notarized from country of origin; provide notarized copies. • Class of medical device on form-7A is C while on DOC its B. Justify the MD class of applied product. • Apply separate registration application for sterile Burs/drills, SAW Blades, Rasps/files.
80.	<p>National Enterprises, 409, 4th Floor, Al-Sehat Centre Annexe Reagent Plaza, Sharah-e- Faisal Karachi (ELI-00043) Dossier#1236c-7A Date:28-02-23 Submitted Fee: 50,000/-PKR Challan No.: 3075952370</p>	<p>Legal Manufacturer: M/S Nakanishi Inc., 700 Shimohinata, Kanuma- shi, Tochigi, 322-8666, Japan</p> <p>FSC: Japan</p> <p>Issued on: 24/03/2021</p>	<p>Primado Air (Primado Air System & Its Assessors)</p> <p>Codes & Sizes: As per FSC</p> <p>Class-C</p> <p>Shelf Life: 05 years</p>	<p>Deferred for the provision of following</p> <ul style="list-style-type: none"> • FSC for the applied product is not provided. • ISO certificate is expired on 26-04-2023. Provide valid ISO certificate • Stability studies of claimed shelf life of 05 years are not provided. • Credentials of manufacturer, CE mark certificate are not duly notarized from country of origin; provide notarized copies. • DOC is not provided.
81.	<p>Oasis medical systems address: bungalow No. A - 86, Block C, Gulshan-e-Jamal, Karachi,75360, Pakistan. (ELI-00495) Dossier#1447-c Date:04-04-23</p> <p>Submitted Fee: 50,000/-PKR (Not attached in dossier) Challan No.: 6359042579</p>	<p>Legal Manufacturer: UTAS Technologies S.R.O. Address; 1, Stavitska st., Bratislava, 83104, Slovika</p> <p>FSC: Slovak Republic</p> <p>Issued: 26-04-2021</p>	<p>UTAS Lung Ventilators (UVENTS-S)</p> <p>Codes & Sizes: UVENTS-A-S UVENTS-M-S UVENTS-T-S</p> <p>Class-C</p> <p>Shelf Life/ Service life: 05 years</p>	<p>Deferred for the provision of following :</p> <ul style="list-style-type: none"> • Challan fee of 50,000/- rupees is not submitted. • ISO certificate expired on 13-12-2021. Provide valid ISO certificate.
82.	<p>Ophtahalmio-Tec, Shahrah-e- Liaqaut Haji Fazal Ellahi Building Opp.</p>	<p>Legal Manufacturer: Ophtahalmic Solution inc. 820 Corridor Park Blvd, Knoxville, TN 37932, USA</p>	<p>MIRADO Hydrophobic acrylic foldable intra ocular lens</p>	<p>Deferred for the provision of following:</p> <ul style="list-style-type: none"> • No original documents are provided.

	<p>Women College Karachi (ELI-00310) Dossier#4892-7A Date:07-07-22</p> <p>Submitted Fee: 50,000/-PKR</p> <p>Challan No.: 96177471743</p>	<p>FSC: Not provided</p>	<p>Codes & Sizes: FSC: Not provided</p> <p>Class-C</p> <p>Shelf Life: 05 years</p>	<ul style="list-style-type: none"> FSC for applied medical device is not provided; provide valid original notarized copy. Specify MD grouping applicable to the medical device on form-7A Stability studies are not provided for claimed shelf life; provide the same.
83.	<p>3M surgicals plot 5, st-172, Sarwar road rawalpindi ELI-00122 Dossier# 1681c/7A Submission date: 24/01/2023 Fee submitted: not provided. Challan No. not provided.</p>	<p>Legal manufacturer: Feng medical Co., Ltd D3 no. 6 dongsheng west road, jiangyin national high-tech zone 214437 jiangsu, china FSC. china valid till. 16-8-23</p>	<p>LUNAR (disposable endoscopic linear cutter staplers & reloads) Class-C Shelf Life: 3 years</p>	<p>Deferred for the provision of following:</p> <ul style="list-style-type: none"> Challan fee of 50,000/- rupees is not submitted. FSC (china) is expired. Provide original & valid FSC of country of origin. CE certificate is expired on 14-02-2023. Provide original & valid notarized copy of CE certificate.
84.	<p>Hashir Surgical Services, 1. Office No. 05, 2nd Floor, Syed's Tower, University Road, Peshawar. 2. Godown # Alaudin & Sons Near overhead bridge Main, GT Road, Peshawar. 3. Godown # G-2, Azam Tower Charsadda Road Near budni Bridge Peshawar ELI: 00075 Dossier#4089-kp Date:16-08-23 Submitted Fee: 25,000/-PKR Challan No.:</p>	<p>Legal Manufacturer: M/s Shandong Yixing Medical Co., Ltd, Government Headquarters Pangjia Town, Boxing Country, Shandong 256500 China FSC: China Valid till: 02/01/2025</p>	<p>BIOSAFE (Infusion Set Y-Port) Codes & Sizes: As per FSC Class-B Shelf Life: 5 years</p>	<p>Deferred for the provision of following:</p> <ul style="list-style-type: none"> FSC of relevant product is not provided; provide valid original notarized copy. CE MARK certificate of relevant product is not provided; provide valid original notarized copy.
85.	<p>Add Life Pharma, 221/6, Khadam Hussain Road, Tariqabad, Rawalpindi. ELI :01102 Dossier#4227-p Date:19-10-22</p>	<p>Legal Manufacturer: M/s Omay (Guangzhou) Med Technologies Co., Ltd. Room No. 501 & 301, No 600-1 Guanshan, 2nd Road Fenghaung Street, Tianhe Dist. Guangzhou, China</p>	<p>OM-A (Enhanced external counterpulsation EECp machine) Codes & Sizes: OM-A</p>	<p>Deferred for the provision of following:</p> <ul style="list-style-type: none"> LOA is not provided. Notarized credentials are not submitted.

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	Submitted Fee: 50,000/-PKR Challan No.: 04107799998	Original FSC: China Valid till: 31/12/2023	Class-C Shelf Life: 10 years	<ul style="list-style-type: none"> Stability studies are not provided for claimed shelf life of 10 years.
86.	Kaumedex, E-144/2, New super Town Link-2, Defense Road, Lahore ELI: 00162 3576-P 22-06-2022	<u>Legal Manufacturer:</u> M/s JR. Engineering and Medical Technologies (M) SDN BHD, LOT NO 8& 10, Jalan Zurah 3 & Lot 1&3, Jalan Zurah 3a/1, Pusat Perindustrian 2, 44200, Rasa, Selangor, Malaysia. FSC: MALAYSIA. Valid till: 28/03/2024	JR Medic (Latex Powder Free Surgical gloves) Class-B Shelf life: 5 years Sizes: 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0 (only mentioned on Form-7A, the sizes are not mentioned on FSC, only names are given)	Deferred for the provision of following: <ul style="list-style-type: none"> Credentials of manufacturer abroad. FSC of any reference country or CE marked document issued by Conformity assessment body (CAB) active in NANDA Database Notified bodies.
87.	M/s Tameer International 112 Aziz Shaheed Road Sialkot Cantt Sialkot ELI: 00639 2228-P 26-02-2021	<u>Legal Manufacturer:</u> Romed located at Van Oostveen Medical B.V Herenweg 269 3648 CH Wilnis Holland FSC: Netherlands Valid till: 11.03.2024	Romed Latex Surgical Gloves (Surgical Glove) Class-B Shelf Life: 5 years	Deferred for the provision of following: <ul style="list-style-type: none"> Valid and original LOA. Product details. Stability studies for the claimed shelf life. Manufacturing and QC testing details. Essential Principle checklist. Labels of applied sizes, approved in the country of origin. There is ambiguity as the Manufacturer name on Form-7A is Romed located at Van Oostveen Medical B.V Herenweg 269 3648 CH Wilnis Holland whereas on the Legal documents it is Van Oostveen Medical B.V Herenweg 269 3648 CH Wilnis Holland, clarification is required.
88.	M/s Tameer International 112 Aziz Shaheed Road Sialkot Cantt Sialkot ELI: 00639 2229-P 26-02-2021	<u>Legal Manufacturer:</u> Romed located at Van Oostveen Medical B.V Herenweg 269 3648 CH Wilnis Holland FSC: Netherlands Valid till: 11.03.2024	Romed Latex Examination Gloves (Examination Glove) Class-A Shelf Life: 4 years	Deferred for the provision of following: <ul style="list-style-type: none"> Valid and original LOA. Product details. Stability studies for the claimed shelf life. Manufacturing and QC testing details. Essential Principle checklist. Labels of applied sizes, approved in the country of origin. There is ambiguity as the

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				Manufacturer name on Form-7A is Romed located at Van Oostveen Medical B.V Herenweg 269 3648 CH Wilnis Holland whereas on the Legal documents it is Van Oostveen Medical B.V Herenweg 269 3648 CH Wilnis Holland, clarification is required.
89.	M/s Tameer International 112 Aziz Shaheed Road Sialkot Cantt Sialkot ELI: 00639 2230-P 26-02-2021	<u>Legal Manufacturer:</u> Romed located at Van Oostveen Medical B.V Herenweg 269 3648 CH Wilnis Holland FSC: Netherlands Valid till: 11.03.2024	Romed Foley Balloon Catheters (Foley Balloon Catheters) Class-B Shelf Life: 5 years	Deferred for the provision of following: <ul style="list-style-type: none"> • Valid and original LOA. • Product details. • Stability studies for the claimed shelf life. • Manufacturing and QC testing details. • Essential Principle checklist. • Labels of applied sizes, approved in the country of origin. • There is ambiguity as the Manufacturer name on Form-7A is Romed located at Van Oostveen Medical B.V Herenweg 269 3648 CH Wilnis Holland whereas on the Legal documents it is Van Oostveen Medical B.V Herenweg 269 3648 CH Wilnis Holland, clarification is required.
90.	M/s Tameer International 112 Aziz Shaheed Road Sialkot Cantt Sialkot ELI: 00639 2231-P 26-02-2021	<u>Legal Manufacturer:</u> Romed located at Van Oostveen Medical B.V Herenweg 269 3648 CH Wilnis Holland FSC: Netherlands Valid till: 11.03.2024	Romed Endotracheal Tubes (Endotracheal Tubes) Class-B Shelf Life: 5 years	Deferred for the provision of following: <ul style="list-style-type: none"> • Valid and original LOA. • Product details. • Stability studies for the claimed shelf life. • Manufacturing and QC testing details. • Essential Principle checklist. • Labels of applied sizes, approved in the country of origin. • There is ambiguity as the Manufacturer name on Form-7A is Romed located at Van Oostveen Medical B.V Herenweg 269 3648 CH Wilnis Holland whereas on the Legal documents it is Van Oostveen Medical B.V Herenweg 269 3648 CH Wilnis Holland, clarification is required.

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91.	<p>M/s Tameer International 112 Aziz Shaheed Road Sialkot Cantt Sialkot</p> <p>ELI: 00639 2232-P 26-02-2021</p>	<p>Legal Manufacturer: Romed located at Van Oostveen Medical B.V Herenweg 269 3648 CH Wilnis Holland</p> <p>FSC: Netherlands Valid till: 11.03.2024</p>	<p>Romed Intravenous Catheter with Injection Port (Intravenous Catheter)</p> <p>Class-B</p> <p>Shelf Life: 5 years</p>	<p>Deferred for the provision of following:</p> <ul style="list-style-type: none"> Valid and original LOA. Product details. Stability studies for the claimed shelf life. Manufacturing and QC testing details. Essential Principle checklist. Labels of applied sizes, approved in the country of origin. There is ambiguity as the Manufacturer name on Form-7A is Romed located at Van Oostveen Medical B.V Herenweg 269 3648 CH Wilnis Holland whereas on the Legal documents it is Van Oostveen Medical B.V Herenweg 269 3648 CH Wilnis Holland, clarification is required.
92.	<p>Promed International CB-6349/A, Amar Pak Plaza Jhelum Road, Rawalpindi, Pakistan</p> <p>ELI: 00044 2692-P 06-09-2021</p>	<p>Legal Manufacturer: Shenzhen Antmed Co. Ltd, 18 Jinhui Ave., Pingshan New District, 518122 Shenzhen China.</p> <p>Manufacturing Site: Shenzhen Antmed Co. Ltd, 46 Keji Ave., Yuquan Industrial Park, Fenggang, 523696 Dongguan, China.</p> <p>FSC: China Valid Till: 08.05.2022</p>	<p>PTCA KIT (Inflation Device+ Hemostasis Valve) (Inflation Kit)</p> <p>Class-B</p> <p>Shelf Life: 3 Years</p> <p>Codes & Sizes: As per FSC</p>	<p>Deferred for the provision of following:</p> <ul style="list-style-type: none"> Valid and original LOA, FSC, ISO 13485 and FQA certificate. Stability studies for the claimed shelf life. Manufacturing and QC testing details. Essential principle checklist of the applied product. The firm applied in kit form whereas the FSC provided are separate for both inflation device and hemostasis valve, clarification is required whether the device will be imported in a kit form or otherwise. Also provide the duly attested FSC of reference country.
93.	<p>Total Technologies Pvt. Ltd. 696 - J-2, M.A. Johar Town, Lahore, Pakistan</p> <p>ELI-00129 4222-P 28-10-2023</p>	<p>Legal Manufacturer: MELAG Medizintechnik Ohg, Geneststr. 6-10, 10829 Berlin, Germany</p> <p>FSC: Germany Date of Issue: 05/04/2023</p>	<p>MELAG (Disinfectant Instruments) for</p> <p>Class-C</p> <p>Shelf Life: Not provided</p> <p>Models: MELAdes 800 MELAdes 801</p>	<p>Deferred for the provision of following:</p> <ul style="list-style-type: none"> The applied models of the subject device are not mentioned in LOA and FSC, clarify. Shelf life and Stability studies. Technical documentation is provided for another device not the subject device. Provide the technical data of the applied product. Labels of applied product approved in the country of origin. Difference between the two models.

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94.	Glo-Med Technologies, A-21/2B-1, KDA Scheme 1 (Ext.) National Stadium Road Karachi. (ELI-00712) 4486 02-06-2022	Legal Manufacturer: Urotronic, Inc. 2495 Xenium Lane N Minneapolis, MN 55441 USA FSC: USA Valid Till: 14-12-2023	Optilume Urethral Drug Coated Balloon catheter (Urethral Drug Coated Balloon Catheter) Class-D Shelf life: 12 Months Codes are not provided. per FSC	Deferred for the provision of following: <ul style="list-style-type: none"> FSC of US FDA missing the device list. The firm has provided document of ARTG certificate mentioning the subject device having ARTG identifier no. 385332 but the document is copy and without attestation.
95.	Hospital Supply Corporation, 42 Darul Aman Housing Society, Block 7& 8, Karachi, Pakistan Lic. No. (ELI-00005) Date of submission :07-04-2022	Haemonetics S.A., Signy Centre, Rue des flecheres 6,1274 Signy-Centre, Switzerland Reagents/Cartridges: Haemonetics Corporation Building 18, Avenue C, Leetsdale PA 15056 USA. Instruments: Leica Biosystems Melbourne Pty Ltd 495 Blackburn Road, Mt Waverley Victoria 3149 Australia FSC: not provided	TEG 6S Thrombelastograph Hemostasis Analyzer System with Accessories and Disposables Item Codes: 07-690, 07-601, 07-614, 07-615, 07-650, 07-651, 07-662 Class : C Shelf Life: 24 Months, Sizes and Model as per FSC,	Deferred for submission of the following documents:- <ul style="list-style-type: none"> Justify the grouping of applied product in multiple systems and codes as per medical device Rules 2017 or Revise Form-7A as per grouping given in MDR 2017. Submit Embassy attested valid FSC in the country of origin. Provide valid LOA and ISO 13485 along with Stability studies.
96.	Hospital Supply Corporation, 42 Darul Aman Housing Society, Block 7& 8, Karachi, Pakistan Lic. No. (ELI-00005)	Haemonetics Corporation, 400 Wood Road, Braintree, Massachusetts, MA 02184, USA. Reagents: Haemonetics Corporation Building 18, Avenue C, Leetsdale PA 15056 USA. Instruments: Sparton Medical Systems, 22740 Lunn Road, Strongsville, Ohio 44149, USA Copy of FSC: USA Valid till: 20-08-2020	TEG 5000 Thrombelastograph Hemostasis Analyzer System with Accessories and Disposables Item Code: 07-033, 07-004 (6300), 07-006 (6212), 07-007 (8001), 07-008 (8002), 07-012 (7003), 07-014, 07-015, 07-016, 07-032, 07-034, 07-047, 07-052 (6211) Class : C, Shelf Life: 48 Months, Sizes and Model as per FSC, Date of submission :07-04-2022	Deferred for submission of the following documents:- <ul style="list-style-type: none"> Justify the grouping of applied product in multiple systems and codes as per medical device Rules 2017 or Revise Form-7A as per grouping given in MDR 2017. Provide Valid and notarized Letter of Authorization covering all the Applied system/ products. The firm has provided notarized Notarized LOA which is expired march 2022 and issued for Directorate general defense purchase. Therefore, provide notarized and valid letter of Authorization The firm has provided expired copy of embassy attested FSC of USFDA which does not cover all codes and system applied, therefore, provide embassy attested valid FSC of all codes and brands applied of the reference country. Provide Complete stability studies of all the system and codes

Signature

				<ul style="list-style-type: none"> • Provide valid ISO 13485 of all the manufacturing sites. • Provide the Brochure and labels of the applied products codes covering all the system/ codes. • The provided FQA and ISO 13485 have expired therefore provide valid ISO 13485 and FQA.
97.	<p>Hospital Supply Corporation, 42 Darul Aman Housing Society, Block 7& 8, Karachi, Pakistan Lic. No. (ELI-00005)</p>	<p>Haemonetics Corporation, 400 Wood Road, Braintree, Massachusetts, MA 02184, USA. Haemonetics Mexico Manufacturing S. de R.L. de C.V Calle Colinas No. 11731 Secc. Colinas Parque Industrial el Florido 22244 Tijuana B.C Mexico. Sanmina- SCI Systems (Malaysia) Sdn. Bhd 202 Lorong Perusahaan Maju 9, Bukit Tengah Industrial Park, Perai Penang 13600, Malaysia. Kawasumi Laboratories (Thailand) Co, Ltd. Nava Nakorn Industrial Promotion Zone, 55/26 MU 13, Phahon Yothin Road, KM-46, Tambon Khlong Nueng, Amphoe Khlong Luang, Changwat Pathum Thani 12120, Thailand</p> <p>Embassy attested FSC, Malaysia Valid: 03-07-2024 ii) Embassy attested USA Valid: 02-12-2021 Copy of USFDA Valid: 09-10-2021</p>	<p>Cell Saver Elite and its Disposables</p> <p>Class: C,</p> <p>ITEM CODE :SHELF LIFE CSE-E-IE :N/A CSE-P-125 :3 YEARS CSE-P-225 :3 YEARS 00205-00 :5 YEARS 00208-00 :5 YEARS HAR-A-1000 :3 YEARS CSE-EA-1000 :N/A Sizes and Model as per FSC, Date of submission :07-04-2022</p>	<p>Deferred for submission of the following documents:-</p> <ul style="list-style-type: none"> • Justify the grouping of applied product in multiple systems and codes as per medical device Rules 2017 or Revise Form-7A as per grouping given in MDR 2017. • Provide Valid and notarized Letter of Authorization covering all the Applied system/ products. The firm has provided notarized LOA which is expired December 2022 and issued for Directorate general defense purchase. • The firm has provided embassy attested FSC of Malaysia and USFDA which does not cover all codes and system applied. therefore, provide embassy attested valid FSC of all codes and brands applied of the reference country. • Provide Complete stability studies of all the system and codes • Provide valid ISO 13485 of all the manufacturing sites. • Provide the Brochure and labels of the applied products codes covering all the system/ codes.
98.	<p>Allmed Solutions, A-21/3, KDA Scheme No.1 (ext) Stadium Road, Karachi (ELI-00029) Submission date 16-06-2020</p>	<p>Nucletron B.V. Subsidiary of Elekta AB. Address: Waardgelder 1, 3905 TH, Veenendaal, The Netherlands.</p> <p>Copy of FSC: Netherlands, Valid Till: 26-05-2024</p>	<p>FLEXITRON COBALT-60 SYSTEM</p> <p>Class C</p> <p>Shelf Life: N/A</p>	<p>Deferred for submission of the following documents:-</p> <ul style="list-style-type: none"> • Justify the grouping of applied product in multiple systems and codes as per medical device Rules 2017 or Revise Form-7A as per grouping given in MDR 2017. • Provide Valid and notarized Letter of Authorization covering all the Applied system/ products. • Provide embassy attested original

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				<p>and valid FSC. The firm provided original FSC but not covering all codes and products.</p> <ul style="list-style-type: none"> • Provide Stability studies. • Provide notarized ISO 13485 and EC certificate
99.	<p>Allmed Solutions, A-21/3, KDA Scheme No.1 (ext) Stadium Road, Karachi (ELI-00029) Submission date 29-06-2021</p>	<p>Elekta Ltd. Address: 2050 Bleury # 200, Montreal, Quebec H3A2J5, Canada Embassy attested FSC: Canada issued 12 November 2018 Expiry not written ,</p>	<p>ELEKTA CLARITY SYSTEM Article no. Class C Shelf Life: N/A Fee 50000/-</p>	<p>Deferred for submission of the following documents:-</p> <ul style="list-style-type: none"> • Notarized and expired LOA submitted therefore submit notarized and valid LOA. • Revise Form 7A a per FSC brand name • The code((C5-2/60)*) and name given below is not present in the FSC. Clarity TPUS Autoscan Probe Position Kit* [For use with the TPUS Autoscan Probe] 9100-00062 Clarity Software9310-00042 Therefore, submit embassy attested FSC for the Codes not present in the submitted FSC or Revise Form7A.
100.	<p>Ophthalmic-tec, shahrah-e-liaquat haji fazal ellahi building opp women college, Karachi (ELI-00310) 734-C</p>	<p>M/s Micromed Guglielmo Oberdan, 2100013 Fonte Nuova (ROME-Italy)</p>	<p>Micro Gas C3F8 50 ML Micro Gas SF6 Gas 50ml Class C Shelf life: 05 Years Fee: 50,000/-</p>	<p>Deferred to apply with required documents as per Form-7A, i.e FSC of country of origin, LOA from principal manufacturer, CE certificate, ISO 13485.</p>
101.	<p>M/s Royal Medical, Office No. 26th 3rd Floor United Trader Center Plot No. 5, Block 6, Gulshan-e- iqbal, Karachi. (ELI-00691) Deficiency Submission date: 03/11/2022</p>	<p>Legal Manufacturer: Bicakcilar Tibbi Cihazlar Sayani ve. Tic A.S. Osmangazi Mah. Gazi Cad. No. 21 Esenyurt 34522, Istanbul, Turkey. FSC: Turkey Date of Issuance: 20-05- 2022 FSC valid till: 19-05-2025</p>	<p>BICAKCILAR Extracorporeal tubing set Shelf Life: 5 years Class: B Models & Codes: 300 8947 1 300 8973 1 300 8979 1 300 8980 1 300 9276 1 300 9277 1 300 9280 1 300 9290 1 300 9291 1 300 9292 1 300 9293 1 300 9294 1 *As per FSC Fee challan No. 8244652419 (Rs.25,000/-)</p>	<p>Deferred with final opportunity to provide required documents i.e</p> <ul style="list-style-type: none"> • Valid CE certificate • Full QA certificate/ Production QA certificate • Original Declaration of Conformity

102.	M/s Royal Medical, Office No. 26th 3rd Floor United Trader Center Plot No. 5, Block 6, Gulshan-e- iqbal, Karachi. (ELI-00691) Deficiency Submission date: 03/11/2022	Legal Manufacturer: Bicakcitar Tibbi Cihazlar Sayani ve. Tic A.S. Osmangazi Mah. Gazi Cad. No. 21 Esenyurt 34522, Istanbul, Turkey. FSC: Turkey Date of Issuance: 20-05-2022 FSC valid till: 19-05-2025	BEX-Cardioplegia Set Cardioplegia set Shelf Life: 5 years Class: B Models & Codes: 325 9234 1 325 9222 1 325 9232 1 325 9233 1 325 9230 1 325 9231 1 *As per FSC Fee challan No. 32487500676 (Rs.25,000/-)	Deffered with final opportunity to provide required documents i.e <ul style="list-style-type: none"> Valid CE certificate Full QA certificate/ Production QA certificate Original Declaration of Conformity
103.	M/s. Noor international, 29-D, Block 6, PECHS, Karachi. ELI-00061.	Legal Manufacturer: M/s Hitec Medical Co., Ltd, No.703, Hengnan RD 1328, Minhang District 201114, Shanghai, China. FSC China Valid Till (14-10-2021)	HITEC CARE Tracheobronchial Tube. Class-B. claimed shelf life: 05-years. Codes & Sizes as per FSC.	Deffered with final opportunity to provide required documents for registration of medical device because the address of the manufacturer on ISO 13485 and CE certificate do not match, as the firm has submitted copies of documents with new address.
104.	M/s. Royal Enterprise SH5 Karimji Building Opp HBL North Napier Road Karachi. (ELI-00062)	Legal Manufacturer: Guangdong Yuehua Medical Instrument Factory Co. Ltd. Ronsheng Science & Technology Zone, Daxue Road, Shantou City, Guangdong China. FSC China Valid till: 11-12-22	UNIKA+++ Compressor Nebulizer. Class: B. Shelf life: N/A. Codes & Sizes as per FSC CN-100, CN-200, CN-300, CN-400, CN-500, CN-600,	Deffered with final opportunity to provide:- <ul style="list-style-type: none"> Valid FSC CE certificate ISO 13485 shelf life data
105.	Sure Bio-Diagnostics & Pharmaceuticals, EE-10, Defense View Phase-II, Near Iqra University Shaheed-e-Millat Express Way, Karachi (ELI-00084)	Legal Manufacturer & mfg. site: Ortho- Legal Manufacturer & mfg. site: Clinical Diagnostics, Inc. Felindre Meadows, Pencoe, Bridgend, CF35 5PZ, United Kingdom FSC: UK Valid Till: 08-07-2023.	ORTHO-CLINICAL Diagnostics, Inc. Class-D Shelf life:08-months. 1. ABD Confirmation (100 Pack) 2. ABD Confirmation RUM1 (100 Pack) 3. BioVue A/B/A+B/D/CDE/CTL (400 Pack) 4. BioVue A/B/D/CTL/REV DIL (100 Pack) Class D 5. BioVue C/E/SMC/SME/K/CTL (400 Pack) 6. BioVue C/E/SMC/SME/K/CTL (100 Pack) 7. BioVue Reverse Diluent (400 Pack) Class C 8. BioVue SYS ABODD GRP Cassette (100 Pack)	Deffered with final opportunity to provide clarification as products are not from same class.

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			class C 9, BioVue SYS Newborn Cassette (100 Pack)	
106.	A.S Enterprises, 03- Mozang Lahore, Pakistan. ELL: 00190 Dossier# 3178 Submission date: 26/04/2022	Legal Manufacturer: A Zhejiang Orient Gene Biotech Co., Ltd, 3787 #, East Yangguang Avenue, Dipu Street Anji 313300 Huzhou Zhejiang, China FSC: not provided	Orient Gene HCV Rapid Test Kit (HCV Ab Rapid Test Cassette) Codes & Sizes: 40T Class-D Shelf Life: 24 months	Deferred for final opportunity for the provision of following: <ul style="list-style-type: none"> Firm has submitted irrelevant & incomplete documents in response to required documents i.e., FSC of country of origin and FSC of any reference country are not provided. CE mark certificate is not provided. Highlight the relevant applied product on the scope of the CE mark & ISO 13485 certificates Provide Packing Label of applied medical device with proper brand & generic name printed on it. EC Design examination certificate is expired on 28-06-2022 Provide notarized EC Design examination certificate Mention medical device class on DOC.
107.	A.S Enterprises, 03- Mozang Lahore, Pakistan. ELL: 00190 Dossier# 3179 Submission date: 26/04/2022	Legal Manufacturer: A Zhejiang Orient Gene Biotech Co., Ltd, 3787 #, East Yangguang Avenue, Dipu Street Anji 313300 Huzhou Zhejiang, China FSC: not provided	Orient Gene HBsAg Rapid Test Kit (HBsAg Rapid Test Cassette) Codes & Sizes: As per FSC Class-D Shelf Life: 24 months	Deferred for final opportunity for the provision of following: <ul style="list-style-type: none"> Firm has submitted irrelevant & incomplete documents in response to required documents i.e., FSC of country of origin and FSC of any reference country are not provided. CE mark certificate is not provided. Highlight the relevant applied product on the scope of the CE mark & ISO 13485 certificates Provide Packing Label of applied medical device with proper brand & generic name printed on it. EC Design examination certificate is expired on 28-06-2022 Provide notarized EC Design examination certificate. Mention medical device class on DOC

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108.	A.S Enterprises, 03- Mozang Lahore, Pakistan. ELI: 00190 Dossier# 3132 Submission date: 11/05/2022	Legal Manufacturer: A Zhejiang Orient Gene Biotech Co., Ltd, 3787 #, East Yangguang Avenue, Dipu Street Anji 313300 Huzhou Zhejiang, China FSC: Belgium Issued on:13-05-2022	Orient Gene TB Rapid Test Kit (TB IgG/IgG Rapid test Casette) Codes & Sizes: GCTB- 302a Class-C Shelf Life: 24 months	Deferred for final opportunity for the provision of following: <ul style="list-style-type: none"> • Firm has submitted irrelevant & incomplete documents in response to required documents i.e., • FSC of country of origin and FSC of any reference country are not provided. • CE mark certificate is not provided. • Highlight the relevant applied product on the scope of the CE mark & ISO 13485 certificates • Provide Packing Label of applied medical device with proper brand & generic name printed on it. • EC Design examination certificate is expired on 28-06-2022 • Provide notarized EC Design examination certificate • Mention medical device class on DOC
109.	A.S Enterprises, 03- Mozang Lahore, Pakistan. ELI: 00190 Dossier# 2993 Submission date: 26/04/2022	Legal Manufacturer: A Zhejiang Orient Gene Biotech Co., Ltd, 3787 #, East Yangguang Avenue, Dipu Street Anji 313300 Huzhou Zhejiang, China FSC: Belgium Issued on:13-05-2022	Orient Gene Syphilis Ab Rapid Test Kit (Syphilis Ab Rapid Test Casette) Codes & Sizes: GCSYP-302a Class-C Shelf Life: 24 months	Deferred for final opportunity for the provision of following: <ul style="list-style-type: none"> • Firm has submitted irrelevant & incomplete documents in response to required documents i.e., • FSC of country of origin and FSC of any reference country are not provided. • CE mark certificate is not provided. • Highlight the relevant applied product on the scope of the CE mark & ISO 13485 certificates • Provide Packing Label of applied medical device with proper brand & generic name printed on it. • EC Design examination certificate is expired on 28-06-2022 • Provide notarized EC Design examination certificate • Mention medical device class on DOC
110.	M/s Ferozs Laboratories Limited, P.O Ferozs,	Legal Manufacturer: Lake Region Medical Limited Butlersland, New Ross, Co Wesford Ireland	Victory™ 14 Polymer Tip Guidewire with Hydrophilic Coating (Guidewire for	Deferred for final opportunity for the provision of following:

	Amangarh, Nowshera (KPK), Pakistan ELI: 00120 3270-KP	Manufacturing Site: Brivant Limited Parkmore West Business Park Galway, Ireland FSC: U.S FDA Valid till: 12/06/2023 FSC: Ireland Issued On: 19-04-2022	intravascular Interventional procedures) Class-D Shelf Life: 3 years Codes & Sizes: As per FSC	<ul style="list-style-type: none"> FQA is not submitted. On FSC & ISO certificate the <i>Legal Manufacturer</i> is Lake Region Medical Limited Butlersland, New Ross, Co Wesford Ireland and <i>Manufacturing Site</i> is Brivant Limited Parkmore West Business Park Galway, Ireland while firm submitted Credentials & LOA of Boston scientific corporation, USA. Provide original and notarized LOA that must be between legal manufacturer and the importer. Justify the manufacturing site that must be same on FSC, ISO, and FQA and also mentioned on Credentials of Legal manufacturer.
111.	M/s Ferozsos Laboratories Limited, P.O Ferozsos, Amangarh, Nowshera (KPK), Pakistan ELI: 00120 3271-KP	Legal Manufacturer: Lake Region Medical Limited Butlersland, New Ross, Co Wesford Ireland Manufacturing Site: Brivant Limited Parkmore West Business Park Galway, Ireland FSC: U.S FDA Valid till: 12/06/2023	Victory™ 18 Polymer Tip Guidewire with Hydrophilic Coating (Guidewire for intravascular Interventional procedures) Class-D Shelf Life: 3 years Codes & Sizes: As per FSC	<p>Deferred for final opportunity for the provision of following:</p> <ul style="list-style-type: none"> FQA is not submitted. On FSC & ISO certificate the <i>Legal Manufacturer</i> is Lake Region Medical Limited Butlersland, New Ross, Co Wesford Ireland and <i>Manufacturing Site</i> is Brivant Limited Parkmore West Business Park Galway, Ireland while firm submitted Credentials & LOA of Boston scientific corporation, USA. Provide original and notarized LOA that must be between legal manufacturer and the importer. Justify the manufacturing site that must be same on FSC, ISO, and FQA and also mentioned on Credentials of Legal manufacturer.
112.	M/s Ferozsos Laboratories Limited, P.O Ferozsos, Amangarh, Nowshera (KPK), Pakistan ELI: 00120	Legal Manufacturer: M/s TOGO MEDIKIT CO., LTD 17148-6 AZA KAMEKAWA OAZA HICHIYA HYUGA CITY Miyazaki Japan, 883-0062 Manufacturing for: Boston Scientific Corporation 300	Super Sheath (Catheter Introducer and Interventional devices) Codes & Sizes: As per FSC Class-B	<p>Deferred for final opportunity for the provision of following:</p> <ul style="list-style-type: none"> Provide original and notarized LOA that must be between legal manufacturer and the importer.

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		Boston Scientific Way Marlborough, MA, USA FSC: USA Valid till: 07/07/2024	Shelf Life: 3 years	
113.	M/s Ferozsans Laboratories Limited, P.O Ferozsans, Amangarh, Nowshera (KPK), Pakistan ELI: 00120	Legal Manufacturer: M/s TOGO MEDIKIT CO., LTD 17148-6 AZA KAMEKAWA OAZA HICHIYA HYUGA CITY Miyazaki Japan, 883-0062 Manufacturing for: Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MA, USA FSC: USA Valid till: 07/07/2024	Super Sheath XL (Catheter Introducer and Interventional devices) Codes & Sizes: As per FSC Class-B Shelf Life: 3 years	Deferred for final opportunity for the provision of following: • Provide original and notarized LOA that must be between legal manufacturer and the importer.
114.	M/s Bajwa Sons, 13- Muslim Street, House No 3, 1st and 2nd Floor, Mayo Hospital Road, Lahore. (ELI-00314) (2755)	Legal Manufacturer: M/s Yancheng Huida Medical Instruments Co., Ltd, (No. 2, Kujiyuan Road) Xuefu Town, Yandu District, Yancheng, City Jiangsu, China FSC: China Valid till: 09.04.2023	Trulene (Polypropylene (Non- absorbable Suture) Codes & Sizes: As per FSC Class-C Shelf Life claimed: 5 years Shelf life studies provided for : 03 years	Deferred for final opportunity for the provision of following: • Valid and notarized CE certificate as it has expired on 09- 05-2023. • Copy of expired FSC is provided on which Applied product is not mentioned. • Stability studies of only 3 years is provided instead of claimed shelf life of 5 years.
115.	M/s Bajwa Sons, 13- Muslim Street, House No 3, 1st and 2nd Floor, Mayo Hospital Road, Lahore. (ELI-00314) (2755)	Legal Manufacturer: M/s Yancheng Huida Medical Instruments Co., Ltd, (No. 2, Kujiyuan Road) Xuefu Town, Yandu District, Yancheng, City Jiangsu, China FSC: China Valid till: 09.04.2023	Trusilk (Silk (Black Braided Non- absorbable Suture) Codes & Sizes: As per FSC Class-C Shelf Life claimed: 5 years Shelf life studies provided for 03 years	Deferred for final opportunity for the provision of following: • Valid & Notarized CE certificate as it has expired on 09-05-2023. • Copy of expired FSC is provided on which Applied product is not mentioned. • Stability studies of only 3 years is provided instead of claimed shelf life of 5 years.
116.	M/s Bajwa Sons, 13- Muslim Street, House No 3, 1st and 2nd Floor, Mayo Hospital Road, Lahore. (ELI-00314) (2755)	Legal Manufacturer: M/s Yancheng Huida Medical Instruments Co., Ltd, (No. 2, Kujiyuan Road) Xuefu Town, Yandu District, Yancheng, City Jiangsu, China FSC: China Valid till: 09.04.2023	Trulon Nylon (Non-Absorbable Suture) Codes & Sizes: As per FSC Class-C Shelf Life claimed: 5 years Shelf life studies provided for: 03 years	Deferred for final opportunity for the provision of following: • Valid & Notarized CE certificate as it has expired on 09-05-2023. • Copy of expired FSC is provided on which Applied product is not mentioned. • Stability studies of only 3 years is provided instead of claimed shelf life of 5 years.

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117.	M/s. Maxitech Pharma PVT LTD, Address: E-178 SITE area Super Highway Karachi Establishment License #: (ELI-00769)	Legal Manufacturer: SIFI . S.P.A Address: via Ercole Patti n.36 Lavinaio Aci S. Antonia CT 95025 Italy Scanned copy of FSC Italy issuance date 18-02-2021	Mini Well (Intraocular Lens (IOL)) Class: C 01) Code: Ass per FSc Claimed Shelf life:4 years Fee 50000/-	Deferred for submission of the following: - • Complete Stability studies of the claimed shelf life, since the already submitted is not complete. • Submit embassy attested valid FSC the submitted FSC does not reflect this product
118.	Hooru Pharma (Pvt) Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi ELI-00037	Fujifilm Healthcare Corporation Medical Systems Operating Group, Kashiwa 1, Shintoyofuta, Kashiwa-shi, Chiba, 277-0804 Japan Copy of Certificate issued by Mo Health, Labour and Welfare Govt of Japan wherein the free sale of the product is not confirmed only written that the product is manufactured under our supervision as per law. ISO 13485 valide upto 26-12-2022. FQA/CE valid till 10-01-2024. EC Design Examination Certificate valid upto 10-01-2024	APERTO Lucent MRI system, Full-body, Permanent magnet Code: Class C Shelf Life/Service Life: 10 years Fee submitted: Rs. 50,000/-	Deferred for submission of Embassy attested Free Sale Certificate, Design Examination Certificate,.

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



No.F.4-12/2023-MD (M-62)
Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
Drug Regulatory Authority of Pakistan

Islamabad the 1st December, 2023


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

The applications of following applicants were considered by Medical Device Board (MDB) in its 62nd meeting held on 6th November, 2023 and Board deferred these applications being deficient of the information/documents as specified in last column (IV) of the Table below:-

Sr. No.	Name & Address of Establishment	Name of Medical Devices With Size	Decision
(I)	(II)	(III)	(IV)
1.	M/s Pharmatec Pakistan (Pvt) Limited., D-86/A, S.I.T.E., Karachi. [ELM-0035] Sections as ELM: Topical Dosage form (Cream, Ointment and Gel)	Brand name: Dermipar Ointment Contents 1. Liquid Paraffin 2. White Soft Paraffin 3. Cetosteryl alcohol 4. Cetomacrogol 1000 Class: Class-A Medical Device Shelf-life: 02 Years Sizes: 500gm & 300gm Fee Challan No. 3232863483 dated 21/11/2022: Rs. 5000/-	Deferred for clarification that the applied formulation is Medical Device.
2.	M/s Pharmatec Pakistan (Pvt) Limited., D-86/A, S.I.T.E., Karachi. [ELM-0035] Sections as ELM: Topical Dosage form (Cream, Ointment and Gel)	Brand name: Hypobase Cream Contents 1. White soft paraffin 2. Light liquid paraffin 3. Anhydrous lanolin Class: Class-A Medical device Shelf-life: 02 Years Sizes: 50gm tube, 125gm Tub, 350gm Tub & 500gm HDPE bottle with pump. Fee Challan No. 56404652 dated 25/11/2022: Rs. 5000/-	Deferred for clarification that the applied formulation is Medical Device.
3.	M/s Pharmatec Pakistan (Pvt) Limited., D-86/A, S.I.T.E., Karachi. [ELM-0035] Sections as ELM: Topical Dosage form (Cream, Ointment and Gel)	Brand name: Exo Cream Contents 1. White soft paraffin 2. Light liquid paraffin 3. Anhydrous lanolin Class: Class-A Medical device Shelf-life: 02 Years Sizes: 50gm, 125gm, 350gm & 500ml Fee Challan No. 3199692910 dated 23/11/2022: Rs. 5000/-	Deferred for clarification that the applied formulation is Medical Device.

Amjad

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