



No.F.4-8/2023-MD (M-59)
Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
Drug Regulatory Authority of Pakistan

Islamabad the 8th August, 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 59th meeting held on 20th July, 2023 and Board deferred these applications being deficient of the information/documents as specified in last column (V) of the Table below:

S#	Name of Importer	Name of Manufacturer	Name of Medical Devices	Decision
I	II	III	IV	V
1.	M/s Lab Diagnostic Systems (SMC) Pvt. Ltd Plot no 36-A, PSIC, SIE, Taxila, Rawalpindi Establishment License number: ELI-00496 Date of issue: 13/02/2020	Legal Manufacturer & Manufacturing Site: LEVENTON, S.A.U. Ronda Can Margarit, 38 Pol. Ind. Can Margarit 08635 Sant Esteve Sesrovires Barcelona, Spain Tel: +34 93 817 6300 leventon.es Legalized Free Sale Certificate (FSC) issued by Spain dated 06-02-2022.	DOSI-FUSER Elastomeric infusion Pump System. Class: D Shelf-life: 24 Months Size/Code: 1. DOSI-FUSER Slow Flow with Capillary Element: L25915-065D1 L25915-065D2 L25915-065D3 L25915-065D5 L25915-065H12 L25915-065H5 L25915-100D1 L25915-100D2 L25915-100D3 L25915-100D5 L25915-100D7 L25915-100D7-MPK L25915-150D1 L25915-150D2 L25915-150D2-MPK L25915-150D3 L25915-150D5 L25915-150D7 L25915-150H12 L25915-250D1 L25915-250D11 L25915-250D1-2MPK L25915-250D2 L25915-250D2-2MPK L25915-250D3 L25915-250D5	The Board deferred the case for submission of valid Free Sale Certificate issued by country of origin mentioning the demanded products types & codes.

Deferred letter of 59th Meeting of MDB (20-07-2023)

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		<p>L25915-250D5-MPK L25915-250D7 L25915-400D2 L25915-500D2 L25915-600D2</p> <p>2. DOSI-FUSER Fast Flow with Restrictor Tube: L25915-065H1 L25915-065H2 L25915-065M30 L25915-100H1 L25915-100H12 L25915-100H2 L25915-100H2 L25915-100H5 L25915-100M30 L25915-100M30-2MPK L25915-100M30-MPK L25915-150H1 L25915-150H2 L25915-150H5 L25915-150M30 L25915-250H1 L25915-250H12 L25915-250H1-2MPK L25915-250H1-MPK L25915-250H2 L25915-250H5 L25915-400H4 L25915-500D1 L25915-500H12 L25915-500H2 L25915-600D1 L25915-600H1 L25915-600H12</p> <p>3. DOSI-FUSER Multiflow with Multiflow system: L25915-100-124 L25915-100-248 L25915-250-124 L25915-250-248 L25915-400-248 L25915-400-248-2PK L25915-600-248</p> <p>4. DOSI-FUSER® PCA with PCA system: L25915-100D5-05x30 L25915-250D2-2x60 L25915-250D5-2x80 L25915-250D7-2x80</p> <p>5. DOSI-FUSER Double Channel with double infusion line: L25915-250D1X2 L25915-250D2X2 L25915-250D3X2 L25915-250D5X2</p> <p>6. FUSER NRFit</p>	
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			with NRFit connector: L2592N-100D2 L2592N-150D2 L2592N-250D1 L2592N-250D2 L2592N-250D2-2MPK L2592N-250D3 L2592N-250D5 L2592N-250D7 L2592N-400D2 L2592N-500D2 L2592N-600D2 L2592N-250D1x2 L2592N-250D2x2 L2592N-250D3x2 L2592N-250D5x2 L2592N-100-124 L2592N-100-248 L2592N-250-124 L2592N-250-248 L2592N-400-248 L2592N-400-248-2PK L2592N-600-248 L2592N-065D1-05x15 L2592N-065D2-05x30 L2592N-100D2-05x15 L2592N-100D5-05x30	
2.	Global Health Care, Midway Commercial Plaza No. 20, back Side of Prism Arcade-2, Phase -7 Bahria Town, Rawalpindi. ELI: 00086	Legal Manufacturer: Boditech Med Inc. 43, Geodudanji 1-gil, Dongnae-myeon, Chungcheon-si, Gang- won-do, 24398, Republic of Korea Copy of FSC No. 20220077747 dated 11-07-2022 issued by Korea	ichroma™ III Automatic Fluorescence Immunoassay Analyzer Class: C Shelf-life: 24 Months Size/Code: As per FSC	Deferred for provision of Embassy attested FSC of country of origin & FSC of any other reference regulatory authority/CE marking & valid ISO 13485.
3.	Global Health Care, Midway Commercial Plaza No. 20, back Side of Prism Arcade-2, Phase -7 Bahria Town, Rawalpindi. ELI: 00086	Legal Manufacturer: Boditech Med Inc. Site 1: 43, Geodudanji 1-gil, Dongnae-myeon, Chungcheon-si, Gang- won-do, 24398, Republic of Korea	Ichroma™ NT-proBNP Class: C Shelf-life: 20 Months Size/Code: As per FSC Fee: 50,000/- Dated: 10-10- 2022	Deferred for provision of Embassy attested FSC of country of origin & FSC of any other reference regulatory authority/CE marking & valid ISO 13485.
4.	Cardio Life House #534 Ground Floor Lane 1 Main Khayaban E Tanveer Shceem 3 Rawalpindi Pakistan	Legal manufacturer Cpt Sutures Co.,Ltd 83 Hai Ba Trung, Ben Nghe Ward, District. Ho Chi Minh City, Vietnam	Caresorb Plus Absorbable Polyglactin 910 Antibacterial coated with Chlorhexidine Diacetate Suture Code: As Per Fsc	Deferred for provision of Embassy attested FSC issued by any reference country /CE marking & Design examination certificate.

	ELI-000984	<p><u>Manufacturing facility:</u> 8 Dao Tri, Phu Thuan Ward, District 7, Ho Chi Minh City, Vietnam</p> <p>Original Legalized Free Sale Certificate (FSC) Issued by Vietnam valid upto 25-09-2023.</p> <p>Legalized Certificate of Foreign Government (CFG) No.7801-3-2021 issued by USFDA valid up 13-04-2023.</p>	<p>Class-D</p> <p>Shelf Life: 5 years</p> <p>Fee: RS:50,000 /- dated 29-11-2022</p>	
5.	<p>Danish international Healthcare (Pvt) Ltd, 51-F, 2nd Floor , Main Boulevard, Punjab Co-operative Housing Society, Ghazi Road Lahore</p> <p>ELI: 00821</p>	<p>Legal Manufacturer: FHC, Inc. Corporate & Manufacturing 1201 main street Bowdoin Maine 04287 USA</p> <p>FSC No.1136-10-2020 U.S.A Valid till: 27.10.2022</p>	<p>FHC (Electrodes and Insertion Tubes)</p> <p>Codes & Sizes: As per FSC</p> <p>Class-C Shelf life: 3 years</p> <p>Fee: 50,000/-</p> <p>Date of Application: 13-06-2022</p>	Deferred for submission of valid Letter of Authorization & FSC.
6.	<p>M/s. Care and Cure International. 65-B, Satellite Town Rahim Yar Khan.</p> <p>ELI-00192</p>	<p>Legal Manufacturer & Manufacturing Site: TG Medical SDN BHD LOT 5091, Jalan Teratal, Batu 5, Selangor D.E, Malaysia</p> <p>Copy of FSC No. (62) MDA.600-2/2/13 Jld 83 issued Malaysia dated 04-08-2022.</p>	<p>Cure (Cure Nitril Gloves powder free)</p> <p>Class-B Shelf Life: 5 years</p> <p>Fee : 5000/-dated 09-03-2022</p>	Deferred. The firm shall submit valid FSC from country of origin & FSC from any reference regulatory authority/CE marking certificate. Revised Form-7 with revised brand name, correct classification, valid FSC & remaining fee.
7.	<p>M/s Intek Corporation Pvt Ltd, Office # 501-502, Kohistan Towers, Mehfooz Road, Saddar Rawalpindi-46000</p> <p>ELI:00794 1406-P 20-03-2020</p>	<p><u>Legal Manufacturer:</u> Lepu Medical Technology (Beijing) Co., Ltd No. 37 Chaoqian Road, Changping District, Beijing, 102200, China.</p> <p>FSC Netherlands valid till 23 June 2020</p>	<p>Angioway Y-Hemostasis Valve set</p> <p>Class-B</p> <p>Shelf life: 3 years</p> <p>Codes as per FSC</p>	<p>Deferred for the provision of following: Updated LOA, ISO 13485 and FSC of Netherland.</p> <p><i>W/8/8/2023</i></p>

8.	M/s ShahCo Medical (Pvt) Ltd, House No. 934, Shadman Colony No.01, Lahore ELI-00230 3051-P 24-06-2022	Legal Manufacturer: Omega Medical Imaging, LLC 3400 St, Johns Parkway, Suite, 1020, Sanford Florida, 32771, USA. US FDA certificate Ref: K182834 (510K)	Omega e-View (Radiographic Fluoroscopy X-ray System, CS-50 Series) Class-C Shelf Life: N/A Codes & Sizes: As per FSC	Deferred for the provision of following documents: Credentials of manufacturer's abroad. Original and notarized/ attested documents, submitted are copies without notarization/ attestation. Valid and notarized ISO and CE marked certificates.
9.	M/s ShahCo Medical (Pvt) Ltd, House No. 934, Shadman Colony No.01, Lahore ELI-00230 3052-P 24-06-2022	Legal Manufacturer: Hologic, Inc. 36 Apple Ridge Road Danbury, CT 07810, USA.	Selenia Dimensions 3 Dimensions Advanced Workflow Manager Contrast Enhanced-Digital Mammography (Digital Mammography) Codes & Sizes: As per FSC Class-C Shelf Life: N/A	Deferred for the provision of following documents: FSC is not provided, provide original, valid and attested FSC. The submitted 510k summary report is for another device. Credentials of manufacturer's abroad. Original and notarized/ attested documents, submitted are copies without notarization/ attestation. Valid and notarized ISO and CE marked certificates.
10.	M/s ShahCo Medical (Pvt) Ltd, House No. 934, Shadman Colony No.01, Lahore ELI-00230 3103-P 29-06-2022	Legal Manufacturer: Hologic, Inc. 36 Apple Ridge Road Danbury, CT 07810, USA. FSC US FDA validity 2018 Ref: 023398 (510k)	Horizon X-ray Bone Densitometry System Class-C Shelf life: N/A Model as per FSC	Deferred for the provision of following documents: Credentials of manufacturer's abroad. FSC is not provided, provide original, valid and attested FSC. The provided FSC is expired and copy. All the legal documents submitted are copies without notarization/ attestation. Valid LOA and ISO 13485.
11.	M/s ShahCo Medical (Pvt) Ltd, House No. 934, Shadman Colony No.01, Lahore ELI-00230 3106-P 29-06-2022	Legal Manufacturer: Metrum Cryoflex sp.z o.o Sp.k, Zielna 29, 05-082 Blizne Laszczynskiego Poland FSC: Poland Date of issue: 13/02/2019	CRYO-S MINI CRYO-S Electric II (CRYO-S MINI CRYO-S Electric II) Class-C Shelf life: N/A	Deferred for the provision of following documents: All the legal documents submitted are copies without notarization/ attestation. Two devices applied in single application, give your priority. Credentials of manufacturer's abroad. All the documentation provided is related to CRYO-S Mini whereas the FSC of Poland submitted missing the device. Updated LOA and ISO 13485.

				<p>FQA certificate is missing, provide updated and notarized FQA certificate.</p> <p>The accessories included probes to be applied in different surgical procedures, so apply in separate application for Gynae and Derma probes.</p>
12.	<p>M/s ShahCo Medical (Pvt) Ltd, House No. 934, Shadman Colony No.01, Lahore</p> <p>ELI-00230 3104-P 29-06-2022</p>	<p>Legal Manufacturer: Hologic, Inc. 36 Apple Ridge Road Danbury, CT 07810, USA.</p> <p>FSC US FDA validity 2018</p>	<p>Fluoroscanner Mini C-arm (Fluoroscopic Imaging System)</p> <p>Class-C</p> <p>Shelf life: N/A</p> <p>Model: InSight FD</p>	<p>Deferred for the provision of following documents:</p> <p>All the legal documents submitted are copies without notarization/ attestation.</p> <p>Credentials of manufacturers abroad are missing.</p> <p>Service life of the device.</p> <p>FSC provided is copy and expired, provide original, valid and attested FSC.</p> <p>Updated LOA and ISO 13485.</p>
13.	<p>M/s ShahCo Medical (Pvt) Ltd, House No. 934, Shadman Colony No.01, Lahore</p> <p>ELI-00230 3105-P 29-06-2022</p>	<p>Legal Manufacturer: Samsung Neurologica, 14 Electronics Ave, Danvers, MA 01923, USA</p> <p>510K REF: K170238 Regulation no. 21CFR 892.1750</p>	<p>BodyTom Elite (computed tomography) X-ray system</p> <p>Class-C</p> <p>Shelf life: N/A</p>	<p>Deferred for the provision of following documents:</p> <p>All the legal documents submitted are copies without notarization/ attestation.</p> <p>Credentials of manufacturers abroad are missing.</p> <p>Service life of the device.</p> <p>510K summary report provided is copy and w/o legalization.</p> <p>Updated and notarized FQA and ISO 13485.</p> <p>Updated LOA.</p> <p>Apply separately for other Brands.</p>
14.	<p>Shams Scientific Traders, 22-Y-J Madina Town, Faisalabad</p> <p>ELI: 00459 3625-P 21-03-2023</p>	<p>Legal Manufacturer: Hangzhou Biotest Biotech Co., Ltd, Address: 17#, Futai Road, Zhongtai Street, Yuhang District Hangzhou, P.R. China</p> <p>FSC: China Valid Till: 2024/09/22</p>	<p>RightSign HBsAg Rapid Test Cassette</p> <p>Class-D</p> <p>Shelf Life: 24 months</p> <p>Codes as per FSC</p>	<p>Deferred for the provision of following:</p> <p>The code of applied device mentioned in FSC of China is different from that mentioned on label and brief description, the same code is mentioned in FSC of China for HbsAb rapid test cassette, clarification is required.</p> <p>FSC of reference country is not provided, only a letter (Notarized) is provided issued by the manufacturer that the same device is registered in Germany mentioning the registration no. DE/CA05/IVD-238321-0863-00 with the code IHBSG-c31. The same code is mentioned on label, brief</p>

				<p>description, design examination and DoC.</p> <p>Manufacturing and QC tests, in details, of the applied device not the general procedure.</p>
15.	<p>Shams Scientific Traders, 22-Y-J Madina Town, Faisalabad</p> <p>ELI: 00459 3614-P 21-03-2023</p>	<p>Legal Manufacturer: Hangzhou Biotest Biotech Co., Ltd, Address: 17#, Futai Road, Zhongtai Street, Yuhang District Hangzhou, P.R. China</p> <p>FSC: China Valid Till: 2024/09/22</p>	<p>RightSign HIV Rapid Test Cassette</p> <p>Class-D</p> <p>Shelf Life: 24 months</p> <p>Codes as per FSC</p>	<p>Deferred for the provision of following:</p> <p>The code of applied device mentioned in FSC of China is different from that mentioned on label and brief description, clarification is required.</p> <p>FSC of reference country is not provided, only a letter (Notarized) is provided issued by the manufacturer that the same device is registered in Germany mentioning the registration no. DE/CA05/IvD-238321-0365-99 with the code IHIV-C42. The same code is mentioned on label, brief description, design examination and DoC.</p> <p>Manufacturing and QC tests, in details, of the applied device not the general procedure.</p>
16.	<p>Shams Scientific Traders, 22-Y-J Madina Town, Faisalabad</p> <p>ELI: 00459 3617-P 21-03-2023</p>	<p>Legal Manufacturer: Hangzhou Biotest Biotech Co., Ltd, Address: 17#, Futai Road, Zhongtai Street, Yuhang District Hangzhou, P.R. China</p> <p>FSC: China Valid Till: 2024/09/22</p>	<p>RightSign Dengue NSI Antigen Rapid Test Cassette</p> <p>Class-C</p> <p>Shelf Life: 24 months</p> <p>Codes: IDEG-C41</p>	<p>Deferred for the provision of following:</p> <p>FSC of reference country is not provided, only a letter (Notarized) is provided issued by the manufacturer that the same device is registered in Germany mentioning the registration no. DE/CA05/IvD-238321-0634-00 with the code IDEG-C41.</p> <p>Manufacturing and QC tests, in details, of the applied device not the general procedure.</p>
17.	<p>Shams Scientific Traders, 22-Y-J Madina Town, Faisalabad</p> <p>ELI: 00459 3619-P 21-03-2023</p>	<p>Legal Manufacturer: Hangzhou Biotest Biotech Co., Ltd, Address: 17#, Futai Road, Zhongtai Street, Yuhang District Hangzhou, P.R. China</p> <p>FSC: China Valid Till: 2024/09/22</p>	<p>RightSign Malaria P.f/ P.v Antigen Rapid Test Cassette</p> <p>Class-C</p> <p>Shelf Life: 24 months</p> <p>Codes as per FSC</p>	<p>Deferred for the provision of following:</p> <p>The name and code of applied device mentioned in FSC of China is different from that mentioned on label and brief description, clarification is required.</p> <p>FSC of reference country is not provided, only a letter (Notarized) is provided issued by the manufacturer that the same device is registered in Germany mentioning the registration no. DE/CA05/IvD-238321-0450-00 with the code IMPV-C52. The same code is mentioned on label, brief description and DoC.</p> <p>Manufacturing and QC tests, in details, of the applied device not the general procedure.</p>

Handwritten signature and date: 08/08/2023

18.	Shams Scientific Traders, 22-Y-J Madina Town, Faisalabad ELI: 00459 3612-P 21-03-2023	Legal Manufacturer: Hangzhou Biotest Biotech Co., Ltd, Address: 17#, Futai Road, Zhongtai Street, Yuhang District Hangzhou, P.R. China FSC: China Valid Till: 2024/09/22	RightSign Malaria P.f/ Pan Antigen Rapid Test Cassette Class-C Shelf Life: 24 months Codes as per FSC	Deferred for the provision of followi The name and code of applied device mentioned in FSC of China is different from that mentioned on label and brief description, clarification is required. FSC of reference country is not provided, only a letter (Notarized) is provided issued by the manufacturer that the same device is registered in Germany mentioning the registration no. DE/CA05/IvD-238321-0450-00 with the code IMPN-C52. The same code is mentioned on label, brief description and DoC. Manufacturing and QC tests, in details, of the applied device not the general procedure.
19.	Shams Scientific Traders, 22-Y-J Madina Town, Faisalabad ELI: 00459 3613-P 21-03-2023	Legal Manufacturer: Hangzhou Biotest Biotech Co., Ltd, Address: 17#, Futai Road, Zhongtai Street, Yuhang District Hangzhou, P.R. China FSC: China Valid Till: 2024/09/22	RightSign Dengue Rapid Test Cassette Class-C Shelf Life: 24 months Codes as per FSC	Deferred for the provision of following: The applied device is not mentioned in FSC of China. FSC of reference country is not provided, only a letter (Notarized) is provided issued by the manufacturer that the same device is registered in Germany mentioning the registration no. DE/CA05/IvD-238321-0456-00 with the code IDEN-C42. Manufacturing and QC tests, in details, of the applied device not the general procedure.
20.	Shams Scientific Traders, 22-Y-J Madina Town, Faisalabad ELI: 00459 3620-P 21-03-2023	Legal Manufacturer: Hangzhou Biotest Biotech Co., Ltd, Address: 17#, Futai Road, Zhongtai Street, Yuhang District Hangzhou, P.R. China FSC: China Valid Till: 2024/09/22	RightSign Tuberculosis Rapid Test Cassette Class-C Shelf Life: 24 months Codes as per FSC	Deferred for the provision of following: The code of applied device mentioned in FSC of China is different from that mentioned on label and brief description, clarification is required. FSC of reference country is not provided, only a letter (Notarized) is provided issued by the manufacturer that the same device is registered in Germany mentioning the registration no. DE/CA05/IvD-238321-0361-00 with the code ITB-C41. Manufacturing and QC tests, in details, of the applied device not the general procedure.
21.	Shams Scientific Traders, 22-Y-J Madina Town, Faisalabad	Legal Manufacturer: Hangzhou Biotest Biotech Co., Ltd, Address: 17#, Futai	RightSign Typhoid Rapid Test Cassette Class-C	Deferred for the provision of following: The applied device is not mentioned in FSC of China.

	ELI: 00459 3624-P 21-03-2023	Road, Zhongtai Street, Yuhang District Hangzhou, P.R. China FSC: China Valid Till: 2024/09/22	Shelf Life: 24 months	FSC of reference country is not provided, only a letter (Notarized) is provided issued by the manufacturer that the same device is registered in Germany mentioning the registration no. DE/CA05/IvD-238321-0628-00 with the code ITYP-C42. Manufacturing and QC tests, in details, of the applied device not the general procedure.
22.	Shams Scientific Traders, 22-Y-J Madina Town, Faisalabad ELI: 00459 3616-P 21-03-2023	Legal Manufacturer: Hangzhou Biotest Biotech Co., Ltd, Address: 17#, Futai Road, Zhongtai Street, Yuhang District Hangzhou, P.R. China FSC: China Valid Till: 2024/09/22	RightSign Cardiac Troponin I Rapid Test Cassette Class-C Shelf Life: 24 months Code: CTNI-C41	Deferred for the provision of following: FSC of reference country is not provided, only a letter (Notarized) is provided issued by the manufacturer that the same device is registered in Germany mentioning the registration no. DE/CA05/IvD-238321-0466-00 with the code CTNI-C41. Manufacturing and QC tests, in details, of the applied device not the general procedure.
23.	Shams Scientific Traders, 22-Y-J Madina Town, Faisalabad ELI: 00459 3615-P 21-03-2023	Legal Manufacturer: Hangzhou Biotest Biotech Co., Ltd, Address: 17#, Futai Road, Zhongtai Street, Yuhang District Hangzhou, P.R. China FSC: China Valid Till: 2024/09/22	RightSign Dengue Antigen & Antibody Combo Rapid Test Cassette Class-C Shelf Life: 24 months Codes as per FSC	Deferred for the provision of following: The applied device is not mentioned in FSC of China. FSC of reference country is not provided, only a letter (Notarized) is provided issued by the manufacturer that the same device is registered in Germany mentioning the registration no. DE/CA05/IvD-238321-0634-00 with the code IDGC-C43. Manufacturing and QC tests, in details, of the applied device not the general procedure.
24.	Optisurg Valencia Town, Lahore ELI: 00305 3149-P 12-08-2022	Legal Manufacturer: HOYO Medical Singapore Pte Ltd 455A, Jalan Ahmad Ibrahim Singapore 639939. Manufacturing site: HOYO Medical Singapore Pte Ltd 455A, Jalan Ahmad Ibrahim Singapore 639939. and Hoya Lamphan Ltd 75/2 Moo 4, Tambol Banking, Amphur	HOYA Vivinex™ Multisert™ (Intra-ocular lens (IOL)) Class-C Shelf Life: 5 years Models: XCI-SP XYI-SP	Deferred for the provision of following documents: Valid and notarized LOA and ISO 13485 certificate.

		Muang, Lamphun 51000, Thailand FSC: Germany Date of Issue: 20/10/2020		
25.	Mediland Pakistan Pvt Office No. b-09, 2nd Floor Masood Arcade IJP Road near Saidpur Road, Rawalpindi. ELL: 00202 3063-P 24-06-2022	Legal Manufacturer: Maquet Cardiopulmonary GmbH Kehler Str. 31 76437 Rastatt Germany. FSC: Germany issuance: 12/17/2021	Cardiohelp (ECMO) Class-C Shelf Life: N/A Codes & Sizes: As per FSC	Deferred for the provision of following documents: Clearly state the generic name of device. There is ambiguity in the name of Legal manufacturer, on Form-7A, it is mentioned as Maquet Cardiopulmonary GmbH Kehler Str. 31 76437 Rastatt Germany whereas the agreement is in between Getinge Group middle East. Provide the original and updated Agency agreement clearly mentioning the Legal manufacturer/ owner of the product and any site or branch involved in the manufacturing of the product. FSC of Sweden submitted missing the device. FSC of Germany provided is copy Valid and notarized ISO 13485 and FQA certificates are missing. Manufacturing and QC processes in detail. Shelf life and shelf life studies. Essential principle checklist of applied device. Declaration of Conformity to be printed on manufacturer's letter head duly filled and signed by responsible person mentioning all the certifications. Justify the grouping of applied product with accessories. Labels of applied product mentioning the reference number approved in the country of origin.
26.	Mediland Pakistan Pvt Office No. b-09, 2nd Floor Masood Arcade IJP Road near Saidpur Road, Rawalpindi.	Legal Manufacturer: Maquet Cardiopulmonary GmbH Kehler Str. 31 76437 Rastatt Germany.	Maquet HCU-40 (Heater Cooler Unit) Class-C Shelf Life: N/A	Deferred for the provision of following documents: There is ambiguity in the name of Legal manufacturer, on Form-7A, it is mentioned as Maquet Cardiopulmonary GmbH Kehler Str. 31 76437 Rastatt

	<p>ELI: 00202 3059-P 24-06-2022</p>	<p>FSC: Germany issuance: 12/17/2021</p>	<p>Codes & Sizes: As per FSC</p>	<p>Germany whereas the agreement is in between Getinge Group middle East. Provide the original and updated Agency agreement clearly mentioning the Legal manufacturer/ owner of the product and any site or branch involved in the manufacturing of the product.</p> <p>FSC of Germany provided is copy</p> <p>Valid and notarized ISO 13485 and FQA certificates are missing.</p> <p>Manufacturing and QC processes in detail.</p> <p>Shelf life and shelf life studies.</p> <p>Essential principle checklist of applied device.</p> <p>Labels of applied product mentioning the reference number approved in the country of origin.</p>
27.	<p>Mediland Pakistan Pvt Office No. b-09, 2nd Floor Masood Arcade IJP Road near Saidpur Road, Rawalpindi.</p> <p>ELI: 00202 3056-P 24-06-2022</p>	<p>Legal Manufacturer: Getinge Streicoll Medikal Aletler Sannyi Ve ticaret Anonim Sirketi Bestepe Mahallesi, Nergiz Sokak No: 7/2 ic Kapi No: 71 Yenimahalle Ankara Turkey</p> <p>FSC: Turkey Valid till: 07.12.2020</p>	<p>Stericool Hydrogen Peroxide Plasma Sterilizer (Low Temp Sterilizer)</p> <p>Class-C</p> <p>Shelf Life: not provided</p> <p>Codes & Sizes: As per FSC</p>	<p>Deferred for the provision of following documents:</p> <p>All the legal documents including LOA, FSC, ISO 13485, Credentials, FQA certificate and DoC, submitted are copies without notarization/ attestation.</p> <p>LOA is between the importer and Getinge Group middle East, Clarification is required as the Legal manufacturer mentioned is Getinge Streicoll Medikal, Turkiye.</p> <p>FSC submitted is expired.</p> <p>ISO 13485 expired.</p>
28.	<p>Mediland Pakistan Pvt Office No. b-09, 2nd Floor Masood Arcade IJP Road near Saidpur Road, Rawalpindi.</p> <p>ELI: 00202 3062-P 24-06-2022</p>	<p>Legal Manufacturer: Maquet Cardiopulmonary GmbH Kehler Str. 31 76437 Rastatt Germany.</p> <p>FSC: Germany issuance: 12/17/2021</p>	<p>HU-35 (Heater Unit)</p> <p>Class-C</p> <p>Shelf Life: N/A</p> <p>Codes & Sizes: As per FSC</p>	<p>Deferred for the provision of following documents:</p> <p>There is ambiguity in the name of Legal manufacturer, on Form-7A, it is mentioned as Maquet Cardiopulmonary GmbH Kehler Str. 31 76437 Rastatt Germany whereas the agreement is in between Getinge Group middle East. Provide the original and updated Agency agreement clearly mentioning the Legal manufacturer/ owner of the product and any site or branch involved in the manufacturing of the product</p> <p>FSC of Sweden submitted missing the device.</p> <p>FSC of Germany provided is copy.</p>

				<p>Credentials of manufacturer abroad.</p> <p>Valid and notarized ISO 13485 and FQA certificates are missing.</p> <p>Manufacturing and QC processes in detail.</p> <p>Essential principle checklist of applied device.</p> <p>Declaration of Conformity to be printed on manufacturer's letter head duly filled and signed by responsible person mentioning all the certifications.</p> <p>Labels of applied product mentioning the reference number approved in the country of origin.</p>
29.	<p>Mediland Pakistan Pvt Office No. b-09, 2nd Floor Masood Arcade IJP Road near Saidpur Road, Rawalpindi.</p> <p>ELI: 00202 3084-P 24-06-2022</p>	<p>Legal Manufacturer: Maquet Cardiopulmonary GmbH Kehler Str. 31 76437 Rastatt Germany.</p> <p>FSC: Germany issuance: 12/17/2021</p>	<p>BMU Arterial and Venous Sensor (BMU Sensor)</p> <p>Class-C</p> <p>Shelf life: N/A</p> <p>Codes & Sizes: As per FSC</p>	<p>Deferred for the provision of following documents:</p> <p>There is ambiguity in the name of Legal manufacturer, on Form-7A, it is mentioned as Maquet Cardiopulmonary GmbH Kehler Str. 31 76437 Rastatt Germany whereas the agreement is in between Getinge Group middle East. Provide the original and updated Agency agreement clearly mentioning the Legal manufacturer/ owner of the product and any site or branch involved in the manufacturing of the product</p> <p>FSC of Sweden submitted missing the device.</p> <p>Credentials of manufacturer abroad.</p> <p>Valid and notarized ISO 13485 and FQA certificates are missing.</p> <p>Manufacturing and QC processes in detail.</p> <p>Essential principle checklist of applied device.</p> <p>Declaration of Conformity to be printed on manufacturer's letter head duly filled and signed by responsible person mentioning all the certifications.</p> <p>Labels of applied product mentioning the reference number approved in the country of origin.</p> <p>Apply separately for BMU cells.</p>

				The DoC showing the subject device in Class-B, clarification is required.
30.	<p>Mediland Pakistan Pvt Office No. b-09, 2nd Floor Masood Arcade IJP Road near Saidpur Road, Rawalpindi.</p> <p>ELI: 00202 3100-P 24-06-2022</p>	<p>Legal Manufacturer: Maquet Cardiopulmonary GmbH Kehler Str. 31 76437 Rastatt Germany.</p> <p>FSC: Germany issuance: 12/17/2021</p>	<p>Maquet HLM Perfusion Tubing Set (Perfusion Tubing Set with oxygenator)</p> <p>Class-C</p> <p>Shelf life: N/A</p> <p>Codes & Sizes: As per FSC</p>	<p>Deferred for the provision of following documents:</p> <p>There is ambiguity in the name of Legal manufacturer, on Form-7A, it is mentioned as Maquet Cardiopulmonary GmbH Kehler Str. 31 76437 Rastatt Germany whereas the agreement is in between Getinge Group middle East. Provide the original and updated Agency agreement clearly mentioning the Legal manufacturer/ owner of the product and any site or branch involved in the manufacturing of the product</p> <p>FSC of Sweden submitted missing the device.</p> <p>Original FSC of Germany is required.</p> <p>Shelf life and shelf life studies.</p> <p>Credentials of manufacturer abroad.</p> <p>Valid and notarized ISO 13485 and FQA certificates are missing.</p> <p>Manufacturing and QC processes in detail.</p> <p>Essential principle checklist of applied device.</p> <p>Declaration of Conformity to be printed on manufacturer's letter head duly filled and signed by responsible person mentioning all the certifications.</p> <p>Labels of applied product mentioning the reference number approved in the country of origin.</p> <p>Multiple subtypes are mentioned in DoC depending upon the age, give your priority in this application and separate the others.</p>
31.	<p>Mediland Pakistan Pvt Office No. b-09, 2nd Floor Masood Arcade IJP Road near Saidpur Road, Rawalpindi.</p> <p>ELI: 00202 3058-P 29-06-2022</p>	<p>Legal Manufacturer: Maquet Cardiopulmonary GmbH Kehler Str. 31 76437 Rastatt Germany.</p> <p>FSC: Germany issuance: 12/17/2021</p>	<p>HL 40 (Heart Lung Machine)</p> <p>Class-C</p> <p>Shelf Life: N/A</p> <p>Codes & Sizes: As per FSC</p>	<p>Deferred for the provision of following documents:</p> <p>There is ambiguity in the name of Legal manufacturer, on Form-7A, it is mentioned as Maquet Cardiopulmonary GmbH Kehler Str. 31 76437 Rastatt Germany whereas the agreement is in between Getinge Group middle East. Provide the original and updated Agency agreement clearly mentioning</p>

				<p>the Legal manufacturer/ owner of the product and any site or branch involved in the manufacturing of the product</p> <p>FSC of Sweden and Germany submitted missing the device.</p> <p>Shelf life and shelf life studies.</p> <p>Credentials of manufacturer abroad.</p> <p>Valid and notarized ISO 13485 and FQA certificates are missing.</p> <p>Manufacturing and QC processes in detail.</p> <p>Essential principle checklist of applied device.</p> <p>Declaration of Conformity to be printed on manufacturer's letter head duly filled and signed by responsible person mentioning all the certifications.</p> <p>Labels of applied product mentioning the reference number approved in the country of origin.</p> <p>Clearly provide the codes and clarification of components applied.</p>
32.	<p>Mediland Pakistan Pvt Office No. b-09, 2nd Floor Masood Arcade IJP Road near Saidpur Road, Rawalpindi.</p> <p>ELI: 00202 3098-P 29-06-2022</p>	<p>Legal Manufacturer: Maquet Critical Care AB 171 54 Solna Sweden.</p> <p>510 (K) number K 180098 (Only for Servo N ventilators and Servo-U)</p> <p>(Copy without legalization)</p>	<p>Servo I Ventilator Servo N ventilators Servo-U (Ventilator Machine)</p> <p>Class-C</p> <p>Shelf life: N/A</p> <p>Codes & Sizes: As per FSC</p>	<p>Deferred for the provision of following documents:</p> <p>There is ambiguity in the name of Legal manufacturer, on Form-7A, it is mentioned as Maquet Critical Care AB 171 54 Solna Sweden whereas the agreement is in between Getinge Group middle East. Provide the original and updated Agency agreement clearly mentioning the Legal manufacturer/ owner of the product and any site or branch involved in the manufacturing of the product</p> <p>FSC of Sweden missing the device, 510 (k) summary notification is provided.</p> <p>Credentials of manufacturer abroad.</p> <p>Valid and notarized ISO 13485 and FQA certificates are missing.</p> <p>Manufacturing and QC processes in detail.</p> <p>Essential principle checklist of applied device.</p> <p>Declaration of Conformity to be printed on manufacturer's letter head duly filled</p>

Handwritten signature and date: 20/07/2023

				<p>and signed by responsible person mentioning all the certifications.</p> <p>Labels of applied product mentioning the reference number approved in the country of origin.</p> <p>Multiple brands applied, give your priority in this application and applied separately for other Brand/models.</p>
33.	<p>Mediland Pakistan Pvt Office No. b-09, 2nd Floor Masood Arcade IJP Road near Saidpur Road, Rawalpindi.</p> <p>ELI: 00202 3213-P 29-06-2022</p>	<p>Legal Manufacturer: Maquet Critical Care AB 171 54 Solna Sweden.</p> <p>510 (K) number K160665 (Only for Flow i)</p> <p>(Copy without legalization)</p>	<p>Flow i (Anesthesia Machine)</p> <p>Class-C</p> <p>Shelf Life: N/A</p> <p>Models as per FDA PMN</p>	<p>Deferred for the provision of following documents:</p> <p>There is ambiguity in the name of Legal manufacturer, on Form-7A, it is mentioned as Maquet Critical Care AB 171 54 Solna Sweden whereas the agreement is in between Getinge Group middle East. Provide the original and updated Agency agreement clearly mentioning the Legal manufacturer/ owner of the product and any site or branch involved in the manufacturing of the product</p> <p>FSC of Sweden missing the device, 510 (k) summary notification is provided.</p> <p>Credentials of manufacturer abroad.</p> <p>Valid and notarized ISO 13485 and FQA certificates are missing.</p> <p>Manufacturing and QC processes in detail.</p> <p>Essential principle checklist of applied device.</p> <p>Declaration of Conformity to be printed on manufacturer's letter head duly filled and signed by responsible person mentioning all the certifications.</p> <p>Labels of applied product mentioning the reference number approved in the country of origin.</p> <p>Apply separately for Flow C type.</p>
34.	<p>Mediland Pakistan Pvt Office No. b-09, 2nd Floor Masood Arcade IJP Road near Saidpur Road, Rawalpindi.</p> <p>ELI: 00202 3097-P</p>	<p>Legal Manufacturer: Maquet Cardiopulmonary GmbH Kehler Str. 31 76437 Rastatt Germany.</p>	<p>Cardiosave Intra-Aortic Balloon Pump (Hybrid) (Intra-Aortic Balloon Pump)</p> <p>Class-C</p> <p>Shelf life: N/A</p> <p>Codes & Sizes: As per FSC</p>	<p>Deferred for the provision of following documents:</p> <p>There is ambiguity in the name of Legal manufacturer, on Form-7A, it is mentioned as Maquet Cardiopulmonary GmbH Kehler Str. 31 76437 Rastatt Germany whereas the agreement is in between Getinge Group middle East.</p>

	29-06-2022			<p>Provide the original and updated Agency agreement clearly mentioning the Legal manufacturer/ owner of the product and any site or branch involved in the manufacturing of the product</p> <p>Manufacturer of the device is not clear, in DoC, ISO the manufacturer is not as mentioned on Form, clarification is required.</p> <p>FSC of Sweden and Germany provided missing the device.</p> <p>Credentials of manufacturer abroad.</p> <p>Valid and notarized ISO 13485 and FQA certificates are missing.</p> <p>Manufacturing and QC processes in detail.</p> <p>Essential principle checklist of applied device.</p> <p>Declaration of Conformity to be printed on manufacturer's letter head duly filled and signed by responsible person mentioning all the certifications.</p> <p>Labels of applied product mentioning the reference number approved in the country of origin.</p> <p>Apply separately for Rescue type.</p>
35.	<p>Mediland Pakistan Pvt Office No. b-09, 2nd Floor Masood Arcade IJP Road near Saidpur Road, Rawalpindi.</p> <p>ELI: 00202 3078-P 29-06-2022</p>	<p>Legal Manufacturer: Getinge AB Lindholmspiren 7A P.O Box 8861 SE-417 56 Goteborg Sweden.</p> <p>FSC: Germany Date of issue: 30/10/2019</p>	<p>Getinge (Steam Sterilizer)</p> <p>Class-C</p> <p>Shelf life: not provided</p> <p>Codes: GSS66H GSS67F</p>	<p>Deferred for the provision of following documents:</p> <p>There is ambiguity in the name of Legal manufacturer, on Form-7A, it is mentioned as Getinge AB Lindholmspiren 7A P.O Box 8861 SE-417 56 Goteborg Sweden. whereas in FSC copy provided it is Maquet Cardiopulmonary GmbH Kehler Str. 31 76437 Rastatt Germany and site mentioned is Getinge Infection control, Poland. Clarification is required.</p> <p>There is ambiguity as the agreement is in between Getinge Group middle East. Provide the original and updated Agency agreement clearly mentioning the Legal manufacturer/ owner of the product and any site or branch involved in the manufacturing of the product</p> <p>Manufacturer of the device is not clear,</p>

				<p>in DoC, ISO the manufacturer is not as mentioned on Form, clarification is required.</p> <p>Germany provided is copy, original is required.</p> <p>Credentials of manufacturer abroad.</p> <p>Valid and notarized ISO 13485 and FQA certificates are missing.</p> <p>Manufacturing and QC processes in detail.</p> <p>Essential principle checklist of applied device.</p> <p>Shelf life and studies supporting the shelf life.</p> <p>Declaration of Conformity to be printed on manufacturer's letter head duly filled and signed by responsible person mentioning all the certifications.</p> <p>Labels of applied product mentioning the reference number approved in the country of origin.</p>
36.	<p>Mediland Pakistan Pvt Office No. b-09, 2nd Floor Masood Arcade IJP Road near Saidpur Road, Rawalpindi.</p> <p>ELI: 00202 3077-P 29-06-2022</p>	<p>Legal Manufacturer: Gebruder Martin GmbH & Co. KG KLS Martin platz 1, 78532 Tutlingen, Germany</p>	<p>RF Surgery units</p> <p>Class-C</p> <p>Shelf life: N/A</p> <p>Model: Not provided</p>	<p>Deferred for the provision of following documents:</p> <p>The agreement, submitted, is copy and expiring on 30th June 2023.</p> <p>Credentials, FSC and DoC is not provided.</p> <p>The ISO 13485 and FQA certificates are copies w/o notarization.</p> <p>Multiple brands are applied in this application, give your priority in this case and apply separately for others.</p> <p>The accessories used with the device should be applied separately depending upon the Class of medical device.</p> <p>Labels o applied model/ codes.</p>
37.	<p>Mediland Pakistan Pvt Office No. b-09, 2nd Floor Masood Arcade IJP Road near Saidpur Road, Rawalpindi.</p> <p>ELI: 00202</p>	<p>Legal Manufacturer: Maquet Cardiopulmonary GmbH Kehler Str. 31 76437 Rastatt Germany.</p> <p>FSC: Germany</p>	<p>BMU-40 (Blood Monitoring Unit)</p> <p>Class-C</p> <p>Shelf Life: N/A</p> <p>Code:</p>	<p>Deferred for the provision of following documents:</p> <p>There is ambiguity in the name of Legal manufacturer, on Form-7A, it is mentioned as Maquet Cardiopulmonary GmbH Kehler Str. 31 76437 Rastatt Germany whereas the agreement is in</p>

	3061-P 29-06-2022	issuance: 12/17/2021	70104.0852	<p>between Getinge Group middle East. Provide the original and updated Agency agreement clearly mentioning the Legal manufacturer/ owner of the product and any site or branch involved in the manufacturing of the product</p> <p>FSC submitted is copy, original is not provided.</p> <p>Shelf life and shelf life studies.</p> <p>Credentials of manufacturer abroad.</p> <p>Valid and notarized ISO 13485 and FQA certificates are missing.</p> <p>Manufacturing and QC processes in detail.</p> <p>Essential principle checklist of applied device.</p> <p>Labels of applied product mentioning the reference number approved in the country of origin.</p>
38.	<p>Mediland Pakistan Pvt Office No. b-09, 2nd Floor Masood Arcade IJP Road near Saidpur Road, Rawalpindi.</p> <p>ELI: 00202 3055-P 29-06-2022</p>	<p>Legal Manufacturer: Maquet Cardiopulmonary GmbH Kehler Str. 31 76437 Rastatt Germany.</p> <p>FSC: Germany issuance: 12/17/2021</p>	<p>ROTAFLOW II (Centrifugal pump system)</p> <p>Class-C</p> <p>Shelf Life: N/A</p>	<p>Deferred for the provision of following documents:</p> <p>There is ambiguity in the name of Legal manufacturer, on Form-7A, it is mentioned as Maquet Cardiopulmonary GmbH Kehler Str. 31 76437 Rastatt Germany whereas the agreement is in between Getinge Group middle East. Provide the original and updated Agency agreement clearly mentioning the Legal manufacturer/ owner of the product and any site or branch involved in the manufacturing of the product</p> <p>FSC submitted is copy, original is not provided. Also clearly state the model of device as the product mentioned is a System whereas the DoC provided is only for the RotaFlow Base unit rather than RotaFlow II base unit. Provide the original DoC mentioning the components including in a System.</p> <p>Service life and its studies.</p> <p>Credentials of manufacturer abroad.</p> <p>Valid and notarized ISO 13485 and FQA certificates are missing.</p> <p>Manufacturing and QC processes in detail.</p> <p>Essential principle checklist of applied device.</p>

				Labels of applied product mentioning the reference number approved in the country of origin.
39.	Mediland Pakistan Pvt Office No. b-09, 2nd Floor Masood Arcade IJP Road near Saidpur Road, Rawalpindi. ELI: 00202 3057-P 24-06-2022	Legal Manufacturer: Maquet Cardiopulmonary GmbH Kehler Str. 31 76437 Rastatt Germany. FSC: Germany issuance: 12/17/2021	Maquet Hemoconcentrator Class-C Shelf life: not mentioned Models: BC 20 plus, BC 60 Plus, BC 140 Plus	Deferred for the provision of following documents: There is ambiguity in the name of Legal manufacturer, on Form-7A, it is mentioned as Maquet Cardiopulmonary GmbH Kehler Str. 31 76437 Rastatt Germany whereas the agreement is in between Getinge Group middle East. Provide the original and updated Agency agreement clearly mentioning the Legal manufacturer/ owner of the product and any site or branch involved in the manufacturing of the product FSC submitted is copy, original is not provided. Shelf life and shelf life studies. Credentials of manufacturer abroad. Valid and notarized ISO 13485 and FQA certificates are missing. Manufacturing and QC processes in detail. Essential principle checklist of applied device. Labels of applied product mentioning the reference number approved in the country of origin.
40.	Mediland Pakistan Pvt Office No. b-09, 2nd Floor Masood Arcade IJP Road near Saidpur Road, Rawalpindi. ELI: 00202 3081-P 29-06-2022	Legal Manufacturer: Maquet Cardiopulmonary GmbH Kehler Str. 31 76437 Rastatt Germany. FSC: Germany issuance: 12/17/2021	Maquet PSL Set (Extracorporeal Supports system) Class-C Shelf life: N/A Model/code: BE-PLS 2050	Deferred for the provision of following documents: Clarification is required as the device is applied in Class-C whereas in CE certificate and DoC mentioning the device falls in Class-D. for Class-D devices additional design examination certificate is required, to be valid and notarized. There is ambiguity in the name of Legal manufacturer, on Form-7A, it is mentioned as Maquet Cardiopulmonary GmbH Kehler Str. 31 76437 Rastatt Germany whereas the agreement is in between Getinge Group middle East. Provide the original and updated Agency agreement clearly mentioning the Legal manufacturer/ owner of the product and any site or branch involved

				<p>in the manufacturing of the product</p> <p>FSC submitted is copy, original is provided.</p> <p>Credentials of manufacturer abroad.</p> <p>Valid and notarized ISO 13485 and FQA certificates are missing.</p> <p>Manufacturing and QC processes in detail.</p> <p>Essential principle checklist of applied device.</p> <p>Labels of applied product mentioning the reference number approved in the country of origin.</p>
41.	<p>Mediland Pakistan Pvt Office No. b-09, 2nd Floor Masood Arcade IJP Road near Saidpur Road, Rawalpindi.</p> <p>ELI: 00202 3109-P 29-06-2022</p>	<p>Legal Manufacturer: Maquet Cardiopulmonary GmbH Kehler Str. 31 76437 Rastatt Germany.</p> <p>FSC: Germany issuance: 12/17/2021</p>	<p>Plegiox (Cardioplegia Exchanger)</p> <p>Class-C</p> <p>Shelf life: N/A</p> <p>Code: CHX 30</p> <p>Heat</p>	<p>Deferred for the provision of following documents:</p> <p>There is ambiguity in the name of Legal manufacturer, on Form-7A, it is mentioned as Maquet Cardiopulmonary GmbH Kehler Str. 31 76437 Rastatt Germany whereas the agreement is in between Getinge Group middle East. Provide the original and updated Agency agreement clearly mentioning the Legal manufacturer/ owner of the product and any site or branch involved in the manufacturing of the product</p> <p>FSC submitted is copy, original is not provided.</p> <p>Credentials of manufacturer abroad.</p> <p>Valid and notarized ISO 13485 and FQA certificates are missing.</p> <p>DoC is missing for the subject device.</p> <p>Manufacturing and QC processes in detail.</p> <p>Essential principle checklist of applied device.</p> <p>Labels of applied product mentioning the reference number approved in the country of origin.</p>
42.	<p>Mediland Pakistan Pvt Office No. b-09, 2nd Floor Masood Arcade IJP Road near Saidpur Road, Rawalpindi.</p> <p>ELI: 00202 3083-P 29-06-2022</p>	<p>Legal Manufacturer: Gebrüder Martin GmbH & Co. KG KLS Martin platz 1. 78532 Tuttlingen, Germany.</p>	<p>MCO 25 Plus, MCO 50 Plus, FlexPen 2.0, Diomax 1550 Limax, Limax 1064 (Laser Surgery Units)</p> <p>Class-C</p> <p>Shelf life: not provided</p>	<p>Deferred for the provision of following documents:</p> <p>Intended purpose of the devices is not clear that the applied surgical units are used for which purpose.</p> <p>The agreement, submitted, is copy and expiring on 30th June 2023.</p>

				<p>Credentials, FSC and DoC are not provided.</p> <p>The ISO 13485 and FQA certificates are copies w/o notarization.</p> <p>Multiple brands are applied in this application, give your priority in this case and apply separately for others.</p> <p>Shelf life and shelf life studies.</p> <p>Labels of applied model/ codes.</p>
43.	<p>Mediland Pakistan Pvt Office No. b-09, 2nd Floor Masood Arcade IJP Road near Saidpur Road, Rawalpindi.</p> <p>ELI: 00202 3081-P 29-06-2022</p>	<p>Legal Manufacturer: Getinge AB Lindholmspiren 7A P.O Box 8861 SE-417 56 Goteborg Sweden</p> <p>FSC Sweden Valid till: 26/03/2024</p>	<p>Getinge 46 Aquadis 56, Getinge 86, Getinge 9100, Getinge WD 14 Tablom Getinge WD 15 Claro, Getinge CM 320 (Washer-disinfector)</p> <p>Class-C</p> <p>Shelf life: N/A</p> <p>Codes & Sizes: As per FSC</p>	<p>Deferred for the provision of following documents:</p> <p>Multiple products applied in Single application, give your priority in this case and apply separately for the other types of washer disinfectors.</p> <p>There is ambiguity in the name of Legal manufacturer, on Form-7A, it is mentioned as Getinge AB Lindholmspiren 7A P.O Box 8861 SE-417 56 Goteborg Sweden whereas the agreement is in between Getinge Group middle East. Provide the original and updated Agency agreement clearly mentioning the Legal manufacturer/ owner of the product and any site or branch involved in the manufacturing of the product</p> <p>FSC submitted is copy, original is not provided.</p> <p>Credentials of manufacturer abroad.</p> <p>Valid ISO 13485 and FQA certificates are provided but without notarization.</p> <p>Manufacturing and QC processes in detail.</p> <p>Essential principle checklist of applied device.</p>
44.	<p>Mediland Pakistan Pvt Office No. b-09, 2nd Floor Masood Arcade IJP Road near Saidpur Road, Rawalpindi.</p> <p>ELI: 00202 3082-P 29-06-2022</p>	<p>Legal Manufacturer: Medi-Care solutions S.r.L, Via Dell a Zecca NI- 40121 Bologna (BO) Italy</p> <p>FSC: Not found</p>	<p>Sterix (Autoclave with Steel chamber)</p> <p>Class-C</p> <p>Shelf life: N/A</p>	<p>Deferred for the provision of following documents:</p> <p>Submit the complete documents as per the requirements of Form-7A.</p> <p><i>Handwritten signature and date: 29/07/2023</i></p>
45.	<p>Sial Traders House No. 156-A, Abu bakkar Block New Garden Town</p>	<p>Legal Manufacturer: Intermedical s.r.l, located in via Enrico Fermi 26, 24050</p>	<p>Intermedical (Mobile C-Arm Image intensifier, Radius DIM)</p>	<p>Deferred for the provision of following documents:</p> <p>Provide revised Form-7A with all the</p>

	<p>Lahore</p> <p>Eli-00138 278-C 10-11-2022</p>	<p>Grassobbio (BG) Italy.</p> <p>FSC Italy issuance 02-03-2022</p>	<p>Class-C</p> <p>Shelf life: 5</p> <p>Model: As per FSC</p>	<p>required information including brand name, generic name, HS code, GMDN code, codes/model of the applied product, brief description and intended purpose of the device.</p> <p>Provide Credentials of manufacturer abroad as per format approved in 3rd meeting of MDB, duly notarized.</p> <p>Provide original LOA, submitted one is a copy.</p> <p>Provided FSC is copy, provide original attested FSC.</p> <p>ISO 13485 is expired and without notarization, submit the updated and notarized ISO 13485 certificate.</p> <p>Provide notarized FQA certificate, the submitted document is without notarization.</p> <p>Provide manufacturing and QC tests of the applied device in details.</p> <p>Provide shelf life/ service life studies supporting the claimed shelf life.</p> <p>Provide MRP of the device.</p> <p>Provide Essential principle checklist of the applied device.</p> <p>Grouping criteria is not mentioned in Form-7A.</p> <p>Multiple types applied in single application, justification is required for grouping the types.</p>
46.	<p>Sial Traders House No. 156-A, Abu bakkar Block New Garden Town Lahore</p> <p>Eli-00138 279-C 10-11-2022</p>	<p>Legal Manufacturer: Intermedical s.r.l, located in via Enrico Fermi 26, 24050 Grassobbio (BG) Italy.</p> <p>FSC Italy issuance 02-03-2022</p>	<p>Intermedical (Mobile C-Arm Image intensifier, Radius XP)</p> <p>Class-C</p> <p>Shelf life: 5</p> <p>Model: As per FSC</p>	<p>Deferred for the provision of following documents:</p> <p>Provide revised Form-7A with all the required information including brand name, generic name, HS code, GMDN code, codes/model of the applied product, brief description and intended purpose of the device.</p> <p>Provide Credentials of manufacturer abroad as per format approved in 3rd meeting of MDB, duly notarized.</p> <p>Provide original LOA, submitted one is a copy.</p> <p>Provided FSC is copy, provide original</p>

Handwritten signature/initials

				<p>attested FSC.</p> <p>ISO 13485 is expired and without notarization, submit the updated and notarized ISO 13485 certificate.</p> <p>Provide notarized FQA certificate, the submitted document is without notarization.</p> <p>Provide manufacturing and QC tests of the applied device in details.</p> <p>Provide shelf life/ service life studies supporting the claimed shelf life.</p> <p>Provide MRP of the device.</p> <p>Provide Essential principle checklist of the applied device.</p> <p>Grouping criteria is not mentioned in Form-7A.</p> <p>Multiple types applied in single application, justification is required for grouping the types.</p>
47.	<p>Sial Traders House No. 156-A, Abu bakkar Block New Garden Town Lahore</p> <p>Eli-00138 277-C 10-11-2022</p>	<p>Legal Manufacturer: Intermedical s.r.l, located in via Enrico Fermi 26, 24050 Grassobbio (BG) Italy.</p> <p>FSC Italy issuance 02-03-2022</p>	<p>Intermedical (Mobile C-Arm Image intensifier, Radius AFG)</p> <p>Class-C</p> <p>Shelf life: 5</p> <p>Model: As per FSC</p>	<p>Deferred for the provision of following documents:</p> <p>Provide revised Form-7A with all the required information including brand name, generic name, HS code, GMDN code, codes/model of the applied product, brief description and intended purpose of the device.</p> <p>Provide Credentials of manufacturer abroad as per format approved in 3rd meeting of MDB, duly notarized.</p> <p>Provide original LOA, submitted one is a copy.</p> <p>Provided FSC is copy, provide original attested FSC.</p> <p>ISO 13485 is expired and without notarization, submit the updated and notarized ISO 13485 certificate.</p> <p>Provide notarized FQA certificate, the submitted document is without notarization.</p> <p>Provide manufacturing and QC tests of the applied device in details.</p> <p>Provide shelf life/ service life studies</p>

				<p>supporting the claimed shelf life.</p> <p>Provide MRP of the device.</p> <p>Provide Essential principle checklist of the applied device.</p> <p>Grouping criteria is not mentioned in Form-7A.</p>
48.	<p>Sial Traders House No. 156-A, Abu bakkar Block New Garden Town Lahore</p> <p>Eli-00138 281-C 10-11-2022</p>	<p>Legal Manufacturer: Intermedical s.r.l, located in via Enrico Fermi 26, 24050 Grassobbio (BG) Italy.</p> <p>FSC Italy issuance 02-03-2022</p>	<p>Intermedical Compact DR Plus (Mobile X-ray equipment)</p> <p>Class-C</p> <p>Shelf life: 5</p> <p>Model: Compact DR Plus</p>	<p>Deferred for the provision of following documents:</p> <p>Provide revised Form-7A with all the required information including brand name, generic name, HS code, GMDN code, codes/model of the applied product, brief description and intended purpose of the device.</p> <p>Provide Credentials of manufacturer abroad as per format approved in 3rd meeting of MDB, duly notarized.</p> <p>Provide original LOA, submitted one is a copy.</p> <p>Provided FSC is copy, provide original attested FSC.</p> <p>ISO 13485 is expired and without notarization, submit the updated and notarized ISO 13485 certificate.</p> <p>Provide notarized FQA certificate, the submitted document is without notarization.</p> <p>Provide manufacturing and QC tests of the applied device in details.</p> <p>Provide shelf life/ service life studies supporting the claimed shelf life.</p> <p>Provide MRP of the device.</p> <p>Provide Essential principle checklist of the applied device.</p> <p>Grouping criteria is not mentioned in Form-7A.</p>
49.	<p>Sial Traders House No. 156-A, Abu bakkar Block New Garden Town Lahore</p> <p>Eli-00138 280-C 10-11-2022</p>	<p>Legal Manufacturer: Control X Medical Ltd Located in Ov Utca 29.H-1141 Budapest, Hungary</p> <p>FSC Hungary Valid till 26-05-2024</p>	<p>Perform-X (Floor mounted Radiographic System)</p> <p>Class-C</p> <p>Service life: 5 years</p> <p>Models/ codes as per FSC</p>	<p>Deferred for the provision of following documents:</p> <p>Provide revised Form-7A with all the required information including brand name, generic name, HS code, GMDN code, codes/model of the applied product, brief description and intended purpose of the device.</p> <p>Provide Credentials of manufacturer abroad as per format approved in 3rd meeting of MDB, duly notarized.</p>

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				<p>Provide original LOA, submitted one is a copy and expired in December 2022.</p> <p>Provided FSC is copy, provide original attested FSC of Hungary.</p> <p>ISO 13485 is expired and without notarization, submit the updated and notarized ISO 13485 certificate.</p> <p>Provide notarized FQA certificate, the submitted document is without notarization.</p> <p>Provide manufacturing and QC tests of the applied device in details.</p> <p>Provide shelf life/ service life studies supporting the claimed shelf life.</p> <p>Provide MRP of the device.</p> <p>Provide Essential principle checklist of the applied device.</p> <p>Grouping criteria is not mentioned in Form-7A, as the device is a system and applied multiple types as Family. Apply separately for Ceiling mounted system.</p> <p>Apply separately for the components depending upon their Classification as Tube Stand is used with the Ceiling mounted and Wall stand are in series.</p>
50.	<p>Medimen (Pakistan) House No. 199, Phase-2, GECHS, Link Road Model Town, Lahore</p> <p>Eli-00559 393-C 30-11-2022</p>	<p>Legal Manufacturer: Kossel Medtech (Suzhou) Co F2-F3, Building No. 6, No 8, JinFeng Road, Suzhou New District, People Republic of China.</p> <p>FSC China valid till 27-04-2024</p>	<p>Selethru (NC PTCA Balloon Dilatation Catheter)</p> <p>Class-D</p> <p>Shelf life: 3 years</p> <p>Codes as per FSC</p>	<p>Deferred for the provision of following documents:</p> <p>All the legal documents submitted are copies and without attestation/ notarization.</p> <p>Shelf life studies for the claimed shelf life.</p> <p>Manufacturing and QC tests in detail.</p> <p>FQA and Design Examination provided are for PTCA Dilatation catheter whereas the applied product is NC PTCA balloon dilatation catheter, clarification is required with revised Form-7A with relevant information if the device applied is PTCA. The certificates provided</p>
51.	<p>MIRAJ CORPORATION Address 1: 13-14, 2nd Floor, Jinnah Business Centre, Chandni Chowk, Murree Road,</p>	<p>Legal Manufacturer: TS Diagnostics Sdn. Bhd Address: No. 7 & 9, Jalan TPP 5/11, Taman Perindustrian Puchong, 47160</p>	<p>Forsure ABO Set (Blood grouping reagents)</p> <p>Class-D</p> <p>Shelf life: 3 years</p>	<p>Deferred for the provision of following documents:</p> <p>FSC of any reference country or CE marked document issued by NANDO data base notified body.</p>

	RAWALPINDI – PAKISTAN. Tel: 0092-51-1571326 ELI-00326 100-C 12-10-2022	Puchong, Selangor Darul Ehsan, Malaysia. FSC Original Valid till 04-08-2024	Code: FS-ABO-B10-003	
52.	Raffay Associates OFFICE NO 04,2nd FLOOR AHMED PLAZA RANGE ROAD RAWALPINDI ELI-00021 1069-C 28-12-2022	Legal Manufacturer: Sewoon Medical Co., Ltd 60 Dorim-gil, Ipjang-myeon, Seobuk-gu, Cheonan-Si, Chungcheongnamdo, Korea. FSC Korea issue on 16-05-2016 FSC MHRA issuance 17-05-2018	Bonastent (Esophageal Covered) Class-C Shelf life: 3 years Codes as per FSC	Deferred for the provision of following documents: All legal documents, submitted, are copies except ISO and FQA certificates. FSC of country of origin and FSC of MHRA need to be submitted since the documents has been expired before the submission of application.
53.	Safeway system Pakistan, Office No. 4, second Floor Amna shopping centre Misrial Road Choor Choke Rawalpindi ELI-00308	Legal Manufacturer: Braile Biomedica Brazil, Av.Pres, Juscelino K. de Oliveira, 1505-Tarrafi, Sao Jose do Rio Preto-SP, 15091-450 Brazil FSC: Brazil issuance 19-12-2019	Braile Biomedica Hemoconcentrator Class-C Shelf Life: 3 years	Deferred for the provision of following documents: FSC of any reference country or CE marked document issued by NANDO data base notified body.
54.	Vertex Medical (Pvt) Ltd, 70-B-1, Gulberg III, Lahore. ELI: 00150 3255-P 21-06-2022	Legal Manufacturer: LivaNova USA, Inc. 100 Cyberonics Boulevard, Houston, TX-77058 USA Original FSC: U.S.A Valid till: 13/11/2021	VNS Therapy ® System (VNS Therapy ® Demipulse) Class-D Shelf Life: 2 years Model: 103 Generator	Deferred for the provision of following documents: Original and attested FSC of US FDA. Valid ISO 13485 certificate.
55.	Vertex Medical (Pvt) Ltd, 70-B-1, Gulberg III, Lahore. ELI: 00150 3253-P 21-06-2022	Legal Manufacturer: LivaNova USA, Inc. 100 Cyberonics Boulevard, Houston, TX-77058 USA Original FSC: U.S.A Valid till: 13/11/2021	VNS Therapy ® System (VNS Therapy ® Tunneler) Class-D Shelf Life: 2 years Model: 402 Tunneler	Deferred for the provision of following documents: Original and attested FSC of US FDA. Valid ISO 13485 certificate.
56.	Vertex Medical (Pvt) Ltd, 70-B-1, Gulberg III, Lahore. ELI: 00150 3256-P 21-06-2022	Legal Manufacturer: LivaNova USA, Inc. 100 Cyberonics Boulevard, Houston, TX-77058 USA Original FSC: U.S.A Valid till: 13/11/2021	VNS Therapy ® System (VNS Therapy ® Programmer) Class-D Service Life: 1 year Model: 3000 Programmer	Deferred for the provision of following documents: Original and attested FSC of US FDA. Valid ISO 13485 certificate.
57.	Vertex Medical (Pvt) Ltd, 70-B-1,	Legal Manufacturer: LivaNova USA, Inc.	VNS Therapy ® System (VNS Therapy ®	Deferred for the provision of following documents:

	Gulberg III, Lahore. ELI: 00150 3254-P 21-06-2022	100 Cyberonics Boulevard, Houston, TX-77058 USA Original FSC: U.S.A Valid till: 13/11/2021	Programming Wand) Class-D Service Life: 2 year Model: 2000 Programming Wand	Original and attested FSC of US FDA. Valid ISO 13485 certificate.
58.	Vertex Medical (Pvt) Ltd, 70-B-1, Gulberg III, Lahore. ELI: 00150 3154-P 22-07-2022	<u>Legal Manufacturer:</u> LivaNova Deutschland GmbH Lindberghstr.25 80939 Munich-Germany FSC: Germany Date of Issue: 23/02/2022	Stockert S5 (Heart Lung Machine) Class-C Shelf Life: 10 years Code: 45-95-02	Deferred for the provision of Valid LOA.
59.	Vertex Medical (Pvt) Ltd, 70-B-1, Gulberg-III, Lahore. ELI-00150 3347-P 06-09-2022	<u>Legal Manufacturer:</u> Steelco S.P.A Via Balegante 27, 31039 Riese Pio X (TV), Italy FSC: Italy Date of Issue: 05/05/2022	Steelco (Endoscope Washers) Class-C Shelf Life. 10 years Codes as per FSC	Deferred for the provision of following documents. Clarification as the applied device is already been applied by M/s Total technologies. Original and valid LOA and Manufacturing and QC tests of the applied device.
60.	Vertex Medical (Pvt) Ltd, 70-B-1, Gulberg-III, Lahore. ELI-00150 3344-P 06-09-2022	<u>Legal Manufacturer:</u> Steelco S.P.A Via Balegante 27, 31039 Riese Pio X (TV), Italy FSC: Italy Date of Issue: 05/05/2022	Steelco (Washer Disinfectors) Class-C Shelf Life. 10 years Codes as per FSC	Deferred for the provision of following documents. Clarification as the applied device is already been applied by M/s Total technologies. Original and valid LOA and Manufacturing and QC tests of the applied device.
61.	Vertex Medical (Pvt) Ltd, 70-B-1, Gulberg-III, Lahore. ELI-00150 3345-P 06-09-2022	<u>Legal Manufacturer:</u> Steelco S.P.A Via Balegante 27, 31039 Riese Pio X (TV), Italy FSC: Italy Date of Issue: 05/05/2022	Steelco (Steam Sterilizing Units) Class-C Shelf Life. 10 years Codes as per FSC	Deferred for the provision of following documents. Clarification as the applied device is already been applied by M/s Total technologies. Original and valid LOA and Manufacturing and QC tests of the applied device.
62.	Vertex Medical (Pvt) Ltd, 70-B-1, Gulberg-III, Lahore. ELI-00150 3346-P 06-09-2022	<u>Legal Manufacturer:</u> Steelco S.P.A Via Balegante 27, 31039 Riese Pio X (TV), Italy FSC: Italy Date of Issue: 05/05/2022	Steelco (Washer Disinfectors) (DS Series) Class-C Shelf Life. 10 years Codes as per FSC	Deferred for the provision of following documents. Clarification as the applied device is already been applied by M/s Total technologies. Original and valid LOA and Manufacturing and QC tests of the applied device.
63.	K.M Enterprises, KM Mansion, 605,	<u>Legal Manufacturer:</u> Zhejiang Kanglidi	AMD (Adhesive Paper Tape, Non-	Deferred for the provision of following documents.

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	D Block, MA Johor Town Lahore ELI: 00054 418-P 05-11-2020	Medical Articals. Co. Ltd, Dongshan Industrial Zone Shahwuzhai Liushi, Yueqing, Zhejiang, China FSC: China Valid till: 27.06.2021	woven) Class-A Shelf Life: Not mentioned Codes as per FSC	Unsigned and unstamped Form-7A, submit properly filled and signed/ stamped Form-7A. All the legal documents submitted are copies and expired, submit original, valid and legalized documents. FSC of any reference country/ CE marked document. Shelf life of the device with supporting shelf life studies. Essential principle checklist
64.	KASBN International, 41-K, Gulberg III, Lahore ELI:00434 1831-P 22-10-2020	<u>Legal Manufacturer:</u> M4 Medical Sp.z.o.o, Ul. Naleczowska 14 20-701 Lubin Poland FSC: Poland Date of issue: 30-12-2022 (Scanned copy)	M. Trace (Electrocardiograph) Class-B Shelf Life: N/A Model/ codes:	Deferred for the provision of following documents. Credentials, LOA, FSC, ISO 13485 and FQA certificates submitted are scanned copies. Original documents are missing. FSC submitted is missing the model/ code only name is given. Essential Principle checklist.
65.	KASBN International, 41-K, Gulberg III, Lahore ELI:00434 421-P 22-10-2020	<u>Legal Manufacturer:</u> Industrias H. Pardo SL, Calle Los Angeles 5. Pol. Ind. Centrovia 50198 La Muela (Zaragoza) Espana FSC SPAIN Date of issue 31st July,2020	Camilla Tarsis, (Stretcher Trolley) Class-A Shelf Life: N/A Model: Tarsis	Deferred for the provision of following documents. LOA, ISO 13485 and FSC submitted are copies. Original documents are missing. FQA certificate is not provided. Essential Principle checklist. Labels are missing. Apply separately for the other brand.
66.	KASBN International, 41-K, Gulberg III, Lahore ELI:00434 422-P 22-10-2020	<u>Legal Manufacturer:</u> Industrias H. Pardo SL, Calle Los Angeles 5. Pol. Ind. Centrovia 50198 La Muela (Zaragoza) Espana FSC SPAIN Date of issue 31st July,2020	Cama Hitech, (Medical bed) Class-A Shelf Life: N/A Model: Hitech,	Deferred for the provision of following documents. LOA and FSC and ISO 13485 submitted are copies. Original documents are missing. FQA certificates are not provided. Essential Principle checklist. Labels are missing. Apply separately for the other brand/ models.
67.	KASBN International, 41-K, Gulberg III, Lahore ELI:00434 1795-P 12-10-2020	<u>Legal Manufacturer:</u> Nouvag AG located at S. Gallestrasse 23, 9403 GOLdach, Switzerland FSC: Switzerland Valid till: 30.07.2022	Dermatome blades (Surgical Blades) Class-B Shelf Life: Not provided Codes: 1919 for dermatome 100	Deferred for the provision of following documents. Brand name of the device. LOA and FSC are expired but valid upon submission. ISO 13485 and FQA certificates are

			1995 for dermatome 75 1996 for dermatome 50 1997 for dermatome 25	expired but valid upon submission. Manufacturing and QC details. Shelf life and shelf life studies are not provided. Labels are missing. Essential principle checklist.
68.	KASBN International, 41-K, Gulberg III, Lahore ELI:00434 1830-P 22-10-2020	<u>Legal Manufacturer:</u> Chest MI located at 3- 25-11 Hongo Bunkyo- ku, Tokyo 113-0033, Japan FSC: Japan Date of issue: 23.09.2020	MostGraph-02 (Electronic Spirometer) Class-B Shelf Life: N/A Model: CHESTGRAPH HI-301	Deferred for the provision of following documents. Original documents are not provided only copies of legal documents provided. FSC submitted is copy, original is missing. ISO 13485 certificate is valid but without notarization. Submit notarized. FQA certificates is valid but without notarization. Submit notarized Manufacturing and QC details. Essential principle checklist. Apply separately for other models.
69.	Pharma Life Distributors, CG- 94/1 Cob Line Sajid Bukhari Road Rawalpindi ELI: 00606 2064-P 14-01-2021	<u>Manufactured for:</u> Sunsoars Co., Ltd, 3F, 3, LN260 SEC4, XINHAI RD, Wenshan TAIPEI 11692m Taiwan <u>Manufactured by:</u> Yangzhou Medline Industry Co. Ltd No. 108 Jinshan Road, Economic Development Zone, Yangzhou 225009 Jiangsu, China FSC: China Valid till: 2022.03.16 FSC Germany issuance 01-06-2018	Apex Life (Disposable Syringes with/ without needle) Class-B Shelf Life: 5 years Sizes: 1ml, 10ml, 20ml, 50ml, 60ml	Deferred for the provision of following documents. Legal documents submitted are original. Provide Credentials of manufacturer abroad. FSC of Germany submitted is copy, original is required. LOA and FSC are expired but valid upon submission. ISO 13485 expired but valid upon submission. Essential principle checklist.
70.	Pharma Life Distributors, CG- 94/1 Cob Line Sajid Bukhari Road Rawalpindi ELI: 00606	<u>Manufactured for:</u> Sunsoars Co., Ltd, 3F, 3, LN260 SEC4, XINHAI RD, Wenshan TAIPEI 11692m Taiwan	Apex Life (Disposable Infusion Set) Class-B Shelf Life: 5 years	Deferred for the provision of following documents. Legal documents submitted are original. Provide Credentials of manufacturer abroad.

	2067-P 14-01-2021	Manufactured by: Yangzhou Medline Industry Co. Ltd No. 108 Jinshan Road, Economic Development Zone, Yangzhou 225009 Jiangsu, China FSC: China Valid till: 2022.03.16 FSC Germany issuance 01-06-2018	Model: Adult use & Child use	FSC of Germany submitted is copy, original is required. LOA and FSC are expired but valid upon submission. ISO 13485 expired but valid upon submission. Essential principle checklist.
71.	Pharma Life Distributors, CG-94/1 Cob Line Sajid Bukhari Road Rawalpindi ELI: 00606 2069-P 14-01-2021	Manufactured for: Sunsoars Co., Ltd, 3F, 3, LN260 SEC4, XINHAI RD, Wenshan TAIPEI 11692m Taiwan Manufactured by: Yangzhou Medline Industry Co. Ltd No. 108 Jinshan Road, Economic Development Zone, Yangzhou 225009 Jiangsu, China FSC: China Valid till: 2022.03.16 FSC Germany issuance 01-06-2018	Apex Life (Disposable Insulin Syringe) Class-B Shelf Life: 5 years Sizes: 1ml, 0.2ml, 0.3ml	Deferred for the provision of following documents. Legal documents submitted are original. Provide Credentials of manufacturer abroad. FSC of Germany submitted is copy, original is required. LOA and FSC are expired but valid upon submission. ISO 13485 expired but valid upon submission. Essential principle checklist. Provide labels of applied models as per FSC approved in the country of origin having the applied Brand name
72.	Pharma Life Distributors, CG-94/1 Cob Line Sajid Bukhari Road Rawalpindi ELI: 00606 2066-P 14-01-2021	Manufactured for: Sunsoars Co., Ltd, 3F, 3, LN260 SEC4, XINHAI RD, Wenshan TAIPEI 11692m Taiwan Manufactured by: Yangzhou Medline Industry Co. Ltd No. 108 Jinshan Road, Economic Development Zone, Yangzhou 225009 Jiangsu, China FSC: China Valid till: 2022.03.16 FSC Germany issuance 01-06-2018	Apex Life (Disposable IV Cannula) Class-B Shelf Life: 5 years Sizes: 14G, 16, 18G, 20G, 22G, 24G <i>U.S. 08/07/2023</i>	Deferred for the provision of following documents. Legal documents submitted are original. Credentials of manufacturer abroad missing. FSC of Germany submitted is copy and missing the subject device, original is required. LOA and FSC are expired but valid upon submission. ISO 13485 expired but valid upon submission. Provide Essential principle checklist. Provide labels of applied models as per FSC approved in the country of origin having the applied Brand name.

				Type is not mentioned, specify the type in the instant case. No technical data of the applied product is provided. Provide complete details, manufacturing, QC testing and stability studies data.
73.	Pharma Life Distributors, CG-94/1 Cob Line Sajid Bukhari Road Rawalpindi ELI: 00606 2065-P 14-01-2021	<u>Manufactured for:</u> Sunsoars Co., Ltd, 3F, 3, LN260 SEC4, XINHAI RD, Wenshan TAIPEI 11692m Taiwan <u>Manufactured by:</u> Yangzhou Medline Industry Co. Ltd No. 108 Jinshan Road, Economic Development Zone, Yangzhou 225009 Jiangsu, China FSC: China Valid till: 2022.03.16 FSC Germany issuance 01-06-2018	Apex Life (Hypodermic needle) Class-B Shelf Life: 5 years Sizes: 16G to 30G	Deferred for the provision of following documents. Legal documents submitted are original. Credentials of manufacturer abroad. FSC of Germany submitted is copy, original is required. LOA and FSC are expired but valid upon submission. ISO 13485 expired but valid upon submission. Essential principle checklist. Provide labels of applied models as per FSC approved in the country of origin having the applied Brand name.
74.	SAFEWAY SYSTEMS PAKISTAN FLAT # 4, 2ND FLOOR, AMNA SHOPPING CENTRE, MISRIAL ROAD, CHOR CHOWK, RAWALPINDI. (ELI-00308) 2219-P 02-03-2021	<u>Legal Manufacturer:</u> BRAIL BIOMEDICA BRAZIL Av. Pres. Juscelino K de. Oliveria, 1505, - Tarraf I, Sao Jose da Rio Preto -SP, 15091-450 Brazil.	PATCH DE PERICARDIO BOVINO MONOCUSPIDE Class-D Shelf Life: 02 Years Codes & Sizes: As per FSC	Deferred for the provision of following documents: Provide English version of FSC of country of origin. Provide FSC of any SRA country or CE marked. Provide Design examination certificate.
75.	Vertex Medical (Pvt) Ltd, 70-B-1, Gulberg-III, Lahore. ELI-00150 3347-P 06-09-2022	<u>Legal Manufacturer:</u> Steelco S.P.A Via Balegante 27, 31039 Riese Pio X (TV), Italy FSC: Italy Date of Issue: 05/05/2022	Steelco (Endoscope Washers) Class-C Shelf Life. 10 years Codes as per FSC	Deferred for the provision of following documents: Updated LOA, ISO 13485 and Production quality assurance certificates.
76.	Vertex Medical (Pvt) Ltd, 70-B-1, Gulberg-III, Lahore. ELI-00150 3344-P 06-09-2022	<u>Legal Manufacturer:</u> Steelco S.P.A Via Balegante 27, 31039 Riese Pio X (TV), Italy FSC: Italy Date of Issue: 05/05/2022	Steelco (Washer Disinfectors) Class-C Shelf Life. 10 years Codes as per FSC	Deferred for the provision of following documents: Updated LOA, ISO 13485 and Production quality assurance certificates.

77.	Vertex Medical (Pvt) Ltd, 70-B-1, Gulberg-III, Lahore. ELI-00150 3345-P 06-09-2022	<u>Legal Manufacturer:</u> Steelco S.P.A Via Balegante 27, 31039 Riese Pio X (TV), Italy FSC: Italy Date of Issue: 05/05/2022	Steelco (Steam Sterilizing Units) Class-C Shelf Life: 10 years Codes as per FSC	Deferred for the provision of following documents: Updated LOA, ISO 13485 and Production quality assurance certificates.
78.	Health Care International, First Floor, 210/J-2, Johar Town, Lahore ELI: 00141 834-P 29-03-2022	<u>Legal Manufacturer:</u> M/s Sunny Medical Device (Shenzhen) Co., Ltd, 1/F and 401, Zhongtianxin Building B, Longgang District, Shenzhen, Guanagdong, China 518172 FSC: China Valid till: 23/02/2023 FSC Spain issuance 14-09-2021	SUNMED™ TR-Closure Band (TR-Closure Band/ Radiseals) Class-A Shelf Life: 3 years Codes & Sizes: As per FSC	Deferred for the provision of following documents: All the legal documents submitted are copies, original are not found. Valid FQA and Design examination certificates. FSC of any reference authority.
79.	Health Care International, First Floor, 210/J-2, Johar Town, Lahore ELI: 00141 833-P 29-03-2022	<u>Legal Manufacturer:</u> M/s Sunny Medical Device (Shenzhen) Co., Ltd, 1/F and 401, Zhongtianxin Building B, Longgang District, Shenzhen, Guanagdong, China 518172 FSC: China Valid till: 23/02/2023 FSC Spain issuance 14-09-2021	SUNMED™ Inflation Device (Sterile Balloon Inflation Device kit) Class-A Shelf Life: 3 years Codes & Sizes: As per FSC	Deferred for the provision of following documents: All the legal documents submitted are copies, original are not found. Valid FQA and Design examination certificates. FSC of any reference authority.
80.	Health Care International, First Floor, 210/J-2, Johar Town, Lahore ELI: 00141 3502-P 29-03-2022	<u>Legal Manufacturer:</u> M/s Sunny Medical Device (Shenzhen) Co., Ltd, 1/F and 401, Zhongtianxin Building B, Longgang District, Shenzhen, Guanagdong, China 518172 FSC: China Valid till: 23/02/2023 FSC Spain issuance 14-09-2021	Sunmed™ Manifolds (Manifolds and Stopcocks) Class-B Shelf Life: 3 years Codes & Sizes: As per FSC	Deferred for the provision of following documents: All the legal documents submitted are copies, original are not found. Valid FQA and Design examination certificates. FSC of any reference authority.
81.	Medicamp International, Office No. 1, First Floor, Raja Naseer Plaza, New Abadi, Morgah, Rawalpindi, Pakistan	<u>Legal Manufacturer:</u> BOZ TIBBI MALZEME SANAYI VE TICARET A.S Saglik Mah. Saglik 1 Sk. NO: 33/5/ Cankaya/ Ankara/ Turkiye	Reoxcel Sigma Knit ® (Absorbable Haemostate Oxidized Regenerated Cellulose (ORC)) Class-D Shelf Life: 3 years	Deferred for the provision of following documents: Valid LOA. Valid ISO 13485. Original Design Examination

	ELI: 00200 3263-P 27-06-2022	FSC: Turkiye Date of Issue: 25/02/2022	Codes & Sizes: As per FSC	certificate. Shelf life studies for the claimed shelf life.
82.	Medicamp International, Office No. 1, First Floor, Raja Naseer Plaza, New Abadi, Morgah, Rawalpindi, Pakistan ELI: 00200 3262-P 27-06-2022	Legal Manufacturer: BOZ TIBBI MALZEME SANAYI VE TICARET A.S Saglik Mah. Saglik 1 Sk. NO: 33/5/ Cankaya/ Ankara/ Turkiye FSC: Turkiye Date of Issue: 25/02/2022	Reoxcel Fibril ® (Absorbable Haemostate Oxidized Regenerated Cellulose (ORC)) Class-D Shelf Life: 3 years Codes & Sizes: As per FSC	Deferred for the provision of following documents: Legal documents submitted are copies. Original are required. FSC of any reference authority.
83.	Medicamp International, Office No. 1, First Floor, Raja Naseer Plaza, New Abadi, Morgah, Rawalpindi, Pakistan ELI: 00200 3261-P 27-06-2022	Legal Manufacturer: BOZ TIBBI MALZEME SANAYI VE TICARET A.S Saglik Mah. Saglik 1 Sk. NO: 33/5/ Cankaya/ Ankara/ Turkiye FSC: Turkiye Date of Issue: 25/02/2022	ZEOCEL ® (Absorbable Haemostate Oxidized Cellulose (OC)) Class-D Shelf Life: 3 years Codes & Sizes: As per FSC	Deferred for the provision of following documents: Legal documents submitted are copies. Original are required. Valid, original and notarized Design examination certificate.
84.	Latif Instruments (Pvt) Ltd, 14- Commercial Buildings, Shahr-e-Quaid-e-Azam, Lahore ELI: 00118 2973-P 05-04-2022	Legal Manufacturer: Carl Zeiss Meditect AG, Goeschwitzer Strasse 51-52, 07745 Jena, Germany FSC: Germany Date of Issue: 25.05.2021	AT ELANA 841P (Intra Ocular Lens) Class-C Shelf Life: 8 year Code: MD 0203	Deferred for the provision of following documents: Valid LOA, ISO 13485 and FQA certificates.
85.	MR Medical Pakistan Private Limited, Office No. 1101, 11th Floor, ISE Tower, Jinnah Avenue, Blue Area Islamabad. ELI-01008 Dossier# 3280 Submission date: 01/08/2022 Evaluator: DD-III	Legal Manufacturer: Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, People's Republic of China FSC: China Valid till: 17/04/2023	MINDRAY (Syringe Pump) Codes & Sizes: As per FSC Class-C Shelf Life: 10 years	Deferred for the provision of following documents: Sumit valid FSC of country of origin Highlight the ISO13485 & FQA certificates scope for the applied product. Product is from a non-reference country and the applicant has not provided FSC of any reference country for this applied product. Provide MRP of applied device on form 7A
86.	Blazon Diagnostic, Blazon House No.	Legal Manufacturer:	ESHERO Anesthesia Machine	Deferred for the provision of following documents:

	<p>45, 46, 47, Cricket Stadium, double road, Rawalpindi. ELI: 00307 Dossier# 3734 Submission date: 16/01/2023 Evaluator: DD-III</p>	<p>M/s Beijing Eternity Electronic Technology Co., Ltd, No. 502-1 & 502-2, F5, Building 1 Yard 19, Pingguoyuan Xixiao Street Shijingshan District 100041 Beijing, China</p> <p>FSC: China</p> <p>Valid till: 19/04/2024</p>	<p>(Anesthesia Machine) Class-C Shelf Life: 8 years</p>	<p>Submit differential fee of 25000/-PKR for class C</p> <p>Provide notarized CE mark certificate.</p> <p>FSC of country of origin is valid but photocopy was provided</p> <p>Provide original dully embassy attested FSC</p> <p>Form-7A is not signed & stamped</p> <p>Specify the grouping of MDs on form-7A as per schedule B-II of MDR 2017</p> <p>Specify the storage conditions and proposed MRP on form-7A</p> <p>Provide notarized copy of ISO 13485 certificate</p> <p>Submit DOC on proper European format mentioning the class of applied MD.</p> <p>Provide notarized Credentials of manufacturer</p> <p>Provide original and notarized Letter of Authorization</p> <p>Justify the address of importer on Letter of Authorization (LOA) as it is changed from the address mentioned on Form-4 (license to import MDs)</p> <p>On LOA the manufacturer allows the distribution and promotion of only two models of Anesthesia Machine (Original AM832 & OEM Model TK-7700G) to importer however model AM832 is mentioned on FSC while OEM Model TK-7700G is not mentioned on FSC of country of origin.</p>
87.	<p>Blazon Diagnostic, Blazon House No. 45, 46, 47, Cricket Stadium, double road, Rawalpindi. ELI: 00307 Dossier# 801 Submission date: 16/01/2023 Evaluator: DD-III</p>	<p>Legal Manufacturer:</p> <p>M/s Biotechnology Medical services K Europe S.L, Calle Castello 23, 6 Izq, 28001 Madrid, Spain</p>	<p>BMS Laboratory Laminar Airflow (Laboratory Laminar Airflow) Class-A Shelf Life: not provided</p> <p><i>Handwritten signature and date: 08/07/2023</i></p>	<p>Deferred for the provision of following documents:</p> <p>Form-6A is not stamped</p> <p>Justify the address of importer on Letter of Authorization (LOA) as it is changed from the address mentioned on Form-4 (license to import MDs)</p> <p>Provide original and notarized Letter of Authorization</p> <p>FSC of country of origin and FSC of any reference country is not provided.</p> <p>Specify the grouping of MDs on form-6A as per schedule B-II of MDR 2017</p>

				<p>Specify the storage conditions and proposed MRP on form-7A</p> <p>Stability data is not provided</p> <p>Provide notarized Credentials of manufacturer</p> <p>Submit DOC on proper European format mentioning the class of applied MD</p> <p>Provide notarized copy of ISO 13485 and FQA certificate of relevant manufacturer</p>
88.	<p>Blazon Diagnostic, Blazon House No. 45, 46, 47, Cricket Stadium, double road, Rawalpindi. ELI: 00307 Dossier# 802 Submission date: 16/01/2023 Evaluator: DD-III</p>	<p>Legal Manufacturer:</p> <p>M/s Biotechnology Medical services K Europe S.L, Calle Castello 23, 6 Izq,28001 Madrid, Spain</p>	<p>BMS Ultralow Temperature Freezers (Ultralow Temperature Freezers) Class-A Shelf Life: not provided</p>	<p>Deferred for the provision of following documents:</p> <p>Form-6A is not stamped</p> <p>Justify the address of importer on Letter of Authorization (LOA) as it is changed from the address mentioned on Form-4 (license to import MDs)</p> <p>Provide original and notarized Letter of Authorization</p> <p>FSC of country of origin and FSC of any reference country is not provided.</p> <p>Specify the grouping of MDs on form-7A as per schedule B-II of MDR 2017</p> <p>Specify the storage conditions and proposed MRP on form-7A</p> <p>Stability data is not provided</p> <p>Provide notarized Credentials of manufacturer</p> <p>Submit DOC on proper European format mentioning the class of applied MD</p> <p>Provide notarized copy of ISO 13485 and FQA certificate of relevant manufacturer</p>
89.	<p>Blazon Diagnostic, Blazon House No. 45, 46, 47, Cricket Stadium, double road, Rawalpindi. ELI: 00307 Dossier# 803 Submission date: 16/01/2023 Evaluator:</p>	<p>Legal Manufacturer:</p> <p>M/s Biotechnology Medical services K Europe S.L, Calle Castello 23, 6 Izq,28001 Madrid, Spain</p>	<p>BMS Laboratory Freezers (Laboratory Freezers) Class-A Shelf Life: not provided</p>	<p>Deferred for the provision of following documents:</p> <p>Form-6A is not stamped</p> <p>Justify the address of importer on Letter of Authorization (LOA) as it is changed from the address mentioned on Form-4 (license to import MDs)</p>

	DD-III			<p>Provide original and notarized Letter of Authorization</p> <p>FSC of country of origin and FSC of any reference country is not provided.</p> <p>Specify the grouping of MDs on form-7A as per schedule B-II of MDR 2017</p> <p>Specify the storage conditions and proposed MRP on form-7A</p> <p>Stability data is not provided</p> <p>Provide notarized Credentials of manufacturer</p> <p>Submit DOC on proper European format mentioning the class of applied MD</p> <p>Provide notarized copy of ISO 13485 and FQA certificate of relevant manufacturer</p>
90.	<p>Blazon Diagnostic, Blazon House No. 45, 46, 47, Cricket Stadium, double road, Rawalpindi. ELI: 00307 Dossier# 800 Submission date: 16/01/2023 Evaluator: DD-III</p>	<p>Legal Manufacturer: M/s Biotechnology Medical services K Europe S.L, Calle Castello 23, 6 Izq.28001 Madrid, Spain</p>	<p>BMS Laboratory CO2 Incubators (Laboratory CO2 Incubators) Class-A Shelf Life: not provided.</p>	<p>Deferred for the provision of following documents:</p> <p>Form-6A is not stamped</p> <p>Justify the address of importer on Letter of Authorization (LOA) as it is changed from the address mentioned on Form-4 (license to import MDs)</p> <p>Provide original and notarized Letter of Authorization</p> <p>FSC of country of origin and FSC of any reference country is not provided.</p> <p>Specify the grouping of MDs on form-6A as per schedule B-II of MDR 2017</p> <p>Specify the storage conditions and proposed MRP on form-7A</p> <p>Stability data is not provided</p> <p>Provide notarized Credentials of manufacturer</p> <p>Submit DOC on proper European format mentioning the class of applied MD</p> <p>Provide notarized copy of ISO 13485 and FQA certificate of relevant manufacturer</p>
91.	Blazon Diagnostic,	<p>Legal Manufacturer:</p>	BMS Blood Extractor	<p>Deferred for the provision of following</p>

	<p>Blazon House No. 45, 46, 47, Cricket Stadium, double road, Rawalpindi. ELI: 00307 Dossier# 804 Submission date: 16/01/2023 Evaluator: DD-III</p>	<p>M/s Biotechnology Medical services K Europe S.L., Calle Castello 23, 6 Izq, 28001 Madrid, Spain</p>	<p>(Blood Extractor) Class-A Shelf Life: not provided</p>	<p>documents: Form-6A is not stamped Justify the address of importer on Letter of Authorization (LOA) as it is changed from the address mentioned on Form-4 (license to import MDs) Provide original and notarized Letter of Authorization FSC of country of origin and FSC of any reference country is not provided. Specify the grouping of MDs on form-7A as per schedule B-II of MDR 2017 Specify the storage conditions and proposed MRP on form-7A Stability data is not provided Provide notarized Credentials of manufacturer Submit DOC on proper European format mentioning the class of applied MD Provide notarized copy of ISO 13485 and FQA certificate of relevant manufacturer</p>
92.	<p>Blazon Diagnostic, Blazon House No. 45, 46, 47, Cricket Stadium, double road, Rawalpindi. ELI: 00307 Dossier# 805 Submission date: 16/01/2023 Evaluator: DD-III</p>	<p>Legal Manufacturer: M/s Biotechnology Medical services K Europe S.L., Calle Castello 23, 6 Izq, 28001 Madrid, Spain</p>	<p>BMS Blood Bag Tube Sealers (Blood Bag Tube Sealers) Class-A Shelf Life: not provided</p>	<p>Deferred for the provision of following documents: Form-6A is not stamped Justify the address of importer on Letter of Authorization (LOA) as it is changed from the address mentioned on Form-4 (license to import MDs) Provide original and notarized Letter of Authorization FSC of country of origin and FSC of any reference country is not provided. Specify the grouping of MDs on form-6A as per schedule B-II of MDR 2017 Specify the storage conditions and proposed MRP on form-7A Stability data is not provided Provide notarized Credentials of manufacturer Submit DOC on proper European</p>

				format mentioning the class of applied MD Provide notarized copy of ISO 13485 and FQA certificate of relevant manufacturer
93.	A&E Medical 323-ATA Turk Block New Garden Town, Lahore ELI-00023 Dossier# 976-C Submission date: 27/12/2022 Evaluator: DD-III	Legal Manufacturer: Fiab S.p.A Via. P. Costoli 4, 50039 Vicchio (FL) Italy FSC: Italy Issued on: 16/01/2019	Disposable Sterile Hand Switch Electrosurgical Pencils Codes & Sizes: As per FSC Class-B Shelf Life: 4 years	Deferred for the provision of following documents: Provide original and notarized Letter of Authorization CE certificate is expired, submit valid & notarized CE certificate Provide notarized copy of ISO 13485 and FQA certificate of relevant manufacturer Provide Packing Labels On DOC class is II-b (class C) for the applied product while firm applied in class B so submit differential fee of 25000/- PKR
94.	A&E Medical 323-ATA Turk Block New Garden Town, Lahore ELI-00023 Dossier# 977-C Submission date: 27/12/2022 Evaluator: DD-III	Legal Manufacturer: Fiab S.p.A Via. P. Costoli 4, 50039 Vicchio (FL) Italy FSC: Italy Issued on: 16/01/2019	Disposable Electrosurgical Grounding plates with connection cable Codes & Sizes: As per FSC Class-B Shelf Life: 4 years	Deferred for the provision of following documents: Provide original and notarized Letter of Authorization CE certificate is expired, submit valid & notarized CE certificate Provide notarized copy of ISO 13485 and FQA certificate of relevant manufacturer Provide Packing Labels On DOC class is II-b (class C) for the applied product while firm applied in class B so submit differential fee of 25000/- PKR
95.	Sudais Associates, Sudais House, Street nO, 7 House No, 1, Khan Bahadur Colony Duran Pur , Peshawar ELI: 00031 Dossier# 3857 Submission date: 19/09/2022 Evaluator: DD-III	Legal Manufacturer: M/s Wellex Company Ltd,Cairo-ismailia desert Road,Ismailia Public Free Zone, 41639 City, Egypt FSC: not provided	Dialysis Catheters (Dialysis Catheters) Codes & Sizes: As per FSC Class- B Shelf Life: 05 years <i>45/8870872023</i>	Deferred for the provision of following documents: FSC of country of origin and FSC of any reference country are not provided. Provide brand name of the applied medical devices. Provide notarized copy of ISO 13485 certificate. Provide notarized copy of CE mark certificate.

				<p>Highlight the relevant applied product on the scope of the CE mark & ISO 13485 certificates.</p> <p>Letter of Authorization must be duly signed & stamped and on the letter head of manufacturer.</p> <p>Provide original and notarized Letter of Authorization</p> <p>Provide notarized Credentials of manufacturer</p> <p>Provide Packing Labels</p> <p>Provide declaration on stamp paper as per form-7A</p>
96.	<p>Sudais Associates, Sudais House, Street nO, 7 House No, 1, Khan Bahadur Colony Duran Pur, Peshawar</p> <p>ELI: 00031 Dossier# 3857 Submission date: 19/09/2022 Evaluator: DD-III</p>	<p>Legal Manufacturer: M/s Wellex Company Ltd,Cairo-ismailia desert Road,Ismailia Public Free Zone, 41639 City, Egypt</p> <p>FSC: not provided</p>	<p>Nephrostomy Catheters (Nephrostomy Catheters)</p> <p>Codes & Sizes: As per FSC Class- B Shelf Life: 05 years</p>	<p>Deferred for the provision of following documents:</p> <p>FSC of country of origin and FSC of any reference country are not provided.</p> <p>Provide brand name of the applied medical devices.</p> <p>Provide notarized copy of ISO 13485 certificate.</p> <p>Provide notarized copy of CE mark certificate.</p> <p>Highlight the relevant applied product on the scope of the CE mark & ISO 13485 certificates.</p> <p>Letter of Authorization must be duly signed & stamped and on the letter head of manufacturer.</p> <p>Provide original and notarized Letter of Authorization</p> <p>Provide notarized Credentials of manufacturer</p> <p>Provide Packing Labels</p> <p>Provide declaration on stamp paper as per form-7A</p>
97.	<p>Sudais Associates, Sudais House, Street nO, 7 House No, 1, Khan Bahadur Colony Duran Pur,</p>	<p>Legal Manufacturer: M/s Wellex Company Ltd,Cairo-ismailia desert Road,Ismailia Public Free Zone, 41639 City, Egypt</p>	<p>Ureteral Stents and Sets (Ureteral Stents and Sets) Codes & Sizes: As per FSC Class- B Shelf Life: 05 years</p>	<p>Deferred for the provision of following documents:</p> <p>FSC of country of origin and FSC of any reference country are not provided.</p>

	<p>Peshawar</p> <p>ELI: 00031</p> <p>Dossier# 3858</p> <p>Submission date: 19/09/2022</p> <p>Evaluator: DD-III</p>	FSC: not provided		<p>Provide brand name of the applied medical devices.</p> <p>Provide notarized copy of ISO 13485 certificate.</p> <p>Provide notarized copy of CE mark certificate.</p> <p>Highlight the relevant applied product on the scope of the CE mark & ISO 13485 certificates.</p> <p>Letter of Authorization must be duly signed & stamped and on the letter head of manufacturer.</p> <p>Provide original and notarized Letter of Authorization</p> <p>Provide notarized Credentials of manufacturer</p> <p>Provide Packing Labels</p> <p>Provide declaration on stamp paper as per form-7A</p>
98.	<p>A.S Enterprises, 03-Mozang Lahore, Pakistan.</p> <p>ELI: 00190</p> <p>Dossier# 3178</p> <p>Submission date: 26/04/2022</p> <p>Evaluator: DD-III</p>	<p>Legal Manufacturer:</p> <p>A Zhejiang Orient Gene Biotech Co., Ltd, 3787 #, East Yangguang Avenue, Dipu Street Anji 313300 Huzhou Zhejiang, China</p> <p>FSC: not provided</p>	<p>Orient Gene HCV Rapid Test Kit</p> <p>(HCV Ab Rapid Test Cassette)</p> <p>Codes & Sizes: As per FSC Class-D</p> <p>Shelf Life: 24 months</p> <p><i>16/05/2023</i></p>	<p>Deferred for the provision of following documents:</p> <p>FSC of country of origin and FSC of any reference country are not provided.</p> <p>CE mark certificate is not provided</p> <p>Highlight the relevant applied product on the scope of the CE mark & ISO 13485 certificates</p> <p>Provide Packing Label of applied medical device with proper brand & generic name printed on it.</p> <p>EC Design examination certificate is expired on 28-06-2022</p> <p>Provide notarized EC Design examination certificate</p> <p>Mention medical device class on DOC</p>
99.	<p>A.S Enterprises, 03-Mozang Lahore, Pakistan.</p> <p>ELI: 00190</p> <p>Dossier# 3179</p> <p>Submission date: 26/04/2022</p> <p>Evaluator: DD-III</p>	<p>Legal Manufacturer:</p> <p>A Zhejiang Orient Gene Biotech Co., Ltd, 3787 #, East Yangguang Avenue, Dipu Street Anji 313300 Huzhou Zhejiang, China</p>	<p>Orient Gene HBsAg Rapid Test Kit</p> <p>(HBsAg Rapid Test Casette)</p> <p>Codes & Sizes: As per FSC Class-D</p> <p>Shelf Life: 24 months</p>	<p>Deferred for the provision of following documents:</p> <p>FSC of country of origin and FSC of any reference country are not provided.</p> <p>CE mark certificate is not provided</p> <p>Highlight the relevant applied product</p>


		FSC: not provided		<p>on the scope of the CE mark & ISO 13485 certificates</p> <p>Provide Packing Label of applied medical device with proper brand & generic name printed on it.</p> <p>EC Design examination certificate is expired on 28-06-2022 Provide notarized EC Design examination certificate</p> <p>Mention medical device class on DOC</p>
100.	<p>A.S Enterprises, 03-Mozang Lahore, Pakistan. ELI: 00190 Dossier# 3132 Submission date: 11/05/2022 Evaluator: DD-III</p>	<p>Legal Manufacturer: A Zhejiang Orient Gene Biotech Co., Ltd, 3787 #, East Yangguang Avenue, Dipu Street Anji 313300 Huzhou Zhejiang, China</p> <p>FSC: not provided</p>	<p>Orient Gene TB Rapid Test Kit</p> <p>(TB IgG/IgG Rapid test Cassette)</p> <p>Codes & Sizes: As per FSC</p> <p>Class-C</p> <p>Shelf Life: 24 months</p>	<p>Deferred for the provision of following documents:</p> <p>FSC of country of origin and FSC of any reference country are not provided.</p> <p>CE mark certificate is not provided</p> <p>Highlight the relevant applied product on the scope of the CE mark & ISO 13485 certificates</p> <p>Provide Packing Label of applied medical device with proper brand & generic name printed on it.</p> <p>Mention medical device class on DOC</p>
101.	<p>A.S Enterprises, 03-Mozang Lahore, Pakistan. ELI: 00190 Dossier# 2993 Submission date: 26/04/2022 Evaluator: DD-III</p>	<p>Legal Manufacturer: A Zhejiang Orient Gene Biotech Co., Ltd, 3787 #, East Yangguang Avenue, Dipu Street Anji 313300 Huzhou Zhejiang, China</p> <p>FSC: not provided</p>	<p>Orient Gene Syphilis Ab Rapid Test Kit</p> <p>(Syphilis Ab Rapid Test Cassette)</p> <p>Codes & Sizes: As per FSC</p> <p>Class-C</p> <p>Shelf Life: 24 months</p>	<p>Deferred for the provision of following documents:</p> <p>FSC of country of origin and FSC of any reference country are not provided.</p> <p>CE mark certificate is not provided</p> <p>Highlight the relevant applied product on the scope of the CE mark & ISO 13485 certificates</p> <p>Provide Packing Label of applied medical device with proper brand & generic name printed on it.</p> <p>Mention medical device class on DOC</p>
102.	<p>A.S Enterprises, 03-Mozang Lahore, Pakistan. ELI: 00190 Dossier# 3134 Submission date: 11/05/2022 Evaluator: DD-III</p>	<p>Legal Manufacturer: A Zhejiang Orient Gene Biotech Co., Ltd, 3787 #, East Yangguang Avenue, Dipu Street Anji 313300 Huzhou Zhejiang, China</p> <p>FSC: not provided</p>	<p>Orient Gene Malaria Pf/Pan Rapid Test Kit (Malaria Pf/Pan Ag Rapid Test Cassette)</p> <p>Codes & Sizes: As per FSC</p> <p>Class-C</p> <p>Shelf Life: 24 month</p>	<p>Deferred for the provision of following documents:</p> <p>FSC of country of origin and FSC of any reference country are not provided.</p> <p>CE mark certificate is not provided</p> <p>Highlight the relevant applied product on the scope of the CE mark & ISO 13485 certificates</p>

				<p>Provide Packing Label of applied medical device with proper brand & generic name printed on it.</p> <p>Mention medical device class on DOC</p>
103	<p>A.S Enterprises, 03-Mozang Lahore, Pakistan. ELI: 00190 Dossier# 3594 Submission date: 26/09/2022 Evaluator: DD-III</p>	<p>Legal Manufacturer: A Zhejiang Orient Gene Biotech Co., Ltd, 3787 #, East Yangguang Avenue, Dipu Street Anji 313300 Huzhou Zhejiang, China</p> <p>FSC: not provided</p>	<p>Orient Gene Dengue NSI Ag Rapid Test Kit (Dengue NSI Ag Rapid Test Cassette) Codes & Sizes: As per FSC Class-C Shelf Life: 24 Months</p>	<p>Deferred for the provision of following documents:</p> <p>FSC of country of origin and FSC of any reference country are not provided.</p> <p>CE mark certificate is not provided</p> <p>Highlight the relevant applied product on the scope of the CE mark & ISO 13485 certificates</p> <p>Provide Packing Label of applied medical device with proper brand & generic name printed on it.</p> <p>Mention medical device class on DOC</p>
104	<p>A.S Enterprises, 03-Mozang Lahore, Pakistan. ELI: 00190 Dossier# 2994 Submission date: 26/04/2022 Evaluator: DD-III</p>	<p>Legal Manufacturer: A Zhejiang Orient Gene Biotech Co., Ltd, 3787 #, East Yangguang Avenue, Dipu Street Anji 313300 Huzhou Zhejiang, China</p> <p>FSC: not provided</p>	<p>Orient Gene H.Pylori Ab Rapid Test Kit (H.Pylori Ab Rapid Test Cassette) Codes & Sizes: As per FSC Class-C Shelf Life: 24 Months</p>	<p>Deferred for the provision of following documents:</p> <p>FSC of country of origin and FSC of any reference country are not provided.</p> <p>CE mark certificate is not provided</p> <p>Highlight the relevant applied product on the scope of the CE mark & ISO 13485 certificates</p> <p>Provide Packing Label of applied medical device with proper brand & generic name printed on it.</p> <p>Mention medical device class on DOC</p>
105	<p>A.S Enterprises, 03-Mozang Lahore, Pakistan. ELI: 00190 Dossier# 3130 Submission date: 11/05/2022 Evaluator: DD-III</p>	<p>Legal Manufacturer: A Zhejiang Orient Gene Biotech Co., Ltd, 3787 #, East Yangguang Avenue, Dipu Street Anji 313300 Huzhou Zhejiang, China</p> <p>FSC: not provided</p>	<p>Orient Gene Malaria Pf/Pv Rapid Test Kit (Malaria Pf/Pv Ag Rapid Test Cassette) Codes & Sizes: As per FSC Class-C Shelf Life: 24 months</p> <p>4/5/2023</p>	<p>Deferred for the provision of following documents:</p> <p>FSC of country of origin and FSC of any reference country are not provided.</p> <p>CE mark certificate is not provided</p> <p>Highlight the relevant applied product on the scope of the CE mark & ISO 13485 certificates</p> <p>Provide Packing Label of applied medical device with proper brand & generic name printed on it.</p> <p>Mention medical device class on DOC</p>

	<p>A.S Enterprises, 03-Mozang Lahore, Pakistan. ELI: 00190 Dossier# 3589 Submission date: 26/09/2022 Evaluator: DD-III</p>	<p>Legal Manufacturer: A Zhejiang Orient Gene Biotech Co., Ltd, 3787 #, East Yangguang Avenue, Dipu Street Anji 313300 Huzhou Zhejiang, China</p> <p>FSC: not provided</p>	<p>Orient Gene Dengue NSI Ag+IgM/IgG Combo Rapid Test Kit (Dengue NSI Ag+IgM/IgG Combo Rapid Test kit) Codes & Sizes: As per FSC Class-C Shelf Life: 24 Months</p>	<p>Deferred for the provision of following documents:</p> <p>FSC of country of origin and FSC of any reference country are not provided.</p> <p>CE mark certificate is not provided</p> <p>Highlight the relevant applied product on the scope of the CE mark & ISO 13485 certificates</p> <p>Provide Packing Label of applied medical device with proper brand & generic name printed on it.</p> <p>Mention medical device class on DOC</p>
107.	<p>A.S Enterprises, 03-Mozang Lahore, Pakistan. ELI: 00190 Dossier# 3135 Submission date: 11/05/2022 Evaluator: DD-III</p>	<p>Legal Manufacturer: A Zhejiang Orient Gene Biotech Co., Ltd, 3787 #, East Yangguang Avenue, Dipu Street Anji 313300 Huzhou Zhejiang, China</p> <p>FSC: not provided</p>	<p>Orient Gene Troponin I Rapid Test Kit (Troponin I Rapid Test Cassette) Codes & Sizes: As per FSC Class-C Shelf Life: 24 months</p>	<p>Deferred for the provision of following documents:</p> <p>FSC of country of origin and FSC of any reference country are not provided.</p> <p>CE mark certificate is not provided</p> <p>Highlight the relevant applied product on the scope of the CE mark & ISO 13485 certificates</p> <p>Provide Packing Label of applied medical device with proper brand & generic name printed on it.</p> <p>Mention medical device class on DOC</p>
108.	<p>A.S Enterprises, 03-Mozang Lahore, Pakistan. ELI: 00190 Dossier# 3133 Submission date: 11/05/2022 Evaluator: DD-III</p>	<p>Legal Manufacturer: A Zhejiang Orient Gene Biotech Co., Ltd, 3787 #, East Yangguang Avenue, Dipu Street Anji 313300 Huzhou Zhejiang, China</p> <p>FSC: not provided</p>	<p>Orient Gene Typhoid IgG/IgM rapid test (Pyphoid IgG/IgM Rapid test cassette) Codes & Sizes: As per FSC Class-C Shelf Life: 24 months</p>	<p>Deferred for the provision of following documents:</p> <p>FSC of country of origin and FSC of any reference country are not provided.</p> <p>CE mark certificate is not provided</p> <p>Highlight the relevant applied product on the scope of the CE mark & ISO 13485 certificates</p> <p>Provide Packing Label of applied medical device with proper brand & generic name printed on it.</p> <p>Mention medical device class on DOC</p>
109.	<p>A.S Enterprises, 03-Mozang Lahore, Pakistan. ELI: 00190 Dossier# 3180</p>	<p>Legal Manufacturer: A Zhejiang Orient Gene Biotech Co., Ltd, 3787 #, East</p>	<p>Orient Gene HIV 1/2 AB Rapid Test Kit (HIV 1/2 Ab Rapid Test Cassette) Codes & Sizes: As per FSC</p>	<p>Deferred for the provision of following documents:</p> <p>FSC of country of origin and FSC of any reference country are not provided.</p>

	Submission date: 26/04/2022 Evaluator: DD-III	Yangguang Avenue, Dipu Street Anji 313300 Huzhou Zhejiang, China FSC: not provided	Class-D Shelf Life: 24 months	CE mark certificate is not provided Highlight the relevant applied prod 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 Zhong Pak Facilitators, Kandi Arbab Sikander Khan Khalil, Tehkal bala, Peshawar, KP ELI: 00768 Dossier# 3820 Submission date: 10/08/2022 Evaluator: DD-III	Legal Manufacturer: M/s Shenzhen Viatom Technology CO.,Ltd, 4E, Plant Building Tingwei Industrial Park, No.6, Liufang Road, Block 67, Xin'an Street Baoan District 518101, Shenzhen, China Manufacturing Sites: 5A, Building, Tingwei Industrial, Park No. 6 Liufang Road,Block 67m Xin'an Street, Baoan District,Shenzhen, 518101, Guangdong, P.R China 501, Building B, Ganghongji High-tech Intelligent Industrial Park, No. 1008 Songbai Road Xili Street, Nshan District, Shenzhen, 518055 Guangdong, P.R. China FSC: China Valid till: 03/09/2022	Viatom (Blood Pressure Monitor (AirBP Plus) Code & Sizes: As per FSC Class-B Shelf Life: 02 years	Deferred for the provision of following documents: FSC of country of origin is expired. Provide notarized CE mark & ISO 13485 certificates. LOA is expired. Submit valid, original & notarized LOA DOC & Credentials must be duly notarized by the country of origin. Form-7 A must be signed & stamped.
111.	Anwar & Sons, Apartment-10, Safari Viollas-2 Commerical Complex, Bahria Town, Phase-7, Rawalpindi ELI: 00017 Dossier# 3914 Submission date: 22/09/2022 Evaluator:	Legal Manufacturer: Bio Health Medical Technology Co., Ltd A: C101-C102 No.145 Dongting Rd TEDA, Tianjin, China, 300457 Original FSC: China Valid till: 21/09/2022	Surgical Mesh Codes & Sizes: As per FSC Class-C Shelf Life: 4 years	Deferred for the provision of following documents: FSC of country of origin is expired at the time of submission of application. Submit valid embassy attested FSC. Provide valid & notarized ISO 13485 certificate. Provide valid & notarized FQA certificate. Brand name is not provided

	DD-III			Doc is not provided
112.	Moody Global Services, Office No. 14, 2nd Floor, Mujajid Plaza Jinnah Avenue, Blue Area Islamabad 44000, Pakistan. ELI:00926 Dossier# 3585 Submission date: 29/09/2022 Evaluator: DD-III	Legal Manufacturer: M/s Jiangsu Yuyue Medical Equipment & Supply Co.,Ltd, No.1 Baisheng road, Development Zone, Danyang, Jiangsu, 212300, China FSC: China Valid till: 2023/02/23 FSC: GERMANY Date of Issue: 29.07.2021	Yuwell (Blood Glucose Meter) Codes & Sizes: As per FSC Class-C Shelf Life: 24 months	Deferred for the provision of following documents: FSC of country of origin is expired. Validity must be mentioned on LOA Y330 model of applied MD is not mentioned on FSC of reference country (Germany) Address of manufacturer on FSC of reference country (Germany) does not match with the address mentioned on LOA, FSC country of origin & ISO certificate. Yuwell brand name is already applied by m/s Tri-Tech International 10-C, 6th Sunset Commercial Lane, Phase 2 Ext, DHA, Karachi from the same manufacturer.
113.	Moody Global Services, Office No. 14, 2nd Floor, Mujajid Plaza Jinnah Avenue, Blue Area Islamabad 44000, Pakistan. ELI:00926 Dossier# 3584 Submission date: 29/09/2022 Evaluator: DD-III	Legal Manufacturer: M/s Jiangsu Yuyue Medical Equipment & Supply Co.,Ltd, No.1 Baisheng road, Development Zone, Danyang, Jiangsu, 212300, China FSC: China Valid till: 2023/02/23 FSC: GERMANY Date of Issue: 29.07.2021	Yuwell (Blood Glucose Test Strip) Codes & Sizes: As per FSC Class-C Shelf Life: 24 months	Deferred for the provision of following documents: FSC of country of origin is expired. Validity must be mentioned on LOA Y330 model of applied MD is not mentioned on FSC of reference country (Germany) Address of manufacturer on FSC of reference country (Germany) does not match with the address mentioned on LOA, FSC country of origin & ISO certificate. Yuwell brand name is already applied by m/s Tri-Tech International 10-C, 6th Sunset Commercial Lane, Phase 2 Ext, DHA, Karachi from the same manufacturer.
114.	A.S Enterprises, 03- Mozang Lahore, Pakistan. ELI: 00190 Dossier# 3174 Submission date: 23/08/2022 Evaluator: DD-III	Legal Manufacturer: Acon laboratories Inc., 5850 Oberlin Drive, # 340, San Diego, CA, 92121, United States of America Manufacturing site: Acon Biotech (Hangzhou) co, Ltd. No 210 Zhenzhong road west lake district Hangzhou P.R. China 310030 FSC: China Valid till 22/02/2024	Acon HIV 1/2/0 Rapid Test (HIV Rapid Test) Codes & Sizes: As per FSC Class-D Shelf Life: 24 months	Deferred for the provision of following documents: Form7 A is not signed & stamped. FSC of any reference country is not provided. Provide valid ISO 13485 certificate for the manufacturing site. FQA certificate is not provided. Provide original & notarized LOA, FSC of country of origin & credentials as photocopies were attached. Mention class of MD on DOC Provide notarized EC Design examination certificate

115.	A.S Enterprises, 03- Mozang Lahore, Pakistan. ELI: 00190 Dossier# 3175 Submission date: 23/08/2022 Evaluator: DD-III	Legal Manufacturer: Acon laboratories Inc., 5850 Oberlin Drive, # 340, San Diego, CA, 92121, United States of America Manufacturing site: Acon Biotech (Hangzhou) co, Ltd. No 210 Zhenzhong road west lake district Hangzhou P.R. China 310030 FSC: China Valid till 22/02/2024	Acon HCV Rapid Test (HCV Rapid Test) Codes & Sizes: As per FSC Class-D Shelf Life: 24 months	Deferred for the provision of following documents: Form7 A is not signed & stamped. FSC of any reference country is not provided. Provide valid ISO 13485 certificate for the manufacturing site. FQA certificate is not provided. Provide original & notarized LOA, FSC of country of origin & credentials as photocopies were attached. Mention class of MD on DOC Provide notarized EC Design examination certificate
116.	A.S Enterprises, 03- Mozang Lahore, Pakistan. ELI: 00190 Dossier# 3176 Submission date: 23/08/2022 Evaluator: DD-III	Legal Manufacturer: Acon laboratories Inc., 5850 Oberlin Drive, # 340, San Diego, CA, 92121, United States of America Manufacturing site: Acon Biotech (Hangzhou) co, Ltd. No 210 Zhenzhong road west lake district Hangzhou P.R. China 310030 FSC: China Valid till 22/02/2024	Acon HBsAg Rapid Test (HBsAg Rapid Test) Codes & Sizes: As per FSC Class-D Shelf Life: 24 months	Deferred for the provision of following documents: Form7 A is not signed & stamped. FSC of any reference country is not provided. Provide valid ISO 13485 certificate for the manufacturing site. FQA certificate is not provided. Provide original & notarized LOA, FSC of country of origin & credentials as photocopies were attached. Mention class of MD on DOC Provide notarized EC Design examination certificate
117.	A.S Enterprises, 03- Mozang Lahore, Pakistan. ELI: 00190 Dossier# 3177 Submission date: 23/08/2022 Evaluator: DD-III	Legal Manufacturer: Acon laboratories Inc., 5850 Oberlin Drive, # 340, San Diego, CA, 92121, United States of America Manufacturing site: Acon Biotech (Hangzhou) co, Ltd. No 210 Zhenzhong road west lake district Hangzhou P.R. China 310030 FSC: China Valid till 22/02/2024	Acon Syphilis Rapid Test (Syphilis Rapid Test) Codes & Sizes: As per FSC Class-C Shelf Life: 24 months 	Deferred for the provision of following documents: Form7 A is not signed & stamped. FSC of any reference country is not provided. Provide valid ISO 13485 certificate for the manufacturing site. FQA certificate is not provided. Provide original & notarized LOA, FSC of country of origin & credentials as photocopies were attached. Mention class of MD on DOC Provide notarized EC Design examination certificate
118.	A.S Enterprises, 03- Mozang Lahore, Pakistan. ELI: 00190 Dossier# 3591 Submission date: 21/09/2022	Legal Manufacturer: Acon laboratories Inc., 5850 Oberlin Drive, # 340, San Diego, CA, 92121, United States of America	Acon Mission Plus Hemoglobin(Hb) Testing strips (Hemoglobin (Hb) Testing strips) Codes & Sizes: As per FSC Class-C	Deferred for the provision of following documents: Form7 A is not signed & stamped. FSC of any reference country is not provided.

	Evaluator: DD-III	Manufacturing site: Acon Biotech (Hangzhou) co, Ltd. No 210 Zhenzhong road west lake district Hangzhou P.R. China 310030 FSC: China Valid till: 2023/01/17	Shelf Life: 24 Months	Provide valid ISO 13485 certificate for the manufacturing site. FQA certificate is not provided. Provide original & notarized LOA, FSC of country of origin & credentials as photocopies were attached. Mention class of MD on DOC.
119.	A.S Enterprises, 03- Mozang Lahore, Pakistan. ELI: 00190 Dossier# 3592 Submission date: 21/09/2022 Evaluator: DD-III	Legal Manufacturer: Acon laboratories Inc., 5850 Oberlin Drive, # 340, San Diego, CA, 92121, United States of America Manufacturing site: Acon Biotech (Hangzhou) co, Ltd. No 210 Zhenzhong road west lake district Hangzhou P.R. China 310030 FSC: China Valid till: 2023/01/17	Acon Mission Plus Hemoglobin (Hb) Testing Meter (Hemoglobin (Hb) Testing System) Codes & Sizes: As per FSC Class-C Shelf Life: 24 Months	Deferred for the provision of following documents: Form 7 A is not signed & stamped. Submit correct & relevant proof of fee deposit for the applied product FSC of any reference country is not provided. Provide valid ISO 13485 certificate for the manufacturing site. FQA certificate is not provided. Provide original & notarized LOA, FSC of country of origin & credentials as photocopies were attached. Mention class of MD on DOC
120.	A.S Enterprises, 03- Mozang Lahore, Pakistan. ELI: 00190 Dossier# 3593 Submission date: 21/09/2022 Evaluator: DD-III	Legal Manufacturer: Acon laboratories Inc., 5850 Oberlin Drive, # 340, San Diego, CA, 92121, United States of America Manufacturing site: Acon Biotech (Hangzhou) co, Ltd. No 210 Zhenzhong road west lake district Hangzhou P.R. China 310030 FSC: China Valid till: 2023/01/17	Acon Mission Ultra Hemoglobin (Hb) Testing Meter (Hemoglobin (Hb) Testing System) Codes & Sizes: As per FSC Class-C Shelf Life: 24 Months	Deferred for the provision of following documents: Form 7 A is not signed & stamped. Submit correct & relevant proof of fee deposit for the applied product FSC of any reference country is not provided. Provide valid ISO 13485 certificate for the manufacturing site. FQA certificate is not provided. Provide original & notarized LOA, FSC of country of origin & credentials as photocopies were attached. Mention class of MD on DOC
121.	Arihat Dental ServicesShop No, G-15, PMA Trade Center, OPPOSITE, District Jail Shama Stop Ferozpora Road, Lahore. ELI-00912 Dossier# 3544 Submission date: 30/09/2022 Evaluator: DD-III	Legal Manufacturer: Shoufu inc., 11 kamitakamastu- cho , fukuine, higashiyama- ku, kyoto 605-0983, Japan. Sales & Marketing, Distribution Dental Asia - Pacific ltd, 10 science Park Road No, 03-12, The Alpha, Science Park 11, Singapore 11784.	SHOFU ZIRCONOMER IMPROVED ZIRCONOMER IMPROVED. Codes & Sizes: As per FSC Class-B Shelf Life: not provided	Deferred for the provision of following documents: The firm shall provide original challan form as proof of fee deposit. Declaration on stamp paper as per form- 7A is not provided. Stability data for the shelf life is not provided. Submit valid, original & notarized ISO certificate. Submit original & notarized credentials

		FSC: Japan (original) Date of Issue: 27.06.2022		of manufacturer. Submit essential principle checklist for the applied product. Justify the proposed MRP, storage conditions & grouping of MDs on form-7A Provide packing label for the applied product.
122.	Arihat Dental Services Shop No, G-15, PMA Trade Center, OPPOSITE, District Jail Shama Stop Ferozpora Road, Lahore. ELI-00912 Dossier# 3528 Submission date: 30/09/2022 Evaluator: DD-III	Legal Manufacturer: Shoufu inc., 11 kamitakamatsu-cho, fukuine, higashiyama-ku, kyoto 605-0983, Japan. Sales & Marketing, Distribution Dental Asia - Pacific Ltd, 10 science Park Road No, 03-12, The Alpha, Science Park 11, Singapore 11784. FSC: Japan Date of Issue: 27.06.2022	SHOFU BEAUTIBOND BEAUTIBOND Codes & Sizes: As per FSC Class-B Shelf Life: not provided	Deferred for the provision of following documents: The firm shall provide original challan form as proof of fee deposit. Declaration on stamp paper as per form-7A is not provided. Stability data for the shelf life is not provided. Submit valid, original & notarized ISO certificate. Submit original & notarized credentials of manufacturer. Submit essential principle checklist for the applied product. Justify the proposed MRP, storage conditions & grouping of MDs on form-7A Provide packing label for the applied product.
123.	Arihat Dental Services Shop No, G-15, PMA Trade Center, OPPOSITE, District Jail Shama Stop Ferozpora Road, Lahore. ELI-00912 Dossier# 3529 Submission date: 30/09/2022 Evaluator: DD-III	Legal Manufacturer: Shoufu inc., 11 kamitakamatsu-cho, fukuine, higashiyama-ku, kyoto 605-0983, Japan. Sales & Marketing, Distribution Dental Asia - Pacific Ltd, 10 science Park Road No, 03-12, The Alpha, Science Park 11, Singapore 11784. FSC: Japan Date of Issue: 27.06.2022	SHOFU BEAUTICEM SA BEAUTICEM SA Codes & Sizes: As per FSC Class-B Shelf Life: not provided <i>Ks 08/07/2023</i>	Deferred for the provision of following documents: The firm shall provide original challan form as proof of fee deposit. Declaration on stamp paper as per form-7A is not provided. Stability data for the shelf life is not provided. Submit valid, original & notarized ISO certificate. Submit original & notarized credentials of manufacturer. Submit essential principle checklist for the applied product. Justify the proposed MRP, storage conditions & grouping of MDs on form-

				7A Provide packing label for the applied product.
124.	Arihat Dental ServicesShop No, G-15, PMA Trade Center, OPPOSITE, District Jail Shama Stop Ferozpora Road, Lahore. ELI-00912 Dossier# 3530 Submission date: 30/09/2022 Evaluator: DD-III	Legal Manufacturer: Shoufu inc., 11 kamitakamastu- cho , fukuine, higashiyama-ku, kyoto 605-0983, Japan. Sales & Marketing, Distribution Dental Asia - Pacific Ltd, 10 science Park Road No, 03-12, The Alpha, Science Park 11, Singapura 11784. FSC: Japan Date of Issue: 27.06.2022	SHOFU BEAUTIFIL - BULK FLOWABLE BEAUTIFIL - BULK FLOWABLE Codes & Sizes: As per FSC Class-B Shelf Life: not provided	Deferred for the provision of following documents: The firm shall provide original challan form as proof of fee deposit. Declaration on stamp paper as per form-7A is not provided. Stability data for the shelf life is not provided. Submit valid, original & notarized ISO certificate. Submit original & notarized credentials of manufacturer. Submit essential principle checklist for the applied product. Justify the proposed MRP, storage conditions & grouping of MDs on form-7A Provide packing label for the applied product.
125.	Arihat Dental ServicesShop No, G-15, PMA Trade Center, OPPOSITE, District Jail Shama Stop Ferozpora Road, Lahore. ELI-00912 Dossier# 3531 Submission date: 30/09/2022 Evaluator: DD-III	Legal Manufacturer: Shoufu inc., 11 kamitakamastu- cho , fukuine, higashiyama-ku, kyoto 605-0983, Japan. Sales & Marketing, Distribution Dental Asia - Pacific Ltd, 10 science Park Road No, 03-12, The Alpha, Science Park 11, Singapura 11784. FSC: Japan Date of Issue: 27.06.2022	SHOFU BEAUTIFILL FLOW PLUS BEAUTIFILL FLOW PLUS Codes & Sizes: As per FSC Class-B Shelf Life: not provided	Deferred for the provision of following documents: The firm shall provide original challan form as proof of fee deposit. Declaration on stamp paper as per form-7A is not provided. Stability data for the shelf life is not provided. Submit valid, original & notarized ISO certificate. Submit original & notarized credentials of manufacturer. Submit essential principle checklist for the applied product. Justify the proposed MRP, storage conditions & grouping of MDs on form-7A Provide packing label for the applied product.

126.	Arihat Dental ServicesShop No, G-15, PMA Trade Center, OPPOSITE, District Jail Shama Stop Ferozpora Road, Lahore. ELI-00912 Dossier# 3532 Submission date: 30/09/2022 Evaluator: DD-III	<p>Legal Manufacturer: Shoufu inc., 11 kamitakamastu- cho , fukuine, higashiyama-ku, kyoto 605-0983, Japan.</p> <p>Sales & Marketing, Distribution Dental Asia - Pacific Ltd, 10 science Park Road No, 03-12, The Alpha, Science Park 11, Singapora 11784.</p> <p>FSC: Japan Date of Issue: 27.06.2022</p>	<p>SHOFU BEAUTIFILL II</p> <p>BEAUTIFILL II Codes & Sizes: As per FSC Class-B Shelf Life: not provided</p>	<p>Deferred for the provision of following documents:</p> <p>The firm shall provide original challan form as proof of fee deposit.</p> <p>Declaration on stamp paper as per form-7A is not provided.</p> <p>Stability data for the shelf life is not provided.</p> <p>Submit valid, original & notarized ISO certificate.</p> <p>Submit original & notarized credentials of manufacturer.</p> <p>Submit essential principle checklist for the applied product.</p> <p>Justify the proposed MRP, storage conditions & grouping of MDs on form-7A</p> <p>Provide packing label for the applied product.</p>
127.	Arihat Dental ServicesShop No, G-15, PMA Trade Center, OPPOSITE, District Jail Shama Stop Ferozpora Road, Lahore. ELI-00912 Dossier# 3533 Submission date: 30/09/2022 Evaluator: DD-III	<p>Legal Manufacturer: Shoufu inc., 11 kamitakamastu- cho , fukuine, higashiyama-ku, kyoto 605-0983, Japan.</p> <p>Sales & Marketing, Distribution Dental Asia - Pacific Ltd, 10 science Park Road No, 03-12, The Alpha, Science Park 11, Singapora 11784.</p> <p>FSC: Japan Date of Issue: 27.06.2022</p>	<p>SHOFU DIAMOND BUR KITS</p> <p>DIAMOND BUR KITS Codes & Sizes: As per FSC Class-B Shelf Life: not provided</p> <p><i>Handwritten signature and date: 08/08/2023</i></p>	<p>Deferred for the provision of following documents:</p> <p>The firm shall provide original challan form as proof of fee deposit.</p> <p>Declaration on stamp paper as per form-7A is not provided.</p> <p>Stability data for the shelf life is not provided.</p> <p>Submit valid, original & notarized ISO certificate.</p> <p>Submit original & notarized credentials of manufacturer.</p> <p>Submit essential principle checklist for the applied product.</p> <p>Justify the proposed MRP, storage conditions & grouping of MDs on form-7A</p> <p>Provide packing label for the applied product.</p>
128.	Arihat Dental ServicesShop No, G-15, PMA Trade Center, OPPOSITE, District Jail Shama Stop Ferozpora Road, Lahore. ELI-00912 Dossier# 3534	<p>Legal Manufacturer: Shoufu inc., 11 kamitakamastu- cho , fukuine, higashiyama-ku, kyoto 605-0983, Japan.</p> <p>Sales & Marketing, Distribution Dental Asia - Pacific Ltd, 10</p>	<p>SHOFU DURA GREEN DIA</p> <p>DURA GREEN DIA Codes & Sizes: As per FSC Class-B Shelf Life: not provided</p>	<p>Deferred for the provision of following documents:</p> <p>The firm shall provide original challan form as proof of fee deposit.</p> <p>Declaration on stamp paper as per form-7A is not provided.</p> <p>Stability data for the shelf life is not</p>

	<p>Submission date: 30/09/2022 Evaluator: DD-III</p>	<p>science Park Road No, 03-12, The Alpha, Science Park 11, Singapore 11784.</p> <p>FSC: Japan Date of Issue: 27.06.2022</p>		<p>provided.</p> <p>Submit valid, original & notarized ISO certificate.</p> <p>Submit original & notarized credentials of manufacturer.</p> <p>Submit essential principle checklist for the applied product.</p> <p>Justify the proposed MRP, storage conditions & grouping of MDs on form-7A</p> <p>Provide packing label for the applied product.</p>
129.	<p>Arihat Dental Services Shop No, G-15, PMA Trade Center, OPPOSITE, District Jail Shama Stop Ferozpur Road, Lahore. ELI-00912 Dossier# 3535 Submission date: 30/09/2022 Evaluator: DD-III</p>	<p>Legal Manufacturer: Shoufu inc., 11 kamitakamatsu-cho, fukuine, higashiyama-ku, kyoto 605-0983, Japan.</p> <p>Sales & Marketing, Distribution Dental Asia - Pacific Ltd, 10 science Park Road No, 03-12, The Alpha, Science Park 11, Singapore 11784.</p> <p>FSC: Japan Date of Issue: 27.06.2022</p>	<p>SHOFU GLASLONOME FX ULTRA</p> <p>GLASLONOME FX ULTRA Codes & Sizes: As per FSC Class-B Shelf Life: not provided</p>	<p>Deferred for the provision of following documents:</p> <p>The firm shall provide original challan form as proof of fee deposit.</p> <p>Declaration on stamp paper as per form-7A is not provided.</p> <p>Stability data for the shelf life is not provided.</p> <p>Submit valid, original & notarized ISO certificate.</p> <p>Submit original & notarized credentials of manufacturer.</p> <p>Submit essential principle checklist for the applied product.</p> <p>Justify the proposed MRP, storage conditions & grouping of MDs on form-7A</p> <p>Provide packing label for the applied product.</p>
130.	<p>Arihat Dental Services Shop No, G-15, PMA Trade Center, OPPOSITE, District Jail Shama Stop Ferozpur Road, Lahore. ELI-00912 Dossier# 3536 Submission date: 30/09/2022 Evaluator: DD-III</p>	<p>Legal Manufacturer: Shoufu inc., 11 kamitakamatsu-cho, fukuine, higashiyama-ku, kyoto 605-0983, Japan.</p> <p>Sales & Marketing, Distribution Dental Asia - Pacific Ltd, 10 science Park Road No, 03-12, The Alpha, Science Park 11, Singapore 11784.</p>	<p>SHOFU HY- BOND</p> <p>HY-BOND GLASIONOMER CX-SMART Codes & Sizes: As per FSC Class-B Shelf Life: not provided</p>	<p>Deferred for the provision of following documents:</p> <p>The firm shall provide original challan form as proof of fee deposit.</p> <p>Declaration on stamp paper as per form-7A is not provided.</p> <p>Stability data for the shelf life is not provided.</p> <p>Submit valid, original & notarized ISO certificate.</p>

		FSC: Japan Date of Issue: 27.06.2022		<p>Submit original & notarized credentials of manufacturer.</p> <p>Submit essential principle checklist for the applied product.</p> <p>Justify the proposed MRP, storage conditions & grouping of MDs on form-7A</p> <p>Provide packing label for the applied product.</p>
131.	<p>Arihat Dental Services Shop No, G-15, PMA Trade Center, OPPOSITE, District Jail Shama Stop Ferozpora Road, Lahore. ELI-00912 Dossier# 3537 Submission date: 30/09/2022 Evaluator: DD-III</p>	<p>Legal Manufacturer: Shoufu inc., 11 kamitakamatsu-cho, fukuine, higashiyama-ku, kyoto 605-0983, Japan.</p> <p>Sales & Marketing, Distribution Dental Asia - Pacific Ltd, 10 science Park Road No, 03-12, The Alpha, Science Park 11, Singapore 11784.</p> <p>FSC: Japan Date of Issue: 27.06.2022</p>	<p>SHOFU HY- BOND POLYCARBOXYLATE CEMENT</p> <p>HY-BOND POLYCARBOXYLATE CEMENT Codes & Sizes: As per FSC Class-B Shelf Life: not provided</p>	<p>Deferred for the provision of following documents:</p> <p>The firm shall provide original challan form as proof of fee deposit.</p> <p>Declaration on stamp paper as per form-7A is not provided.</p> <p>Stability data for the shelf life is not provided.</p> <p>Submit valid, original & notarized ISO certificate.</p> <p>Submit original & notarized credentials of manufacturer.</p> <p>Submit essential principle checklist for the applied product.</p> <p>Justify the proposed MRP, storage conditions & grouping of MDs on form-7A</p> <p>Provide packing label for the applied product.</p>
132.	<p>Arihat Dental Services Shop No, G-15, PMA Trade Center, OPPOSITE, District Jail Shama Stop Ferozpora Road, Lahore. ELI-00912 Dossier# 3538 Submission date: 30/09/2022 Evaluator: DD-III</p>	<p>Legal Manufacturer: Shoufu inc., 11 kamitakamatsu-cho, fukuine, higashiyama-ku, kyoto 605-0983, Japan.</p> <p>Sales & Marketing, Distribution Dental Asia - Pacific Ltd, 10 science Park Road No, 03-12, The Alpha, Science Park 11, Singapore 11784.</p> <p>FSC: Japan Date of Issue: 27.06.2022</p>	<p>SHOFU HY-BOND RESIGLASS</p> <p>HY-BOND RESIGLASS Codes & Sizes: As per FSC Class-B Shelf Life: not provided</p> <p><i>Handwritten signature and date: 30/08/2023</i></p>	<p>Deferred for the provision of following documents:</p> <p>The firm shall provide original challan form as proof of fee deposit.</p> <p>Declaration on stamp paper as per form-7A is not provided.</p> <p>Stability data for the shelf life is not provided.</p> <p>Submit valid, original & notarized ISO certificate.</p> <p>Submit original & notarized credentials of manufacturer.</p>

				<p>Submit essential principle checklist for the applied product.</p> <p>Justify the proposed MRP, storage conditions & grouping of MDs on form-7A</p> <p>Provide packing label for the applied product.</p>
133.	<p>Arihat Dental Services Shop No, G-15, PMA Trade Center, OPPOSITE, District Jail Shama Stop Ferozpora Road, Lahore. ELI-00912 Dossier# 3539 Submission date: 30/09/2022 Evaluator: DD-III</p>	<p>Legal Manufacturer: Shoufu inc., 11 kamitakamastu-cho, fukuine, higashiyama-ku, kyoto 605-0983, Japan.</p> <p>Sales & Marketing, Distribution Dental Asia - Pacific Ltd, 10 science Park Road No, 03-12, The Alpha, Science Park 11, Singapura 11784.</p> <p>FSC: Japan Date of Issue: 27.06.2022</p>	<p>SHOFU SUPER SNAP</p> <p>SUPER SNAP</p> <p>Codes & Sizes: As per FSC Class-B</p> <p>Shelf Life: not provided</p>	<p>Deferred for the provision of following documents:</p> <p>The firm shall provide original challan form as proof of fee deposit.</p> <p>Declaration on stamp paper as per form-7A is not provided.</p> <p>Stability data for the shelf life is not provided.</p> <p>Submit valid, original & notarized ISO certificate.</p> <p>Submit original & notarized credentials of manufacturer.</p> <p>Submit essential principle checklist for the applied product.</p> <p>Justify the proposed MRP, storage conditions & grouping of MDs on form-7A</p> <p>Provide packing label for the applied product.</p>
134.	<p>Arihat Dental Services Shop No, G-15, PMA Trade Center, OPPOSITE, District Jail Shama Stop Ferozpora Road, Lahore. ELI-00912 Dossier# 3540 Submission date: 30/09/2022 Evaluator: DD-III</p>	<p>Legal Manufacturer: Shoufu inc., 11 kamitakamastu-cho, fukuine, higashiyama-ku, kyoto 605-0983, Japan.</p> <p>Sales & Marketing, Distribution Dental Asia - Pacific Ltd, 10 science Park Road No, 03-12, The Alpha, Science Park 11, Singapura 11784.</p> <p>FSC: Japan Date of Issue: 27.06.2022</p>	<p>SHOFU VINTAGE ART UNIVERSAL</p> <p>VINTAGE ART UNIVERSAL</p> <p>Codes & Sizes: As per FSC Class-B</p> <p>Shelf Life: not provided</p>	<p>Deferred for the provision of following documents:</p> <p>The firm shall provide original challan form as proof of fee deposit.</p> <p>Declaration on stamp paper as per form-7A is not provided.</p> <p>Stability data for the shelf life is not provided.</p> <p>Submit valid, original & notarized ISO certificate.</p> <p>Submit original & notarized credentials of manufacturer.</p> <p>Submit essential principle checklist for the applied product.</p> <p>Justify the proposed MRP, storage</p>

				<p>conditions & grouping of MDs on form-7A</p> <p>Provide packing label for the applied product.</p>
135.	<p>Arihat Dental Services Shop No, G-15, PMA Trade Center, OPPOSITE, District Jail Shama Stop Ferozpora Road, Lahore. ELI-00912 Dossier# 3541 Submission date: 30/09/2022 Evaluator: DD-III</p>	<p>Legal Manufacturer: Shoufu inc., 11 kamitakamastu-cho, fukuine, higashiyama-ku, kyoto 605-0983, Japan.</p> <p>Sales & Marketing, Distribution Dental Asia - Pacific Ltd, 10 science Park Road No, 03-12, The Alpha, Science Park 11, Singapore 11784.</p> <p>FSC: Japan Date of Issue: 27.06.2022</p>	<p>SHOFU VINTAGE LD VINTAGE LD Codes & Sizes: As per FSC Class-B Shelf Life: not provided</p>	<p>Deferred for the provision of following documents:</p> <p>The firm shall provide original challan form as proof of fee deposit.</p> <p>Declaration on stamp paper as per form-7A is not provided.</p> <p>Stability data for the shelf life is not provided.</p> <p>Submit valid, original & notarized ISO certificate.</p> <p>Submit original & notarized credentials of manufacturer.</p> <p>Submit essential principle checklist for the applied product.</p> <p>Justify the proposed MRP, storage conditions & grouping of MDs on form-7A</p> <p>Provide packing label for the applied product.</p>
136.	<p>Arihat Dental Services Shop No, G-15, PMA Trade Center, OPPOSITE, District Jail Shama Stop Ferozpora Road, Lahore. ELI-00912 Dossier# 3542 Submission date: 30/09/2022 Evaluator: DD-III</p>	<p>Legal Manufacturer: Shoufu inc., 11 kamitakamastu-cho, fukuine, higashiyama-ku, kyoto 605-0983, Japan.</p> <p>Sales & Marketing, Distribution Dental Asia - Pacific Ltd, 10 science Park Road No, 03-12, The Alpha, Science Park 11, Singapore 11784.</p> <p>FSC: Japan Date of Issue: 27.06.2022</p>	<p>SHOFU VINTAGE PRO VINTAGE PRO Codes & Sizes: As per FSC Class-B Shelf Life: not provided</p> <p><i>Handwritten signature and date: 08/08/2023</i></p>	<p>Deferred for the provision of following documents:</p> <p>The firm shall provide original challan form as proof of fee deposit.</p> <p>Declaration on stamp paper as per form-7A is not provided.</p> <p>Stability data for the shelf life is not provided.</p> <p>Submit valid, original & notarized ISO certificate.</p> <p>Submit original & notarized credentials of manufacturer.</p> <p>Submit essential principle checklist for the applied product.</p> <p>Justify the proposed MRP, storage conditions & grouping of MDs on form-7A</p> <p>Provide packing label for the applied product.</p>

				product.
	<p>Arihat Dental Services Shop No, G-15, PMA Trade Center, OPPOSITE, District Jail Shama Stop Ferozpora Road, Lahore. ELI-00912 Dossier# 3543 Submission date: 30/09/2022 Evaluator: DD-III</p>	<p>Legal Manufacturer: Shoufu inc., 11 kamitakamatsu-cho, fukuine, higashiyama-ku, kyoto 605-0983, Japan.</p> <p>Sales & Marketing, Distribution Dental Asia - Pacific Ltd, 10 science Park Road No, 03-12, The Alpha, Science Park 11, Singapore 11784.</p> <p>FSC: Japan Date of Issue: 27.06.2022</p>	<p>SHOFU VINTAGE ZR VINTAGE ZR Codes & Sizes: As per FSC Class-B Shelf Life: not provided</p>	<p>Deferred for the provision of following documents:</p> <p>The firm shall provide original challan form as proof of fee deposit.</p> <p>Declaration on stamp paper as per form-7A is not provided.</p> <p>Stability data for the shelf life is not provided.</p> <p>Submit valid, original & notarized ISO certificate.</p> <p>Submit original & notarized credentials of manufacturer.</p> <p>Submit essential principle checklist for the applied product.</p> <p>Justify the proposed MRP, storage conditions & grouping of MDs on form-7A</p> <p>Provide packing label for the applied product.</p>
138.	<p>Hashir Surgical Services, Office No 15, Street 1m F-2, Phase 6, Hayatabad, Peshawar • Office No. 05, 2nd Floor, Syed's Tower, University Road, Peshawar • House No. 2 Street No. 1m Gulshan Colony, GT Road, Peshawar</p> <p>ELI: 00075 Dossier# 1983 Submission date: 10/12/2020 Evaluator: DD-III</p>	<p>Legal Manufacturer: Revital Healthcare (EPZ) limited LR No. 5025/1239 Msumarini-Mombasa-Malindi Rd, P.O Box 80713-80100 Mombasa-Kenya.</p> <p>FSC: Kenya Valid till: 31.12.2020</p>	<p>REFLON IV Cannula (IV CANNULA) G-14, G-16, G-18, G-20, G-22, G-24, G-26 Class-B Shelf Life: not provided</p>	<p>Deferred for the provision of following documents:</p> <p>FSC of country of origin (Kenya) is expired.</p> <p>Name of manufacturer is not provided on form-7A</p> <p>Stability data for the shelf life is not provided</p> <p>Submit original & notarized credentials of manufacturer.</p> <p>Submit valid, original & notarized LOA/agency agreement.</p> <p>Submit valid, original & notarized ISO & FQA certificates.</p> <p>Justify the grouping of MDs on form-7A.</p> <p>DOC is not submitted. <i>Uw/8/18/2023</i></p>
139.	<p>Bio Sphere Marketing House 2, Street 4, Adjacent to the best grammar school,</p>	<p>Legal Manufacturer: Jangsu Audicomn Mdical Technology, 4F, No.4 Building,</p>	<p>HAEMOGLOBIN A1c Kit HAEMOGLOBIN A1c Analyzer (HAEMOGLOBIN A1c)</p>	<p>Deferred for the provision of following documents:</p> <p>Submit valid, original & embassy attested FSC of reference country as</p>

	<p>Pak Town Chungi Amar Sidhu Lahore ELI: 00922 Dossier#3877 Submission date: 21/06/2022 Evaluator: DD-III</p>	<p>High- tech Industrial Park No.36 Nanwei 4 Rd, Dingmao, Zhenjiang, Jiangsu, China</p> <p>FSC: China Valid till: 2023/12/27</p>	<p>Code & Sizes: As per FSC</p> <p>Class-B Shelf Life: 12 months</p>	<p>product is from non-reference country.</p> <p>Submit valid, original & notar. LOA/agency agreement</p> <p>Stability data for the shelf life is not provided</p> <p>Submit original & notarized credentials of manufacturer.</p> <p>Submit valid, original & notarized ISO & FQA certificates.</p> <p>DOC is not submitted</p> <p>Apply separate application for HAEMOGLOBIN A1c Analyzer on form-6A Submit fee of PKR 5000/-</p>
140.	<p>ASTO Life Science Pvt. Ltd Plaza No. 1 Block Orchard 1, Paragon City Barki Road, Lahore Cantt</p> <p>ELI-00103 Dossier#753-C Submission date: 16/12/2022 Evaluator: DD-III</p>	<p>Legal Manufacturer: Surgical Specialties Mexico S. DE R.L. DE CV Corredor Tijuana- Rosarito 2000, 24702- B Ejido Francisco VilaTijuana, B>C., C.P. 22235 Mexico</p> <p>FSC: USA valid till: 22-05-2024</p>	<p>Sharpoint-TM polypropylene sutures LOOK -TM polypropylene sutures Sharpoint TM plus polypropylene sutures ExactEtchTM polypropylene sutures Code & Sizes: As per FSC Class-B Shelf Life:05 years</p>	<p>Deferred for the provision of following documents:</p> <p>Form-7A is not signed & stamped.</p> <p>The address of importer mentioned on LOA & Form-7A does not matched with address mentioned on Form-4(license to import MD).</p> <p>Submit Credentials of manufacturer duly notarized from country of origin.</p> <p>LOA is expired on 31-12-2022. Submit valid, original & duly notarized LOA.</p> <p>According to the MDR 2017 & the technical document given by manufacturer (DOC) polypropylene sutures fall in class III(D) while firm is applied in class B</p> <p>Submit differential fee of 25000/- PKR.</p> <p>The firm proposed four different brand names i.e., SharePoint-TM, LOOK -TM, SharePoint TM plus, ExactEtchTM polypropylene sutures respectively.</p> <p>Specify a single brand name for this applied product.</p> <p>Submit valid, original & notarized ISO 13485 & FQA certificates.</p> <p>Submit valid, original & notarized Design Examination certificates.</p>

141.	<p>ASTO Life Science Pvt. Ltd Plaza No. 1 Block Orchard 1, Paragon City Barki Road, Lahore Cantt</p> <p>ELI-00103 Dossier#754-C Submission date: 16/12/2022 Evaluator: DD-III</p>	<p>Legal Manufacturer: Surgical Specialties Mexico S. DE R.L. DE CV Corredor Tijuana-Rosarito 2000, 24702-B Ejido Francisco VilaTijuana, B>C., C.P. 22235 Mexico</p> <p>FSC: USA valid till: 18-02-2023</p>	<p>Quill-TM Monoderm-TM knotless tissue-closure device Stratafix -TM spiral PGA-PCL knotless tissue control device. Code & Sizes: As per FSC Class-B Shelf Life:05 years</p>	<p>Deferred for the provision of following documents:</p> <p>Form-7A is not signed & stamped.</p> <p>FSC (USA) is expired.</p> <p>The address of importer mentioned on LOA & Form-7A does not matched with address mentioned on Form-4(license to import MD).</p> <p>Submit Credentials of manufacturer duly notarized from country of origin. LOA is expired on 31-12-2022 Submit valid, original & duly notarized LOA</p> <p>According to the MDR 2017 & the technical document given by manufacturer (DOC) these sutures fall in class III(D) while firm is applied in class B</p> <p>Submit differential fee of 25000/- PKR.</p> <p>The firm proposed two different brand names i.e., Quill-TM Monoderm-TM knotless tissue-closure device & Stratafix -TM spiral PGA-PCL knotless tissue control device respectively. Specify a single brand name for this applied product.</p> <p>Submit valid, original & notarized ISO 13485 & FQA certificates.</p> <p>Submit valid, original & notarized Design Examination certificates.</p>
142.	<p>ASTO Life Science Pvt. Ltd Plaza No. 1 Block Orchard 1, Paragon City Barki Road, Lahore Cantt</p> <p>ELI-00103 Dossier#755-C Submission date: 16/12/2022 Evaluator: DD-III</p>	<p>Legal Manufacturer: Surgical Specialties Mexico S. DE R.L. DE CV Corredor Tijuana-Rosarito 2000, 24702-B Ejido Francisco VilaTijuana, B>C., C.P. 22235 Mexico</p> <p>FSC: USA valid till: 18-02-2023</p>	<p>Sharpoin-TM Polysyn -TM Suture LOOK -TM Polysyn -TM Suture Sharpoin-TM PLUS Polysyn -TM Suture ExactEtchTM PGA Suture Code & Sizes: As per FSC Class-B Shelf Life:05 years</p>	<p>Deferred for the provision of following documents:</p> <p>Form-7A is not signed & stamped.</p> <p>FSC (USA) is expired</p> <p>The address of importer mentioned on LOA & Form-7A does not matched with address mentioned on Form-4(license to import MD).</p> <p>Submit Credentials of manufacturer duly notarized from country of origin. LOA is expired on 31-12-2022 Submit valid, original & duly notarized LOA</p> <p>According to the MDR 2017 & the technical document given by manufacturer (DOC) Polyglycolic acid suture fall in class III(D) while firm is applied in class B, aubmit differential fee of 25000/- PKR.</p> <p>The firm proposed three different brand names i.e., Sharpoin-TM Polysyn -TM Suture, LOOK -TM Polysyn -TM Suture & ExactEtchTM PGA Suture respectively.</p> <p>Specify a single brand name for this</p>

				<p>applied product.</p> <p>Submit valid, original & notarize ISO 13485 & FQA certificates.</p> <p>Submit valid, original & notarized Design Examination certificates.</p>
143.	<p>ASTO Life Science Pvt. Ltd Plaza No. 1 Block Orchard 1, Paragon City Barki Road, Lahore Cantt</p> <p>ELI-00103 Dossier#756-C Submission date: 16/12/2022 Evaluator: DD-III</p>	<p>Legal Manufacturer: Surgical Specialties Mexico S. DE R.L. DE CV Corredor Tijuana-Rosarito 2000, 24702-B Ejido Francisco VilaTijuana, B>C., C.P. 22235 Mexico</p> <p>FSC: USA valid till: 18-02-2023</p>	<p>LOOK -TM - Sharpoint-TM- Sharpoint-TM plus Code & Sizes: As per FSC Class-B Shelf Life:05 years</p>	<p>Deferred for the provision of following documents:</p> <p>Form-7A is not signed & stamped. FSC (USA) is expired.</p> <p>The address of importer mentioned on LOA & Form-7A does not matched with address mentioned on Form-4(license to import MD).</p> <p>Submit Credentials of manufacturer duly notarized from country of origin.</p> <p>LOA is expired on 31-12-2022. Submit valid, original & duly notarized LOA</p> <p>According to the MDR 2017 & the technical document given by manufacturer (DOC) Plain or chronic Gut suture fall in class III(D) while firm is applied in class B</p> <p>Submit differential fee of 25000/- PKR.</p> <p>The firm proposed three different brand names i.e., LOOK -TM - Sharpoint-TM- SharePoint-TM plus respectively. Specify a single brand name for this applied product.</p> <p>Submit valid, original & notarized ISO 13485 & FQA certificates.</p> <p>Submit valid, original & notarized Design Examination certificates.</p>
144.	<p>ASTO Life Science Pvt. Ltd Plaza No. 1 Block Orchard 1, Paragon City Barki Road, Lahore Cantt</p> <p>ELI-00103 Dossier#751-C Submission date: 16/12/2022 Evaluator: DD-III</p>	<p>Legal Manufacturer: Surgical Specialties Mexico S. DE R.L. DE CV Corredor Tijuana-Rosarito 2000, 24702-B Ejido Francisco VilaTijuana, B>C., C.P. 22235 Mexico</p> <p>FSC: USA valid till: 18-02-2023</p>	<p>Quill-TM Polypropylene knotless tissue-closure device Stratafix -TM spiral Polypropylene knotless tissue control device. Code & Sizes: As per FSC Class-B Shelf Life:05 years</p>	<p>Deferred for the provision of following documents:</p> <p>Form-7A is not signed & stamped. FSC (USA) is expired.</p> <p>The address of importer mentioned on LOA & Form-7A does not matched with address mentioned on Form-4(license to import MD).</p> <p>Submit Credentials of manufacturer duly notarized from country of origin.</p> <p>LOA is expired on 31-12-2022 Submit valid, original & duly notarized LOA</p>

				<p>According to the MDR 2017 & the technical document given by manufacturer (DOC) polypropylene sutures fall in class III(D) while firm is applied in class B</p> <p>Submit differential fee of 25000/- PKR.</p> <p>The firm proposed two different brand names i.e., Quill-TM Polypropylene knotless tissue-closure device & Stratafix -TM spiral Polypropylene knotless tissue control device respectively.</p> <p>Specify a single brand name for this applied product.</p> <p>Submit valid, original & notarized ISO 13485 & FQA certificates.</p> <p>Submit valid, original & notarized Design Examination certificates.</p>
145.	<p>ASTO Life Science Pvt. Ltd Plaza No. 1 Block Orchard 1, Paragon City Barki Road, Lahore Cantt</p> <p>ELI-00103 Dossier#752-C Submission date:16/12/2022 Evaluator: DD-III</p>	<p>Legal Manufacturer: Surgical Specialties Mexico S. DE R.L. DE CV Corredor Tijuana-Rosarito 2000, 24702-B Ejido Francisco VilaTijuana, B>C., C.P. 22235 Mexico</p> <p>FSC: USA valid till: 18-02-2023</p>	<p>Look-TM PTFE Sutures Code & Sizes: As per FSC Class-B Shelf Life:05 years</p>	<p>Deferred for the provision of following documents:</p> <p>Form-7A is not signed & stamped.</p> <p>FSC (USA) is expired.</p> <p>The address of importer mentioned on LOA & Form-7A does not matched with address mentioned on Form-4(license to import MD).</p> <p>Submit Credentials of manufacturer duly notarized from country of origin.</p> <p>LOA is expired on 31-12-2022 Submit valid, original & duly notarized LOA</p> <p>According to the MDR 2017 & the technical document given by manufacturer (DOC) Non-absorbable polytetrafluoroethylene (PTFE) sutures fall in class III(D) while firm is applied in class B, Submit differential fee of 25000/- PKR.</p> <p>Submit valid, original & notarized ISO 13485 & FQA certificates.</p> <p>Submit valid, original & notarized Design Examination certificates.</p>
146.	<p>ASTO Life Science Pvt. Ltd Plaza No. 1 Block</p>	<p>Legal Manufacturer: Surgical Specialties Mexico S. DE R.L. DE</p>	<p>Quill-TM PDO Knotless Tissue Closer Device Stratafix -TM spiral PDO</p>	<p>Deferred for the provision of following documents:</p>


	<p>Orchard 1, Paragon City Barki Road, Lahore Cantt</p> <p>ELI-00103 Dossier#730-C Submission date: 16/12/2022 Evaluator: DD-III</p>	<p>CV Corredor Tijuana-Rosarito 2000, 24702-B Ejido Francisco VilaTijuana, B>C., C.P. 22235 Mexico</p> <p>FSC: USA valid till: 18-02-2023</p>	<p>knotless tissue control device. Code & Sizes: As per FSC Class-B Shelf Life:05 years</p>	<p>Form-7A is not signed & stamped. FSC (USA) is expired.</p> <p>The address of importer mentioned on LOA & Form-7A does not matched with address mentioned on Form-4(license to import MD).</p> <p>Submit Credentials of manufacturer duly notarized from country of origin.</p> <p>LOA is expired on 31-12-2022 Submit valid, original & duly notarized LOA</p> <p>According to the MDR 2017 & the technical document given by manufacturer (DOC) polydioxanone surgical sutures fall in class III(D) while firm is applied in class B</p> <p>Submit differential fee of 25000/- PKR.</p> <p>The firm proposed two different brand names i.e., Quill-TM PDO Knotless Tissue Closer Device &Stratafix -TM spiral PDO knotless tissue control device respectively.</p> <p>Specify a single brand name for this applied product.</p> <p>Submit valid, original & notarized ISO 13485 & FQA certificates.</p> <p>Submit valid, original & notarized Design Examination certificates.</p>
147.	<p>ASTO Life Science Pvt. Ltd Plaza No. 1 Block Orchard 1, Paragon City Barki Road, Lahore Cantt</p> <p>ELI-00103 Dossier#731-C Submission date: 16/12/2022 Evaluator: DD-III</p>	<p>Legal Manufacturer: Surgical Specialties Mexico S. DE R.L. DE CV Corredor Tijuana-Rosarito 2000, 24702-B Ejido Francisco VilaTijuana, B>C., C.P. 22235 Mexico</p> <p>FSC: USA valid till: 18-02-2023</p>	<p>Sharpoin-TM Silk Sutures Sharpoin-TM Plus Silk Sutures LOOK -TM Silk Sutures ExactEtch-TM Silk Sutures Code & Sizes: As per FSC Class-B Shelf Life:05 years</p>	<p>Deferred for the provision of following documents:</p> <p>Form-7A is not signed & stamped.</p> <p>FSC (USA) is expired</p> <p>The address of importer mentioned on LOA & Form-7A does not matched with address mentioned on Form-4(license to import MD).</p> <p>Submit Credentials of manufacturer on the letter head of the company duly notarized from country of origin.</p> <p>LOA is expired on 31-12-2022 Submit valid, original & duly notarized LOA</p> <p>According to the MDR 2017 & the technical document given by manufacturer (DOC) silk sutures fall in class III(D) while firm is applied in</p>

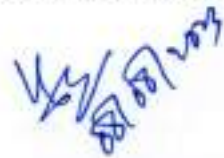
				<p>class B</p> <p>Submit differential fee of 25000/- PKR.</p> <p>The firm proposed four different brand names i.e., Sharpoint-TM Silk Sutures, Sharpoint-TM Plus Silk Sutures, LOOK -TM Silk Sutures & ExactEtch-TM Silk Sutures respectively.</p> <p>Specify a single brand name for this applied product.</p> <p>Submit valid, original & notarized ISO 13485 & FQA certificates.</p> <p>Submit valid, original & notarized Design Examination certificates.</p>
148.	<p>ASTO Life Science Pvt. Ltd Plaza No. 1 Block Orchard 1, Paragon City Barki Road, Lahore Cantt</p> <p>ELI-00103 Dossier#732-C Submission date: 16/12/2022 Evaluator: DD-III</p>	<p>Legal Manufacturer: Surgical Specialties Mexico S. DE R.L. DE CV Corredor Tijuana-Rosarito 2000, 24702-B Ejido Francisco VilaTijuana, B>C., C.P. 22235 Mexico</p> <p>FSC: USA valid till: 18-02-2023</p>	<p>Sharpoint-TM nylon Sutures LOOK -TM nylon Sutures Sharpoint-TM Plus nylon Sutures ExactEtch-TM nylon Sutures Code & Sizes: As per FSC Class-B Shelf Life:05 years</p>	<p>Deferred for the provision of following documents:</p> <p>Form-7A is not signed & stamped.</p> <p>FSC (USA) is expired.</p> <p>The address of importer mentioned on LOA & Form-7A does not matched with address mentioned on Form-4(license to import MD).</p> <p>Submit Credentials of manufacturer duly notarized from country of origin.</p> <p>LOA is expired on 31-12-2022 Submit valid, original & duly notarized LOA</p> <p>According to the MDR 2017 & the technical document given by manufacturer (DOC) nylon sutures fall in class III(D) while firm is applied in class B</p> <p>Submit differential fee of 25000/- PKR.</p> <p>The firm proposed four different brand names i.e., Sharpoint-TM nylon Sutures, LOOK -TM nylon Sutures, Sharpoint-TM Plus nylon Sutures & ExactEtch-TM nylon Sutures respectively.</p> <p>Specify a single brand name for this applied product.</p> <p>Submit valid, original & notarized ISO 13485 & FQA certificates.</p> <p>Submit valid, original & notarized Design Examination certificates.</p>

149.	<p>ASTO Life Science Pvt. Ltd Plaza No. 1 Block Orchard 1, Paragon City Barki Road, Lahore Cantt</p> <p>ELI-00103 Dossier#733-C Submission date: 16/12/2022 Evaluator: DD-III</p>	<p>Legal Manufacturer: Surgical Specialties Mexico S. DE R.L. DE CV Corredor Tijuana-Rosarito 2000, 24702-B Ejido Francisco VilaTijuana, B>C., C.P. 22235 Mexico</p> <p>FSC: USA valid till: 18-02-2023</p>	<p>Surgical Specialties Bone Wax Code & Sizes: As per FSC Class-B Shelf Life:05 years</p>	<p>Deferred for the provision of following documents:</p> <p>Form-7A is not signed & stamped.</p> <p>FSC (USA) is expired. The address of importer mentioned on LOA & Form-7A does not matched with address mentioned on Form-4(license to import MD).</p> <p>Submit Credentials of manufacturer duly notarized from country of origin.</p> <p>LOA is expired on 31-12-2022 Submit valid, original & duly notarized LOA</p> <p>According to the MDR 2017 & the technical document given by manufacturer (DOC) the applied product fall in class III(D) while firm is applied in class B</p> <p>Submit differential fee of 25000/- PKR.</p> <p>Submit valid, original & notarized ISO 13485 & FQA certificates.</p> <p>Submit valid, original & notarized Design Examination certificates.</p>
150.	<p>Mian Enterprises, Office no. UG-400, Deans Trade Center, Peshawar Cantt.</p> <p>ELI-00507 Dossier# 911-C Submission date: 24/01/2023 Evaluator: DD-III</p>	<p>Legal Manufacturer: Kowa Company, Ltd 4-14, 3-Chrome, Nihonbashi-Honcho, Chuo-Ku, Tokyo 103-8433, Japan</p> <p>Manufacturing site: Kowa Company, Ltd, Hamamatsu Factory 3-1, shin-miyakoda 1-chrome, kita-ku, Hamamatsu, shizuoka 431-2103, japan</p> <p>FSC : Japan Date of Issue: 25/11/2020</p>	<p>Avansee Preload IP (Posterior chamber intraocular lens with an injector sterile.) (Model: YP2.2R) Class: C</p> <p>Shelf Life: 5 years</p>	<p>Deferred for the provision of following documents:</p> <p>FQA certificate is expired, provide valid and notarized FQA certificate</p> <p>DOC is not provided</p> <p>The address mentioned for the legal manufacturer on FSC(Japan) is Kowa Company, Ltd, 6-29, Nishiki 3-chrome, Naka-ku Nagoya, Aichi, Japan while address for legal manufacturer on all other documents including credentials, LOA, & ISO certificate is Kowa Company, Ltd 4-14, 3-Chrome, Nihonbashi-Honcho, Chuo-Ku, Tokyo 103-8433, Japan, justify it.</p>
151.	<p>Mian Enterprises, Office no. UG-400, Deans Trade Center, Peshawar Cantt.</p> <p>ELI-00507 Dossier# 489-C</p>	<p>Legal Manufacturer: Kowa Company, Ltd 4-14, 3-Chrome, Nihonbashi-Honcho, Chuo-Ku, Tokyo 103-8433, Japan</p> <p>Manufacturing site:</p>	<p>Avansee preset UV (Posterior chamber intraocular lens with an injector sterile.) (Model:PU6A & PU6AS) Class: C</p>	<p>Deferred for the provision of following documents:</p> <p>FQA certificate is expired, provide valid and notarized FQA certificate</p> <p>DOC is not provided</p>

	Submission date: 30/11/2022 Evaluator: DD-III	Kowa Company, Ltd, Hamamatsu Factory 3- 1, shin-miyakoda 1- chrome, kita-ku , Hamamatsu, shizuoka 431-2103, japan FSC : Japan Date of Issue: 25/11/2020	Shelf Life: 5 years	The address mentioned for the legal manufacturer on FSC(Japan) is Kowa Company, Ltd, 6-29, Nishiki 3-chrome, Naka-ku Nagoya, Aichi, Japan while address for legal manufacturer on all other documents including credentials, LOA, & ISO certificate is Kowa Company, Ltd 4-14, 3-Chrome, Nihonbashi-Honcho, Chuo-Ku, Tokyo 103-8433, Japan , justify it.
152.	Sudais Associates, Sudais House, Street nO, 7 House No, 1, Khan Bahadur Colony Duran Pur , Peshawar ELI: 00031 Dossier# 3070 Submission date: 27/06/2022 Evaluator: DD-III	Legal Manufacturer: Samyang Holdings Corporation, Head office: 295, Pangyo-ro, Bundang- gu, Seongnam- si, Gyeonggi-do, Korea Original FSC: Korea Date of Issue: 13.07.2021	Absorbable Hemostat (Surgiguard) Codes & Sizes: As per FSC Class-C Shelf Life: 36 months	Deferred for the provision of following documents: ISO 13485 certificate is expired, provide valid and notarized ISO 13485 certificate. Submit valid, original & duly notarized LOA On DOC class is III (Class D) for the applied product while firm applied in class C.submit revised form-7A.
153.	Zaki & Wasi Associates Flat No. C-21 Jason Lurury Apartment, Block 3, Clifton Karachi ELI-01000	Beasat Industrial Complex (BIC) Km10, Qom-Tehran Old Rd, Qom 3718838345, Qom provinces, Iran	Beasat Blood Bag Shelf Life: 2.5years Codes & Sizes: Not mentioned	Deferred till decision regarding the finalization/ vacation of the stay order passed by <i>Honorable Civil Court, Lahore, in Suit titled "Amson Vaccines V/s DRAP"</i> . <i>Honorable Court on 13-07-2023</i> . Since the products are already registered in the name of the Amsons, Islamabad. The firm shall submit the following documents: Blood bags are of various types and configuration depending upon design, with & without anti-coagulant and type of coagulant present in them, Firm has not mentioned the type of blood bag in the application Form. Copy of LoA provided, Original valid & Notarized is required. Valid and Embassy attested FSC of country of origin not provided therefore provide valid embassy attested original FSC. Provide CE marking certificates including notarized Full quality assurance, Design Examination certificate and ISO 13485 certificate.
154.	A.Feroz & Co	JIANGSU KANGHUA	Star-Burette-Type Infusion Sets for	Deferred for submission of Valid, Embassy attested FSC of China

Handwritten signature/initials in blue ink.

	Medicine Street No 1, Marriot Road, Karachi, 74000, Pakistan	MEDICAL EQUIPMENT CO. LTD. Sanhekou, Changzhou, Jiangsu, China P.C.:213115 Copy of LOA valid till 05 th Nov 2024, Copy of CE valid till 26 th May 2024, Copy of china FSC valid till 09-10-2020	Single use Class B Shelf Life: 5 Years Size:50ml, 100ml, 150ml, 200ml Fee 25000/- Dossier Submission: 13-03-2020	Notasried and valid LOA, CE marking Certificate or embassy attested valid FSC of RRA, and ISO 13485 Stabilty studies and DOC.
155.	A.Feroz & Co Medicine Street No 1, Marriot Road, Karachi, 74000, Pakistan	JIANGSU KANGHUA MEDICAL EQUIPMENT CO. LTD. Sanhekou, Changzhou, Jiangsu, China P.C.:213115 Dossier Submission: 13-03-2020 Copy of LOA valid till 05 th Nov 2024, Copy of CE valid till 26 th May 2024, Copy of FSC valid till 09-10-2020	Star Intravenous Needle for single use Class B Shelf Life: 5 Years Size:27G,26G,25G, 24G,23G,22G,21G, 20G,19G,18G Copy of slip Fee 25000/-	Deferred for submission Valid, Embassy attested FSC of China Notasried and valid LOA, CE marking Certificate or embassy attested valid FSC of RRA, ISO 13485 Stabilty studies and DOC.
156.	A.Feroz & Co Medicine Street No 1, Marriot Road, Karachi, 74000, Pakistan	JIANGSU KANGHUA MEDICAL EQUIPMENT CO. LTD. Sanhekou, Changzhou, Jiangsu, China P.C.:213115 Dossier Submission: 13-03-2020 Copy of LOA valid till 05 th Nov 2024, Copy of CE valid till 26 th May 2024, Copy of china FSC valid till 09-10-2020	Star Disposable Transfusion Set Class B Shelf Life: 5 Years Copy of fee slip 25000/- Size:TS-AD, TS-B	Deferred for submission Valid, Embassy attested FSC of China Notasried and valid LOA, CE marking Certificate or embassy attested valid FSC of RRA, ISO 13485 Stabilty studies and DOC. 
157.	A.Feroz & Co Medicine Street No 1, Marriot Road,	JIANGSU KANGHUA MEDICAL EQUIPMENT CO.	Star Sterile Hypodermic Needles for Single use	Deferred for submission Valid, Embassy attested FSC of China Notasried and valid LOA, CE marking

	Karachi, 74000, Pakistan	LTD. Sanhekou, Changzhou, Jiangsu, China P.C.:213115 Dossier Submission: 13-03-2020 Copy of LOA valid till 05 th Nov 2024, Copy of CE valid till 26 th May 2024, Copy of china FSC valid till 09-10-2020	Class B Shelf Life: 5 Years Fee 25000/- Size:30G, 29G, 28G, 27G, 26G, 25G, 24G, 23G, 22G, 21G, 20G, 19G, 18G, 16G,15G, 14G	Certificate or embassy attested valid FSC of RRA, ISO 13485 Stability studies and DOC.
158.	M/s Ali Gohar & Company (Private) Limited State Life Building I-B, I.I Chundrigar Road. Karachi (ELI-00004) DATE OF SUBMISSION: 7-9-2022	Legal Manufacturer: Smiths Medical ASD Inc, 6000 Nathan Ln N, Minneapolis, MN 55442 United States Manufacturing Facility: Smiths Medical International Ltd. 52 Grayhill Road, Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	Portex Epidural Minipack System I Class: C Shelf Life: 5 Years Codes: 100/391/818, 100/391/016, 100/391/018, 100/391/318, 100/391/116, 100/391/118, 100/391/190, 100/391/516, 100/391/518 FSC Czech Republic Expiry date 26-08-2024 ISO 13485 Expiry date 1-10-2023 Full Quality Assurance Expiry date 18-03-2023	Deferred for submission of the following documets: Valid and notarsied FQA and CE certifcaite having product name / generic name or embassy attested valid FSC of RRA. Submit stability studies and provide Relation between Smiths Medical ASD and Smiths Medical international UK
159.	M/s Ali Gohar & Company (Private) Limited State Life Building I-B, I.I Chundrigar Road, Karachi (ELI-00004) DATE OF SUBMISSION: 7-9-2022	Legal Manufacturer: Smiths Medical ASD Inc, 6000 Nathan Ln N, Minneapolis, MN 55442 United States Manufacturing Facility: Smiths Medical International Ltd. 52 Grayhill Road, Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	Portex Epidural Minipack Paediatric Class: C Shelf Life: 5 Years Codes: 100/391/180 FSC Czech Republic Expiry date 26-08-2024 ISO 13485 Expiry date 1-10-2023 Full Quality Assurance Expiry date 18-03-2023	Deferred for submissionof the Folowing documets: Fee of RS 50000/- for the applied product or justify. Valid and notarsied FQA and CE certifcaite having product name / generic name or embassy attested valid FSC of RRA. Submit stability studies and provide Relation between Smiths Medical ASD and Smiths Medical international UK 
160.	M/s Ali Gohar & Company (Private) Limited	Legal Manufacturer: Smiths Medical ASD	Portex Extra Length Tuohy Needle	Deferred for submissionof the Folowing documets:

	State Life Building I-B, I.I Chundrigar Road. Karachi (ELI-00004) DATE OF SUBMISSION: 7-9-2022	Inc, 6000 Nathan Ln N, Minneapolis, MN 55442 United States Manufacturing Facility: Smiths Medical International Ltd. 52 Grayhill Road, Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	Class: B Shelf Life: 5 Years Codes: 100/395/560, 100/395/580 FSC Czech Republic Expiry date 26-08-2024 ISO 13485 Expiry date 1-10-2023 Full Quality Assurance Expiry date 18-03-2023	Brand name on FSC and Form 7A does not match. Clarify. Valid and notarsied FQA and CE certificaite having product name / generic name or embassy attested valid FSC of RRA. Submit stability studies and provide Relation between Smiths Medical ASD and Smiths Medical international UK
161.	M/s Ali Gohar & Company (Private) Limited State Life Building I-B, I.I Chundrigar Road. Karachi (ELI-00004) DATE OF SUBMISSION: 7-9-2022	Legal Manufacturer: Smiths Medical ASD Inc, 6000 Nathan Ln N, Minneapolis, MN 55442 United States Manufacturing Facility: Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Parque Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425, Mexico.	Portex Tuohy Needle Class: B Shelf Life: 5 Years Codes: 100/395/160, 100/395/180 FSC Czech Republic Expiry date 26-08-2024 ISO 13485 Expiry date 27-06-2024 Full Quality Assurance Expiry date 18-03-2023	Deferred for submissionof the Following documets: Brand name on FSC and Form 7A does not match. Clarify. Valid and notarsied FQA and CE certificaite having product name / generic name or embassy attested valid FSC of RRA. Submit stability studies and provide Relation between Smiths Medical ASD and Smiths Medical international UK
162.	HOSPITAL SERVICES & SALES 13-C Annex, Block 6, PECHS, Karachi - 75400, PAKISTAN Lic. No.ELI-00081	GUANGDONG HAIYOU MEDICAL APPARATUS CO., LTD Nanyuan Industrial Area, North Liusha, Puning City, Guangdong Province, China. ISO Valid Till (17-10- 2019) FSC Valid Till (01-12- 2019) EC Certificate Valid Till (25-12-2021) DoC Valid Till (25-10-2021)	HAIYOU DISPOSAL BREATHING CIRCUIT (HO-HO1, HO-HO2, HO- HO3 & HO-HO4) Class - B Shelf Life 5 Years	Deferred for submission of the following documents : Notasried and embassy attested valid FSC and notarsied CE marking certificate, ISO 13485 certificaite. Notarsied and valid LOA Satbilty study
163.	HOSPITAL SERVICES & SALES 13-C Annex, Block 6, PECHS, Karachi - 75400, PAKISTAN	GUANGDONG HAIYOU MEDICAL APPARATUS CO., LTD Nanyuan Industrial Area, North Liusha, Puning City,	HAIYOU DISPOSABLE NEBULIZER KIT (HO- WO1, HO-WO2, HO-WO3, HO-WO4, HO-WO5, HO- WO6 AND HO-WO7) Class - B	Deferred for submission of the following documents : Notasried and embassy attested valid FSC and notarsied CE marking certificate, ISO 13485 certificaite.

	Lic. No.ELI-00081	Guangdong Province, China. ISO Valid Till (17-10-2019) FSC Valid Till (01-12-2019) EC Certificate Valid Till (25-12-2021) DoC Valid Till (25-10-2021)	Shelf Life 5 Years	Notarised and valid LOA Satisfactory study
164.	HOSPITAL SERVICES & SALES 13-C Annex, Block 6, PECHS, Karachi – 75400, PAKISTAN Lic. No.ELI-00081	GUANGDONG HAIYOU MEDICAL APPARATUS CO., LTD Nanyuan Industrial Area, North Liusha, Puning City, Guangdong Province, China. ISO Valid Till (17-10-2019) FSC Valid Till (0-12-2019) EC Certificate Valid Till (25-12-2021) DoC Valid Till (25-10-2021)	HAIYOU BACTERIUM / VIRUS FILTER (HO6020, HO6130, HO7010) Class – B Shelf Life 5 Years	Deferred for submission of the following documents: Notarised and embassy attested valid FSC and notarised CE marking certificate, ISO 13485 certificate. Notarised and valid LOA Satisfactory study.
165.	HOSPITAL SERVICES & SALES 13-C Annex, Block 6, PECHS, Karachi – 75400, PAKISTAN Lic. No.ELI-00081	GUANGDONG HAIYOU MEDICAL APPARATUS CO., LTD Nanyuan Industrial Area, North Liusha, Puning City, Guangdong Province, China. ISO Valid Till (17-10-2019) FSC Valid Till (02-12-2020) EC Certificate Valid Till (25-12-2021) DoC Valid Till (25-10-2021)	HAIYOU DISPOSABLE INFUSION SET WITH NEEDLE (Type A1, B3 Size: 0.45x13, 0.5x19, 0.55x25, 0.6x25, 0.7x25, 0.8x25, 0.9x25 and 1.2x25)* Class – B Shelf Life 3 Years	Deferred for submission of the following documents: Notarised and embassy attested valid FSC and notarised CE marking certificate, ISO 13485 certificate. Notarised and valid LOA Satisfactory study.
166.	HOSPITAL SERVICES & SALES 13-C Annex, Block 6, PECHS, Karachi – 75400, PAKISTAN Lic. No.ELI-00081	GUANGDONG HAIYOU MEDICAL APPARATUS CO., LTD Nanyuan Industrial Area, North Liusha, Puning City, Guangdong Province, China.	HAIYOU DISPOSABLE NASAL OXYGEN CANNULA WITH HUMIDIFIER BOTTLE (HO-A-I, HO-A-II, HO-B-I, HO-B-II) Class – B	Deferred for submission of the following documents: Notarised and embassy attested valid FSC and notarised CE marking certificate, ISO 13485 certificate. Notarised and valid LOA Satisfactory study

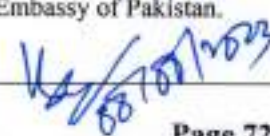
		ISO Valid Till (17-10-2019) FSC Valid Till (01-12-2019) EC Certificate Valid Till (25-12-2021) DoC Valid Till (25-10-2021)	Shelf Life 5 Years	
167.	HOSPITAL SERVICES & SALES 13-C Annex, Block 6, PECHS, Karachi – 75400, PAKISTAN Lic. No.ELI-00081	GUANGDONG HAIYOU MEDICAL APPARATUS CO., LTD Nanyuan Industrial Area, North Liusha, Puning City, Guangdong Province, China. ISO Valid Till (17-10-2019) FSC Valid Till (02-12-2020) EC Certificate Valid Till (25-12-2021) DoC Valid Till (25-10-2021)	HAIYOU DISPOSABLE NASAL OXYGEN CANNULA (I TYPE & II TYPE) Class – B Shelf Life 5 Years	Deferred for submission of the following documents Notarized and embassy attested valid FSC and notarsied CE marking certificate, ISO 13485 certificate. Notarsied and valid LOA Satbilty study.
168.	HOSPITAL SERVICES & SALES 13-C Annex, Block 6, PECHS, Karachi – 75400, PAKISTAN Lic. No.ELI-00081	GUANGDONG HAIYOU MEDICAL APPARATUS CO., LTD Nanyuan Industrial Area, North Liusha, Puning City, Guangdong Province, China. ISO Valid Till (17-10-2019) FSC Valid Till (01-12-2019) EC Certificate Valid Till (25-12-2021) DoC Valid Till (25-10-2021)	HAIYOU DISPOSABLE PERCISION INFUSION SET WITH NEEDLE (THE PORE SIZE OF FILTER MEMBRANE B3; 5um, 3um, 2um) Class – B Shelf Life 3 Years	Deferred for submission of the following documents : Notasried and embassy attested valid FSC and notarsied CE marking certificate, ISO 13485 certificate. Notarsied and valid LOA Satbilty study
169.	HOSPITAL SERVICES & SALES 13-C Annex, Block 6, PECHS, Karachi – 75400, PAKISTAN Lic. No.ELI-00081	GUANGDONG HAIYOU MEDICAL APPARATUS CO., LTD Nanyuan Industrial Area, North Liusha, Puning City, Guangdong Province, China. ISO Valid Till (17-10-2019) FSC Valid Till (01-12-	HAIYOU DISPOSABLE STERILE SYRINGE AND INJECTION NEEDLE (1ml, 2.5ml, 5ml, 10ml, 20ml, 30ml, and 50ml) Class – B Shelf Life 5 Years	Deferred for submission of the following documents: Notarized and embassy attested valid FSC and notarsied CE marking certificate, ISO 13485 certificate. Notarsied and valid LOA Satbilty study. Apply separately for 10 ml and above size. Furthermore, 2.5ml and 5ml are ban sizes

		2019) EC Certificate Valid Till (25-12-2021) DoC Valid Till (25-10-2021)		
170.	HOSPITAL SERVICES & SALES 13-C Annex, Block 6, PECHS, Karachi - 75400, PAKISTAN Lic. No.ELI-00081	GUANGDONG HAIYOU MEDICAL APPARATUS CO., LTD Nanyuan Industrial Area, North Liusha, Puning City, Guangdong Province, China, ISO Valid Till (17-10- 2019) FSC Valid Till (02-12- 2020) EC Certificate Valid Till (25-12-2021) DoC Valid Till (25-10-2021)	HAIYOU DISPOSABLE SUCTION CATHETER (6Fr, 8Fr, 10Fr, 12Fr, 14Fr, 16Fr and 18Fr) Class – B Shelf Life 5 Years	Deferred for submission of the following documents: Notarized and embassy attested valid FSC and notarized CE marking certificate, ISO 13485 certificate. Notarized and valid LOA Stability study.
171.	HOSPITAL SERVICES & SALES 13-C Annex, Block 6, PECHS, Karachi - 75400, PAKISTAN Lic. No.ELI-00081	GUANGDONG HAIYOU MEDICAL APPARATUS CO., LTD Nanyuan Industrial Area, North Liusha, Puning City, Guangdong Province, China, ISO Valid Till (17-10- 2019) FSC china Valid Till (01-12-2019) EC Certificate Valid Till (25-12-2021) DoC Valid Till (25-10-2021)	HAIYOU DISPOSABLE ANESTHESIA CIRCUIT (HO-M01, HO-M02, HO- M03, HO-M04, HO-M05, HO-M06, HO-M07, HO- M08) Class – B Shelf Life 5 Years	Deferred for submission of the following documents: Notarized and embassy attested valid FSC and notarized CE marking certificate, ISO 13485 certificate. Notarized and valid LOA Stability study
172.	M/s. Maxitech Pharma PVT LTD Address: E-178 SITE area Super Highway Karachi Establishment License #(ELI- 00769)	Legal Manufacturer: M/s SIFI . S.P.A Address: via Ercole Patti n.36 Lavinaio Aci S. Antonia CT 95025 Italy Manufacturing site: Same address FSC copy Italy issuance date 18-02- 2021	Mini Well Toric Intraocular Lens (IOL) Class: C Code: AS per FSC Claimed Shelf life: 4 Year Fee 50000/-	Deferred till finalization of decision of these product regarding the deregistration from parazalsis, Karachi and submission of the following documents Notarized and valid LOA Embassy attested valid and original FSC in the country of origin. Notarized ISO 13485, FQA, DOC and Credentials. Submit Stability studies
173.	M/s. Maxitech Pharma PVT LTD	Legal Manufacturer:	Mini 4 (Intraocular Lens (IOL)	Deferred till finalization of decision of these product regarding the

Handwritten signature and date: 18/08/2023

	Address: E-178 SITE area Super Highway Karachi Establishment License #: (ELI-00769))	M/s SIFI .S.P.A Address: via Ercole Patti n.36 Lavinaio=Aci S. Antonia CT 95025 Italy Manufacturing site: Same address	Class: C Code: As per FSC Claimed Shelf life: 4 years Fee 50000/-	deregistration from parazalsis, Karachi and submission of following documents : Noatsrised and valid LOA Embassy attested valid and original FSC in the country of origin. Notarsied ISO 13485, FQA, DOC and Credentials. Submit Stabily studies
174.	M/s. Maxitech Pharma PVT LTD Address: E-178 SITE area Super Highway Karachi Establishment License #: (ELI-00769))	Legal Manufacturer: M/s SIFI . S.P.A Address: via Ercole Patti n.36 Lavinaio=Aci S. Antonia CT 95025 Italy Manufacturing site: Same address	Mini Well (Intraocular Lens (IOL)) Class: C 01) Code: Ass per FSc Claimed Shelf life:4 years Fee 50000/-	Deferred till finalization of decision of these product regarding the deregistration from parazalsis, Karachi and submission of the following documents : Noatsrised and valid LOA Embassy attested valid and original FSC in the country of origin. Notarsied ISO 13485, FQA, DOC and Credentials. Submit Stabily studies
175.	M/s. Maxitech Pharma PVT LTD Address: E-178 SITE area Super Highway Karachi Establishment License #: (ELI-00769))	Legal Manufacturer: M/s SIFI . Address: via Ercole Patti n.36 Lavinaio=Aci S. Antonia CT 95025 Italy Manufacturing site: Same address	Mini 4 Yellow Ready (Intraocular Lens (IOL)) Class: C 01) Code: as per FSC Claimed Shelf life: 4 years Fee 50000/-	Deferred till finalization of decision of these product regarding the deregistration from parazalsis, Karachi and submission of the following documents: Noatsrised and valid LOA Embassy attested valid and original FSC in the country of origin. Notarsied ISO 13485, FQA, DOC and Credentials. Submit Stabily studies
176.	M/s. Maxitech Pharma PVT LTD Address: E-178 SITE area Super Highway Karachi Establishment License (ELI-00769))	Legal Manufacturer: M/s SIFI . Address: via Ercole Patti n.36 Lavinaio=Aci S. Antonia CT 95025 Italy Manufacturing site: Same address	Mini Well Proxa (Intraocular Lens (IOL)) Class: C 01) Code: As per FSc Claimed Shelf life: 4 Years Fee 50000/-	Deferred till finalization of decision of these product regarding the deregistration from parazalsis, Karachi and submission of the following documents: Noatsrised and valid LOA Embassy attested valid and original FSC in the country of origin. Notarsied ISO 13485, FQA, DOC and Credentials. Submit Stabily studies
177.	M/s. Maxitech Pharma PVT LTD Address: E-178 SITE area Super	Legal Manufacturer: M/s SIFI . . S.P.A Address: via Ercole	Evolux Intraocular Lens Class: C	Deferred till finalization of decision of these product regarding the deregistration from parazalsis, Karachi and submission of the following documents:

	Highway Karachi Establishment License #: (ELI-00769)	Patti n.36 Lavinaio=Aci S. Antonia CT 95025 Italy Manufacturing site: Same address	Code: As per FSc Claimed Shelf life: 4 years Fee 50000/-	Noatsrised and valid LOA Embassy attested valid and original FSC in the country of origin. Notarsied ISO 13485, FQA, DOC and Credentials. Submit Stabily studies
178.	AJ International Company Suite # 313, 3rd Floor, Mashriq Center, Gulshan-e-Iqbal Block 14, Karachi Pakistan	Evolutis S.A.S Avenue De La Liberation 42720 Briennon France Embassy attested original FSC of France issued on 18 December 2018	FREELINER Cementless Cups with Fixed Liner Class D Fee 50000/-	Deferred for submission of Clarification the brand name required since the applied brand name is not identical with the brand name given in FSC also clarify and justify if applied as a system/family. Submit notarsied and valid LOA , ISO 13485, FQA and DOC. Submit stability studies
179.	AJ International Company Suite # 313, 3rd Floor, Mashriq Center, Gulshan-e-Iqbal Block 14, Karachi Pakistan	Evolutis S.A.S Avenue De La Liberation 42720 Briennon France Copy FSC of France issued on July 2019	STEMSYS Code as per FSC Class C Fee 25000/-	Deferred for submission of the following: Since the product is class C. Therefore, submit Diffrential fee of Rs 25000/- and proof of fee of Rs 25000/- already submitted. Embassy attesdted original and valid FSC in the country of origin. Notarsied and valid LOA, ISO 13485, FQA and DOC. Submit stability studies
180.	AJ international Company Mashriq Center, Suite 313, 3rd floor, Gulshan-e-iqbal block 14, Karachi ELI-00288 840-C	Evolutis S.A.S Avenue De La Liberation 42720 Briennon France Copy FSC of France issued on July 2019	Unic F02-42-DM Description UNIC Reverse Shoulder F02-42-DM Description UNIC Anatomic Shoulder F02-35-reference IUD- UNIC Anatoimic Shoulder Iud-Unic Reverse Shoulder Description Class C Fee 50000/-	Deferred for submissionof the following: Clarify the brand name required since the applied brand name is not identical with the brand name given in FSC also clarify and justify if applied as a system/family. Submit Form 7A and notarsied and valid LOA, ISO 13485, FQA and DOC. Submit stability studies
181.	AJ international Company Mashriq Center, Suite 313, 3rd floor, Gulshan-e-iqbal block 14, Karachi ELI-00288 718-C	Evolutis S.A.S Avenue De La Liberation 42720 Briennon France Copy FSC of France issued on July 2019	Prius F02-42-DM Description Cementless Stem-prius Class C Fee 50000/- <i>14/10/2023</i>	Deferred for submissionof the following: Clarify the brand name required since the applied brand name is not identical with the brand name given in FSC also clarify and justify if applied as a system/family. Submit Form 7A and notarsied and valid LOA, ISO 13485, FQA and DOC. Submit stability studies

182.	M/s Safeway Systems Pakistan, Flat No. 4, 2nd Floor, Amna Shopping Centre, Misrial Road, Rawalpindi. (ELI-00308) Evaluator: AD-IV [2739-P]	Legal Manufacturer: M/s CPT Sutures Co., LTD, 83 Hai Ba Trung, Ben Nghe Ward, District 1, Ho Chi Minh City, 700000, Vietnam FSC Vietnam issuance 25-09-2020 valid for 3 years (Original)	Carepace Temporary Cardiac Pacing Lead (Wire) Class-D Shelf life: 5 years Codes & Sizes:	Deferred with final opportunity for the provision of FSC of any reference country or CE marked document.
183.	The Aesthetic Alliance, H# 418, Col. Sher Khan Shaheed Road, F-11/3, Islamabad. (ELI: 00811) Evaluator AD-II [2814-P]	Legal Manufacturer: M/s Genoss Co., Ltd, 1F, Gyeonggi R&DB Center 226, GSaBC, 105 Gwanggyo-ro, Yeongtong-gu, Suwon-si, Gyeonggi-do, 443-270, Korea FSC: Korea Date of Issue: 18-10-2021	MONALISA Lidocaine Filler (Sterile Absorbable Injectable dermal filler) Codes & Sizes: As per FSC Class-D Shelf Life: 2 years	Deferred for provision of following documents: Original and valid Free sale certificate in the country of origin duly attested by Embassy of Pakistan. Original and valid free sale certificate of any RRA as per rule 67 duly attested by embassy of Pakistan. Credentials of manufacturer abroad duly notarized from the country of origin. Provide the Original Agency agreement or letter of authorization from manufacturer (legal) / owner or market authorization holder (MAH) or its authorized distributor, containing name and complete address of manufacturer, product or category of medical device(s) for which sole authorization is given, validity of agreement, duly notarized by the country of origin. Already submitted is scanned copy. Production Quality Management System Certificate (ISO 13485) / GMP Certificate duly notarized by the country of origin. Design examination certificate (if applicable), duly notarized by the country of origin. Full QA certificate or equivalent, duly notarized by the country of origin
184.	The Aesthetic Alliance, H# 418, Col. Sher Khan Shaheed Road, F-11/3, Islamabad. (ELI: 00811) Evaluator AD-II	Legal Manufacturer: M/s Genoss Co., Ltd, 1F, Gyeonggi R&DB Center 226, GSaBC, 105 Gwanggyo-ro, Yeongtong-gu, Suwon-si, Gyeonggi-do, 443-270, Korea	MONALISA Filler (Sterile Absorbable Injectable dermal filler) Codes & Sizes: As per FSC Class-D Shelf Life: 3 years	Deferred for provision of following documents: Original and valid Free sale certificate in the country of origin duly attested by Embassy of Pakistan. 

	[2815-P]	FSC: Korea Date of Issue: 18-10-2021		<p>Original and valid free sale certificate of any RRA as per rule 67 duly attested by embassy of Pakistan.</p> <p>Credentials of manufacturer abroad duly notarized from the country of origin.</p> <p>Provide the Original Agency agreement or letter of authorization from manufacturer (legal) / owner or market authorization holder (MAH) or its authorized distributor, containing name and complete address of manufacturer, product or category of medical device(s) for which sole authorization is given, validity of agreement, duly notarized by the country of origin. Already submitted is scanned copy.</p> <p>Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized by the country of origin.</p> <p>Design examination certificate (if applicable), duly notarized by the country of origin.</p> <p>Full QA certificate or equivalent, duly notarized by the country of origin</p>
185.	Ghazali Brothers, 1 st Floor, Azainab Court, Campbell Street, Karachi	Manufacturer: Scientillence Sdn Bhd, No 65, Persiaran Selangor, Section 15, 40200, Shah Alam, Selangor, Darul Ehsan, Malaysia Embassy attested Malaysia FSC valid till 23.03.2022	IBP Hemodialyzer Class C Codes as per FSC Shelf life 03 years	<p>Deferred for submission of the following:</p> <p>Notarised, valid and original FSC of Malaysia</p> <p>Notarised FQA and or CE marking certificate or FSC of RRA</p> <p>Also submit complete Stability studies</p>
186.	DKT Pakistan (Pvt) Ltd. RJ Building, 4th Floor, Plot No. 37-C, Stadium Lane No. 2, Stadium Commercial Area, Phase V, DHA Karachi (ELI-00515) Evaluator: AD-IV [4300]	Manufacturer: Pregna International Ltd. Plot No. 219, Survey # 168, Dabhel Industrial Co-operative Soc. Ltd. Dabhel Damam (U.T) India 396210 FSC India date of Issue: 09-9-2020	Heer IUCD TCu 380A Plus (Copper T 380 A) Class D Shelf Life: 7 years	<p>The Board did not accede to the firm's request since the firm has not provided proper justification/requirement to import IUCD from India & hence deferred the case.</p> <p><i>Handwritten signature and date: 5/10/2023</i></p>

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.



(BABAR KHAN)
Additional Director (MDMC)/
Secretary MDB