



**No.F.4-15/2023-MD (M-64)**  
Government of Pakistan  
Ministry of National Health Services, Regulations & Coordination  
Drug Regulatory Authority of Pakistan  
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Islamabad the 19<sup>th</sup> February, 2024

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

The applications of following applicants were considered by Medical Device Board (MDB) in its 64<sup>th</sup> meeting held on 19<sup>th</sup> December, 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.	Moody Global Services, No.14, 2nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad. ELI: 00926 Dossier# 4000 Submission date: 15/03/2023 Fee submitted: 50,000/- Challan No. 2923070168	Legal Manufacturer: M/s Shenzhen Lifotronic Co., Ltd (China), Unit A, 4th Floor, Building 15, Yijing Estate, No. 1008 Songbae Road, Nanshan, District, Shenzhen City, Guangdong Province, 518055, P.R China  FSC: China Valid till: 22/03/2024	Lifotronic (Negative Pressure Wound Therapy Dressing Kit)  Codes & Sizes: Model: NPWT-1-100A, NPWT-1-180A, NPWT-1-260A, NPWT-1-180B, NPWT-1-260B, NPWT-2-100A, NPWT-2-180A, NPWT-2-260A, NPWT-2-180B, NPWT-2-260B, NPWT-3-100A, NPWT-3-180A, NPWT-3-260A, NPWT-3-180B, NPWT-3-260B Class-C Shelf Life: 03 years	<b>Deferred</b> for the provision of following:  Provide CE mark certificate/ FSC of any reference country.
2.	Moody Global Services, No.14, 2nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad. ELI: 00926 Dossier# 3999 Submission date: 15/03/2023 Fee submitted: 50,000/- Challan No. 125625790162	Legal Manufacturer: M/s Shenzhen Lifotronic Co., Ltd (China), Unit A, 4th Floor, Building 15, Yijing Estate, No. 1008 Songbae Road, Nanshan, District, Shenzhen City, Guangdong Province, 518055, P.R China  FSC: China Valid till: 22/03/2024	Lifotronic (Temperature Management System) Codes & Sizes: Model: TC-200 Class-C Shelf Life: 5 years	<b>Deferred</b> for the provision of following:  Provide CE mark certificate/ FSC of any reference country.
3.	Hoora Pharma (Pvt.) Ltd. Wh- 01-20-A7 - A8, Korangi Creek Industrial Park, Karachi.  ELI-00037	<u>Legal Manufacturer:</u> Terumo BCT, Ltd., Old Belfast Road, Millbrook, Larne BT40 2SH, United Kingdom. <u>Manufacturing site:</u>	REVEOS LR SET (Blood Donor set)  Class-C  Shelf life: 2 years	<b>Deferred</b> for the clarification as Same device applied by Sure-Bio and is deferred in 49 <sup>th</sup> meeting but the legal manufacturer is Terumo BCT Inc. 10811 West Collins Ave., Lakewood, Colorado, 80215,

	1852-C 23-06-2023	Terumo BCT Vietnam Co. Ltd. Long Duc Industrial Park, Long Duc Commune, Long Thanh District, Dong Nai Province, Vietnam.  FSC Belgium Issuance 22-11-2025	Code: 4FG456S0Y	USA  Manufacturing site "Terumo BCT Vietnam Co. Ltd. Long Duc Industrial Park, Long Duc Commune, Long Thanh District, Dong Nai Province, Vietnam" is also not mentioned on provided FSC of Belgium. So clarification is required that whether the device manufactured in Vietnam is on free sale in UK/Belgium or not. Also for personal Hearing of both the firms M/S Hooraa Pharma (Pvt.) Ltd. and M/S Sure-Bio Karachi for confirmation of rights of the product to import in Pakistan.  Apply separately for other two models.
4.	M/s SOHAIL CORPORATION Plot no 7, SR-5 Serai Quarters, Techno City Mall WH-42, Karachi- Pakistan  Establishment License No: ELI 00676  Date of Submission: 30-Nov-2022	M/s Changzhou Jinliyan Medical Devices Co., Ltd. Address: No. 6, West Xihe Road, Sanhekou, Zhenglu Town, Tianning District, Changzhou, Jiangsu, China 213115  FSC: China Valid till 07-06-23 expired	Metro Sterile Disposable Hypodermic Syringes for Single Use with needle  Sizes and Codes: 1ml,2ml,10ml,20ml,30ml,50ml  Class B  Shelf life: 5 years	<b>Deferred</b> for provision of Valid LOA& FSC.
5.	M/s SOHAIL CORPORATION Plot no 7, SR-5 Serai Quarters, Techno City Mall WH-42, Karachi- Pakistan  Establishment License No: ELI 00676  Date of Submission: 30-Nov-2022	M/s Changzhou Jinliyan Medical Devices Co., Ltd. Address: No. 6, West Xihe Road, Sanhekou, Zhenglu Town, Tianning District, Changzhou, Jiangsu, China 213115  FSC: China Valid till 07-06-23 expired	Metro Disposable Infusion Set for Single Use  Sizes and Codes: as per FSC  Class B 25000  Shelf life: 5 years	<b>Deferred</b> for provision of Valid LOA& FSC.
6.	NEW PAKISTAN TRADERS Office No. 306/I, Trade Tower, Altaf Hussain Road, New Challi, Karachi. ELI-00161	M/s NANTONG EGENS BIOTECHNOLOGY CO., LTD ADDRESS: Block A Fifteenth Factory-building No.1692 Xinghu Avenue,Nantong Economic &	Accurate pregnancy test kit  CLASS: B  Shelf life: 2 years	<b>Deferred</b> for provision of valid LOA issued from the legal manufacturer &, ISO 13485.

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	R&I 16/05/2022	Technological Development Zone, NANTONG, CHINA  FSC original China valid till 05-05-24	Fee 25000:-	
7.	Royal Medical Registered AddressOffice No. 26th, 3rd Floor United Trade Center Plot # 5, Block-6, Gulshan-e-Iqbal Karachi Establishment License: ELI-00691 08-12-22	Chalice Medical Ltd. Address: Manton Wood Enterprise Park, Worksop, Nottinghamshire, S80 2RS, United Kingdom  FSC-MHRA UK: valid till 26-May, 2025.	Paragon Oxygenator Codes/Models: XCMOP1300MN, XCMOP1300PP, XCMOP305PMP, XCMOP1260MN, XCMOP1260PP, XCMOP265PMP, XCMOP1140MN, XCMOP1140PP, XCMOP145PMP  Class B Shelf life 2 Years Fee Rs. 25,000/-	<b>Deffered</b> for applying in Class C and payment of differential fees, separate applications & fees for the mentioned 3 sizes, notorised Audit report in compliance to ISO 13485.
8.	Shirazi Trading Company Private Limited 114-C, Al Murtaza Commercial Lane 3, Khayaban-e-Iqbal, Phase 8, D.H.A., Karachi.  Establishment Licence No.: ELI- 000263	<b>Legal manufacturer &amp; Site</b> Datex Ohmeda Inc. 3030 Ohmeda Drive, Madison, WI 53707-7550, USA.  Legalized FSC issued F.D.A. (U.S.A.) Certificate No.8165-4- 2022 Valid until: 27.04.2024.	Tec 850 Isoflurane Vaporizer  Isoflurane Anesthesia Vaporizer  Class C  Shelf Life:  GMDN Code:- 36890  Fee submitted: Rs. 50,000/-  Date of submission: 16.12.2019	<b>Deffered</b> for provision of valid LOA
9.	Shirazi Trading Company Private Limited 114-C, Al Murtaza Commercial Lane 3, Khayaban-e-Iqbal, Phase 8, D.H.A., Karachi.  Establishment Licence No.: ELI- 000263	<b>Legal manufacturer &amp; Site</b> Datex Ohmeda Inc. 3030 Ohmeda Drive, Madison, WI 53707-7550, USA.  Legalized FSC issued F.D.A. (U.S.A.) Certificate No.8165-4- 2022 Valid until: 27.04.2024.  Notarized copy of ISO valid till 10-07-2024  Notarized copy of FQA/CE valid till 26-05- 2024	Tec 850 Sevoflurane Vaporizer  Anesthesia Vaporizer  Class C  Shelf Life: There is no shelf life limitation. The device and its components do not require a "use by" date because there are no safety related performances or safety related characteristics which are likely to deteriorate over time.  GMDN Code:- 36980  Fee submitted: Rs. 50,000/-  Date of submission: 16.12.2019	Deffered for provision of valid LOA

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10.	Shirazi Trading Company Private Limited 114-C, Al Murtaza Commercial Lane 3, Khayaban-e-Iqbal, Phase 8, D.H.A., Karachi.  Establishment Licence No.: ELI-000263	Legal manufacturer & Site Datex Ohmeda Inc. 3030 Ohmeda Drive, Madison, WI 53707-7550, USA.  Legalized FSC issued F.D.A. (U.S.A.) Certificate No.8165-4-2022 Valid until: 27.04.2024.  Notarized copy of ISO valid till 10-07-2024  Notarized copy of FQA/CE valid till 26-05-2024	Tec 6 Plus  Desflurane Anesthesia Vaporizer  Class C  Shelf Life: There is no shelf life limitation. The device and its components do not require a "use by" date because there are no safety related performances or safety related characteristics which are likely to deteriorate over time.  GMDN Code:- 36979  Fee submitted: Rs. 50,000/-  Date of submission: 16.12.2019	<b>Deffered</b> for provision of valid LOA
11.	Shirazi Trading Company Private Limited 114-C, Al Murtaza Commercial Lane 3, Khayaban-e-Iqbal, Phase 8, D.H.A., Karachi.  Establishment Licence No.: ELI-000263	Legal manufacturer & Site Datex Ohmeda Inc. 3030 Ohmeda Drive, Madison, WI 53707-7550, USA.  Legalized FSC issued F.D.A. (U.S.A.) Certificate No.8165-4-2022 Valid until: 27.04.2024.  Notarized copy of ISO valid till 10-07-2024  Notarized copy of FQA/CE valid till 26-05-2024	Tec 820 Sevoflurane Vaporizer  Anesthesia Vaporizer  Class C  Shelf Life: There is no shelf life limitation. The device and its components do not require a "use by" date because there are no safety related performances or safety related characteristics which are likely to deteriorate over time.  GMDN Code:- 36980  Fee submitted: Rs. 50,000/-  Date of submission: 16.12.2019	<b>Deffered</b> for provision of valid LOA
12.	Nasir Brothers 22B, 2 <sup>ND</sup> Floor, Zeenat Medicine Market, North Napier Road, Karachi, Pakistan. ELI-00036	Well lead medical co., Ltd No 47 Guomao Avenue south china  FSC MHRA copy 18-04-19  FSC original china valid till 17-12-23	Brand name: VCARE Generic: All Silicone Foley Catheter 2way and 3way.  2-way pediatric, 2- way standard, 2-way female 3 -way standard  Class: B  Shelf-life:5 Years  Sizes: 6Fr, 8Fr, 10Fr, 12Fr, 14Fr, 16Fr, 18Fr, 20Fr, 22Fr, 24Fr , 26Fr Fee Challan No. :  DATED: Rs. /-25030	<b>Deffered</b> to apply in class C with differential fees and separate applications for 2way & 3 Way and valid FSC copy.

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13.	Nasir Brothers 22B, 2 <sup>ND</sup> FLOOR, ZEENAT MEDICINE MARKET, NORTH NAPIER ROAD, KARACHI, PAKISTAN. ELI-00036	<u>Well lead medical co., Ltd</u> <u>No 47 Guomao Avenue</u> <u>south china</u>  <u>FSC MHRA copy 18-04-</u> <u>19</u>  <u>FSC original china valid</u> <u>till 17-12-23</u>	Brand name: VCARE  Generic: Latex Foley Catheter 2way and 3way.  Class: B  Shelf-life: 5 Years  Sizes: 6Fr, 8Fr, 10Fr, 12Fr, 14Fr, 16Fr, 18Fr, 20Fr, 22Fr, 24Fr, 26Fr, 28Fr, 30Fr  Fee Challan No. : DATED: Rs. 25030/-	<b>Deffered</b> to apply in class C with differential fees and separate applications for 2way & 3 Way and valid FSC copy.
14.	M/s TRI TECH INTERNATIONAL 10-C, 6TH Sunset Commercial Lane, Phase 2 EXT, DHA, KARACHI, PAKISTAN ELI-00247	Legal manufacturer FORAS BILG.ELEKT. MEDIKAL SAN.VE TIC.LTD.STI <u>Ostim OSB Mahallesi</u> <u>1269.Cadde, No: 35</u> <u>06374 Ankara/Turkey</u>	Brand Name: BiNefes Generic Name: ICU VENTIALTOR DEM T-19 Code: DEM T-19  Class: C  Shelf Life: 10 years Fee: Rs 50,000/-	<b>Deffered</b> for provision of Notorised LOA & ISO 13485 & CE certificate with relevant product and notorised FSC.
15.	M/s TRI TECH INTERNATIONAL 10-C, 6TH Sunset Commercial Lane, Phase 2 EXT, DHA, KARACHI, PAKISTAN ELI-00247	Legal manufacturer FORAS BILG.ELEKT. MEDIKAL SAN.VE TIC.LTD.STI <u>Ostim OSB Mahallesi</u> <u>1269.Cadde, No: 35</u> <u>06374 Ankara/Turkey</u> Tel: + 903123957766 Fax: +903123957767 Web: www.foras.com.tr Free Sale Certificate (FSC) copy turkey 10-07- 23	Brand Name: BiNefes (Generic Name: BiNefes Ventilator SP-100  Code: SP-100  Class: C  Shelf Life: 10 years Fee: Rs 50,000/-	<b>Deffered</b> for provision of Notorised LOA & ISO 13485 & CE certificate with relevant product and notorised and countersigned by embassy FSC.
16.	M/s TRI TECH INTERNATIONAL 10-C, 6TH Sunset Commercial Lane, Phase 2 EXT, DHA, KARACHI, PAKISTAN ELI-00247	Legal manufacturer FORAS BILG.ELEKT. MEDIKAL SAN.VE TIC.LTD.STI <u>Ostim OSB Mahallesi</u> <u>1269.Cadde, No: 35</u> <u>06374 Ankara/Turkey</u> Tel: + 903123957766 Fax: +903123957767 Web: www.foras.com.tr Original Legalized Free Sale Certificate (FSC)	Brand Name: BiNefes (Generic Name: BiNefes Ventilator SV-100  Code: SV-100  Class: C  Shelf Life: 10 years Fee: Rs 50,000/-	<b>Deffered</b> for provision of Notorised LOA & ISO 13485 & CE certificate with relevant product and notorised and countersigned by embassy FSC.
17.	Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS,	Legal Manufacturer: Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA	VITROS Immunodiagnostic Product Anti-HBC IgM Reagent, Calibrator & Control Cal: 1100387 Rgt: 8577413 Cont: 6800834	<b>Deffered.</b> The firm M/s Sieco Scientific Traders Rawalpindi is advised to submit fresh valid notarised letter of Auhorization from the Ortho Clinical

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	Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Initial Submission: 02-Dec-2022 Final Submission: 27-Sept-2023	Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom  embassy attested Free Sale Certificate Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom Date of Issue: 04-July-2023 Validity: 26-May-2025	Shelf life: Reagent: 52 weeks Calibrator: 52 weeks Control: 52 weeks  Storage Conditions: 2-8°C  Class: D  Fees: 50,000/-  Date of submission December 2022 then 27-Sept-23	Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA or inform the MDB if their principal manufacturer has terminated its authorization for the said brands. as the same legal manufacture has issued LOA to M/s Martin Dow, Karachi for the same products with the same brand name.
18.	Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah- e-Faisal, Karachi ELI-00160 Initial Submission: 02-Dec-2022 Final Submission: 27-Sept-2023	Legal Manufacturer: Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA  Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom  embassy attested Free Sale Certificate Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom Date of Issue: 04-July-2023 Validity: 26-May-2025	VITROS Immunodiagnostic Product, Anti-HBe Reagent, Calibrator & HBe Control Cal: 1523984 Rgt: 8864860 Cont: 6800837  Shelf life: Reagent: 52 weeks Calibrator: 52 weeks Control: 52 weeks  Storage Conditions: Reagent: 2-8°C Calibrator: 2-8°C Control: +25°C  Class: D  Fees: 50,000/-	<b>Deferred.</b> The one applied is VITROS Immunodiagnostic Product Anti-HBe Reagent, Calibrator. However, the HBe Control is also applied with the Anti HBe, clarify or revise Form-7A.  Clarify the fee submitted reflecting Anti HBe Igm reagent, calibrator and control  Clarify the stability study of 52 months. the firm has provided stability studies but 52 months not confirmed.
19.	Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah- e-Faisal, Karachi ELI-00160 Initial Submission: 02-Dec-2022  Final Submission: 27-Sept-2023	Legal Manufacturer: Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA  Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom  embassy attested Free Sale Certificate Ortho Clinical Diagnostics Felindre Meadows	VITROS Immunodiagnostic Product HIV Combo Reagent & Calibrator  Cal: 6842780 Rgt: 6842779 Shelf life: Reagent: 52 weeks Calibrator: 52 weeks  Storage Conditions: 2-8°C  Class: D  Fees: 50,000/-	<b>Deferred.</b> The firm M/s Sieco Scientific Traders Rawalpindi is advised to submit fresh valid notarised letter of Authorization from the Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA or inform the MDB if their principle manufacturer has terminated its authorization for the said brands. As the same legal manufacture has issued LOA to M/s Martin Dow, Karachi for the same products with the same brand name.

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		Pencoed Bridgend CF35 5PZ United Kingdom Date of Issue: 04-July-2023 Validity: 26-May-2025		
20.	Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah- e-Faisal, Karachi ELI-00160 Initial Submission: 02-Dec-2022  Final Submission: 27-Sept-2023	Legal Manufacturer: Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA  Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom  embassy attested Free Sale Certificate Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom Date of Issue: 04-July-2023 Validity: 26-May-2025	VITROS Immunodiagnostic Product AFP Reagent & Calibrator: Cal: 1515154 Rgt: 1925551  Shelf Life: Reagent: 52 weeks Calibrator: 52 weeks  Storage Conditions: 2-8°C  Class: C  Fees: 50,000/-  Date of submission 27-Sept-23	<b>Deferred.</b> The firm M/s Sieco Scientific Traders Rawalpindi is advised to submit fresh valid notarised letter of Auhorization from the Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA or inform the MDB if their principle manufacturer has terminated its authorization for the said brands. As the same legal manufacture has issued LOA to M/s Martin Dow, Karachi for the same products with the same brand name.
21.	Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah- e-Faisal, Karachi ELI-00160 Initial Submission: 02-Dec-2022  Final Submission: 27-Sept-2023	Legal Manufacturer: Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA  Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom  embassy attested Free Sale Certificate Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom Date of Issue: 04-July-2023 Validity: 26-May-2025	VITROS Immunodiagnostic Product CA 15-3 Reagent & Calibrator: Cal: 6800033 Rgt: 6800039  Shelf Life: Reagent: 12 months Calibrator: 12 months  Storage Conditions: 2-8°C  Class: C  Fees: 50,000/-	<b>Deferred.</b> The firm M/s Sieco Scientific Traders Rawalpindi is advised to submit fresh valid notarised letter of Auhorization from the Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA or inform the MDB if their principle manufacturer has terminated its authorization for the said brands. As the same legal manufacture has issued LOA to M/s Martin Dow, Karachi for the same products with the same brand name.
22.	Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah- e-Faisal, Karachi ELI-00160	Legal Manufacturer: Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA  Manufacturing site: Ortho Clinical Diagnostics	VITROS Immunodiagnostic Product CA 125II Reagent & Calibrator: Cal: 6800034 Rgt: 6800038	<b>Deferred.</b> The firm M/s Sieco Scientific Traders Rawalpindi is advised to submit fresh valid notarised letter of Auhorization from the Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA or inform the

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	<p>Initial Submission: 02-Dec-2022</p> <p>Final Submission: 27-Sept-2023</p>	<p>Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom</p> <p>embassy attested Free Sale Certificate Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom Date of Issue: 04-July-2023 Validity: 26-May-2025</p>	<p>Shelf Life: Reagent: 32 weeks Calibrator:32 weeks</p> <p>Storage Conditions: 2-8°C</p> <p>Class: C</p> <p>Fees: 50,000/-</p>	<p>MDB if their principle manufacturer has terminated its authorization for the said brands. As the same legal manufacture has issued LOA to M/s Martin Dow, Karachi for the same products with the same brand name.</p>
23.	<p>Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&amp;B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi</p> <p>ELI-00160 Initial Submission: 02-Dec-2022 Final Submission: 27-Sept-2023</p>	<p>Legal Manufacturer: Ortho Clinical Diagnostics, 100 Indigo Creek Drive Rochester, NY, 14626 USA</p> <p>Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom</p> <p>embassy attested Free Sale Certificate Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom Date of Issue: 04-July-2023 Validity: 26-May-2025</p>	<p>VITROS Immunodiagnostic Product CA 19-9 Reagent &amp; Calibrator:</p> <p>Cal: 6800035 Rgt: 6800040</p> <p>Shelf Life: Reagent: 09 months Calibrator:09 months</p> <p>Storage Conditions: 2-8°C</p> <p>Class: C</p> <p>Fees: 50,000/-</p>	<p><b>Deferred.</b> The firm M/s Sieco Scientific Traders Rawalpindi is advised to submit fresh valid notarised letter of Authorization from the Ortho Clinical Diagnostics, 100 Indigo Creek Drive Rochester, NY, 14626 USA or inform the MDB if their principle manufacturer has terminated its authorization for the said brands. As the same legal manufacture has issued LOA to M/s Martin Dow, Karachi for the same products with the same brand name.</p> <p>Provide undertaking of the stamp paper as required in Form7A</p>
24.	<p>Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&amp;B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi</p> <p>ELI-00160 Initial Submission: 02-Dec-2022 Final Submission: 27-Sept-2023</p>	<p>Legal Manufacturer: Ortho Clinical Diagnostics, 100 Indigo Creek Drive Rochester, NY, 14626 USA</p> <p>Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom</p> <p>embassy attested Free Sale Certificate Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom Date of Issue: 04-July-2023 Validity: 26-May-2025</p>	<p>VITROS Immunodiagnostic Product CEA Reagent &amp; Calibrator:</p> <p>Cal: 1062306 Rgt: 1920115</p> <p>Shelf Life: Reagent: 32 weeks (+4 weeks post expiry) Calibrator:32 weeks (+4 weeks post expiry)</p> <p>Storage Conditions: 2-8°C</p> <p>Class: C</p> <p>Fees: 50,000/-</p>	<p><b>Deferred.</b> The firm M/s Sieco Scientific Traders Rawalpindi is advised to submit fresh valid notarised letter of Authorization from the Ortho Clinical Diagnostics, 100 Indigo Creek Drive Rochester, NY, 14626 USA or inform the MDB if their principle manufacturer has terminated its authorization for the said brands. As the same legal manufacture has issued LOA to M/s Martin Dow, Karachi for the same products with the same brand name.</p> <p>Provide undertaking of the stamp paper as required in Form7A. The MDB under the MDR 2017 will consider the shelf life as per stability studies provided i.e 32 weeks only.</p>

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25.	<p>Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&amp;B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160</p> <p>Initial Submission: 02-Dec-2022 Final Submission: 27-Sept-2023</p>	<p>Legal Manufacturer: Ortho Clinical Diagnostics, 100 Indigo Creek Drive Rochester, NY, 14626 USA</p> <p>Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom</p> <p>embassy attested Free Sale Certificate Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom Date of Issue: 04-July-2023 Validity: 26-May-2025</p>	<p>VITROS Immunodiagnostic Product HBeAg Reagent &amp; Calibrator:</p> <p>Cal: 1914498 Rgt: 8211880</p> <p>Shelf Life: Reagent: 52 weeks Calibrator: 52 weeks</p> <p>Storage Conditions: 2-8°C</p> <p>Class: D</p> <p>Fees: 50,000/-</p>	<p><b>Deferred.</b> The firm M/s Sieco Scientific Traders Rawalpindi is advised to submit fresh valid notarised letter of Authorization from the Ortho Clinical Diagnostics, 100 Indigo Creek Drive Rochester, NY, 14626 USA or inform the MDB if their principle manufacturer has terminated its authorization for the said brands. As the same legal manufacture has issued LOA to M/s Martin Dow, Karachi for the same products with the same brand name.</p> <p>Provide undertaking of the stamp paper as required in Form 7A</p>
26.	<p>Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&amp;B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160</p> <p>Initial Submission: 02-Dec-2022 Final Submission: 27-Sept-2023</p>	<p>Legal Manufacturer: Ortho Clinical Diagnostics, 100 Indigo Creek Drive Rochester, NY, 14626 USA</p> <p>Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom</p> <p>embassy attested Free Sale Certificate Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom Date of Issue: 04-July-2023 Validity: 26-May-2025</p>	<p>VITROS Immunodiagnostic Product HBsAg ES Reagent, Calibrator &amp; HBsAg Control :</p> <p>Cal: 6802132 Rgt: 6802131 Cont: 6800598</p> <p>Shelf Life: Reagent: 56 weeks Calibrator: 56 weeks Control: 56 weeks</p> <p>Storage Conditions: 2-8°C</p> <p>Class: D</p> <p>Fees: 50,000/-</p>	<p><b>Deferred.</b> The firm M/s Sieco Scientific Traders Rawalpindi is advised to submit fresh valid notarised letter of Authorization from the Ortho Clinical Diagnostics, 100 Indigo Creek Drive Rochester, NY, 14626 USA or inform the MDB if their principle manufacturer has terminated its authorization for the said brands. As the same legal manufacture has issued LOA to M/s Martin Dow, Karachi for the same products with the same brand name.</p> <p>Clarify the VITROS Immunodiagnostic Product HBsAg Control under the MDR 2017 for grouping, since the Product HBsAg ES Reagent, Calibrator is different than control (HBsAg Control). The brand name applied on 7A is different than on company letter Clarify.</p> <p>The stability study provided reflect 52 months However, the firm claim 56 week, clarify</p>
27.	<p>Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&amp;B,</p>	<p>Legal Manufacturer: Ortho Clinical Diagnostics, 100 Indigo Creek Drive Rochester, NY, 14626 USA</p>	<p>VITROS Immunodiagnostic Product hs Troponin-I Reagent &amp; Calibrator:</p> <p>Cal: 6844437</p>	<p><b>Deferred.</b> The firm M/s Sieco Scientific Traders Rawalpindi is advised to submit fresh valid notarised letter of Authorization from</p>

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	Block-6, PECHS, Razi Road, Shahrah- e-Faisal, Karachi ELI-00160  Initial Submission: 02-Dec-2022 Final Submission: 27-Sept-2023	Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom  embassy attested Free Sale Certificate Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom Date of Issue: 04-July-2023 Validity: 26-May-2025	Rgt: 6844436  Shelf Life: Reagent: 52 weeks Calibrator: 60 weeks  Storage Conditions: 2-8°C  Class: C  Fees: 50,000/-	the Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA or inform the MDB if their principle manufacturer has terminated its authorization for the said brands. As the same legal manufacture has issued LOA to M/s Martin Dow, Karachi for the same products with the same brand name.
28.	Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah- e-Faisal, Karachi ELI-00160 Initial Submission: 02-Dec-2022 Final Submission: 27-Sept-2023	Legal Manufacturer: Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA  Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom  embassy attested Free Sale Certificate Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom Date of Issue: 04-July-2023 Validity: 26-May-2025	VITROS Immunodiagnostic Product FSH Reagent & Calibrator: Cal: 1901263 Rgt: 1931922 Shelf Life: Reagent: 52 weeks Calibrator: 52 weeks  Storage Conditions: 2-8°C  Class: C  Fees: 50,000/-	<b>Deferred.</b> The firm M/s Sieco Scientific Traders Rawalpindi is advised to submit fresh valid notarised letter of Authorization from the Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA or inform the MDB if their principle manufacturer has terminated its authorization for the said brands. As the same legal manufacturer has issued LOA to M/s Martin Dow, Karachi for the same products with the same brand name.  Clarify the following The firm has provided stability studies of 36 months and new shelf life 52months where in it is written that the report/result support 52 months, therefore the firm is advised to submit documentary evidence in the country of origin like label of the product mentioning claimed shelf life
29.	Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah- e-Faisal, Karachi ELI-00160 Initial Submission: 02-Dec-2022 Final Submission:	Legal Manufacturer: Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA  Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom	VITROS Immunodiagnostic Product LH Reagent & Calibrator: Cal: 1090133 Rgt: 1350198  Shelf Life: Reagent: 52 weeks Calibrator: 52 weeks  Storage Conditions:	<b>Deferred.</b> The firm M/s Sieco Scientific Traders Rawalpindi is advised to submit fresh valid notarised letter of Authorization from the Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA or inform the MDB if their principle manufacturer has terminated its authorization for the said

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	27-Sept-2023	embassy attested Free Sale Certificate Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom Date of Issue: 04-July-2023 Validity: 26-May-2025	2-8°C  Class: C  Fees: 50,000/-	brands. As the same legal manufacture has issued LOA to M/s Martin Dow, Karachi for the same products with the same brand name.
30.	Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Initial Submission: 02-Dec-2022 Final Submission: 27-Sept-2023	Legal Manufacturer: Ortho Clinical Diagnostics, 100 Indigo Creek Drive Rochester, NY, 14626 USA  Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom  Embassy attested Free Sale Certificate Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom Date of Issue: 04-July-2023 Validity: 26-May-2025	VITROS Immunodiagnostic Product Progesterone Reagent & Calibrator: Cal: 8254898 Rgt: 1938570  Shelf Life: Reagent: 52 weeks Calibrator: 52 weeks  Storage Conditions: 2-8°C  Class: C  Fees: 50,000/-	<b>Deferred.</b> The firm M/s Sieco Scientific Traders Rawalpindi is advised to submit fresh valid notarised letter of Authorization from the Ortho Clinical Diagnostics, 100 Indigo Creek Drive Rochester, NY, 14626 USA or inform the MDB if their principle manufacturer has terminated its authorization for the said brands. As the same legal manufacture has issued LOA to M/s Martin Dow, Karachi for the same products with the same brand name.  Clarify The Stability Study, Since the Document Provided Reflect 30 Weeks and The Firm Claimed 52 Weeks shelf life.
31.	Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Initial Submission: 02-Dec-2022 Final Submission: 27-Sept-2023	Legal Manufacturer: Ortho Clinical Diagnostics, 100 Indigo Creek Drive Rochester, NY, 14626 USA  Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom  Embassy attested Free Sale Certificate Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom Date of Issue: 04-July-2023 Validity: 26-May-2025	VITROS Immunodiagnostic Product Testosterone Reagent & Calibrator:  Cal: 1306026 Rgt: 1435205  Shelf Life: Reagent: 30 weeks Calibrator: 30 weeks  Storage Conditions: 2-8°C  Class: C  Fees: 50,000/-	<b>Deferred.</b> The firm M/s Sieco Scientific Traders Rawalpindi is advised to submit fresh valid notarised letter of Authorization from the Ortho Clinical Diagnostics, 100 Indigo Creek Drive Rochester, NY, 14626 USA or inform the MDB if their principle manufacturer has terminated its authorization for the said brands. As the same legal manufacture has issued LOA to M/s Martin Dow, Karachi for the same products with the same brand name.
32.	Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B,	Legal Manufacturer: Ortho Clinical Diagnostics, 100 Indigo Creek Drive Rochester, NY, 14626 USA	VITROS Immunodiagnostic Product Prolactin Reagent & Calibrator:  Cal: 1113596	<b>Deferred.</b> The firm M/s Sieco Scientific Traders Rawalpindi is advised to submit fresh valid notarised letter of Authorization from

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	Block-6, PECHS, Razi Road, Shahrah- e-Faisal, Karachi ELI-00160 Initial Submission: 02-Dec-2022 Final Submission: 27-Sept-2023	Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom  Embassy attested Free Sale Certificate Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom Date of Issue: 04-July-2023 Validity: 26-May-2025	Rgt: 1849793  Shelf Life: Reagent: 52 weeks Calibrator: 52 weeks  Storage Conditions: 2-8°C  Class: C  Fees: 50,000/-	the Ortho Clinical Diagnostics, 100 Indigo Creek Drive Rochester, NY, 14626 USA or inform the MDB if their principle manufacturer has terminated its authorization for the said brands. As the same legal manufacture has issued LOA to M/s Martin Dow, Karachi for the same products with the same brand name.
33.	Allmed Solutions, A-21/3, KDA Scheme No.1 (ext) Stadium Road, Karachi  (ELI-00029)  Date of Submission: 16-05-2022	INTUITIVE SURGICAL INC. Address: 1266 Kifer Road, Sunnyvale, CA 94086 USA FSC: US FDA, Valid Till: 10-2-2024. Original provided Issue on 11.02.2022	ENDO-WRIST ENERGY  Class C  Shelf Life: as above  Fees Rs. 50,000/- Challan no. 87540168143	<b>Deferred</b> for clarification of the family under the MDR 2017 and provision of the DOC with the applied brand name. Clarify since different Classes of medical device are applied in this application
34.	Allmed Solutions, A-21/3, KDA Scheme No.1 (ext) Stadium Road, Karachi  (ELI-00029)  Date of submission: 26-12-2022	TONGLU ZHOUJI MEDICAL INSTRUMENT CO. LTD., CHINA.  Address No.1 Huanzhen West Road, Fengchuan Town, Tonglu County, Zhejiang Province, China	HEMOLOCK CLIPS (POLYMER LIGATION CLIPS)  Class C  Shelf life: N/A  Fees Rs. 50,000/- challan no. 057557678	<b>Deferred</b> for Clarification of the brand name and models as per FSC. the name in the FSC is disposable Ligation clips The firm has submitted brand name Hemolock which is not reflected from the documents  Provide valid and embassy attested FSC in the country of origin and notarized LOA.  Provide notarized and valid ISO 13485 and FQA /EC certificates
35.	M/s Hospital Solutions Karachi H.No.174E, BLOCK 2, P.E.C.H.S., KARACHI. Tel:92-21- 34526671-2 ELI-00250  Submission Date: 01.02.2023	M/s Beijing Jinhengwei Technology Development Co. Ltd. China. Add: No. Room 501, Building 3, No. 27 Yongwang Road, Daxing Biomedical and Industrial Base, Zhongguancun Science Park, Daxing District 102629, Beijing, China.  FSC Validity (22.02.2024) China ISO Valid Till (01.09.2025)	(Electrosurgical Generator)  Class – D Fee 50000/-	<b>Deferred</b> for clarification of the models and name AHANVOS.  Provide valid and embassy attested FSC of reference country or notarised and valid CE certificate  Provide Stability studies.  Provide notarsied ISO 13485 or clarify.

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		FDA Valid Till (31.12.2023) LOA Valid Till (Nov,2025)		
36.	Health Services Appartment No. A-3 (3rd Floor), Plaza no. 08, Civic Center, Phase IV, Bahria Town, Islamabad ELI-00500 Dossier# 1528-c Submission date: 11/04/2023 Fee submitted: 50,000/- Challan No. 46403277453	Legal Manufacturer: IVIS Technologies S.r.l Luigi Corsi, 50 Taranto, Italy Manufacturing Site (s): Chimilab S.R.L. Address: Delle Grotte, 25, Ariccia (Rome). Italy. FSC: Italy Date of issuance: 31-05-2022	SafeCross ® Codes& sizes: SafeCross OX0001 Class-C Shelf Life: 36months	<b>Deferred</b> for the provision of following:  Apply separately alongwith separate fee of 50,000/-PKR & form-7A for SafeCross+. Mention the generic name on form 7A.  Provide duly notarized manufacturer credentials on proper format.  Provide original & duly notarized LOA.  Photocopied FSC (Italy) is submitted. Provide original, valid & embassy attested FSC.  ISO certificate is expired on 01-08-2023 but valid upon submission. Provide valid & duly notarized ISO certificate.  Provide duly notarized FQA certificate as colored Photocopy was submitted.  Clarify the medical device class of the applied product as its mentioned IIA (B) on DOC & FQA while firm applied in class C.
37.	Muller & Phipps Pakistan (Pvt) Ltd., Uzma Court, Main Clifton Road, Karachi (ELI- 00030) Dossier# 4263 Submission date: 16/02/2022 Fee submitted: 50,000/- Challan No. 503886318200	Legal Manufacturer: ASP International GmbH Zweigniederlassung Zug Gubelstrasse 34 6300 Zug Switzerland Manufacturing Site (s): Systagenix Wound Management Manufacturing, Limited Gargrave, North Yorkshire BD23 3RX United Kingdom FSC: Switzerland Valid till: 26-04-2024	CIDEX™ OPA SOLUTION (Ortho-Phthaladehyde high level disinfectant solution) Codes& sizes: 20391 Class-C Shelf Life: 22 months	<b>Deferred</b> for the provision of following:  Provide original & valid LOA.  Provide valid ISO certificate for Manufacturing Site.  Provide duly notarized FQA certificate for the legal manufacturer
38.	Ali sons room no 37, 2 <sup>nd</sup> floor Luxmi Building M.A Jinnah Road, Karachi (ELI- 00711)	Legal Manufacturer: NRS Global Partners Sdn Bhd no.30, Jalan Tasik selatan, 57000, Kuala Lumpur, Malaysia.	Ectasy Latex Condoms (Male Prophylactic Condoms) Codes& sizes: Length: min. 180mm Packing: 3s, 6s, 12s	<b>Deferred</b> for the provision of following:  FSC (Malaysia) is expired on 16-11-2023 provide valid

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	<p>Godown: KPT plot no 30, West Wharf, Karachi. Dossier# 4368 Submission date: 22/04/2022 Fee submitted: 50,000/- Challan No. 02645472630</p>	<p>FSC: Malaysia. (Original) Valid till: 16-11-2023</p>	<p>Design: Reservoir ended Type: contoured super dotted Class-C Shelf Life: 5 Years</p>	<p>FSC. Provide valid &amp; duly notarized CE certificate.  Provide original &amp; duly notarized (from country of origin) LOA. As photocopied LOA is provided having stamp of notary public Karachi, Pakistan.</p>
39.	<p>Usmanco International 220, Block 3, DMCHS, S. Abdul Tawwab Road, Karachi ELI-00121 Dossier# 988-c Submission date: 27/12/2022 Fee submitted: 50,000/- Challan No. 49241487362</p>	<p>Legal Manufacturer: AKO MED d.o.o 11000 Belgrade, Zdravka Celara 12, Serbia Manufacturing Site 35000 Jagodina, Slovenski Put, Serbia.  FSC Serbia issued on 29-04-2022</p>	<p>Jost Polypropilen Suture (Polypropylen, Non-Absorbable Monofilament surgical suture) Codes: Not provided on FSC Class-C Shelf Life: Not provided.</p>	<p><b>Deferred</b> for the provision of following:  Form-7A is not signed.  Photocopied documents are provided.  Photocopy of FSC (Serbia) is submitted. Provide original, valid &amp; embassy attested FSC.  Provide duly notarized manufacturer credentials on proper format.  Provide valid &amp; duly notarized CE certificate.  Provide original &amp; duly notarized (from country of origin) LOA.  Provide valid &amp; duly notarized EC Design examination certificate.  Provide valid &amp; duly notarized ISO certificate.  Provide DOC.  Clarify the medical device class as its D on FSC and C on form-7A.  Stability studies are not provided.  Provide establishment license renewal status.</p>
40.	<p>Usmanco International 220, Block 3, DMCHS, S. Abdul Tawwab Road, Karachi ELI-00121 Dossier# 989-c Submission date: 27/12/2022 Fee submitted: 50,000/- Challan No.</p>	<p>Legal Manufacturer: AKO MED d.o.o 11000 Belgrade, Zdravka Celara 12, Serbia Manufacturing Site 35000 Jagodina, Slovenski Put, Serbia.  FSC Serbia issued on 29-04-2022</p>	<p>Jost PGLA Quick Suture (Polyglycolide-co-L-Lactide Quick absorbable, multifilament surgical suture) Codes: Not provided on FSC Class-C Shelf Life: Not provided.</p>	<p><b>Deferred</b> for the provision of following:  Form-7A is not signed.  Photocopied documents are provided.  Photocopy of FSC (Serbia) is submitted. Provide original, valid &amp; embassy attested FSC.</p>

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	610959750076			<p>Provide duly notarized manufacturer credentials on proper format.</p> <p>Provide valid &amp; duly notarized CE certificate.</p> <p>Provide original &amp; duly notarized (from country of origin) LOA.</p> <p>Provide valid &amp; duly notarized EC Design examination certificate.</p> <p>Provide valid &amp; duly notarized ISO certificate.</p> <p>Provide DOC.</p> <p>Clarify the medical device class as its D on FSC and C on form-7A.</p> <p>Stability studies are not provided.</p> <p>Provide establishment license renewal status.</p>
41.	<p>Usmanco International 220, Block 3, DMCHS, S. Abdul Tawwab Road, Karachi ELI-00121 Dossier# 990-c Submission date: 27/12/2022 Fee submitted: 50,000/- Challan No. 39569017</p>	<p>Legal Manufacturer: AKO MED d.o.o 11000 Belgrade, Zdravka Celara 12, Serbia Manufacturing Site 35000 Jagodina, Slovenski Put, Serbia.</p> <p>FSC Serbia issued on 29-04-2022</p>	<p>Jost Silk Suture (silk Non-Absorbable, Multifilament Surgical Suture) Codes: Not provided on FSC Class-C Shelf Life: Not provided.</p>	<p><b>Deferred</b> for the provision of following:</p> <p>Form-7A is not signed.</p> <p>Photocopied documents are provided.</p> <p>Photocopy of FSC (Serbia) is submitted. Provide original, valid &amp; embassy attested FSC.</p> <p>Provide duly notarized manufacturer credentials on proper format.</p> <p>Provide valid &amp; duly notarized CE certificate.</p> <p>Provide original &amp; duly notarized (from country of origin) LOA.</p> <p>Provide valid &amp; duly notarized EC Design examination certificate.</p> <p>Provide valid &amp; duly notarized ISO certificate. Provide DOC.</p>

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				<p>Clarify the medical device class as its D on FSC and C on form-7A.</p> <p>Stability studies are not provided.</p> <p>Provide establishment license renewal status.</p>
42.	<p>Usmanco International 220, Block 3, DMCHS, S. Abdul Tawwab Road, Karachi ELI-00121 Dossier# 991-c Submission date: 27/12/2022 Fee submitted: 50,000/- Challan No. 71699393872</p>	<p>Legal Manufacturer: AKO MED d.o.o 11000 Belgrade, Zdravka Celara 12, Serbia Manufacturing Site 35000 Jagodina, Slovenski Put, Serbia.</p> <p>FSC Serbia issued on 29-04-2022</p>	<p>Jost PGLA Suture (Polyglycolide-co-L-Lactide absorbable, multifilament surgical suture) Codes: Not provided on FSC Class-C Shelf Life: Not provided.</p>	<p><b>Deferred</b> for the provision of following:</p> <p>Form-7A is not signed.</p> <p>Photocopied documents are provided.</p> <p>Photocopy of FSC (Serbia) is submitted. Provide original, valid &amp; embassy attested FSC.</p> <p>Provide duly notarized manufacturer credentials on proper format.</p> <p>Provide valid &amp; duly notarized CE certificate.</p> <p>Provide original &amp; duly notarized (from country of origin) LOA.</p> <p>Provide valid &amp; duly notarized EC Design examination certificate.</p> <p>Provide valid &amp; duly notarized ISO certificate.</p> <p>Provide DOC.</p> <p>Clarify the medical device class as its D on FSC and C on form-7A.</p> <p>Stability studies are not provided.</p> <p>Provide establishment license renewal status.</p>
43.	<p>Usmanco International 220, Block 3, DMCHS, S. Abdul Tawwab Road, Karachi ELI-00121 Dossier# 992-c Submission date: 27/12/2022 Fee submitted: 50,000/-</p>	<p>Legal Manufacturer: AKO MED d.o.o 11000 Belgrade, Zdravka Celara 12, Serbia Manufacturing Site 35000 Jagodina, Slovenski Put, Serbia.</p> <p>FSC Serbia issued on 29-04-2022</p>	<p>Jost PDO Suture (Polydioxanone Absorbable, monofilament surgical suture) Codes: Not provided on FSC Class-C Shelf Life: Not provided.</p>	<p><b>Deferred</b> for the provision of following:</p> <p>Form-7A is not signed.</p> <p>Photocopied documents are provided.</p> <p>Photocopied FSC (Serbia) is submitted. Provide original, valid &amp; embassy attested FSC.</p>

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	Challan No. 68754673362			<p>Provide duly notarized manufacturer credentials on proper format.</p> <p>Provide valid &amp; duly notarized CE certificate.</p> <p>Provide original &amp; duly notarized (from country of origin) LOA.</p> <p>Provide valid &amp; duly notarized EC Design examination certificate.</p> <p>Provide valid &amp; duly notarized ISO certificate.</p> <p>Provide DOC.</p> <p>Clarify the medical device class as its D on FSC and C on form-7A.</p> <p>Stability studies are not provided.</p> <p>Provide establishment license renewal status.</p>
44.	<p>Biosorin (Pvt) Ltd, 19-Usman Block, Main Boulevard New Garden Town Lahore ELI-00186 Dossier# 703-c Submission date: 08/12/2022 Fee submitted: 50,000/- Challan No. 9587096587</p>	<p>Legal Manufacturer: Kitazato Corporation, 100-10 Yanagishima, Fuji, Shizuoka 416-0907, Japan</p> <p>FSC Japan Issued: 28-9-2021</p>	<p>Vitrification Media Thawing Media. Vitrification Media Composed of: BS(Basic solution) ES(Equilibrium solution) VS( Vitrification solution) Codes: VT601 VT601(O) VT601N Class-D Shelf Life: 12 Months.</p>	<p><b>Deferred</b> for the provision of following:</p> <p>Apply separate case with separate fee of 50,000/-PKR for Thawing Media.</p> <p>ISO certificate for legal manufacturer expired on 24-11-23 provide valid ISO certificate.</p> <p>Provide original, valid &amp; embassy attested FSC of country of origin issued by regulatory body of Japan (Ministry of health, Labor and welfare).</p>
45.	<p>Biosorin (Pvt) Ltd, 19-Usman Block, Main Boulevard New Garden Town Lahore ELI-00186 Dossier# 704-c Submission date: 08/12/2022 Fee submitted: 50,000/- Challan No. 72259695</p>	<p>Legal Manufacturer: Altona Diagnostics GmbH Morkenstr. 12 22767 Hamburg Germany. FSC: Germany. Issued: 19-04-2022</p>	<p>Real Star® Chikungunya RT-PCR Kit 2.0 IVD Kit Composed of: Master A &amp; Master B (PCR Buffer, reverse transcriptase, DNA polymerase, magnesium salt, primers and probes) Positive control, Internal control, water (PCR grade). Codes: 012013(Article No. as provided on FSC) Class-C Shelf Life: 15 Months.</p>	<p><b>Deferred</b> for the provision of following:</p> <p>Provide valid ISO certificate for legal manufacturer.</p> <p>Provide valid &amp; original LOA as submitted one expired on 31-12-2022.</p>
46.	<p>Ferozsons Laboratories Limited P.O Ferozsons, Amargarh,</p>	<p>Legal Manufacturer &amp; manufacturing site: Lake Region Medical 340 Lake Hazeltine Dr. CHASKA, MN USA 55318</p>	<p>Safari 2™ Guidewires (Cardiac catheter guidewire, single- use) Codes &amp; Sizes: H74939406L1</p>	<p><b>Deferred</b> for the provision of following:</p> <p>On FSC the name of distributor is <i>Boston Scientific</i></p>

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	<p>Nowshera (KPK) ELI-00120 Dossier# 2709 Submission date: 10.09.2021 Fee submitted: 50,000/- Challan No. 91133737024</p>	<p>Distributor: Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752, USA FSC: U.S Valid till: 13.04.2022</p>	<p>H74939406S1 H74939406XS1 H74939407L0 H74939407S0 H74939407XS0 Class-D Shelf Life: 3 years</p>	<p>Corporation, marina bay Cust. Fulfillment center 500 commander shea Boulevard Quincy, MA USA 02171 while on form-7A distributor name is mentioned as: Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752, USA clarify please. Provide notarized credentials of legal manufacturer i.e., M/S Lake Region Medical 340 Lake Hazeltine Dr. CHASKA, MN USA 55318. LOA is expired on 31-12- 2021 .</p> <p>FSC (U.S) is expired on 13- 04-2022. Provide valid FSC certificate.</p> <p>ISO certificate for legal manufacturer expired on 04- 03-22 but valid upon submission.</p> <p>EC design examination certificate is expired on 09- 10-21 expired on submission.</p> <p>Provide valid &amp; notarized FQA certificate.</p>
47.	<p>A.S Enterprises 03- Mozang road Lahore ELI-00190 Dossier# 905-c Submission date: 24/01/2023 Fee submitted: 50,000/- Challan No. 69236336548</p>	<p>Legal Manufacturer: Acon Laboratories, Inc., 5850 Oberlin Drive, 340, San Diego, CA 92121, United States of America FSC not provided.</p>	<p>Acon Malaria PF/Pan Rapid Test Codes &amp; Sizes: FSC not provided. Class-C Shelf Life: 24 months</p>	<p><b>Deferred</b> for the provision of following:</p> <p>ISO certificate for legal manufacturer expired (06-09- 22) upon submission. Provide notarized ISO certificate.</p> <p>Provide original, valid &amp; embassy attested FSC of country of origin.</p> <p>Provide notarized FQA certificate.</p>
48.	<p>A.S Enterprises 03- Mozang Lahore ELI-00190 Dossier# 906-c Submission date: 24/01/2023 Fee submitted: 50,000/- Challan No. 0889158651</p>	<p>Legal Manufacturer: Acon Laboratories, Inc., 5850 Oberlin Drive, 340, San Diego, CA 92121, United States of America FSC not provided.</p>	<p>Acon Dengue Combo NS1 AG &amp; IgG/IgM Rapid Test Kit Codes &amp; Sizes: FSC not provided. Class-C Shelf Life: 24 months</p>	<p><b>Deferred</b> for the provision of following:</p> <p>ISO certificate for legal manufacturer expired (06-09- 22) upon submission. Provide notarized ISO certificate.</p> <p>Provide original, valid &amp; embassy attested FSC of country of origin.</p> <p>Provide notarized FQA certificate.</p>

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49.	A.S Enterprises 03-Mozang Lahore ELI-00190 Dossier# 908-c Submission date: 24/01/2023 Fee submitted: 50,000/- Challan No. 016006787760	Legal Manufacturer: Acon Laboratories, Inc., 5850 Oberlin Drive, 340, San Diego, CA 92121, United States of America FSC not provided.	Acon Malaria PF/Pv Ag Rapid Test Codes & Sizes: FSC not provided. Class-C Shelf Life: 24 months	<b>Deferred</b> for the provision of following:  ISO certificate for legal manufacturer expired (06-09-22) upon submission. Provide notarized ISO certificate.  Provide original, valid & embassy attested FSC of country of origin.  Provide notarized FQA certificate.
50.	A.s Enterprises 03-Mozang Lahore ELI-00190 Dossier# 916-c Submission date: 24/01/2023 Fee submitted: 50,000/- Challan No. 0768077351	Legal Manufacturer: Acon Laboratories, Inc., 5850 Oberlin Drive, 340, San Diego, CA 92121, United States of America FSC not provided.	Acon Dengue NS1 Ag Rapid Test Codes & Sizes: FSC not provided. Class-C Shelf Life: 24 months	<b>Deferred</b> for the provision of following:  ISO certificate for legal manufacturer expired (06-09-22) upon submission. Provide notarized ISO certificate.  Provide original, valid & embassy attested FSC of country of origin.  Provide notarized FQA certificate.
51.	A.s Enterprises 03-Mozang Lahore ELI-00190 Dossier# 907-c Submission date: 24/01/2023 Fee submitted: 50,000/- Challan No. 345234024192	Legal Manufacturer: Zhejiang Orint Gene Biotech Co., Ltd 3787, East Yangguang Avenue, Dipu Street Anji 313300 Huzhou, Zhejiang, China  FSC China valid till 02-07-2022	Orient Gene FOB Rapid Test Kit (fecal occult blood rapid test cassette) Codes & Sizes: Strip: 1tests/kit, 20tests/kit, 25tests/kit, 50tests/kit, (without collection tube) 100tests/kit, Class-C Shelf Life: 24 months	<b>Deferred</b> for the provision of following:  Form-7A is not signed & stamped from importer. Provide original, valid & embassy attested FSC of country of origin.  Provide notarized FQA certificate.
52.	Alam Medix, 9/1 Hannan Plaza Mayo Hospital Road, Lahore ELI: 00033 Dossier# 2374-p Submission date: 12.04.2021 Fee submitted: 50,000/- Challan No. 6366609163	Legal Manufacturer: BNG Medical Instrument Co., Ltd located at Room 205, Block F, Funing High-tech Industry Park, Fuyong, Baoan District, Shenzhen City, Guangdong Province, 518067, P.R China FSC: China	Ecola 3000 (Baby Incubator) Codes & Sizes: Model: 3000 Class-C Shelf Life: N/A	<b>Deferred</b> for the provision of following:  Provide original, valid & notarized LOA of legal manufacturer i.e., BNG Medical Instrument Co., Ltd, china whereas the firm has submitted LOA of M/s Metran co., Ltd Japan.  ISO certificate (not notarized) is expired on 22-02-2022, provide valid ISO certificate.  Provide FSC in the country of origin to be valid, original & attested by embassy of Pakistan.

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				<p>Provide FSC of reference country to be valid, original &amp; attested by embassy of Pakistan.</p> <p>Provide valid &amp; notarized ISO 13485 &amp; FQA certificate.</p> <p>Provide notarized manufacturer credentials.</p> <p>Provide European type DOC to be printed on manufacturer's letter head.</p>
53.	<p>MR Medical Pakistan Private Limited, Office No. 1101, 11th Floor, ISE Tower, Jinnah Avenue, Blue Area Islamabad. ELI-01008 Dossier# 4135 Submission date: 22/02/2023 Fee submitted: 50,000/- Challan No.596387764</p>	<p>Legal Manufacturer: M/s Shenzhen Mindray Bio Medical Electronics Co., Ltd Mindray Building Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, People's Republic of China</p> <p>FSC: China Valid till: 11/02/2023</p>	<p>MINDRAY (Human Epididymal Protein 4) (CLIA)</p> <p>Codes &amp; Sizes: Class-C</p> <p>Shelf Life: 18 months</p>	<p><b>Deferred</b> for the provision of following:</p> <p>FSC (China) is expired on 11-02-2023 upon submission. Provide FSC in the country of origin to be valid, original &amp; attested by embassy of Pakistan.</p>
54.	<p>Ali Gohar &amp; Company (Pvt) Ltd State Life Building 1-B, I.I Chundrigarh Road, Karachi</p> <p>Eli-00004 1558-C 13-03-2023</p>	<p><u>Legal Manufacturer:</u> Zimmer Surgical Inc. 200 West Ohio Ave, Dover Oh 444622 USA 330-343-8801.</p> <p>FSC USFDA Valid till 14-04-2023</p>	<p>Zimmer Dermatome Skin Grafting System (Dermatome Skin Grafting System)</p> <p>Class-C</p> <p>Shelf life: 5 years</p> <p>Codes as per FSC</p>	<p><b>Deferred</b> for the provision of following:</p> <p>Original documents including LOA, valid FSC, ISO 13485 and FQA certificates.</p> <p>The firm is also advised to give its priority on this since Two dermatome systems are applied in single application (Air dermatome and Electrical dermatome);</p> <p>Apply separately for the other type dermatome.</p>
55.	<p>Ali Gohar &amp; Company (Pvt) Ltd State Life Building 1-B, I.I Chundrigarh Road, Karachi</p> <p>Eli-00004 1557-C 13-03-2023</p>	<p><u>Legal Manufacturer:</u> Zimmer Surgical Inc. 200 West Ohio Ave, Dover Oh 444622 USA 330-343-8801.</p> <p>FSC USFDA Valid till 14-04-2023</p>	<p>Zimmer A.T.S 2200TS Tourniquet System (Automatic tourniquet system)</p> <p>Class-C</p> <p>Shelf life: 5 years</p> <p>Codes as per FSC</p>	<p><b>Deferred</b> for the provision of following:</p> <p>Original documents including LOA, valid FSC, ISO 13485 and FQA certificates.</p> <p>Also justification is required as the Cuffs used in applied system are of both sterile and non-sterile nature, how they are grouped together and if the cuffs are supplied separately than apply separate application.</p>

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56.	Ali Gohar & Company (Pvt) Ltd State Life Building 1-B, I.I Chundrigarh Road, Karachi  Eli-00004 1558-C 13-03-2023	<u>Legal Manufacturer:</u> Zimmer Surgical Inc. 200 West Ohio Ave, Dover Oh 444622 USA 330-343- 8801.  FSC USFDA Valid till 14- 04-2023	Zimmer Mesh Graft II Expansion System (Mesh Graft II Expansion System)  Class-C  Shelf life: 5 years  Codes as per FSC: Meshgraft II Tissue Expansion System Complete (00219500000) Meshgraft II Dermatome with Ratchet (00219500100) Graft II Autoclave Case (00219500600)	<b>Deferred</b> for the provision of following:  Original documents including LOA, valid FSC, ISO 13485 and FQA certificates.  Apply separately for Derma carrier II Skin Graft carrier.
57.	Fabnos traders Pvt Ltd, Building 26-c, 3rd floor, Touheed commercial area, street no 26 phase v DHA, Karachi.  ELI-00750 1359-C 30-03-2023	<u>Legal Manufacturer:</u> Biodinamica Quimica e Farmaceutica Ltda rua Ronat Walter Sodre, 4350, Lbipora-Brazil.  FSC Brazil validity 04-06-2027	Formocresol (Dental Pulp Mummification Material)  Class-D  Shelf life: not provided  Code: 7540 (as per DoC)	<b>Deferred</b> for the provision of following:  Original, valid and notarized LOA, ISO 13485 and FQA certificates.  Original, valid and attested FSC (with English translation) in the country of origin and FSC of any RRA country or CE marked document of the applied device.  Design examination certificates (Class-D).  Credentials of manufacturer abroad duly notarized.  Shelf life and shelf life studies.  Manufacturing and QC tests protocols.  Product details.  Essential Principle Checklist.  MRP of the device.  Sterilization/ validation report for sterile products.  Label of applied device approved in the country of origin.
58.	Fabnos traders Pvt Ltd, Building 26-c, 3rd floor, Touheed commercial area, street no 26 phase v DHA, Karachi.	<u>Legal Manufacturer:</u> Biodinamica Quimica e Farmaceutica Ltda rua Ronat Walter Sodre , 4350, Lbipora-Brazil.  FSC Brazil validity	Alveolex (Alveolar dressing based on Propolis)  Class-D  Shelf life: not provided	<b>Deferred</b> for the provision of following:  Original, valid and notarized LOA, ISO 13485 and FQA certificates.  Original, valid and attested

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	ELI-00750 1358-C 30-03-2023	04-06-2027	Code: 7500 (as per DoC)	<p>FSC (with English translation) in the country of origin and FSC of any SRA country or CE marked document of the applied device.</p> <p>Design examination certificates (Class-D).</p> <p>Credentials of manufacturer abroad duly notarized.</p> <p>Shelf life and shelf life studies.</p> <p>Manufacturing and QC tests protocols.</p> <p>Product details.</p> <p>Essential Principle Checklist.</p> <p>MRP of the device.</p> <p>Sterilization/ validation report for sterile products.</p> <p>Label of applied device approved in the country of origin.</p>
59.	<p>Fabnos traders Pvt Ltd, Building 26-c, 3rd floor, Touheed commercial area, street no 26 phase v DHA, Karachi.</p> <p>ELI-00750 1361-C 30-03-2023</p>	<p><u>Legal Manufacturer:</u> Biodinamica Quimica e Farmaceutica Ltda rua Ronat Walter Sodre, 4350, Lbipora-Brazil.</p> <p>FSC Brazil validity 04-06-2027</p>	<p>Tricresol Formalin (Material for Root Canal Disinfection)</p> <p>Class-D</p> <p>Shelf life: not provided</p> <p>Code: 7635 (as per DoC)</p>	<p><b>Deferred</b> for the provision of following:</p> <p>Original, valid and notarized LOA, ISO 13485 and FQA certificates.</p> <p>Original, valid and attested FSC (with English translation) in the country of origin and FSC of any SRA country or CE marked document of the applied device.</p> <p>Design examination certificates (Class-D).</p> <p>Credentials of manufacturer abroad duly notarized.</p> <p>Shelf life and shelf life studies.</p> <p>Manufacturing and QC tests protocols.</p> <p>Product details.</p> <p>Essential Principle Checklist.</p> <p>MRP of the device.</p> <p>Sterilization/ validation report for sterile products.</p> <p>Label of applied device approved in the country of origin.</p>

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60.	A. Feroz & Co Medicine street No. 1, Marriot Road Karachi.  ELI-00066 1443-C 04-04-2023	<u>Legal Manufacturer:</u> Guangdong Wondfo Biotech Co., Ltd No. 8 Lizhishan Road Science City, Luogang District, 510663, Guangzhou. P.R. China.  FSC China valid till 21-01-24	Safety One Step HIV 1/2 Whole Blood/Serum Test  Class-D  Shelf life: 2 years  Code: W006-C	<b>Deferred</b> for the provision of following:  Original documents including Credentials, LOA, FSC of China, FSC of any RRA country, ISO 13485, FQA and DE certificates.  Labels of applied codes.
61.	A. Feroz & Co Medicine street No. 1, Marriot Road Karachi.  ELI-00066 1521-C 11-04-2023	<u>Legal Manufacturer:</u> Guangdong Wondfo Biotech Co., Ltd No. 8 Lizhishan Road Science City, Luogang District, 510663, Guangzhou. P.R. China.  FSC China valid till 21-1-24 FSC Belgium issuance 23-09-2022	Safety One Step Dengue IgG/IgM Whole Blood/Serum/Plasma Test cassette  Class-C  Shelf life: 2 years  Code: W109-C	<b>Deferred</b> for the provision of following:  Original documents including Credentials, LOA, FSC of China, FSC of any RRA country, ISO 13485, FQA certificates.  Labels of applied codes.
62.	A. Feroz & Co Medicine street No. 1, Marriot Road Karachi.  ELI-00066 1457-C 04-04-2023	<u>Legal Manufacturer:</u> Guangdong Wondfo Biotech Co., Ltd No. 8 Lizhishan Road Science City, Luogang District, 510663, Guangzhou. P.R. China.  FSC China valid till 21-1-24 FSC Belgium issuance 23-09-2022	Safety Combined Diagnostic kit Dengue NSI Antigen and IgG/IgM Antibody test (Colloidal Gold)  Class-C  Shelf life: 2 years  Code: W111-C	<b>Deferred</b> for the provision of following:  Original documents including Credentials, LOA, FSC of China, FSC of Belgium, ISO 13485, FQA certificates.  Labels of applied codes.
63.	A. Feroz & Co Medicine street No. 1, Marriot Road Karachi.  ELI-00066 1456-C 04-04-2023	<u>Legal Manufacturer:</u> Guangdong Wondfo Biotech Co., Ltd No. 8 Lizhishan Road Science City, Luogang District, 510663, Guangzhou. P.R. China.  FSC China valid till 21-1-24 FSC Belgium issuance 23-09-2022	Safety One Step One Step Malaria HRP2/pLDH (P.f/P.v) test  Class-C  Shelf life: 2 years  Code: W056-C	<b>Deferred</b> for the provision of following:  Original documents including Credentials, LOA, FSC of China, FSC of Belgium, ISO 13485, FQA certificates.  Labels of applied codes.
64.	A. Feroz & Co Medicine street No. 1, Marriot Road Karachi.  ELI-00066 1520-C 10-04-2023	<u>Legal Manufacturer:</u> Guangdong Wondfo Biotech Co., Ltd No. 8 Lizhishan Road Science City, Luogang District, 510663, Guangzhou. P.R. China.  FSC China valid till 21-1-24 FSC Belgium issuance 23-09-2022	Safety One Step Dengue NSI Antigen Whole Blood/Serum/Plasma Test cassette  Class-C  Shelf life: 2 years  Code: W041-C	<b>Deferred</b> for the provision of following:  Original documents including Credentials, LOA, FSC of China, FSC of Belgium, ISO 13485, FQA certificates.  Labels of applied codes.

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65.	Nisa Impex Pvt. Ltd. Office: Maxim Arcade Plot No. 13-14, Usman Block, Jaddah Town, Phase-I, Opp. DHA-II, G.T. Road, Islamabad. Godown: Office No. 2, 1st Floor Akbar Khan, Plaza Collage Road, Rawalpindi[ELI-00064]-2393-	Legal Manufacturer Chengdu Xinjin Shifeng Medical Apparatus & Instrument Co. Ltd. No. 46 7th Group Wanjie, Xinping Town, Xinjin County, Chengdu, China.  FSC: China	NISA Disposable Hemodialysis Blood Tubing Set  (Extracorporeal Blood Circuit for Hemodialysers )  Model/Specification: BPC-A, BPC-B, BPC-C, BPC-D (As per provided FSC)  Code: GXZZ-20173453302  Class: B Shelf Life: 3 years Fee Slip No. 2068340 Rs. 25000/-	<b>Deferred with final opportunity</b> for the provision of following:  Stability studies of the applied medical device.  FSC of the applied product i.e., NISA Disposable Hemodialysis Blood Tubing Set is not provided.
66.	Nisa Impex Pvt. Ltd. Office: Maxim Arcade Plot No. 13-14, Usman Block, Jaddah Town, Phase-I, Opp. DHA-II, G.T. Road, Islamabad. Godown: Office No. 2, 1st Floor Akbar Khan, Plaza Collage Road, Rawalpindi[ELI-00064]-2392-	Legal Manufacturer Chengdu Xinjin Shifeng Medical Apparatus & Instrument Co. Ltd. No. 46 7th Group Wanjie, Xinping Town, Xinjin County, Chengdu, China.  FSC: China Valid Till: 28-01-2025	NISA Nasal Oxygen Tube  Disposable Nasal Oxygen Tube  Model: YG-Z, YG-T, YG-II  Class: B  Shelf Life: 3 years Fee Slip No. 2068343 Rs. 25000/-	<b>Deferred with final opportunity</b> for the provision of following:  Stability studies of the applied medical device.
67.	Nisa Impex Pvt. Ltd. Office: Maxim Arcade Plot No. 13-14, Usman Block, Jaddah Town, Phase-I, Opp. DHA-II, G.T. Road, Islamabad. Godown: Office No. 2, 1st Floor Akbar Khan, Plaza Collage Road, Rawalpindi[ELI-00064]-2391-	Legal Manufacturer Chengdu Xinjin Shifeng Medical Apparatus & Instrument Co. Ltd. No. 46 7th Group Wanjie, Xinping Town, Xinjin County, Chengdu, China.  FSC: China Valid Till: 09-03-2024	NISA Urine Bag  MODEL: YLD-1000 & YLD-2000ml Code: CCDXB 20140035 Class: B MRP: Rs. 140/- Shelf Life: 3 years Fee Slip No. 2068344 Rs. 25000/-	<b>Deferred with final opportunity</b> for the provision of following:  Stability studies of the applied medical device.
68.	M/s Ferozs Laboratories Limited, P.O Ferozs, Amangarh, Nowshera (KPK)  ELI: 00120 Evaluator: AD – II (3546-P)	Legal Manufacturer: M/s Apollo Endosurgery, Inc., 1120 South Capital of Texas Highway, Building 1, Suite 300, Austin, Texas 78746 USA. Manufacturing site: Apollo Endosurgery, Costa Rica S.R.L Building B13.3, Zona Franca Coyol, Alajuela, Costa Rica 20113. FSC: Costa Rica Date Of Issue: 24.11.2022	X-TACK Endoscopic HeliX Tacking System  Codes & Sizes: XTACK-160-H XTACK-235-H- CNH-C01-213-L  Class-C Shelf Life: 3 years	<b>Deferred with final opportunity</b> for the provision of following:  Provide notarized Full Quality Assurance System Certificate of the relevant applied product.

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69.	M/s Royal Enterprises, Shop No. 5, Karimji Building, Opp HBL North Napier Road, Karachi (ELI-00062) [792]	Manufacturer: M/s Jiangsu Folee Medical Equipment Co., Ltd., No. 16, Xingmao Road, Zhenjiang City, China (FSC China Valid Till 26-02-2022)	Folee Oxygen Concentrator (Model: Y007-1) Class B Shelf Life: Not applicable Fee Submitted: Rs. 25,000/-	<b>Deferred with final opportunity</b> to provide valid Notorised CE certificate as mentioned in DOC and valid ISO.
70.	M/s Royal Enterprises, Shop No. 5, Karimji Building, Opp HBL North Napier Road, Karachi (ELI-00062) [793]	Manufacturer: M/s Jiangsu Folee Medical Equipment Co., Ltd., No. 16, Xingmao Road, Zhenjiang City, China (FSC China Valid Till 26-02-2022)	Folee Air Compressing Nebulizer (W003, W003-A, W003-B) Class B Shelf Life: Not Applicable Fee Submitted: Rs. 25,000/-	<b>Deferred with final opportunity</b> to provide valid Notorised CE certificate as mentioned in DOC and valid ISO.
71.	M/s Royal Enterprises, Shop No. 5, Karimji Building, Opp HBL North Napier Road, Karachi (ELI-00062) [794]	Manufacturer: M/s Jiangsu Folee Medical Equipment Co., Ltd., No. 16, Xingmao Road, Zhenjiang City, China (FSC China Valid Till 26-02-2022)	Folee Arm Blood Pressure Monitor Class B Shelf Life: Not Applicable DX-B1, DX-B1Y, DX-B2, DX-B2Y, DX-B3, DX-B3Y, DX-B4, DX-B10, DX-B10Y, DX-B15, DX-B15Y, DX-B16, DX-B17, DX-B17Y Fee Submitted: Rs. 25,000/-	<b>Deferred with final opportunity</b> to provide valid Notorised CE certificate as mentioned in DOC and valid ISO.
72.	M/s Royal Enterprises, Shop No. 5, Karimji Building, Opp HBL North Napier Road, Karachi (ELI-00062) [795]	Manufacturer: M/s Jiangsu Folee Medical Equipment Co., Ltd., No. 16, Xingmao Road, Zhenjiang City, China (FSC China Valid Till 26-02-2022)	Folee Electric Suction Unit Class B Shelf Life: Not Applicable H001, H002 Fee Submitted: Rs. 25,000/-	<b>Deferred with final opportunity</b> to provide valid Notorised CE certificate as mentioned in DOC and valid ISO.
73.	M/s Royal Enterprises, Shop No. 5, Karimji Building, Opp HBL North Napier Road, Karachi (ELI-00062)	Manufacturer: M/s Jiangsu Folee Medical Equipment Co., Ltd. No. 16, Xingmao Road, Zhenjiang City, China (FSC China Valid Till 26-02-2022) Fee submitted: Rs.25,000/-	Folee Portable Phlegm Suction Unit Class B Shelf Life: Not applicable H003-A, H003-B, H003-C	<b>Deferred with final opportunity</b> to provide valid Notorised CE certificate as mentioned in DOC and valid ISO.
74.	M/s. Popular International (PVT) Ltd, House No. 141 Justice Inamullah Road, Block 7&8 K.M.C.H.S Near Hill Park Karachi. Eli No.00091 55-C	Legal Manufacturer: M/s. Covidien LLC Hamshire street, Mansfield MA 02048, USA. Manufactured by: M/s. Covidien Avenue Henequen No. 1181 Park industrial Salvacar Ciudad Juarez, Chihuahua Mexico, 32573	Shiley Endotracheal Tube, Cuffed Class-C Shelf life: not provided Codes as per FSC	<b>Deferred with final opportunity</b> to provide Notorised ISO, Apostille USA is for FSC HPRA certificate no CGS11339 which is not Provided FSC with highlighted codes required

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		Apostille USA is for Medtronic certificate of authenticity is for FSC HPRA certificate no CGS11339 mentioned on it that is not provided  FSC Ireland HPRA provided valid till 10-08-25		
75.	Popular International (Pvt) Ltd., House No. 141, Justice Inamullah Road, Block 7 & 8 KMCHS Near Hill Park, Karachi. (ELI-00091) 4836	Legal Manufacturer: M/s Covidien LLC 15 Hampshire Street Mansfield, MA 02048, USA. Manufacturer Site: Mallinckrodt DAR S.R.L., Via G. Bove 2/4/6/8, 41037 MIRANDOLA (MO) Italy. FSC HPRA issuance 18-02-2022	Shiley Tracheostomy system  Adult tracheostomy tube, cuffed  Class-B  Shelf life: 5 years  Codes Flexible Adult disposable and reusable inner cannula tracheostomy tube	<b>Deferred with final opportunity</b> for provision of original LOA, FSC with codes & relevant labels and brochures
76.	M/s. Popular International (PVT) Ltd, House No. 141 Justice Inamullah Road, Block 7&8 K.M.C.H.S Near Hill Park Karachi. Eli No.00091 55-C	Legal Manufacturer: M/s. Covidien LLC Hampshire street, Mansfield MA 02048, USA.  Manufactured by: M/s. Covidien Avenue Henequen No. 1181 Park industrial Salvacar Ciudad Juarez, Chihuahua Mexico, 32573  FSC Netherlands valid till 21-02-2027	Shiley Oral / nasal Rae Endotracheal tubes  Class-C  Shelf life: not provided  Codes as per FSC Shiley Oral / nasal Endotracheal tubes intermediate cuff Non DEHP	<b>Deferred with final opportunity</b> for provision of notorised ISO,  Submit DoC with clearly highlighted the Product applied with codes.
77.	Allmed Solutions, A-21/3, KDA Scheme No.1 (ext) Stadium Road, Karachi  (ELI-00029) Date of submission: 18-07-2022	KARL STORZ SE & CO. KG Address: Dr.-Karl-Storz-StraBe 34 78532 Tuttlingen, Germany FSC: Embassy attested Germany Issue date : 12.10.2022  Expiry not written on FSC	KARL STORZ Laser lithotripsy System CALCULASE III Basic Unit CALCULASE II fiber reusable , CALCULASE III single use and reusable & Laser Accessories  Class C  Shelf Life: N/A  Fees Rs. 50,000/- challan no. 2390438944	<b>Deferred</b> for clarification of the family under the MDR 2017.  Clarify the shelf life/ service life
78.	Allmed Solutions, A-21/3, KDA Scheme No.1 (ext) Stadium Road, Karachi  (ELI-00029) Date of submission: 04-07-2022	KARL STORZ SE & CO. KG Address: Dr.-Karl-Storz-StraBe 34 78532 Tuttlingen, Germany FSC: Embassy attested Germany Issue date : 12.10.2022  Expiry not written on FSC	KARL STORZ SIMMEN Coagulation Suction Tubes and Coagulation and Dissection Electrodes  Class C  Shelf Life: N/A  Fees Rs. 50,000/- Challan no. 4069720117	<b>Deferred</b> for clarification of the family under the MDR 2017.  Clarify the shelf life


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79.	Allmed Solutions, A-21/3, KDA Scheme No.1 (ext) Stadium Road, Karachi  (ELI-00029) Date of Submission: 18-01-2023	KARL STORZ SE & CO. KG Address: Dr.-Karl-Storz- StraBe 34 78532 Tutlingen, Germany FSC: Embassy attested Germany Issue date : 12.10.2022  Expiry not written on FSC	KARL STORZ PUMPS ( ENDOMAT SELECT)WITH ACCESSORIES  Article no.  Class C Shelf life: N/A Fees Rs. 50,000/- Challan no. 3086870610	<b>Deferred</b> for clarification of brand name or revise the name as per FSC (One- pedal-Footswitch two stages ) of the product at serial no 15 One-pedal- Footswitch
80.	M/s Kain Medical, Ali Bhai Center 3 <sup>rd</sup> Floor Office # 35 Main Shahrah-e- Qauideen, Karachi (ELI-00506)  Date of submission 24.01.2022	<u>Legal Manufacture</u> M/s TEKIA, Inc., 17 Hammond, Suite 414 Irvine, California 92618, USA  <u>Sterilization Process:</u> M/s Pro-Tech Design & Manufacturing Inc. 14561 Marquardt Avenue Santa Fe Springs, CA 90670, USA  Us Embassy attes FSC France issuance date: 15-10-2020	Tek Lens II (Intraocular Lens)  Class C  Shelf Life: 03 Years  Codes & Sizes as per FSC  811, 811Y  Fee 50000/-	<b>Deferred</b> for provision of Embassy attested valid FSC of France.  Shelf life need clarification with respect to the name mentioned in the report.  Provide notarized and valid ISO13485 certificate
81.	M/s Kain Medical, Ali Bhai Center 3 <sup>rd</sup> Floor Office # 35 Main Shahrah-e- Qauideen, Karachi (ELI-00506) Date of submission 05.07.2022	<u>Legal Manufacture:</u> M/s Zhejiang Chuangxiang Medical Technology Co., Ltd., Room 101, 201, 301, 401, 501, Building 50 No.650 Hongfeng Road Donghu Street, Yuhang District, Hangzhou City, Zhejiang Province 311100, P.R. China  Copy of FSC China valid till 10-06-2023	G-Tec Sphinctero tome  Class C  Shelf Life: 03 Years  Codes & Sizes as per FSC  MD-A-TM0530 MD-A-TM1530 MD-A-TM0525 MD-A-TM1525 MD-A-TM0520 MD-A-TM1520 MD-B-TM0604	<b>Deferred</b> for clarification of brand name in LOA medonova  Provide embassy attested valid FSC in the country of origin.  Provide embassy attested valid FSC of reference country or CE certificate issued by notified body present in Nando data base.  Valid and notarized, LOA , ISO 13485 and FQA .

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

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

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