



No.F.4-7/2023-MD (M-58)
Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
Drug Regulatory Authority of Pakistan

Islamabad the 21st June, 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 58th meeting held on 25th May, 2023 and Board deferred these applications being deficient of the information/documents as specified in last column (V) of the Table below:

S#	Name of Importer	Name of Manufacturer	Name of Medical Devices	Decision
I	II	III	IV	V
1.	Gulf Marketing International, Gulf House 10& 11-B/2, Satellite Town Abdullah Jan Masjid Street Near Kali Tanki Said Pur Road, Rawalpindi ELI-00194	Legal Manufacturer: Healgen Scientific Limited Liability Company 3818 Fuqua Street Houston USA Manufacturing Site: Zhejiang Orient Gene Biotech Co., Ltd., 3787, East Yangguang Avenue, Dipu Street Anji 313300 Huzhou Zhejiang, China. Original Legalized Free Sale Certificate (FSC) issued by Belgium dated 14-04-2021.	Diagnostar HBsAg Hepatitis B Surface Antigen Rapid Test (Serum/Plasma) Class: D Shelf-life: 24 months Size/Code: Fee: 50,000/- -dated 07-04-2022.	Deferred for provision of Embassy attested FSC of Belgium or any other reference regulatory authority mentioning the physical manufacture which is located at China.
2.	Gulf Marketing International, Gulf House 10& 11-B/2, Satellite Town Abdullah Jan Masjid Street Near Kali Tanki Said Pur Road, Rawalpindi ELI-00194	Legal Manufacturer: Healgen Scientific Limited Liability Company 3818 Fuqua Street Houston USA Manufacturing Site: Zhejiang Orient Gene Biotech Co., Ltd., 3787, East Yangguang Avenue, Dipu Street Anji 313300 Huzhou Zhejiang, China. Original Legalized Free Sale Certificate (FSC) issued by Belgium dated 14-04-2021.	Diagnostar HCV Ab Rapid Test Cassette (Serum/Plasma) Class: D Shelf-life: 24 months Size/Code: Fee: 50,000/- -dated 07-04-2022.	Deferred for provision of Embassy attested FSC of Belgium or any other reference regulatory authority mentioning the physical manufacture which is located at China.

3.	Gulf Marketing International, Gulf House 10& 11-B/2, Satellite Town Abdullah Jan Masjid Street Near Kali Tanki Said Pur Road, Rawalpindi ELI-00194	Legal Manufacturer: Healgen Scientific Limited Liability Company 3818 Fuqua Street Houston USA Manufacturing Site: Zhejiang Orient Gene Biotech Co., Ltd., 3787, East Yangguang Avenue, Dipu Street Anji 313300 Huzhou Zhejiang, China. Original Legalized Free Sale Certificate (FSC) issued by Belgium dated 14-04-2021.	Diagnostar HIV (Human Immunodeficiency Virus) Rapid Test Cassette (Serum /Plasma) Class: D Shelf-life: 24 months Size/Code: Fee: 50,000/-dated 07-04-2022.	Deferred for provision of Embassy attested FSC of Belgium or any other reference regulatory authority mentioning the physical manufacture which is located at China.
4.	Gulf Marketing International, Gulf House 10& 11-B/2, Satellite Town Abdullah Jan Masjid Street Near Kali Tanki Said Pur Road, Rawalpindi ELI-00194	Legal Manufacturer: Healgen Scientific Limited Liability Company 3818 Fuqua Street Houston USA Manufacturing Site: Zhejiang Orient Gene Biotech Co., Ltd., 3787, East Yangguang Avenue, Dipu Street Anji 313300 Huzhou Zhejiang, China. Original Legalized Free Sale Certificate (FSC) issued by Belgium dated 14-04-2021.	Diagnostar Syphilis Ab Rapid Test (Cassette) (Serum /Plasma) Class: C Shelf-life: 24 months Size/Code: Fee: 50,000/-dated 07-04-2022.	Deferred for provision of Embassy attested FSC of Belgium or any other reference regulatory authority mentioning the physical manufacture which is located at China.
5.	Gulf Marketing International, Gulf House 10& 11-B/2, Satellite Town Abdullah Jan Masjid Street Near Kali Tanki Said Pur Road, Rawalpindi ELI-00194	Legal Manufacturer: Healgen Scientific Limited Liability Company 3818 Fuqua Street Houston USA Manufacturing Site: Zhejiang Orient Gene Biotech Co., Ltd., 3787, East Yangguang Avenue, Dipu Street Anji 313300 Huzhou Zhejiang, China. Original Legalized Free Sale Certificate (FSC) issued by Belgium dated 14-04-2021.	Diagnostar Toxoplasma gondii(Toxo)IgG/IgM Rapid Test (Cassette) (Serum/Plasma) Class: C Shelf-life: 24 months Size/Code: Fee: 50,000/-dated 07-04-2022.	Deferred for provision of Embassy attested FSC of Belgium or any other reference regulatory authority mentioning the physical manufacture which is located at China.
6.	Gulf Marketing International, Gulf House 10& 11-B/2, Satellite Town Abdullah Jan Masjid	Legal Manufacturer: Healgen Scientific Limited Liability Company 3818 Fuqua Street Houston USA	Diagnostar Typhoid IgG/IgM Rapid Test Cassette (Serum/Plasma)	Deferred for provision of Embassy attested FSC of Belgium or any other reference regulatory authority mentioning the physical manufacture which is located at

	Street Near Kali Tanki Said Pur Road, Rawalpindi ELI-00194	Manufacturing Site: Zhejiang Orient Gene Biotech Co., Ltd., 3787, East Yangguang Avenue, Dipu Street Anji 313300 Huzhou Zhejiang, China. Original Legalized Free Sale Certificate (FSC) issued by Belgium dated 14-04-2021.	Class: B Shelf-life: 24 months Size/Code: GCTYP-302a, GCTB-302a Fee: 25,000/-dated 01-03-2022.	China.
7.	Gulf Marketing International, Gulf House 10& 11-B/2, Satellite Town Abdullah Jan Masjid Street Near Kali Tanki Said Pur Road, Rawalpindi ELI-00194	Legal Manufacturer: Healgen Scientific Limited Liability Company 3818 Fuqua Street Houston USA Manufacturing Site: Zhejiang Orient Gene Biotech Co., Ltd., 3787, East Yangguang Avenue, Dipu Street Anji 313300 Huzhou Zhejiang, China. Original Legalized Free Sale Certificate (FSC) issued by Belgium dated 14-04-2021.	Diagnostar Urinalysis Strips Class: B Shelf-life: 24 months Size/Code: Fee: 25,000/-dated 07-04-2022.	Deferred for provision of Embassy attested FSC of Belgium or any other reference regulatory authority mentioning the physical manufacture which is located at China.
8.	Gulf Marketing International, Gulf House 10& 11-B/2, Satellite Town Abdullah Jan Masjid Street Near Kali Tanki Said Pur Road, Rawalpindi ELI-00194	Legal Manufacturer: Healgen Scientific Limited Liability Company 3818 Fuqua Street Houston USA Manufacturing Site: Zhejiang Orient Gene Biotech Co., Ltd., 3787, East Yangguang Avenue, Dipu Street Anji 313300 Huzhou Zhejiang, China. Original Legalized Free Sale Certificate (FSC) issued by Belgium dated 14-04-2021.	Diagnostar HCG One Test Pregnancy Test Strip (urine) Class: B Shelf-life: 24 months Size/Code: Fee: 25,000/-dated 07-04-2022.	Deferred for provision of Embassy attested FSC of Belgium or any other reference regulatory authority mentioning the physical manufacture which is located at China.
9.	Gulf Marketing International, Gulf House 10& 11-B/2, Satellite Town Abdullah Jan Masjid Street Near Kali Tanki Said Pur	Legal Manufacturer: Healgen Scientific Limited Liability Company 3818 Fuqua Street Houston USA Manufacturing Site: Zhejiang Orient Gene	Diagnostar Dengue NS1 Antigen Rapid Test (Whole blood, serum, plasma) Malaria P.f./Pan Ag Rapid Test Cassette (Whole blood) Class: B	Deferred for provision of Embassy attested FSC of Belgium or any other reference regulatory authority mentioning the physical manufacture which is located at China.

	Road, Rawalpindi ELI-00194	Biotech Co., Ltd.,3787, East Yangguang Avenue, Dipu Street Anji 313300 Huzhou Zhejiang, China. Original Legalized Free Sale Certificate (FSC) issued by Belgium dated 14-04-2021.	Shelf-life: 24 months Size/Code: Fee: 25,000/-dated 07-04- 2022.	
10.	Gulf Marketing International, Gulf House 10& 11-B/2, Satellite Town Abdullah Jan Masjid Street Near Kali Tanki Said Pur Road, Rawalpindi ELI-00194	Legal Manufacturer: Healgen Scientific Limited Liability Company 3818 Fuqua Street Houston USA Manufacturing Site: Zhejiang Orient Gene Biotech Co., Ltd.,3787, East Yangguang Avenue, Dipu Street Anji 313300 Huzhou Zhejiang, China. Original Legalized Free Sale Certificate (FSC) issued by Belgium dated 14-04-2021.	Diagnostar H.pylori Ab Rapid Test Cassette (Whole blood, serum , plasma) Class: B Shelf-life: 24 months Size/Code: Fee: 25,000/-dated 07-04- 2022.	Deferred for provision of Embassy attested FSC of Belgium or any other reference regulatory authority mentioning the physical manufacture which is located at China.
11.	Gulf Marketing International, Gulf House 10& 11-B/2, Satellite Town Abdullah Jan Masjid Street Near Kali Tanki Said Pur Road, Rawalpindi ELI-00194	Legal Manufacturer: Healgen Scientific Limited Liability Company 3818 Fuqua Street Houston USA Manufacturing Site: Zhejiang Orient Gene Biotech Co., Ltd.,3787, East Yangguang Avenue, Dipu Street Anji 313300 Huzhou Zhejiang, China. Original Legalized Free Sale Certificate (FSC) issued by Belgium dated 14-04-2021.	Diagnostar Tuberculosis IgG/IgM Rapid Test Cassete Class: B Shelf-life: 24 months Size/Code: Fee: 25,000/-dated 07-04- 2022.	Deferred for provision of Embassy attested FSC of Belgium or any other reference regulatory authority mentioning the physical manufacture which is located at China.
12.	M/s RHS International 1st Floor of Building S60- R34 Mozang Road Opp, Total Petrol Pump, Lahore Warehouse	Legal Manufacturer: Jiangsu Pedo-Care Medical Equipment Co., Ltd NANMO Industrial Town Haian, Jiangsu China FSC: China validity	Certeza (Air Nebulizer) Compressor Class-B Shelf life: Model: JK-15	Deferred for the provision of following documents: Valid LOA, FSC, ISO 13485 and CE certificates. 

	Address 2nd Floor of Building, S60-R34 Mozang Road, Opp., Total Petrol Pump, Lahore ELI: 00354 1148-P 03-02-2020 Court case	03-12-2021	JK-16	
13.	Shams Scientific Traders, 22-Y-J Madina Town, Faisalabad ELI: 00459 2663-P 24-08-2021	Legal Manufacturer: Healgen Scientific LLC, 3818 Fuqua Street, Houston, TX 77047, USA. Manufacturing site: M/s Zhejiang Orient Gene Biotech Co., Ltd., 3787, east Yangguang Avenue, Dipu street Anji 313300 Huzhou, Zhejiang, China FSC: Belgium, (10006614-04-21) issued on 14/04/2021.	Healgen One Step Pregnancy Test Strip (Urine) Class-B Shelf Life: 24 Months Model: GAHCG-101a	Deferred for the provision of FSC of Belgium mentioning the site involved in manufacturing i.e China or any other FSC of reference country mentioning the site of China. Apply separately for test cassettes.
14.	Shams Scientific Traders, 22-Y-J Madina Town, Faisalabad ELI: 00459 2662-P 24-08-2021	Legal Manufacturer: Healgen Scientific LLC, 3818 Fuqua Street, Houston, TX 77047, USA FSC: Belgium Date of Issue: 14.04.2021	Healgen H. Pylori Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) Class-B Shelf Life: 24 Months Code: GCHP-402a	Deferred for the provision of FSC of Belgium mentioning the site involved in manufacturing i.e China or any other FSC of reference country mentioning the site of China. The firm may also provide any evidence of the China site involved in manufacturing. Apply separately for H. Pylori Ag rapid test cassettes.
15.	Shams Scientific Traders, 22-Y-J Madina Town, Faisalabad ELI: 00459 2661-P 24-08-2021	Legal Manufacturer: Healgen Scientific LLC, 3818 Fuqua Street, Houston, TX 77047, USA FSC: Belgium Date of Issue: 14.04.2021	Healgen One Step Multi-Drug Screen Test Dip Card (Urine) Class-B Shelf Life: 24 months Codes & Sizes: As per FSC	Deferred for the provision of FSC of Belgium mentioning the site involved in manufacturing i.e China or any other FSC of reference country mentioning the site of China. The firm may also provide any evidence of the China site involved in manufacturing. Labels for applied codes. Apply separately for Cassette.
16.	M/s ZH Traders, 1st floor House NO. 16, Street	Legal Manufacturer: Zhejiang Kindly Medical Devices Co., Ltd, No. 758, 5th Binhai Road,	CL (Blood-Collecting Needles)	Deferred for the provision of following documents: Valid LOA and FSC.

	No.03, Sharif Park, Begumpura, Lahore ELI: 00763 3183-P 24-01-2022	Binhai Industrial Park, Longwan district 325025 Wenzhou Zhejiang China FSC China validity 30-05-2022	Class-B Shelf Life: 5 years Codes & Sizes: As per FSC	
17.	Vertex Medical (Pvt) Ltd, 70-B-1, Gulberg III, Lahore. ELI: 00150 3257-P 21-06-2022	<u>Legal Manufacturer:</u> LivaNova USA, Inc. 100 Cyberonics Boulevard, Houston, TX-77058 USA Original FSC: U.S.A Valid till: 13/11/2021	VNS Therapy ® (VNS Therapy Accessory Pack) ® Class-D Shelf Life: 4 years Model: 502	Deferred for the provision of following documents: Original, valid and attested FSC of US FDA. Valid ISO 13485 certificate.
18.	Vertex Medical (Pvt) Ltd, 70-B-1, Gulberg III, Lahore. ELI: 00150 3252-P 21-06-2022	<u>Legal Manufacturer:</u> LivaNova USA, Inc. 100 Cyberonics Boulevard, Houston, TX-77058 USA Original FSC: U.S.A Valid till: 13/11/2021	VNS Therapy ® (PerenniaDURA) Class-D Shelf Life: 4 years Model: VNS Therapy ® PerenniaDURA 303 Lead	Deferred for the provision of following documents: Original, valid and attested FSC of US FDA. Valid ISO 13485 certificate.
19.	Vertex Medical (Pvt) Ltd, 70-B-1, Gulberg III, Lahore. ELI: 00150 3251-P 21-06-2022	<u>Legal Manufacturer:</u> LivaNova USA, Inc. 100 Cyberonics Boulevard, Houston, TX-77058 USA Original FSC: U.S.A Valid till: 13/11/2021	VNS Therapy ® (VNS Therapy ® AspireSR) ® Class-D Shelf Life: 2 years Model: 106 Generator	Deferred for the provision of following documents: Original, valid and attested FSC of US FDA. Valid ISO 13485 certificate.
20.	Vertex Medical (Pvt) Ltd, 70-B-1, Gulberg III, Lahore. ELI: 00150 3250-P 21-06-2022	<u>Legal Manufacturer:</u> LivaNova USA, Inc. 100 Cyberonics Boulevard, Houston, TX-77058 USA Original FSC: U.S.A Valid till: 13/11/2021	VNS Therapy ® (VNS Therapy ® Cyberonics 220) ® Class-D Shelf Life: 3 years Model: Cyberonics 220 Patients Magnets	Deferred for the provision of following documents: Original, valid and attested FSC of US FDA. Valid ISO 13485 certificate.
21.	Vertex Medical (Pvt) Ltd, 70-B-1, Gulberg III, Lahore. ELI: 00150 3249-P 21-06-2022	<u>Legal Manufacturer:</u> LivaNova USA, Inc. 100 Cyberonics Boulevard, Houston, TX-77058 USA Original FSC: U.S.A Valid till: 13/11/2021	VNS Therapy ® (PerenniaFlex ®) Class-D Shelf Life: 3 years Model: PerenniaFlex 304 Lead	Deferred for the provision of following documents: Original, valid and attested FSC of US FDA. Valid ISO 13485 certificate.

	<p>M/s Shafia Enterprises, Shafia Enterprises 2nd Floor, Nigar Centre, Patiala Ground Link Meleod Road, Lahore</p> <p>ELI:00766 2836-P 23-09-2021</p>	<p>Legal Manufacturer: M/s Haiyan Kangyuan Medical Instrument Co., Ltd, Songpodong Road, Shendang, Haiyan Zhejiang China 314311</p> <p>FSC: China</p> <p>Validity 05-02-2022</p>	<p>Endotracheal Tube (Endotracheal Tube Cuffed)</p> <p>Class-B</p> <p>Shelf Life: 7 years</p> <p>Sizes: 2.0mm, 2.5mm, 3.0mm, 3.5mm, 4.0mm, 4.5mm, 5.0mm, 5.5mm, 6.0mm, 6.5mm, 7.0mm, 7.5mm, 8.0mm, 8.5mm, 9.0mm, 9.5mm, 10.0mm</p>	<p>Deferred for the provision of following documents.</p> <p>Brand name of the device.</p> <p>Original, valid and attested FSC of China.</p> <p>Justifiable shelf life studies for the claimed shelf life of 7 years.</p> <p>The product is from non-reference country therefore Provide valid and attested FSC of any SRA country.</p> <p>Valid and notarized ISO 13485 Certificate and FQA certificate.</p> <p>Valid and notarized Authorization letter and Credential.</p> <p>MRP of the device.</p>
23.	<p>M/s Shafia Enterprises, Shafia Enterprises 2nd Floor, Nigar Centre, Patiala Ground Link Meleod Road, Lahore</p> <p>ELI:00766 2835-P 23-09-2021</p>	<p>Legal Manufacturer: M/s Haiyan Kangyuan Medical Instrument Co., Ltd, Songpodong Road, Shendang, Haiyan Zhejiang China 314311</p> <p>FSC: China</p> <p>Validity 05-02-2022</p>	<p>Endotracheal Tube (Endotracheal Tube UnCuffed)</p> <p>Class-B</p> <p>Shelf Life: 7 years</p> <p>Sizes: 2.0mm, 2.5mm, 3.0mm, 3.5mm, 4.0mm, 4.5mm, 5.0mm, 5.5mm, 6.0mm, 6.5mm, 7.0mm, 7.5mm, 8.0mm, 8.5mm, 9.0mm, 9.5mm, 10.0mm</p>	<p>Deferred for the provision of following documents.</p> <p>Brand name of the device.</p> <p>Original, valid and attested FSC of China.</p> <p>Justifiable shelf life studies for the claimed shelf life of 7 years.</p> <p>The product is from non-reference country therefore Provide valid and attested FSC of any SRA country.</p> <p>Valid and notarized ISO 13485 Certificate and FQA certificate.</p> <p>Valid and notarized Authorization letter and Credential.</p> <p>MRP of the device.</p>
24.	<p>M/s Shafia Enterprises, Shafia Enterprises 2nd Floor, Nigar Centre, Patiala Ground Link Meleod Road, Lahore</p> <p>ELI:00766 2835-P 16-06-2022</p>	<p>Legal Manufacturer: M/s Arrow for Medical Necessities Part No. 59, 60, 62, 63 Industrial Zone of ArabEI Awamer Abnub, Asyut Egypt</p> <p>Original FSC: Egypt Date of Issue: 22/12/2021 valid till 26-05-2024</p>	<p>Arrow Sterile hypodermic syringes for single use only</p> <p>Class-B</p> <p>Shelf Life: 8 years</p> <p>Sizes: 0.5ml, 1ml, 10ml</p>	<p>Deferred for the provision of following:</p> <p>Three different types of syringes are applied in single application, apply in separate application for safety syringe and insulin syringe. Also submit the revised covering letter as the product mention is auto-disable syringe whereas on Form-7A it is hypodermic syringes.</p> <p>Validity is not mentioned on the agency agreement.</p> <p>justifiable stability studies for the</p>

				<p>claimed shelf life of 8 years.</p> <p>Essential Principle checklist for the applied product.</p> <p>updated ISO 13485 certificate.</p> <p>MRP of the device.</p>
25.	<p>M/s Shafia Enterprises, Shafia Enterprises 2nd Floor, Nigar Centre, Patiala Ground Link Meleod Road, Lahore</p> <p>ELI:00766 3814-P 16-06-2022</p>	<p><u>Legal Manufacturer:</u> M/s Ningbo Yingmed Medical Instrument Co., Ltd, Southern Business Zone, Yinzhou district Ningbo, China</p> <p>Original FSC: China Date of issue: 10/03/2020</p>	<p>Latex Surgical Gloves (Surgical Gloves, Powdered)</p> <p>Class-B</p> <p>Shelf Life: 8 years</p> <p>Sizes: 6, 6.5, 7, 7.5, 8, 8.5, 9</p>	<p>Deferred for the provision of following:</p> <p>Brand name of the device.</p> <p>Stability studies for the claimed shelf life.</p> <p>valid FSC of China, duly attested.</p> <p>Original and Embassy attested FSC of UK MHRA.</p> <p>Valid and notarized Authorization letter and Credential.</p> <p>Apply separately for Powdered free surgical gloves.</p>
26.	<p>Med-El, 63/3A, Block D-1, Gulberg III, Sir Sayed Road Opp. Hijaz Hospital, Lahore</p> <p>ELI-00597 831-C 16-12-2022</p>	<p><u>Legal Manufacturer:</u> Med-El Elerktromedizinische Gerate Gmbh Furstenweg 77a 6020 Innsbruck Austria.</p> <p>FSC Austria 26-05-2024</p>	<p>Med-El Synchrony 2 (Cochlear implant)</p> <p>Class-D</p> <p>Shelf life: 5 years</p> <p>Codes as per FSC</p>	<p>Deferred for the provision of following:</p> <p>Credentials of manufacturer abroad.</p> <p>Manufacturing and QC tests in details.</p> <p>Shelf life studies for the claimed shelf life.</p> <p>Original, valid and notarized agency agreement.</p> <p>FSC provided is copy, provide original and attested FSC.</p> <p>Product detail.</p> <p>Labels of applied product (all codes).</p> <p>MRP of the device.</p> <p>grouping of applied product.</p> <p>Essential principle checklist.</p>

	Med-El, 63/3A, Block D-1, Gulberg III, Sir Sayed Road Opp. Hijaz Hospital, Lahore ELI-00597 832-C 16-12-2022	Legal Manufacturer: Med-El Elektronmedizinsche Geräte GmbH Furstenweg 77a 6020 Innsbruck Austria. FSC Austria 26-05-2024	Med-El Concerto 2 Pin (Cochlear Implant) Class-D Shelf life: not mentioned Codes as per FSC	Deferred for the provision of following: Credentials of manufacturer abroad. Manufacturing and QC tests in details. Shelf life studies for the claimed shelf life. Original, valid and notarized agency agreement. FSC provided is copy, provide original and attested FSC. Product detail. Labels of applied product (all codes). MRP of the device. grouping of applied product. Essential principle checklist.
28.	Med-El, 63/3A, Block D-1, Gulberg III, Sir Sayed Road Opp. Hijaz Hospital, Lahore ELI-00597 833-C 16-12-2022	Legal Manufacturer: Med-El Elektronmedizinsche Geräte GmbH Furstenweg 77a 6020 Innsbruck Austria. FSC Austria 25-04-2024	Med-El Synchrony 2 Pin (Cochlear Implant) Class-D Shelf life: not mentioned Codes as per FSC	Deferred for the provision of following: Credentials of manufacturer abroad. Manufacturing and QC tests in details. Shelf life studies for the claimed shelf life. Original, valid and notarized agency agreement. FSC provided is copy, provide original and attested FSC. Product detail. Labels of applied product (all codes). MRP of the device. grouping of applied product. Essential principle checklist.
29.	Med-El, 63/3A, Block D-1, Gulberg III, Sir Sayed Road Opp. Hijaz Hospital,	Legal Manufacturer: Med-El Elektronmedizinsche Geräte GmbH Furstenweg 77a 6020 Innsbruck Austria.	Med-El Sonnet Audio Processor (Audio Processor) Class-D	Deferred for the provision of following: Credentials of manufacturer abroad. Manufacturing and QC tests in

	Lahore ELI-00597 834-C 16-12-2022	FSC Austria 26-05-2024	Shelf life: not mentioned Codes as per FSC	details. Shelf life studies for the claimed shelf life. Original, valid and notarized agency agreement. FSC provided is copy, provide original and attested FSC. Product detail. Labels of applied product (all codes). MRP of the device. grouping of applied product. Essential principle checklist.
30.	Med-El, 63/3A, Block D-1, Gulberg III, Sir Sayad Road Opp. Hijaz Hospital, Lahore ELI-00597 835-C 16-12-2022	<u>Legal Manufacturer:</u> Med-El Elektronmedizinische Geräte GmbH Furstenweg 77a 6020 Innsbruck Austria. FSC Austria 25-04-2024	Med-El Sonata 2 (Cochlear Implant) Class-D Shelf life: not mentioned Codes as per FSC	Deferred for the provision of following: Credentials of manufacturer abroad. Manufacturing and QC tests in details. Shelf life studies for the claimed shelf life. Original, valid and notarized agency agreement. FSC provided is copy, provide original and attested FSC. Product detail. Labels of applied product (all codes). MRP of the device. grouping of applied product. Essential principle checklist
31.	Med-El, 63/3A, Block D-1, Gulberg III, Sir Sayad Road Opp. Hijaz Hospital, Lahore ELI-00597 836-C	<u>Legal Manufacturer:</u> Med-El Elektronmedizinische Geräte GmbH Furstenweg 77a 6020 Innsbruck Austria. FSC Austria 26-05-2024	Med-El Rondo 2 Audio Processor (Audio Processor) Class-D Shelf life: not mentioned Codes as per FSC	Deferred for the provision of following: Credentials of manufacturer abroad. Manufacturing and QC tests in details. Shelf life studies for the claimed shelf life.

	16-12-2022			<p>Original, valid and notarized agency agreement.</p> <p>FSC provided is copy, provide original and attested FSC.</p> <p>Product detail.</p> <p>Labels of applied product (all codes).</p> <p>MRP of the device.</p> <p>grouping of applied product.</p> <p>Essential principle checklist.</p>
32.	<p>Shams Scientific Traders, 22-Y-J Madina Town, Faisalabad</p> <p>ELI: 00459 2664-P 24-08-2021</p>	<p>Legal Manufacturer: Healgen Scientific LLC, 3818 Fuqua Street, Houston, TX 77047, USA</p> <p>FSC: Belgium Date of Issue: 14.04.2021</p>	<p>Healgen Urinalysis Strips</p> <p>Class-B</p> <p>Shelf Life: 24 months</p> <p>Codes: URS-3, URS-4, URS-8, URS-10, URS-11</p>	<p>Deferred for the provision of FSC of Belgium mentioning the site involved in manufacturing i.e China or any other FSC of reference country mentioning the site of China. The firm may also provide any evidence of the China site involved in manufacturing.</p> <p>The subject device is not mentioned in FSC of Belgium.</p>
33.	<p>Medical Equipment & System, 60/61, F.C.C Syed Maratab Ali Road, Gulberg-IV, Lahore</p> <p>ELI: 00554 2955-P 25-02-2022</p>	<p>Legal Manufacturer: Atom Medical Corporation 18-15, Hongo-3-chome, Bunkyo-ku, Tokyo, 113-0033, Japan</p> <p>FSC: Japan Date of Issue: 29.03.2019</p>	<p>Sunflower warmer (Radiant Warmer)</p> <p>Class-C</p> <p>Shelf Life/ service life: Not provided</p> <p>Codes: list provided</p>	<p>Deferred for provision of following:</p> <p>Original, updated and notarized Letter of Authorization mentioning complete name and address of the applicant and the applied product.</p> <p>MRP of the product since it is not mentioned in Form 7A.</p> <p>Original, legalized Free Sale Certificate. Copy is submitted.</p> <p>Notarized and valid ISO 13485 certificate and Full Quality Assurance Certificate.</p> <p>Shelf life or service life of the applied product along with the supporting data.</p>
34.	<p>Medical Equipment & System, 60/61, F.C.C Syed Maratab Ali Road, Gulberg-IV, Lahore</p> <p>ELI: 00554 2936-P 10-02-2022</p>	<p>Legal Manufacturer: Zoll Medical Corporation Chelmsford, Massachusetts, USA, 269 Mill Rd # 269, Chelmsford, MA 01824</p> <p>FSC: U.S.A Valid till: 06.07.2023</p>	<p>ZOLL AED Plus Semi-Automatic Defibrillator (Defibrillator)</p> <p>Class-C</p> <p>Shelf Life: 10 years</p> <p>Codes are not provided</p>	<p>Deferred for provision of all the legal documents.</p>

35.	<p>Medical Equipment & System, 60/61, F.C.C Syed Maratab Ali Road, Gulberg-IV, Lahore</p> <p>ELI: 00554 2937-P 25-02-2022</p>	<p><u>Legal Manufacturer:</u> Zoll Medical Corporation Chelmsford, Massachusetts, USA, 269 Mill Rd # 269, Chelmsford, MA 01824</p> <p>FSC: U.S.A Valid till: 24-02-2023</p>	<p>Auto Pulse (Resuscitation Model 100) System</p> <p>Class-C</p> <p>Shelf Life: 10 years</p> <p>Codes as per FSC</p>	<p>Deferred for the provision of following:</p> <p>All the legal documents provided are copies, original documents are required.</p> <p>The ISO 13485, FQA certificates and labels provided are mentioning the legal manufacturer as ZOLL Circulation, Inc. 2000 Ringwood Avenue San Jos, CA 95131, USA, whereas on the Form-7A and LOA, the Legal manufacturer mentioned is Zoll Medical Corporation Chelmsford, Massachusetts, USA, 269 Mill Rd # 269, Chelmsford, MA 01824, clarification is required or submit the linkup letter between the two.</p> <p>The Credentials submitted mentioning the Suzhou Zoll medical China, as subsidiary owned by Zoll Medical Corporation Chelmsford, Massachusetts, USA, 269 Mill Rd # 269, Chelmsford, MA 01824, Clarification is required whether the stated firm of China is involved in manufacturing or any other step of manufacturing.</p> <p>Provide updated FSC of US FDA.</p>
36.	<p>Medical Equipment & System, 60/61, F.C.C Syed Maratab Ali Road, Gulberg-IV, Lahore</p> <p>ELI: 00554 2939-P 25-02-2022</p>	<p><u>Legal Manufacturer:</u> Zoll Medical Corporation Chelmsford, Massachusetts, USA, 269 Mill Rd # 269, Chelmsford, MA 01824</p> <p>FSC: U.S.A Valid till: 06.07.2023</p>	<p>ZOLL AED PRO Defibrillator (Defibrillator)</p> <p>Class-C</p> <p>Shelf Life: 10 years</p> <p>Codes & Sizes: As per FSC</p>	<p>Deferred for the provision of following:</p> <p>All the legal documents provided are copies. Submit the original documents.</p> <p>The Credentials submitted mentioning the Suzhou Zoll medical China, as subsidiary owned by Zoll Medical Corporation Chelmsford, Massachusetts, USA, 269 Mill Rd # 269, Chelmsford, MA 01824, Clarification is required whether the stated firm of China is involved in manufacturing or any other step of manufacturing or provide linkup letter between the two.</p>

	<p>Medical Equipment & System, 60/61, F.C.C Syed Maratab Ali Road, Gulberg-IV, Lahore</p> <p>ELI: 00554 2941-P 25-02-2022</p>	<p><u>Legal Manufacturer:</u> Zoll Medical Corporation Chelmsford, Massachusetts, USA, 269 Mill Rd # 269, Chelmsford, MA 01824</p> <p>FSC: U.S.A Valid till: 06.07.2023</p>	<p>ZOLL X SERIES ADVANCED Defibrillator (Defibrillator)</p> <p>Class-C</p> <p>Shelf Life: 10 years</p> <p>Model: X SERIES ADVANCED Defibrillator</p>	<p>Deferred for the provision of following:</p> <p>All the legal documents provided are copies. Submit the original documents.</p> <p>The Credentials submitted mentioning the Suzhou Zoll medical China, as subsidiary owned by Zoll Medical Corporation Chelmsford, Massachusetts, USA, 269 Mill Rd # 269, Chelmsford, MA 01824, Clarification is required whether the stated firm of China is involved in manufacturing or any other step of manufacturing or provide linkup letter between the two.</p> <p>Codes of applied product.</p>
38.	<p>Medical Equipment & System, 60/61, F.C.C Syed Maratab Ali Road, Gulberg-IV, Lahore</p> <p>ELI: 00554 3005-P 19-05-2022</p>	<p><u>Legal Manufacturer:</u> Zoll Medical Corporation Chelmsford, Massachusetts, USA, 269 Mill Rd # 269, Chelmsford, MA 01824</p> <p>FSC: U.S.A Valid till: 06.07.2023</p>	<p>ZOLL 731 Series ® Ventilator (Ventilator)</p> <p>Class- C</p> <p>Shelf Life:10 years</p> <p>Model: EMV+ EMV+MR</p>	<p>Deferred for the provision of following:</p> <p>Notarized Letter of Authorization mentioning complete name and address of the applicant and the applied product.</p> <p>notarized Declaration of Conformity for the applied product.</p> <p>MRP of the product since it is not mentioned in Form 7A.</p> <p>original, legalized and valid Free Sale Certificate.</p> <p>Notarized and valid ISO-13485 and Full Quality Assurance Certificate.</p>
39.	<p>Medical Equipment & System, 60/61, F.C.C Syed Maratab Ali Road, Gulberg-IV, Lahore</p> <p>ELI: 00554 3139-P 04-07-2022</p>	<p><u>Legal Manufacturer:</u> Liebel-Flarsheim Company, LLC 2111 E. Galbraith Rd Cincinnati, OH, 45237, U.S.A</p> <p>Original FSC: U.S.A (Original) Valid till:20/10/2023</p>	<p>Optivantage Dual-Head CT Delivery System (Injector System)</p> <p>Class-C</p> <p>Shelf Life: 7 years</p> <p>Codes & Sizes: As per FSC</p>	<p>Deferred for the provision of following:</p> <p>Provided agency agreement is copy and not between the importer and legal manufacturer i.e Liebel-Flarsheim Company, LLC 2111 E. Galbraith Rd Cincinnati, OH, 45237, U.S.A.</p> <p>Clearly state the model required on this application.</p>

40.	Medical Equipment & System, 60/61, F.C.C Syed Maratab Ali Road, Gulberg-IV, Lahore ELI: 00554 3235-P 04-07-2022	Legal Manufacturer: Liebel-Flarsheim Company, LLC 2111 E. Galbraith Rd Cincinnati, OH, 45237, U.S.A Original FSC: U.S.A (Original) Valid till:20/10/2023	OptiStar Elite Contrast Delivery System (Injector System) Class-C Shelf Life: 7 years Codes as per FSC:	Deferred for the provision of following: Provided agency agreement is copy and not between the importer and legal manufacturer i.e Liebel-Flarsheim Company, LLC 2111 E. Galbraith Rd Cincinnati, OH, 45237, U.S.A. clarification is required.
41.	Mediland Pakistan Pvt Office No. b-09, 2nd Floor Masood Arcade IJP Road near Saidpur Road, Rawalpindi. ELI: 00202 3314-P 18-08-2022	Legal Manufacturer: Medivators Inc. 14605 28th Avenue North Minneapolis, MN 55447 USA FSC: U.S.A Valid Till: 04/03/2023	RAPICIDE PA RTU High-Level Disinfectant and Sterilant test strips (Disinfectant endoscopes) for Class-C Shelf Life: N/A Codes: ML02-0117 ML02-0116 ML02-0115 ML02-0118 (Test strips)	Deferred for the provision of following: Credentials of manufacturer abroad. Agency agreement submitted is copy and expired before the submission of application. FSC of US FDA is copy, original is required. 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. Multiple products applied in single application, PA RTU is considered in this application. Apply in separate applications for the rest of the types (PA RTU Test strips, Rapicide OPA disinfectant, OPA test strips and other types etc.
42.	Mediland Pakistan Pvt Office No. b-09, 2nd Floor Masood Arcade IJP Road near Saidpur Road, Rawalpindi. ELI: 00202	Legal Manufacturer: Maquet Cardiopulmonary GmbH Kehler Str. 31 76437 Rastatt Germany FSC: Germany issuance: 12/17/2021	Pulsion PICCO with Optional CEVOX Accessories (advance hemodynamic monitor) Class-C Shelf life: N/A	Deferred for the provision of following: 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 Geringe Group middle

	<p>3110-P 29-06-2022</p>		<p>Codes & Sizes: As per FSC</p>	<p>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 and missing the applied device. Also in the FSC of Sweden submitted, the manufacturer for the product is mentioning that it is the US based manufacturer. Clarification is required regarding the multiple parties involved in.</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>Shelf life and shelf life studies.</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.</p> <p>Justify the grouping of applied product with accessories.</p> <p>Labels of applied product mentioning the reference number approved in the country of origin.</p>
43.	<p>Mediland Pakistan Pvt Office No. b-09, 2nd Floor Masood Arcade IJP Road near Saidpur Road, Rawalpindi.</p> <p>ELI: 00202 3099-P 29-06-2022</p>	<p><u>Legal Manufacturer:</u> Maquet Cardiopulmonary GmbH Kehler Str. 31 76437 Rastatt Germany</p> <p>FSC: Germany issuance: 12/17/2021</p>	<p>HLS Set Advanced (Heart Lung Support Set)</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:</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</p>

				<p>and any site or branch involved in the manufacturing of the product.</p> <p>FSC of Germany provided is copy, submit original and attested FSC.</p> <p>Provide Credentials of manufacturer abroad (Maquet Cardiopulmonary GmbH Kehler Str. 31 76437 Rastatt Germany).</p> <p>Valid and notarized ISO 13485 is missing.</p> <p>Provide Manufacturing and QC processes in detail.</p> <p>Provide Shelf life/ Service life and shelf life studies.</p> <p>Provide Essential principle checklist of applied device.</p> <p>Labels of applied product mentioning the reference number approved in the country of origin.</p>
44.	<p>Mediland Pakistan Pvt Office No. b-09, 2nd Floor Masood Arcade IJP Road near Saidpur Road, Rawalpindi.</p> <p>ELI: 00202 3079-P 29-06-2022</p>	<p><u>Legal Manufacturer:</u> Maquet Cardiopulmonary GmbH Kehler Str. 31 76437 Rastatt Germany</p> <p>FSC: Germany issuance: 12/17/2021</p>	<p>AVALON Elite Bi-Caval Dual Lumen Catheter (Dual Lumen Catheter)</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:</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 Germany provided is copy, submit original and attested FSC.</p> <p>Provide Credentials of manufacturer abroad (Maquet Cardiopulmonary GmbH Kehler Str. 31 76437 Rastatt Germany).</p> <p>Valid and notarized ISO 13485 is missing.</p> <p>Provide Manufacturing and QC</p>

				<p>processes in detail.</p> <p>Provide Shelf life/ Service life and shelf life studies.</p> <p>Provide Essential principle checklist of applied device.</p> <p>Labels of applied product mentioning the reference number approved in the country of origin.</p>
45.	<p>Mediland Pakistan Pvt Office No. b-09, 2nd Floor Masood Arcade IJP Road near Saidpur Road, Rawalpindi.</p> <p>ELI: 00202 3076-P 29-06-2022</p>	<p><u>Legal Manufacturer:</u> Maquet Cardiopulmonary GmbH Kehler Str. 31 76437 Rastatt Germany</p> <p>FSC: Germany issuance: 12/17/2021</p>	<p>PICCO Catheter (PICCO Catheter)</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:</p> <p>Brand name of the device as the LOA mentioning the Brand Pulsion. Clarification is required. 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 Germany provided is copy and missing the applied device. Also in the FSC of Sweden submitted, the manufacturer for the product is mentioning that it is the US based manufacturer. Clarification is required regarding the multiple parties involved in.</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>Shelf life and shelf life studies.</p> <p>Essential principle checklist of applied device.</p> <p>Declaration of Conformity to be</p>

				<p>printed on manufacturer's letter head duly filled and signed by responsible person.</p> <p>Justify the grouping of applied product with accessories.</p> <p>Labels of applied product mentioning the reference number approved in the country of origin.</p>
46.	<p>Mediland Pakistan Pvt Office No. b-09, 2nd Floor Masood Arcade IJP Road near Saidpur Road, Rawalpindi.</p> <p>ELI: 00202 3075-P 29-06-2022</p>	<p><u>Legal Manufacturer:</u> Maquet Cardiopulmonary GmbH Kehler Str. 31 76437 Rastatt Germany</p> <p>FSC: Germany issuance: 12/17/2021</p>	<p>Beating Heart Family (Beating Heart Family)</p> <p>Class-C</p> <p>Shelf Life: not provided</p>	<p>Deferred for the provision of following:</p> <p>Brand name of the device as the Broachers provided showing the multiple Brand names, give your priority in this application and apply separately for other brand names.</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 Germany provided is copy and missing the applied device. Also in the FSC of Sweden submitted, the manufacturer for the product is mentioning that it is the US based manufacturer and the device is also not mentioned. Clarification is required regarding the multiple parties involved in.</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>Shelf life and shelf life studies.</p>

				<p>Essential principle checklist of applied device.</p> <p>Declaration of Conformity provided is showing the Legal manufacturer Maquet Cardiopulmonary, LLC USA whereas the Maquet Cardiopulmonary GmbH Kehler Str. 31 76437 Rastatt Germany as authorized representative in Europe, clarification is required. Labels of applied product mentioning the reference number approved in the country of origin.</p>
47.	<p>Mediland Pakistan Pvt Office No. b-09, 2nd Floor Masood Arcade IJP Road near Saidpur Road, Rawalpindi.</p> <p>ELI: 00202 3108-P 29-06-2022</p>	<p><u>Legal Manufacturer:</u> Maquet Cardiopulmonary GmbH Kehler Str. 31 76437 Rastatt Germany</p> <p>FSC: Germany issuance: 12/17/2021</p>	<p>Maquet HLS cannula (Heart Lung Support Set cannula, Arterial Cannulae)</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:</p> <p>All the legal documents provided are copies, submit original, attested/ notarized and valid 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 Germany provided is copy, submit original document.</p> <p>Credentials of manufacturer abroad i.e Maquet Cardiopulmonary GmbH Kehler Str. 31 76437 Rastatt Germany</p> <p>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 device approved</p>


				<p>in the country of origin, the attached label is of HLS advance set.</p> <p>Apply in separate application for venous cannulae.</p>
48.	<p>Quality Medical Services, H49, Gordon College Road, Rawalpindi</p> <p>ELI: 00123 2176-P 10-02-2021</p>	<p><u>Legal Manufacturer:</u> King Systems 15011 Herriman Boulevard Noblesville, IN 46060 * subsidiary of AMBU in USA</p> <p><u>Manufacturing site:</u> Ambu A/s, Baltorpbakken 13, DK-2750 Ballerup, Denmark,</p> <p>FSC US FDA validity 13-11-2019</p>	<p>King Vision Video Laryngoscope (Video Laryngoscope)</p> <p>Class-B</p> <p>Shelf Life: 5 years</p> <p>Codes & Sizes: As per FSC</p>	<p>Deferred for the provision of following:</p> <p>Credentials of manufacturer abroad clearly stating the Legal manufacturer and the manufacturing site.</p> <p>LOA and FSC submitted are expired before the submission of application. Provide original, updated and attested/notarized documents.</p> <p>ISO 13485 is expired but valid upon submission.</p> <p>Shelf life studies for the claimed shelf life.</p> <p>FQA certificate/ CE marked document is not provided, Submit it.</p> <p>Essential Principle checklist.</p> <p>Labels of applied codes.</p>
49.	<p>Quality Medical Services, H49, Gordon College Road, Rawalpindi</p> <p>ELI: 00123 1757-P 21-09-2020</p>	<p><u>Legal Manufacturer:</u> AMBU A/S, BAL TORPBAKKEN 13 BALLERUP, DK-2750, DENMARK.</p> <p>FSC: Denmark Valid till 03-09-2020 FSC Malaysia validity 12-03-2025</p>	<p>Ambu aScope Broncho (Sterile Disposable Endoscopes)</p> <p>Class-B</p> <p>Shelf Life: 3 years</p> <p>Codes as per FSC</p>	<p>Deferred for the provision of following:</p> <p>Credentials of manufacturer abroad clearly stating the Legal manufacturer and the manufacturing site.</p> <p>LOA and FSC submitted are expired before the submission of application. Provide original, updated and attested/notarized documents.</p> <p>ISO 13485 is expired but valid upon submission.</p> <p>Shelf life studies for the claimed shelf life.</p> <p>FQA certificate/ CE marked document is not provided, Submit it.</p> <p>FSC of Malaysia submitted is</p>

				<p>copy.</p> <p>Essential Principle checklist.</p> <p>Product details.</p> <p>Declaration of Conformity.</p> <p>Ambu aScope Broncho 3 and Ambu aScope Broncho 4 are applied in single application, give your priority for any 1 and apply separately for the other type.</p>
50.	<p>Quality Medical Services, H49, Gordon College Road, Rawalpindi</p> <p>ELI: 00123 3644-P 17-02-2023</p>	<p>Legal Manufacturer: M/s PROGETTI S.R.L, Stardo del Rondello. 5 10028 Trofarello (TO) Italy</p>	<p>Rescue Sam (Semi-automated external cardiac defibrillator, AED)</p> <p>Class-C</p> <p>Shelf Life: Not provided.</p> <p>Model: SAM 4.0</p>	<p>Deferred for the provision of following:</p> <p>Credentials of manufacturer abroad.</p> <p>LOA submitted is copy and without notarization, submit original and notarized LOA.</p> <p>FSC is not provided. Provide original, updated and attested FSC mentioning the applied products.</p> <p>ISO 13485 and FQA are without notarization, submit notarized document.</p> <p>Shelf life supported with shelf life studies.</p> <p>Essential Principle checklist.</p> <p>Apply separately for SAM 4.0d.</p>
51.	<p>M/s Mian Scientific Corporation (Pvt) Ltd 534-Jinnah Colony Faisalabad</p> <p>ELI: 00442 1491-P 20-05-2020</p>	<p>Legal Manufacturer: CTK BIOTECH, INC. 13855 STOWE Dr. Poway, California USA</p> <p>FSC California, USA Date of Issue: 23-01-2020 Valid for 1 year FSC USA FDA Validity 06-10-2023</p>	<p>OnSite TROP-1 COMBO RAPID TEST kit</p> <p>Class-B</p> <p>Shelf Life: 24 months</p> <p>Code: R3002C</p>	<p>Deferred for the provision of following:</p> <p>Credentials of manufacturer's abroad as per format approved in 3rd meeting of MDB.</p> <p>LOA and ISO 13485.</p> <p>MDB approved the subject device in Class-C, so differential fee of rs-25,000/- is to be submitted.</p> <p>Fee challan submitted is copy.</p>
52.	<p>M/s Mian Scientific Corporation (Pvt) Ltd 534-Jinnah Colony</p>	<p>Legal Manufacturer: CTK BIOTECH, INC. 13855 STOWE Dr. Poway, California USA</p>	<p>CTK Vitamin-D Total ELISA Test kit</p> <p>Class-B</p>	<p>Deferred for the provision of following:</p> <p>Credentials of manufacturer's abroad as per format approved in</p>

	Faisalabad ELI: 00442 1468-P 20-05-2020	FSC California, USA Date of Issue: 23-01-2020 Valid for 1 year FSC USA FDA Validity 06-10-2023	Shelf Life: 15 months Code: E8010	3 rd meeting of MDB. LOA and ISO 13485. MDB approved the subject device in Class-C, so differential fee of rs-25,000/- is to be submitted. Fee challan submitted is copy.
53.	M/s Mian Scientific Corporation (Pvt) Ltd 534-Jinnah Colony Faisalabad ELI: 00442 1471-P 20-05-2020	<u>Legal Manufacturer:</u> CTK BIOTECH, INC. 13855 STOWE Dr. Poway, California USA FSC California, USA Date of Issue: 23-01-2020 Valid for 1 year FSC USA FDA Validity 06-10-2023	Recombilisa HEV IgM ELISA test kit Class-B Shelf Life: 12 months Code: E0105	Deferred for the provision of following: Credentials of manufacturer's abroad as per format approved in 3 rd meeting of MDB. LOA and ISO 13485. MDB approved the subject device in Class-C, so differential fee of rs-25,000/- is to be submitted. Fee challan submitted is copy.
54.	M/s Mian Scientific Corporation (Pvt) Ltd 534-Jinnah Colony Faisalabad ELI: 00442 1470-P 20-05-2020	<u>Legal Manufacturer:</u> CTK BIOTECH, INC. 13855 STOWE Dr. Poway, California USA FSC California, USA Date of Issue: 23-01-2020 Valid for 1 year FSC USA FDA Validity 06-10-2023	Recombilisa Chagas IgG ELISA Test kit Class-B Shelf Life: 12 months Code: E0170	Deferred for the provision of following: Credentials of manufacturer's abroad as per format approved in 3 rd meeting of MDB. LOA and ISO 13485. MDB approved the subject device in Class-C, so differential fee of rs-25,000/- is to be submitted. Fee challan submitted is copy.
55.	M/s Mian Scientific Corporation (Pvt) Ltd 534-Jinnah Colony Faisalabad ELI: 00442 1476-P 20-05-2020	<u>Legal Manufacturer:</u> CTK BIOTECH, INC. 13855 STOWE Dr. Poway, California USA FSC California, USA Date of Issue: 23-01-2020 Valid for 1 year FSC USA FDA Validity 06-10-2023	CTK Progesterone ELISA test kit Class-B Shelf Life: 15 months Code: E1220	Deferred for the provision of following: Credentials of manufacturer's abroad as per format approved in 3 rd meeting of MDB. LOA and ISO 13485. MDB approved the subject device in Class-C, so differential fee of rs-25,000/- is to be submitted. Fee challan submitted is copy.
56.	M/s Mian Scientific Corporation	<u>Legal Manufacturer:</u> CTK BIOTECH, INC. 13855 STOWE Dr.	CTK Vitamin-B12 Total ELISA Test kit	Deferred for the provision of following:

	(Pvt) Ltd 534-Jinnah Colony Faisalabad ELI: 00442 1469-P 20-05-2020	Poway, California USA FSC California, USA Date of Issue: 23-01-2020 Valid for 1 year FSC USA FDA Validity 06-10-2023	Class-B Shelf Life: 15 months Code: E8030	Credentials of manufacturer's abroad as per format approved in 3 rd meeting of MDB. LOA and ISO 13485. MDB approved the subject device in Class-C, so differential fee of rs-25,000/- is to be submitted. Fee challan submitted is copy.
57.	M/s Mian Scientific Corporation (Pvt) Ltd 534-Jinnah Colony Faisalabad ELI: 00442 1469-P 20-05-2020	<u>Legal Manufacturer:</u> CTK BIOTECH, INC. 13855 STOWE Dr. Poway, California USA FSC California, USA Date of Issue: 23-01-2020 Valid for 1 year FSC USA FDA Validity 06-10-2023	OnSite S. typhi/ Paratyphi Ag Rapid Test kit Class-B Shelf Life: 24 months Code: R0162C	Deferred for the provision of following: Credentials of manufacturer's abroad as per format approved in 3 rd meeting of MDB. LOA and ISO 13485. MDB approved the subject device in Class-C, so differential fee of rs-25,000/- is to be submitted. Fee challan submitted is copy.
58.	M/s Mian Scientific Corporation (Pvt) Ltd 534-Jinnah Colony Faisalabad ELI: 00442 1469-P 20-05-2020	<u>Legal Manufacturer:</u> Getein Biotech, Inc. No. 9 Bofu Road Luhe District Nanjing, 211505 China. FSC China Valid Till 26.12.2021	Getein Bio Inc. (Hs-Crp-Fast Test Kit) Class-B Shelf Life: 24 months Code: IF1003	Deferred for the provision of following: Valid LOA and FSC. FSC of any reference country/ CE marked document.
59.	M/s Mian Scientific Corporation (Pvt) Ltd 534-Jinnah Colony Faisalabad ELI: 00442 2042-P 07-01-2021	<u>Legal Manufacturer:</u> Getein Biotech, Inc. No. 9 Bofu Road Luhe District Nanjing, 211505 China. FSC China Valid Till 26.12.2021	Getein Biotech Inc. (T3-Fast Test Kit) Class-B Shelf Life: 24 months Code and sizes: IF1022 (1 test, 5 tests, 10 tests, 25 tests, 50 tests and 100 tests)	Deferred for the provision of following: Valid LOA and FSC. FSC of any reference country/ CE marked document.
60.	M/s Mian Scientific Corporation (Pvt) Ltd 534-	<u>Legal Manufacturer:</u> Getein Biotech, Inc. No. 9 Bofu Road Luhe District Nanjing, 211505 China.	Getein Bio Inc. (HbA1c Fast Test Kit) Class-B	Deferred for the provision of following: Fee Challan is missing.

	Jinnah Colony Faisalabad ELI: 00442 2044-P 07-01-2021	FSC China Valid Till 26.12.2021	Shelf Life: 24 months Code: IF1017 (1 test, 5 tests, 10 tests, 25 tests, 50 tests and 100 tests)	Valid LOA and FSC. FSC of any reference country/ CE marked document.
61.	M/s Mian Scientific Corporation (Pvt) Ltd 534-Jinnah Colony Faisalabad ELI: 00442 2043-P 07-01-2021	<u>Legal Manufacturer:</u> Getein Biotech, Inc. No. 9 Bofu Road Luhe District Nanjing, 211505 China. FSC China Valid Till 26.12.2021	Getein Bio Inc. (hs-cTnI Fast Test Kit) Class-B Shelf Life: 24 months Code & sizes: IF1019 (1 test, 5 tests, 10 tests, 25 tests, 50 tests and 100 tests)	Deferred for the provision of following: Fee Challan is missing. Valid LOA and FSC. FSC of any reference country/ CE marked document. MDB approved the subject device in Class-C, so differential fee of rs-25,000/- is to be submitted.
62.	M/s Mian Scientific Corporation (Pvt) Ltd 534-Jinnah Colony Faisalabad ELI: 00442 2049-P 07-01-2021	<u>Legal Manufacturer:</u> Getein Biotech, Inc. No. 9 Bofu Road Luhe District Nanjing, 211505 China. FSC China Valid Till 26.12.2021	Getein Bio Inc. (FSH-Fast Test Kit) Class-B Shelf Life: 24 months Code & sizes: IF1056 (1 test, 5 tests, 10 tests, 25 tests, 50 tests and 100 tests)	Deferred for the provision of following: Fee Challan is missing. Valid LOA and FSC. FSC of any reference country/ CE marked document.
63.	M/s Mian Scientific Corporation (Pvt) Ltd 534-Jinnah Colony Faisalabad ELI: 00442 2046-P 07-01-2021	<u>Legal Manufacturer:</u> Getein Biotech, Inc. No. 9 Bofu Road Luhe District Nanjing, 211505 China. FSC China Valid Till 26.12.2021	Getein Bio Inc. (LH-Fast Test Kit) Class-B Shelf Life: 24 months Code & sizes: IF1055 (1 test, 5 tests, 10 tests, 25 tests, 50 tests and 100 tests)	Deferred for the provision of following: Fee Challan is missing. Valid LOA and FSC. FSC of any reference country/ CE marked document.
64.	M/s Mian Scientific Corporation (Pvt) Ltd 534-Jinnah Colony Faisalabad ELI: 00442 2050-P	<u>Legal Manufacturer:</u> Getein Biotech, Inc. No. 9 Bofu Road Luhe District Nanjing, 211505 China. FSC China Valid Till 26.12.2021	Getein Bio Inc. (CK-MB/cTnL/Myo Fast Test Kit) Class-B Shelf Life: 24 months Code & sizes: IF1005	Deferred for the provision of following: Fee Challan is missing. Valid LOA and FSC. FSC of any reference country/ CE marked document.

	07-01-2021		(1 test, 5 tests, 10 tests, 25 tests, 50 tests and 100 tests)	MDB approved the subject device in Class-C, so differential fee of rs-25,000/- is to be submitted.
65.	M/s Mian Scientific Corporation (Pvt) Ltd 534-Jinnah Colony Faisalabad ELI: 00442 464-P 22-02-2021	Legal Manufacturer: Getein Biotech, Inc. No. 9 Bofu Road Luhe District Nanjing, 211505 China. FSC China Valid Till 26.12.2021	Getein Immunofluorescence Quantitative Analyzer Class-A Shelf life: N/A Model: 1100	Deferred for the provision of following: LOA and FSC are expired. Apply separately for the other model.
66.	M/s Moazzam Traders, Shop No 4, Jalil Plaza Gujranwala ELI: 00775 3692-P 13-02-2023	Legal Manufacturer: M/s Yasee Biomedical, No.9. Xiuyuan Road, High-tech Development Zone, Chengyang District, Qingdao, 266000 China FSC: China Valid Till: 12/07/2023	Blood Glucose Meter System/GLM-79 (Blood Glucose Monitoring System) Class: B Shelf Life: 2 years 	Deferred for the provision of following: Brand name of the device. Notarized credentials of manufacturer abroad as per format approved in 3 rd meeting of MDB. Original, updated and notarized agency agreement between you and the manufacturer as the provided agreement is between the mentioned manufacturer and the Bio Med Vision, Lahore. Original and attested FSC of China since the provided one is copy. Original, updated and attested FSC of any reference country as the product is from non-reference country Updated and notarized ISO 13485 and FQA certificates. Original Declaration of Conformity document to be filled and duly signed by responsible person on manufacturer's letter head. Label of applied model approved in the country of origin. Shelf life studies for the claimed shelf life and clarify whether the provided shelf life is for strips included in system or the overall product i.e Blood Glucose Monitoring System.
67.	M/s Lab.Care	Legal Manufacturer:	GF-1 VIRAL NUCLEIC	Deferred for the provision of

	<p>services, Office No. 321, 3rd Floor, New Subhan Centre, H-3 Block, MA Johar Town, Lahore</p> <p>ELI: 00846 3756-P 25-07-2022</p>	<p>M/s Vivantis Technologies Sdn.Bhd. Level 17, Top glove tower, No. 16, Persiaran Setia Dagang, Setia Alam, Seksyen U13, 40170 Shah Alam, Selangor Darul Ehsan, Malaysia.</p> <p>Manufacturing site: M/s Vivantis Technologies Sdn.Bhd. Level 1, Enterprise 2, Technology Park Malaysia, Lebuhraya Puchong-Sungai Besi, 57000 Bukit Jalil, Kuala Lumpur, Malaysia</p> <p>Export only certificate, Malaysia validity 16-07-2025</p>	<p>ACID EXTRACTION KIT (Nucleic Acid Extraction/ Isolation Kit IVD)</p> <p>Class-B Shelf Life: As per stability study.</p> <p>Codes: GF-RD-100 GF-RD-300 COGF-RD-300</p>	<p>following:</p> <p>FSC is not provided, the device is only for export, provide FSC of country of origin and FSC of any SRA country, duly attested.</p> <p>FQA/ CE mark certificate.</p> <p>Declaration of conformity to be printed on manufacturer's letter head duly filled and signed by responsible person.</p>
68.	<p>Shams Scientific Traders, 22-Y-J Madina Town, Faisalabad</p> <p>ELI: 00459 3870-P 24-08-2021</p>	<p>Legal Manufacturer: Healgen Scientific LLC, 3818 Fuqua Street, Houston, TX 77047, USA</p> <p>FSC: Belgium Date of Issue: 14.04.2021</p>	<p>Healgen Malaria P.f. Ab Rapid Test Cassette (Whole Blood) (Malaria p.f Ab Rapid Test)</p> <p>Class-C</p> <p>Shelf Life: 24 months</p> <p>Code as per FSC.</p>	<p>Deferred for the provision of FSC of Belgium mentioning the site involved in manufacturing i.e China or any other FSC of reference country mentioning the site of China. The firm may also provide any evidence of the China site involved in manufacturing.</p> <p>Provide details of manufacturing and QC specifically of applied product.</p> <p>Applied device is Malaria Ab rapid test whereas the FSC mentioning the Malaria Ag rapid test. Submit original, attested FSC mentioning the applied device.</p>
69.	<p>Nisa Impex (Pvt) Limited, Maxim Arcade, Plot # 13-14, Usman Block, Jeddah Town, Phase 1, Opp, DHA-II, G.T Road, Islamabad</p> <p>ELI: 00064</p> <p>Evaluator:</p>	<p>Legal Manufacturer: Chengdu Xinjin Shifteng Medical Apparatus & Instrument Co. Ltd No. 46 7th Group, Wanjie, XinPING Town, Xinjin County, Chengdu, P.R China</p> <p>FSC: China Valid till: 2022.03.26</p>	<p>NISA AV FISTULA NEEDLE (AV FISTULA NEEDLE)</p> <p>Codes & Sizes: As per FSC</p> <p>Class-B</p> <p>Shelf Life: 3 years</p>	<p>Deferred for the provision of following documents:</p> <p>Provide original & valid FSC duly attested by embassy</p> <p>Provide notarized Full QA certificate</p> <p>Provide credentials of manufacturer abroad duly notarized from country of origin</p> <p>Provide valid & original Doc</p>

	DD-III			<p>Submit notarized copy of ISO13485 certificate</p> <p>Submit notarized original Agency agreement</p> <p>Provide stability data</p> <p>Provide documents related to manufacturing & QC processes</p> <p>Product is from a non-reference country and the applicant has not provided FSC of any reference country or WHO pre-qualification or CE mark certificates</p>
70.	<p>Nisa Impex (Pvt) Limited, Maxim Arcade, Plot # 13-14, Usman Block, Jeddah Town, Phase I, Opp, DHA-II, G.T Road, Islamabad</p> <p>ELI: 00064</p> <p>Evaluator: DD-III</p>	<p>Legal Manufacturer:</p> <p>Chengdu Xinjin Shifteng Medical Apparatus & Instrument Co. Ltd No. 46 7th Group, Wanjie, XinPING Town, Xinjin County, Chengdu, P.R China</p> <p>FSC: China</p> <p>Valid till: 2022.03.26</p>	<p>NISA NASAL OXYGEN TUBE</p> <p>(NASAL OXYGEN TUBE)</p> <p>Codes & Sizes: As per FSC</p> <p>Class-B</p> <p>Shelf Life: 3 years</p>	<p>Deferred for the provision of following documents:</p> <p>Provide original & valid FSC duly attested by embassy</p> <p>Provide notarized Full QA certificate</p> <p>Provide credentials of manufacturer abroad duly notarized from country of origin</p> <p>Provide valid & original Doc</p> <p>Submit notarized copy of ISO13485 certificate</p> <p>Submit notarized original Agency agreement</p> <p>Provide stability data</p> <p>Provide documents related to manufacturing & QC processes</p> <p>Product is from a non-reference country and the applicant has not provided FSC of any reference country or WHO pre-qualification or CE mark certificates</p>
71.	<p>Nisa Impex (Pvt) Limited, Maxim Arcade, Plot # 13-14, Usman Block, Jeddah Town, Phase I, Opp, DHA-II, G.T</p>	<p>Legal Manufacturer:</p> <p>Chengdu Xinjin Shifteng Medical Apparatus & Instrument Co. Ltd No. 46 7th Group, Wanjie, XinPING Town, Xinjin County, Chengdu, P.R</p>	<p>Disposable Hemodialysis Blood Tubing Set</p> <p>(Disposable Hemodialysis blood Tubing Set)</p> <p>Codes & Sizes: As per FSC</p>	<p>Deferred for the provision of following documents:</p> <p>Provide original & valid FSC duly attested by embassy</p> <p>Provide notarized Full QA certificate</p>

	Road, Islamabad ELI: 00064 Evaluator: DD-III	China FSC: China Valid till: 2022.03.26	Class-B Shelf Life: 3 years	Provide credentials of manufacturer abroad duly notarized from country of origin Provide valid & original Doc Submit notarized copy of ISO13485 certificate Submit notarized original Agency agreement Provide stability data Provide documents related to manufacturing & QC processes Product is from a non-reference country and the applicant has not provided FSC of any reference country or WHO pre-qualification or CE mark certificates
72.	Nisa Impex (Pvt) Limited, Maxim Arcade, Plot # 13-14, Usman Block, Jeddah Town, Phase 1, Opp, DHA-II, G.T Road, Islamabad ELI: 00064 Evaluator: DD-III	Legal Manufacturer: Chengdu Xinjin Shifteng Medical Apparatus & Instrument Co. Ltd No. 46 7th Group, Wanjie, XinPING Town, Xinjin County, Chengdu, P.R China FSC: China Valid till: 2022.03.26	NISA URINE BAG (URINE BAG) Codes & Sizes: As per FSC Class-B Shelf Life: 3 years	Deferred for the provision of following documents: Provide original & valid FSC duly attested by embassy Provide notarized Full QA certificate Provide credentials of manufacturer abroad duly notarized from country of origin Provide valid & original Doc Submit notarized copy of ISO13485 certificate Submit notarized original Agency agreement Provide stability data Provide documents related to manufacturing & QC processes Product is from a non-reference country and the applicant has not provided FSC of any reference country or WHO pre-qualification or CE mark certificates
73.	MR Medical Pakistan Private Limited, Office No. 1101, 11th	Legal Manufacturer: Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Mindray Building,	MINDRAY (Infusion pump management unit, mobile)	Deferred for the provision of following documents: FSC of country of origin is

				<p>Provide documents related to manufacturing & QC processes</p> <p>Product is from a non-reference country and the applicant has not provided FSC of any reference country or WHO pre-qualification or CE mark certificates</p>
73	<p>MR Medical Pakistan Private Limited, Office No. 1101, 11th Floor, ISE Tower, Jinnah Avenue, Blue Area Islamabad.</p> <p>ELI-01008 Evaluator: DD-III</p>	<p>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</p>	<p>MINDRAY</p> <p>(Infusion pump management unit, mobile)</p> <p>Class-C</p> <p>Shelf Life: 12 months</p>	<p>Deferred for the provision of following documents:</p> <p>FSC of country of origin is expired.</p> <p>Doc is not on proper format.</p> <p>ISO13485 & FQA certificates not covering the Scope for the applied product.</p> <p>Product is from a non-reference country and the applicant has not provided FSC of any reference country for this applied product.</p> <p>Provide MRP of applied device on form 7A.</p> <p>Brand name clarification regarding the similarity.</p>
74	<p>MR Medical Pakistan Private Limited, Office No. 1101, 11th Floor, ISE Tower, Jinnah Avenue, Blue Area Islamabad.</p> <p>ELI-01008 Evaluator: DD-III</p>	<p>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</p>	<p>MINDRAY</p> <p>(Infusion pump) e VP-n VP</p> <p>Class-C</p> <p>Shelf Life: 10 years</p>	<p>Deferred for the provision of following documents:</p> <p>FSC of country of origin is expired.</p> <p>ISO13485 & FQA certificates not covering the Scope for the applied product.</p> <p>Product is from a non-reference country and the applicant has not provided FSC of any reference country for this applied product.</p> <p>Provide MRP of applied device on form 7A.</p> <p>Brand name clarification regarding the similarity.</p>
75	<p>MR Medical Pakistan Private Limited, Office No. 1101, 11th Floor, ISE Tower, Jinnah Avenue, Blue</p>	<p>Legal Manufacturer: Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057,</p>	<p>MINDRAY</p> <p>(Infusion PUMP) VP1-VP3-VP-5</p> <p>Class-C</p>	<p>Deferred for the provision of following documents:</p> <p>FSC of country of origin is expired.</p> <p>ISO13485 & FQA certificates not</p>

	Area Islamabad. ELI-01008 Evaluator: DD-III	Shenzhen, People's Republic of China FSC: China Valid till: 17/04/2023	Shelf Life: 10 years	covering the 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. Brand name clarification regarding the similarity.
76.	MR Medical Pakistan Private Limited, Office No. 1101, 11th Floor, ISE Tower, Jinnah Avenue, Blue Area Islamabad. ELI-01008 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 (Infusion Supervision System), DS5 Class-C Shelf Life: 10 years	Deferred for the provision of following documents: FSC of country of origin is expired. ISO13485 & FQA certificates not covering the 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. Brand name clarification regarding the similarity.
77.	MR Medical Pakistan Private Limited, Office No. 1101, 11th Floor, ISE Tower, Jinnah Avenue, Blue Area Islamabad. ELI-01008 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 (Infusion Supervision system, nDS, eDS Class-C Shelf Life: 10 years	Deferred for the provision of following documents: FSC of country of origin is expired. ISO13485 & FQA certificates not covering the 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. Brand name clarification regarding the similarity.
78.	MR Medical Pakistan Private Limited, Office	Legal Manufacturer: Shenzhen Mindray Bio-	MINDRAY (Syringe Pump)	Deferred for the provision of following:

	No. 1101, 11th Floor, ISE Tower, Jinnah Avenue, Blue Area Islamabad. ELI-01008 Evaluator: DD-III	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	e SP-n SP Class-C Shelf Life: 10 years	FSC of country of origin is expired but valid at the time of submission of dossier. Provide MRP of applied device on form 7A ISO13485 & FQA certificates not covering the 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. Brand name clarification regarding the similarity.
79	MR Medical Pakistan Private Limited, Office No. 1101, 11th Floor, ISE Tower, Jinnah Avenue, Blue Area Islamabad. ELI-01008 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 (Infusion supervision system nCS) Codes & Sizes: As per FSC Class-C Shelf Life: 10 years	Deferred for the provision of following: FSC of country of origin is expired. ISO13485 & FQA certificates not covering the 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. Brand name clarification regarding the similarity.
80	Sind Medical Stores, 13-B, Block 6, PECHS, Shahrah e Faisal, Karachi – 75400, PAKISTAN Lic. No.ELI-00010	Changzhou Lookmed Medical Instrument Co. Ltd Building 3, Building 5 No.10 Chenghe Road Lijia Town Industry Zone, Wujin Changzhou City 213176 Jiangsu - China. ISO Valid Till (20.06.2024) EC Certificate (20.06.2023)	LOOKMED DISPOSABLE SKIN PLASTERS Class – B SHELF LIFE 02 YEARS	Deferred for provision of the following Documents. Original valid and Embass Attested FSc in the country of origin FSC of reference country or Ce Mark certificate Provide Stability ofr the claimed shelf life and DOC
81.	Sind Medical Stores, 13-B, Block 6, PECHS,	Changzhou Lookmed Medical Instrument Co. Ltd Building 3, Building 5	LOOKMED LIGATION CLIPS	Deferred for provision of the Following Documents. Original valid and Embass Attested

	Shahrah e Faisal, Karachi – 75400, PAKISTAN Lic. No.ELI-00010	No,10 Chenghe Road Lijia Town Industry Zone, Wujin Changzhou City 213176 Jiangsu - China. ISO Valid Till (20.06.2024) EC Certificate (20.06.2023)	Class – B SHELF LIFE 03 YEARS	FSc in the country of origin FSC of reference country or Ce Mark certificate Provide Stability ofr the claimed shelf life and DOC
82.	Sind Medical Stores, 13-B, Block 6, PECHS, Shahrah e Faisal, Karachi – 75400, PAKISTAN Lic. No.ELI-00010	<u>Legal Manufacturer:</u> DiaMed GmbH Pra Rond 23, 1785 Cressier FR Switzerland. <u>Head Quarter (Parent Company):</u> Bio-Rad Laboratories Inc., 1000 Alfred Nobel Drive, Hercules, California 94547- USA. <u>European HQ:</u> Bio-Rad Europe GmbH, Holbeinstrasse 75, 4051 Basel, Switzerland. FSC Switzerland Valid Till (18.10.2022) ISO 13485:2016 Certificate Valid till (30.10.2021) LOA Valid until (31.12.2020)	ABO/Rh(D) MULTIPLE BLOOD GROUPING IVD, KITS, AGGLUTINATION (FAMILY) Class – B	Deferred for provision of the following documents The firm shall submit DOC for all the IVDs and check Class of MD. The firm shall apply separately and arrange clustering as per MDR 2017 and submit revise Form-7 or claify. The firm shall submit original and valid FSC in the country of origin Submit Valid and notarized LOA. Valid ISO 13485 and FQA Clarify stability studies
83.	Sind Medical Stores, 13-B, Block 6, PECHS, Shahrah e Faisal, Karachi – 75400, PAKISTAN Lic. No.ELI-00010	DiaMed GmbH Pra Rond 23, 1785 Cressier FR Switzerland. <u>Head Quarter (Parent Company):</u> Bio-Rad Laboratories Inc., 1000 Alfred Nobel Drive, Hercules, California 94547- USA. <u>European HQ:</u> Bio-Rad Europe GmbH, Holbeinstrasse 75, 4051 Basel, Switzerland.	POLYSPECIFIC ANTIHUMAN GLOBULIN-COMPLEMENT IVD, ANTIBODY, AGGLUTINATION (FAMILY) Class – C	Deferred for provision of the following documents The firm shall submit DOC for all the IVDs. The firm shall apply separately and arrange clustering as per MDR 2017 and submit revise Form-7 or claify. The firm shall submit original and valid FSC in the country of origin. Submit Valid and notarized LOA. Valid ISO 13485 and FQA

		<p>FSC Switzerland Valid Till (18.10.2022)</p> <p>ISO 13485:2016 Certificate Valid till (30.10.2021)</p> <p>LOA Valid until (31.12.2020)</p>		Clarify stability studies
84.	<p>Sind Medical Stores, 13-B, Block 6, PECHS, Shahrah e Faisal, Karachi – 75400, PAKISTAN Lic. No.ELI-00010</p>	<p>DiaMed GmbH Pra Rond 23, 1785 Cressier FR Switzerland.</p> <p><u>Head Quarter (Parent Company):</u> Bio-Rad Laboratories Inc., 1000 Alfred Nobel Drive, Hercules, California 94547- USA.</p> <p><u>European HQ:</u> Bio-Rad Europe GmbH, Holbeinstrasse 75, 4051 Basel, Switzerland.</p> <p>FSC Switzerland Valid Till (18.10.2022)</p> <p>ISO 13485:2016 Certificate Valid till (30.10.2021)</p> <p>LOA Valid until (31.12.2020)</p>	<p>LOW-IONIC-STRENGTH SALT SOLUTION (LISS) IMMUNOHAEMATOLOGY REAGENT IVD (FAMILY)</p> <p>Class – B</p>	<p>Deferred for provision of the following documents</p> <p>The firm shall submit DOC for all the IVDs.</p> <p>The firm shall apply separately and arrange clustering as per MDR 2017 and submit revise Form-7 or clarify.</p> <p>The firm shall submit original and valid FSC in the country of origin.</p> <p>Submit Valid and notarized LOA.</p> <p>Valid ISO 13485 and FQA</p> <p>Clarify stability studies</p>
85.	<p>Sind Medical Stores, 13-B, Block 6, PECHS, Shahrah e Faisal, Karachi – 75400, PAKISTAN Lic. No.ELI-00010</p>	<p>DiaMed GmbH Pra Rond 23, 1785 Cressier FR Switzerland.</p> <p><u>Head Quarter (Parent Company):</u> Bio-Rad Laboratories Inc., 1000 Alfred Nobel Drive, Hercules, California 94547- USA.</p> <p><u>European HQ:</u> Bio-Rad Europe GmbH, Holbeinstrasse 75, 4051 Basel, Switzerland.</p>	<p>MULTIPLE IMMUNOHAEMATOLOGY TEST IVD, CONTROL (FAMILY)</p> <p>Class – B</p>	<p>Deferred for provision of the following documents</p> <p>The firm shall submit DOC for all the IVDs.</p> <p>The firm shall apply separately and arrange clustering as per MDR 2017 and submit revise Form-7 or clarify.</p> <p>The firm shall submit original and valid FSC in the country of origin.</p> <p>Submit Valid and notarized LOA.</p> <p>Valid ISO 13485 and FQA</p>

		<p>FSC Switzerland Valid Till (18.10.2022)</p> <p>ISO 13485:2016 Certificate Valid till (30.10.2021)</p> <p>LOA Valid until (31.12.2020)</p>		Clarify stability studies
86.	<p>Sind Medical Stores, 13-B, Block 6, PECHS, Shahrah e Faisal, Karachi – 75400, PAKISTAN Lic. No.ELI-00010</p>	<p>DiaMed GmbH Pra Rond 23, 1785 Cressier FR Switzerland.</p> <p><u>Head Quarter (Parent Company):</u> Bio-Rad Laboratories Inc., 1000 Alfred Nobel Drive, Hercules, California 94547- USA.</p> <p><u>European HQ:</u> Bio-Rad Europe GmbH, Holbeinstrasse 75, 4051 Basel, Switzerland.</p> <p>FSC Switzerland Valid Till (18.10.2022)</p> <p>ISO 13485:2016 Certificate Valid till (30.10.2021)</p> <p>LOA Valid until (31.12.2020)</p>	<p>HAM's ACID RED CELL TEST IVD, REAGENT (FAMILY)</p> <p>Class – B</p>	<p>Deferred for provision of the following documents</p> <p>The firm shall submit DOC for all the IVDs and check class of MD.</p> <p>The firm shall apply separately and arrange clustering as per MDR 2017 and submit revise Form-7 or clarify.</p> <p>The firm shall submit original and valid FSC in the country of origin.</p> <p>Submit Valid and notarized LOA.</p> <p>Valid ISO 13485 and FQA</p> <p>Clarify stability studies</p>
87.	<p>Sind Medical Stores, 13-B, Block 6, PECHS, Shahrah e Faisal, Karachi – 75400, PAKISTAN Lic. No.ELI-00010</p>	<p>DiaMed GmbH Pra Rond 23, 1785 Cressier FR Switzerland.</p> <p><u>Head Quarter (Parent Company):</u> Bio-Rad Laboratories Inc., 1000 Alfred Nobel Drive, Hercules, California 94547- USA.</p> <p><u>European HQ:</u> Bio-Rad Europe GmbH, Holbeinstrasse 75, 4051 Basel, Switzerland.</p> <p>FSC Switzerland Valid Till (18.10.2022)</p> <p>ISO 13485:2016</p>	<p>COLUMN AGGLUTINATION IVD (FAMILY)</p> <p>Class – B</p>	<p>Deferred for provision of the following documents</p> <p>The firm shall submit DOC for all the IVDs.</p> <p>The firm shall apply separately and arrange clustering as per MDR 2017 and submit revise Form-7 or clarify.</p> <p>The firm shall submit original and valid FSC in the country of origin.</p> <p>Submit Valid and notarized LOA.</p> <p>Valid ISO 13485 and FQA</p> <p>Clarify stability studies</p>

		<p>Certificate Valid till (30.10.2021)</p> <p>LOA Valid until (31.12.2020)</p>		
88	<p>Sind Medical Stores, 13-B, Block 6, PECHS, Shahrah e Faisal, Karachi – 75400, PAKISTAN Lic. No.ELI-00010</p>	<p>DiaMed GmbH Pra Rond 23, 1785 Cressier FR Switzerland.</p> <p><u>Head Quarter (Parent Company):</u> Bio-Rad Laboratories Inc., 1000 Alfred Nobel Drive, Hercules, California 94547- USA.</p> <p><u>European HQ:</u> Bio-Rad Europe GmbH, Holbeinstrasse 75, 4051 Basel, Switzerland. FSC Switzerland Valid Till (18.10.2022)</p> <p>ISO 13485:2016 Certificate Valid till (30.10.2021)</p> <p>LOA Valid until (31.12.2020)</p>	<p>ANTIBODY SCREENING REAGENT RED BLOOD CELL IVD, KIT, AGGLUTINATION, (FAMILY)</p> <p>Class – C</p>	<p>Deferred for provision of the following documents</p> <p>The firm shall submit DOC for all the IVDs.</p> <p>The firm shall apply separately and arrange clustering as per MDR 2017 and submit revise Form-7 or clarify.</p> <p>The firm shall submit original and valid FSC in the country of origin.</p> <p>Submit Valid and notarized LOA.</p> <p>Valid ISO 13485 and FQA</p> <p>Clarify stability studies</p>
89	<p>Sind Medical Stores, 13-B, Block 6, PECHS, Shahrah e Faisal, Karachi – 75400, PAKISTAN Lic. No.ELI-00010</p>	<p>DiaMed GmbH Pra Rond 23, 1785 Cressier FR Switzerland.</p> <p><u>Head Quarter (Parent Company):</u> Bio-Rad Laboratories Inc., 1000 Alfred Nobel Drive, Hercules, California 94547- USA.</p> <p><u>European HQ:</u> Bio-Rad Europe GmbH, Holbeinstrasse 75, 4051 Basel, Switzerland.</p> <p>FSC Switzerland Valid Till (18.10.2022)</p> <p>ISO 13485:2016 Certificate Valid till (30.10.2021)</p>	<p>REVERSE ABO GROUPING REAGENT RED BLOOD CELL A1 A2 B AB O IVD KIT, AGGLUTINATION (FAMILY)</p> <p>Class – B</p>	<p>Deferred for provision of the following documents</p> <p>The firm shall submit DOC for all the IVDs.</p> <p>The firm shall apply separately and arrange clustering as per MDR 2017 and submit revise Form-7 or clarify.</p> <p>The firm shall submit original and valid FSC in the country of origin.</p> <p>Submit Valid and notarized LOA.</p> <p>Valid ISO 13485 and FQA</p> <p>Clarify stability studies</p>


		LOA Valid until (31.12.2020)		
90.	Sind Medical Stores, 13-B, Block 6, PECHS, Shahrah e Faisal, Karachi – 75400, PAKISTAN Lic. No.ELI-00010	DiaMed GmbH Pra Rond 23, 1785 Cressier FR Switzerland. <u>Head Quarter (Parent Company):</u> Bio-Rad Laboratories Inc., 1000 Alfred Nobel Drive, Hercules, California 94547- USA. <u>European HQ:</u> Bio-Rad Europe GmbH, Holbeinstrasse 75, 4051 Basel, Switzerland. FSC Switzerland Valid Till (18.10.2022) ISO 13485:2016 Certificate Valid till (30.10.2021) LOA Valid until (31.12.2020)	ANTIBODY IDENTIFICATION PANEL REAGENT RED BLOOD CELL IVD, KIT, AGGLUTINATION, (FAMILY) Class – C	Deferred for provision of the following documents The firm shall submit DOC for all the IVDs. The firm shall apply separately and arrange clustering as per MDR 2017 and submit revise Form-7 or clarify. The firm shall submit original and valid FSC in the country of origin. Submit Valid and notarized LOA. Valid ISO 13485 and FQA Clarify stability studies
91.	New Pakistan Traders, Office No. 306/I, Trade Tower, Altaf Hussain Road, New Challi, Karachi. ELI-00161	M/s NANTONG EGENS BIOTECHNOLOGY CO., LTD. ADDRESS: Block A Fifteenth Factory-building No.1692 Xinghu Avenue, Nantong Economic & Technological Development Zone, NANTONG, CHINA 20/03/2023	Accurate Hepatitis B Surface Antigen(HbsAg) test kit CLASS:C Shelf life 2 years	Deferred for submesion of the following documents <ul style="list-style-type: none"> • Fee of RS 50000/- fro the applied product • Original and Notarised LOA having prodcut list. • The Brand name on the FSC do not match with the name mentioned on Form 7A. therefore clarify. • Provide CE certification from Cab present in the nando data base since it is not provided and the submitted certificate do not cover this product. • The DOC need clarification • Stability studies not provided therefore provide • Expired and Notarized ISO 13485 certificate submitted

				therefore provide valid ISO 13485.
92.	New Pakistan Traders, Office No. 306/I, Trade Tower, Altaf Hussain Road, New Challi, Karachi. ELI-00161	M/s NANTONG EGENS BIOTECHNOLOGY CO., LTD_ ADDRESS: Block A Fifteenth Factory-building No.1692 Xinghu Avenue,Nantong Economic & Technological Development Zone, NANTONG, CHINA 20/03/2023	Accurate Hepatitis C (HCV) test kit CLASS: C Shelf life 2 years FSC valid till 5.5.2024	Deferred for submesion of the following documents <ul style="list-style-type: none"> • Fee of RS 50000/- fro the applied product • Orihinal and Notarised LOA having prodcut list. • The Brand name on the FSC do not match with the name mentioned on Form 7A. therefore clarify. • Provide CE certification from Cab present in the nando data base since it is not provided and the submitted certificate do not cover this product. • the DOC need clarification • Stability studies not provided therefore provide • Expired and Notarized ISO 13485 certificate submitted therefore provide valid ISO 13485 .
93.	M/S Zedco Office No 203, Sky Mark Tower, Plot A-13,Block 7/8,K.C.H.S.U, Shahrah-E-Faisal ,Karachi (Eli-00347)	Legal Manufacturer & Mfg- Site: M/s Perfect Medical Industry (VN) Co Ltd, Vitenam Vietnam FSC Valid till 11-09-2022)	Perfect Medical Blood Transfusion Set L Type and Y Type Class B Shelf Life: 36 Months Product codes: V0512305030001 V0522305030001 Sizes & Codes as Per FSC.	Deferred for submission of the following Doc. <ol style="list-style-type: none"> 1. Original and valid FSC and revise the Form7A as per brand name in the FSC 2. The Ltype and Y type not mentioned on the FSC s, provide clarification and clarify wether needle resent or not. 3. Provide stability studies. for the claimed shelf life 4. Provide FSC of Reference country or CE certificate issued by Cabs mentioned in nando database 5. Provide valid ISO 13485
94.	Hanson International, Office No. 57 3rd Floor	<u>Legal Manufacturer:</u> QINGDAO HAINUO BIOLOGICAL ENGINEERING CO.,	HYNAUT (Adhesive Medical Tape) Class-A	Deferred for the provision of following: Valid and original LOA duly


	Block, DHA EME, Multan Road, Lahore ELI: 00773 635-P 15-11-2021	LTD, NO.1 GUANGDONG ROAD, JIANGSHAN INDUSTRIAL PARK LAXI. QINGDAO, CHINA.	Shelf Life: 2 years Sizes: 1.25 cm x 5 Meter (24 Pes/Box) 2.5 cm x 5 Meter (12 Pes/Box) 5.0 cm x 5 Meter (12 Pes/Box) 7.5cm x 5 Meter (12 Pes/Box)	notarized. Provided FSC in the country of origin, is not issued by any Chinese regulatory authority. Provide original, valid and attested FSC mentioning the subject device. Provide Manufacturing and QC tests in detail. Provide Valid and notarized ISO 13485 certificate. Provide Valid and notarized CE document/ FSC of any reference country. Provide Declaration of Conformity to be printed on manufacturer's letter head duly filled and signed by responsible person.
95.	Hanson International, Office No. 57 3rd Floor Block, DHA EME, Multan Road, Lahore ELI: 00773 636-P 15-11-2021	<u>Legal Manufacturer:</u> QINGDAO HAINUO BIOLOGICAL ENGINEERING CO., LTD, NO.1 GUANGDONG ROAD, JIANGSHAN INDUSTRIAL PARK LAXI. QINGDAO, CHINA.	HYNAUT STERILE WOUND DRESSING (Sterile Wound Dressing) Class-A Shelf Life: 3 years Sizes: 6cmx7cm 9cmx10cm 9cmx15 cm 9cmx20cm 9cmx25cm 9cmx35cm	Deferred for the provision of following: Valid and original LOA duly notarized. Provided FSC in the country of origin, is not issued by any Chinese regulatory authority. Provide original, valid and attested FSC mentioning the subject device. Provide Manufacturing and QC tests in detail. Provide Valid and notarized ISO 13485 certificate. Provide Valid and notarized CE document/ FSC of any reference country. Provide Declaration of Conformity to be printed on manufacturer's letter head duly filled and signed by responsible person.
96.	Hanson International, Office No. 57 3rd Floor	<u>Legal Manufacturer:</u> M/s Qingdao Hainuo Biological Engineering Co., Ltd, No. 1	Hynaut Medical P.E Tape (Adhesive Medical P.E Tape)	Deferred for the provision of following: Valid and original LOA duly

	Block, DHA EME. Multan Road, Lahore ELI: 00773 839-P 07-05-2022	Guangdong Road Jiangshan Industrial Park Laxi, Qingdao, China	Class-A Shelf Life: 3 year	notarized. Provided FSC in the country of origin, is not issued by any Chinese regulatory authority. Provide original, valid and attested FSC mentioning the subject device. Provide Manufacturing and QC tests in detail. Provide Valid and notarized ISO 13485 certificate. Provide Valid and notarized CE document/ FSC of any reference country. Provide Declaration of Conformity to be printed on manufacturer's letter head duly filled and signed by responsible person.
97.	M/s Metro Commercial Enterprises, Suit No. 1, L.G.F. Abrar Business, Center, Wahat Road, Lahore ELI: 00137 564-P 06-05-2021	<u>Legal Manufacturer:</u> Rudolf Riester GmbH, BruckstraBe 31, 72417 Jungingen, Germany FSC: Germany issuance 02-01-2020	Ri-focus Head Mirrors and Head Lamps Class-A Shelf Life: 10 years Codes are not provided	Deferred for the provision of following: Provide original and valid LOA, duly notarized. Provide original and attested FSC in the country of origin mentioning the applied product with codes and model. The submitted copy of FSC missing the applied device. Provide manufacturing and QC details. Provide shelf life/ service life studies for the claimed shelf life. Provide updated ISO 13485 certificate. The CE certificate provided does not mention the applied product, neither its brand name nor its generic, so provide the CE certificate mentioning the applied device. Provide essential principle checklist. Provide Declaration of Conformity


				<p>to be printed on manufacturer's letter head duly filled and signed by responsible person mentioning the device Brand name its Class and codes/ models to be registered.</p> <p>Only one brand name is allowed to apply on a single application, for rest of the brand name apply in separate application.</p>
98.	<p>M/s Metro Commercial Enterprises, Suit No. 1, L.G.F, Abrar Business, Center, Wahat Road, Lahore</p> <p>ELI: 00137 563-P 06-05-2021</p>	<p>Legal Manufacturer: Rudolf Riester GmbH, BruckstraBe 31, 72417 Jungingen, Germany</p> <p>FSC: Germany issuance 02-01-2020</p>	<p>Ri-Magoc Head Mirrors and Head Lamps</p> <p>Class-A</p> <p>Shelf Life: 10 years</p> <p>Codes are not provided</p>	<p>Deferred for the provision of following:</p> <p>Provide original and valid LOA, duly notarized.</p> <p>Provide original and attested FSC in the country of origin mentioning the applied product with codes and model. The submitted copy of FSC missing the applied device.</p> <p>Provide manufacturing and QC details.</p> <p>Provide shelf life/ service life studies for the claimed shelf life.</p> <p>Provide updated ISO 13485 certificate.</p> <p>The CE certificate provided does not mention the applied product, neither its brand name nor its generic, so provide the CE certificate mentioning the applied device.</p> <p>Provide essential principle checklist.</p> <p>Provide Declaration of Conformity to be printed on manufacturer's letter head duly filled and signed by responsible person mentioning the device Brand name its Class and codes/ models to be registered.</p> <p>Only one brand name is allowed to apply on a single application, for rest of the brand name apply in separate application.</p>
99.	<p>M/s Metro Commercial</p>	<p>Legal Manufacturer: Rudolf Riester GmbH,</p>	<p>Sphygmomanometer</p>	<p>Deferred for the provision of following:</p>

	Enterprises, Suit No. 1, L.G.F, Abrar Business, Center, Wahat Road, Lahore ELI: 00137 562-P 06-05-2021	BruckstraBe 31, 72417 Jungingen, Germany FSC: Germany issuance 02-01-2020	Class-A Shelf Life: 8 years Codes & Sizes: As per FSC	Provide original and valid LOA, duly notarized. Provide original and attested FSC in the country of origin mentioning the applied product with codes and model. The submitted copy of FSC missing the applied device. Provide manufacturing and QC details. Provide shelf life/ service life studies for the claimed shelf life. Provide updated ISO 13485 certificate. The CE certificate provided does not mention the applied product, neither its brand name nor its generic, so provide the CE certificate mentioning the applied device. Provide essential principle checklist. Provide Declaration of Conformity to be printed on manufacturer's letter head duly filled and signed by responsible person mentioning the device Brand name its Class and codes/ models to be registered. Only one brand name is allowed to apply on a single application, for rest of the brand name apply in separate application.
100	M/s Metro Commercial Enterprises, Suit No. 1, L.G.F, Abrar Business, Center, Wahat Road, Lahore ELI: 00137 561-P 06-05-2021	<u>Legal Manufacturer:</u> Rudolf Riester GmbH, BruckstraBe 31, 72417 Jungingen, Germany FSC: Germany issuance 02-01-2020	Straight Blade Laryngoscope Class-A Shelf Life: 2 years Codes & Sizes: As per FSC 	Deferred for the provision of following: Provide original and valid LOA, duly notarized. Provide original and attested FSC in the country of origin mentioning the applied product with codes and model. The submitted copy of FSC missing the applied device. Provide manufacturing and QC details.

				<p>Provide shelf life/ service life studies for the claimed shelf life.</p> <p>Provide updated ISO 13485 certificate.</p> <p>The CE certificate provided does not mention the applied product, neither its brand name nor its generic, so provide the CE certificate mentioning the applied device.</p> <p>Provide essential principle checklist.</p> <p>Provide Declaration of Conformity to be printed on manufacturer's letter head duly filled and signed by responsible person mentioning the device Brand name its Class and codes/ models to be registered.</p> <p>Only one brand name is allowed to apply on a single application, for rest of the brand name apply in separate application.</p>
101.	<p>M/s Metro Commercial Enterprises, Suit No. 1, L.G.F, Abrar Business, Center, Wahat Road, Lahore</p> <p>ELI: 00137 560-P 06-05-2021</p>	<p>Legal Manufacturer: Rudolf Riester GmbH, BruckstraBe 31, 72417 Jungingen, Germany</p> <p>FSC: Germany issuance 02-01-2020</p>	<p>Ri-scope L Retinoscopy Set</p> <p>Class-A</p> <p>Shelf Life: 8 years</p> <p><i>Ww</i></p>	<p>Deferred for the provision of following:</p> <p>Provide original and valid LOA, duly notarized.</p> <p>Provide original and attested FSC in the country of origin mentioning the applied product with codes and model. The submitted copy of FSC missing the applied device.</p> <p>Provide manufacturing and QC details.</p> <p>Provide shelf life/ service life studies for the claimed shelf life.</p> <p>Provide updated ISO 13485 certificate.</p> <p>The CE certificate provided does not mention the applied product, neither its brand name nor its generic, so provide the CE certificate mentioning the applied device.</p> <p>Provide essential principle checklist.</p>

				<p>Provide Declaration of Conformity to be printed on manufacturer's letter head duly filled and signed by responsible person mentioning the device Brand name its Class and codes/ models to be registered.</p> <p>Only one brand name is allowed to apply on a single application, for rest of the brand name apply in separate application.</p>
102.	<p>M/s Metro Commercial Enterprises, Suit No. 1, L.G.F. Abrar Business, Center, Wahat Road, Lahore</p> <p>ELI: 00137 559-P 06-05-2021</p>	<p>Legal Manufacturer: Rudolf Riester GmbH, BruckstraBe 31, 72417 Jungingen, Germany</p> <p>FSC: Germany issuance 02-01-2020</p>	<p>Ri-clip Tourniquet Class-A Shelf Life: 2 years Codes & Sizes: As per FSC</p> <p></p>	<p>Deferred for the provision of following:</p> <p>Provide original and valid LOA, duly notarized.</p> <p>Provide original and attested FSC in the country of origin mentioning the applied product with codes and model. The submitted copy of FSC missing the applied device.</p> <p>Provide manufacturing and QC details.</p> <p>Provide shelf life/ service life studies for the claimed shelf life.</p> <p>Provide updated ISO 13485 certificate.</p> <p>The CE certificate provided does not mention the applied product, neither its brand name nor its generic, so provide the CE certificate mentioning the applied device.</p> <p>Provide essential principle checklist.</p> <p>Provide Declaration of Conformity to be printed on manufacturer's letter head duly filled and signed by responsible person mentioning the device Brand name its Class and codes/ models to be registered.</p> <p>Only one brand name is allowed to apply on a single application, for rest of the brand name apply in separate application.</p>
103.	M/s Metro	Legal Manufacturer:	Uni-I Otoscope	Deferred for the provision of

	<p>Commercial Enterprises, Suit No. 1, L.G.F, Abrar Business, Center, Wahat Road, Lahore</p> <p>ELI: 00137 558-P 06-05-2021</p>	<p>Rudolf Riester GmbH, BruckstraBe 31, 72417 Jungingen, Germany</p> <p>FSC: Germany issuance 02-01-2020</p>	<p>Class-A</p> <p>Shelf Life: 2 years</p> <p>Codes & Sizes: As per FSC</p>	<p>following:</p> <p>Provide original and valid LOA, duly notarized.</p> <p>Provide original and attested FSC in the country of origin mentioning the applied product with codes and model. The submitted copy of FSC missing the applied device.</p> <p>Provide manufacturing and QC details.</p> <p>Provide shelf life/ service life studies for the claimed shelf life.</p> <p>Provide updated ISO 13485 certificate.</p> <p>The CE certificate provided does not mention the applied product, neither its brand name nor its generic, so provide the CE certificate mentioning the applied device.</p> <p>Provide essential principle checklist.</p> <p>Provide Declaration of Conformity to be printed on manufacturer's letter head duly filled and signed by responsible person mentioning the device Brand name its Class and codes/ models to be registered.</p> <p>Only one brand name is allowed to apply on a single application, for rest of the brand name apply in separate application.</p>
104.	<p>M/s Metro Commercial Enterprises, Suit No. 1, L.G.F, Abrar Business, Center, Wahat Road, Lahore</p> <p>ELI: 00137 557-P 06-05-2021</p>	<p>Legal Manufacturer: Rudolf Riester GmbH, BruckstraBe 31, 72417 Jungingen, Germany</p> <p>FSC: Germany issuance 02-01-2020</p>	<p>Uni-I Ophthalmoscope</p> <p>Class-A</p> <p>Shelf Life: 2 years</p> <p>Codes & Sizes: As per FSC</p>	<p>Deferred for the provision of following:</p> <p>Provide original and valid LOA, duly notarized.</p> <p>Provide original and attested FSC in the country of origin mentioning the applied product with codes and model. The submitted copy of FSC missing the applied device.</p> <p>Provide manufacturing and QC details.</p> <p>Provide shelf life/ service life studies for the claimed shelf life.</p>

				<p>Provide updated ISO 13485 certificate.</p> <p>The CE certificate provided does not mention the applied product, neither its brand name nor its generic, so provide the CE certificate mentioning the applied device.</p> <p>Provide essential principle checklist.</p> <p>Provide Declaration of Conformity to be printed on manufacturer's letter head duly filled and signed by responsible person mentioning the device Brand name its Class and codes/ models to be registered.</p> <p>Only one brand name is allowed to apply on a single application, for rest of the brand name apply in separate application.</p>
105.	<p>M/s Metro Commercial Enterprises, Suit No. 1, L.G.F, Abrar Business, Center, Wahat Road, Lahore</p> <p>ELI: 00137 556-P 06-05-2021</p>	<p>Legal Manufacturer: Rudolf Riester GmbH, BruckstraBe 31, 72417 Jungingen, Germany</p> <p>FSC: Germany issuance 02-01-2020</p>	<p>Econom Ophthalmoscope Class-A Shelf Life: 2 years Codes & Sizes: As per FSC</p> <p></p>	<p>Deferred for the provision of following:</p> <p>Provide original and valid LOA, duly notarized.</p> <p>Provide original and attested FSC in the country of origin mentioning the applied product with codes and model. The submitted copy of FSC missing the applied device.</p> <p>Provide manufacturing and QC details.</p> <p>Provide shelf life/ service life studies for the claimed shelf life.</p> <p>Provide updated ISO 13485 certificate.</p> <p>The CE certificate provided does not mention the applied product, neither its brand name nor its generic, so provide the CE certificate mentioning the applied device.</p> <p>Provide essential principle checklist.</p>


				<p>Provide Declaration of Conformity to be printed on manufacturer's letter head duly filled and signed by responsible person mentioning the device Brand name its Class and codes/ models to be registered.</p> <p>Only one brand name is allowed to apply on a single application, for rest of the brand name apply in separate application.</p>
106.	<p>A&E Medical 323-ATA Turk Block New Garden Town, Lahore ELI-00023 Evaluator: DD-III</p>	<p>Legal Manufacturer: Graphic Control D.B.A Nisha Medical Technologies, Vermed, Biomedical Innovations 400 Exchange St, Buffalo, NY 14204</p> <p>FSC: France issued on 07-10-2021</p>	<p>Heartsync Multifunction Electrodes Codes & Sizes: As per FSC</p> <p>Class-A</p> <p>Shelf Life: 3 years</p>	<p>Deferred for the provision of following documents:</p> <p>Submit application on form-6 A as firm wrongly applied on form-7 A</p> <p>Clarify the legal manufacturer name and address i.e., On Agency Agreement the name& address of manufacturer is Nissha medical technologies Ltd torbay business park UK and on FSC its Nissha medical technologies SAS,23-25 Boulevard de la paix, France while on application form and ISO 13485 certificate its Graphic controls d.b.a. nissha medical technologies, vermed,400 exchange N.Y, USA</p> <p>FSC of reference country(France) is provided</p>
107.	<p>M/s Bajwa Sons, 13- Muslim Street, House No 3, 1st and 2nd Floor, Mayo Hospital Road, Lahore. (ELI-00314) (2751) Evaluator: AD-II</p>	<p>Legal Manufacturer: M/s Yancheng Huida Medical Instruments Co., Ltd, (No. 2, Kujyuan Road) Xuefu Town, YanduDistrict, Yancheng, City Jiangsu, China</p> <p>FSC: China</p> <p>Valid till: 09.04.2023</p>	<p>Truprone (Poliglecaprone (PGCL) Absorbable Suture)</p> <p>Class D</p> <p>Shelf Life: 3 Years</p> <p>Sizes as per FSC</p>	<p>Deferred for the submission of the following documnets as fina oportunity within four weeks:</p> <p>Provide Original and valid FSC dully attested by embassy</p> <p>Provide notarized copy of CE Mark certificate</p>
108.	<p>M/s Bajwa Sons, 13- Muslim Street, House No 3, 1st and 2nd Floor, Mayo Hospital Road, Lahore.</p>	<p>Legal Manufacturer: M/s Yancheng Huida Medical Instruments Co., Ltd, (No. 2, Kujyuan Road) Xuefu Town, YanduDistrict, Yancheng, City</p>	<p>Truglactin-910 (PGLA (Polyglactin 910)</p> <p>Codes & Sizes: As per FSC</p> <p>Class-D</p>	<p>Deferred for the submission of the following documnets as fina oportunity within four weeks:</p> <p>Provide Original and valid FSC dully attested by embassy</p> <p>Provide notarized copy of CE</p>

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	(ELI-00314) (2748) Evaluator: AD-II	Jiangsu, China FSC: China Valid till: 09.04.2023	Shelf Life: 3 years	Mark certificate
109.	M/s Bajwa Sons, 13- Muslim Street, House No 3, 1st and 2nd Floor, Mayo Hospital Road, Lahore. (ELI-00314) (2747) Evaluator: AD-II	Legal Manufacturer: M/s Yancheng Huida Medical Instruments Co., Ltd, (No. 2, Kujyuan Road) Xuefu Town, Yandu District, Yancheng, City Jiangsu, China FSC: China Valid till: 09.04.2023	TruCryl Rapid (Polyglycolic Acid Rapids (Absorbable Suture) Codes & Sizes: As per FSC Class-D Shelf Life: 5 years	Deferred for the submission of the following documents as final opportunity within four weeks: Provide Original and valid FSC duly attested by embassy Provide notarized copy of CE Mark certificate
110.	M/s Bajwa Sons, 13- Muslim Street, House No 3, 1st and 2nd Floor, Mayo Hospital Road, Lahore. (ELI-00314) (2755) Evaluator: AD-II	Legal Manufacturer: M/s Yancheng Huida Medical Instruments Co., Ltd, (No. 2, Kujyuan Road) Xuefu Town, Yandu District, Yancheng, City Jiangsu, China FSC: China Valid till: 09.04.2023	Trulene (Polypropylene (Non-absorbable Suture) Codes & Sizes: As per FSC Class-C Shelf Life: 5 years	Deferred for the submission of the following documents as final opportunity within four weeks: Provide Original and valid FSC duly attested by embassy Provide notarized copy of CE Mark certificate
111.	M/s Bajwa Sons, 13- Muslim Street, House No 3, 1st and 2nd Floor, Mayo Hospital Road, Lahore. (ELI-00314) (2756) Evaluator: AD-II	Legal Manufacturer: M/s Yancheng Huida Medical Instruments Co., Ltd, (No. 2, Kujyuan Road) Xuefu Town, Yandu District, Yancheng, City Jiangsu, China FSC: China Valid till: 09.04.2023	Trusilk (Silk (Black Braided Non-absorbable Suture) Codes & Sizes: As per FSC Class-C Shelf Life: 5 years	Deferred for the submission of the following documents as final opportunity within four weeks: Provide Original and valid FSC duly attested by embassy Provide notarized copy of CE Mark certificate
112.	M/s Bajwa Sons, 13- Muslim Street, House No 3, 1st and 2nd Floor, Mayo Hospital	Legal Manufacturer: M/s Yancheng Huida Medical Instruments Co., Ltd, (No. 2, Kujyuan Road) Xuefu Town, Yandu District,	Trulon Nylon (Non-Absorbable Suture) Codes & Sizes: As per FSC	Deferred for the submission of the following documents as final opportunity within four weeks: Provide Original and valid FSC duly attested by embassy

	Road, Lahore. (ELI-00314) (2754) Evaluator: AD-II	Yancheng, City Jiangsu, China FSC: China Valid till: 09.04.2023	Class-C Shelf Life: 5 years	Provide notarized copy of CE Mark certificate
113.	M/s Bajwa Sons, 13- Muslim Street, House No 3, 1st and 2nd Floor, Mayo Hospital Road, Lahore. (ELI-00314) (2749) Evaluator: AD-II	Legal Manufacturer: M/s Yancheng Huida Medical Instruments Co., Ltd, (No. 2, Kujyuan Road) Xuefu Town, Yandu District, Yancheng, City Jiangsu, China FSC: China Valid till: 09.04.2023	Truxanon (Polydioxanon (Absorbable Suture)) Codes & Sizes: As per FSC Class-D Shelf Life: 3 years	Deferred for the submission of the following documents as final opportunity within four weeks: Provide Original and valid FSC duly attested by embassy Provide notarized copy of CE Mark certificate
114.	M/s Reaction Scientific Private Ltd), 337, Street No. 17, Block-B, Sector B- 17, Islamabad. ELI: 00228 Evaluator: AD-VII	Legal Manufacturer: M/s Spinreact, S.A.U. Carretera Santa Coloma, 7. 17176. Sant Esteve de Bas. Girona, Spain FSC: Spain issued on 3-9-2018	ASO Latex (Slide Agglutination Serology Test Kit) Codes & sizes: As per FSC FSC issued on 3 September 2018 Class-C Shelf Life: 30 months	Deferred for the submission of the following documents as final opportunity within four weeks: Provide Notarised and valid Full Quality assurance certificate. the submitted FQA was expired before submission. Stability studies of the product is not provided
115.	M/s Reaction Scientific Private Ltd), 337, Street No. 17, Block-B, Sector B- 17, Islamabad. ELI: 00228 Evaluator: AD-VII	Legal Manufacturer: M/s Spinreact, S.A.U. Carretera Santa Coloma, 7. 17176. Sant Esteve de Bas. Girona, Spain FSC: Spain issued on 3-9-2018	Spinreact RF Latex (kit) [Slide Agglutination Serology Test Kit] Codes: 1200201 (50 test) 1200202 (100 test) 1200205 (200 test) Class B (applied as C) Shelf Life: 30 months	Deferred for the submission of the following documents as final opportunity within four weeks: Brand name of the applied product is not provided Justification from manufacturer for classifying the applied product in Class C by giving reference from the relevant provision in latest IMDRF document of IVD medical device classification is not provided. CE mark certificate is expired. CE mark certificate is not covering the scope of the applied product Design Examination certificate

				<p>issued by CAB notified in NANDO Database for the applied product is not provided</p> <p>Essential Principles of safety and performance (EPSP)/ Essential Requirements checklist is not provided</p> <p>Declaration of Conformity (DOC) is not provided</p>
116	<p>M/s Reaction Scientific Private Ltd), 337, Street No. 17, Block-B, Sector B- 17, Islamabad. ELI: 00228 Evaluator: AD-VII</p>	<p>Legal Manufacturer: M/s Spinreact, S.A.U. Carretera Santa Coloma, 7. 17176. Sant Esteve de Bas. Girona, Spain FSC: Spain issued on 3-9-2018</p>	<p>Spinreact RPR Carbon (kit) Code: 1200402 (500 tests) Class C Shelf Life: 30 months</p>	<p>Deferred for the submission of the following documents as final opportunity within four weeks:</p> <p>Brand name of the applied product is not provided</p> <p>Justification from manufacturer for classifying the applied product in Class C by giving reference from the relevant provision in latest IMDRF document of IVD medical device classification is not provided.</p> <p>CE mark certificate is expired.</p> <p>CE mark certificate is not covering the scope of the applied product</p> <p>Design Examination certificate issued by CAB notified in NANDO Database for the applied product is not provided</p> <p>Essential Principles of safety and performance (EPSP)/Essential Requirements checklist is not provided</p> <p>Declaration of Conformity (DOC) is not provided</p>
117	<p>M/s Reaction Scientific Private Ltd), 337, Street No. 17, Block-B, Sector B- 17, Islamabad. ELI: 00228 Evaluator:</p>	<p>Legal Manufacturer: M/s Spinreact, S.A.U. Carretera Santa Coloma, 7. 17176. Sant Esteve de Bas. Girona, Spain FSC: Spain issued on 3-9-2018</p>	<p>Spinreact CRP Latex (kit) [Slide Agglutination Serology Test Kit] Code: 1200301 (50 tests) 1200302 (100 tests) 1200305 (200 tests) Class C Shelf Life: 30 months</p>	<p>Deferred for the submission of the following documents as final opportunity within four weeks:</p> <p>Brand name of the applied product is not provided</p> <p>Justification from manufacturer for classifying the applied</p>

	AD-VII			<p>product in Class C by giving reference from the relevant provision in latest IMDRF document of IVD medical device classification is not provided.</p> <p>CE mark certificate is expired.</p> <p>CE mark certificate is not covering the scope of the applied product</p> <p>Design Examination certificate issued by CAB notified in NANDO Database for the applied product is not provided</p> <p>Essential Principles of safety and performance (EPSP)/Essential Requirements checklist is not provided</p> <p>Declaration of Conformity (DOC) is not provided</p>
118.	M/s K.S. Agencies, Suit# 210, 2nd Floor, Business Arcade, Main University Road Karachi. (ELI-00382)	<p>Legal Manufacturer: Huaiyin Medical Instruments Co., Ltd, No.8 West Mingyuan Road, Huain City China.</p>	<p>Catgut plain</p> <p>Class D</p> <p>Shelf Life: 6 Years</p> <p>Sizes as per FSC</p>	<p>Deferred for provision of FSC of any RRA and Real time stability studies of claimed shelf life.</p>
119.	<p>M/s Mehran International, 498/C Feroz Shah Mehta Road, Karachi</p> <p>ELI: 00351</p> <p>Evaluator AD-II</p> <p>(3521-P)</p>	<p>Legal Manufacturer: M/s Suzhou Laishi Transfusion Equipment Co., Ltd, Changsheng Road, Tongli Town 215217 Wujiang City, Jiangsu, Province China</p> <p>FSC: China</p> <p>Valid till: 22/04/2024</p> <p>FSC: Copy Spain</p> <p>Date of issue: 19-10-2021</p>	<p>M.I Blood Bag CPDA-I (DC) 500 ML</p> <p>[Disposable Plastic Blood Bag, with Anticoagulant Citrate Phosphate Dextrose Adenine (CPDA)]</p> <p>Class-D</p> <p>Shelf Life: 36 months</p> <p></p>	<p>The MDB after deliberation decided to DEFER the application since the firm submitted letter dated 10th February 2023 where in they submitted only copy of ISO 13485, Full quality assurance system only.</p> <p>Furthermore the Name of the blood bag is not aligned with the the embassy attested copy FSC of China.</p> <p>Since CPDA and MI not mentioned in the FSC with the brand name.</p> <p>CE certification not provided from the CAB mentioned in the Nando Data Base.</p>

				<p>Need stability studies clarification.</p> <p>Need clarification for the exporter name present in the LOA.</p>
120.	<p>M/s Mehran International, 498/C Feroz Shah Mehta Road, Karachi</p> <p>ELI: 00351</p> <p>Evaluator AD-II</p> <p>(3522-P)</p>	<p>Legal Manufacturer:</p> <p>M/s Suzhou Laishi Transfusion Equipment Co., Ltd, Changsheng Road, Tongli Town 215217 Wujiang City, Jiangsu, Province China</p> <p>FSC: China</p> <p>Valid till: 22/04/2024</p> <p>FSC: Spain</p> <p>Date of issue: 19-10-2021</p>	<p>M.I Blood Bag CPDA-I (TC) 250 ML</p> <p>[Disposable Plastic Blood Bag, with Anticoagulant Citrate Phosphate Dextrose Adenine (CPDA)]</p> <p>Class-D</p> <p>Shelf Life: 36 months</p>	<p>The MDB after deliberation decided to DEFER the application since The firm submitted letter dated 10th February 2023 where in they submitted only copy of ISO 13485, Full quality assurance system only.</p> <p>Furthermore the Name of the blood bag is not aligned with the the embassy attested copy FSC of China.</p> <p>Since CPDA and MI not mentioned in the FSC with the brand name.</p> <p>CE certification not provided from the CAB mentioned in the nando Data Base.</p> <p>Need stability studies clarification.</p> <p>Need clarification for the exporter name present in the LOA.</p>
121	<p>M/s Mehran International, 498/C Feroz Shah Mehta Road, Karachi</p> <p>ELI: 00351</p> <p>Evaluator AD-II</p> <p>(3523-P)</p>	<p>Legal Manufacturer:</p> <p>M/s Suzhou Laishi Transfusion Equipment Co., Ltd, Changsheng Road, Tongli Town 215217 Wujiang City, Jiangsu, Province China</p> <p>FSC: China</p> <p>Valid till: 22/04/2024</p> <p>FSC: Spain</p> <p>Date of issue: 19-10-2021</p>	<p>M.I Blood Bag CPDA-I (TC) 500 ML</p> <p>[Disposable Plastic Blood Bag, with Anticoagulant Citrate Phosphate Dextrose Adenine (CPDA)]</p> <p>Class-D</p> <p>Shelf Life: 36 months Fsc ok only tc not cpda</p> <p><i>U.S.</i></p>	<p>The MDB after deliberation decided to DEFER the application since The firm submitted letter dated 10th February 2023 wher in they submitted only copy of ISO 13485, Full quality assurance system only.</p> <p>Furthermore the Name of the blood bag is not aligned with the the embassy attested copy FSC of China.</p> <p>Since CPDA and MI not mentioned in the FSC with the brand name.</p> <p>CE certification not provided from the CAB mentioned in the nando Data Base.</p> <p>Need stability studies clarification.</p>

				Need clarification for the exporter name present in the LOA.
122.	<p>M/s Mehran International, 498/C Feroz Shah Mehta Road, Karachi</p> <p>ELI: 00351</p> <p>Evaluator AD-II (3524-P)</p>	<p>Legal Manufacturer:</p> <p>M/s Suzhou Laishi Transfusion Equipment Co., Ltd, Changsheng Road, Tongli Town 215217 Wujiang City, Jiangsu, Province China</p> <p>FSC: China</p> <p>Valid till: 22/04/2024</p> <p>FSC: Spain</p> <p>Date of issue: 19-10-2021</p>	<p>M.I Blood Bag CPDA-1 (QC) 250 ML</p> <p>[Disposable Plastic Blood Bag, with Anticoagulant Citrate Phosphate Dextrose Adenine (CPDA)]</p> <p>Class-D</p> <p>Shelf Life: 36 months Fsc ok only Qc not cpda</p>	<p>The MDB after deliberation decided to DEFER the application since The firm submitted letter dated 10th February 2023 wher in they submitted only copy of ISO 13485, Full quality assurance system only.</p> <p>Furthermore the Name of the blood bag is not aligned with the the original embassy attested copy FSC of China.</p> <p>Since CPDA and MI not mentioned in the FSC with the brand name.</p> <p>Notarised CE certification not provided from the CAB mentioned in the nando Data Base.</p> <p>Need stability studies clarification.</p> <p>Need clarification for the exporter name present in the LOA.</p>
123.	<p>M/s Mehran International, 498/C Feroz Shah Mehta Road, Karachi</p> <p>ELI: 00351</p> <p>Evaluator AD-II (3525-P)</p>	<p>Legal Manufacturer:</p> <p>M/s Suzhou Laishi Transfusion Equipment Co., Ltd, Changsheng Road, Tongli Town 215217 Wujiang City, Jiangsu, Province China</p> <p>FSC: China</p> <p>Valid till: 22/04/2024</p> <p>FSC: Spain</p> <p>Date of issue: 19-10-2021</p>	<p>M.I Blood Bag CPDA-1 (QC) 500 ML</p> <p>[Disposable Plastic Blood Bag, with Anticoagulant Citrate Phosphate Dextrose Adenine (CPDA)]</p> <p>Class-D</p> <p>Shelf Life: 36 months Fsc ok only Qc ,not cpda</p> <p></p>	<p>The MDB after deliberation decided to DEFER the application The firm submitted letter dated 10th February 2023 wher in they submitted only copy of ISO 13485, Full quality assurance system only.</p> <p>Furthermore, the Name of the blood bag is not aligned with the the original embassy attested copy FSC of China.</p> <p>Since CPDA and MI not mentioned in the FSC with the brand name.</p> <p>Notarised CE certification not provided from the CAB mentioned in the nando Data Base.</p> <p>Need stability studies clarification.</p> <p>Need clarification for the exporter name present in the LOA.</p>

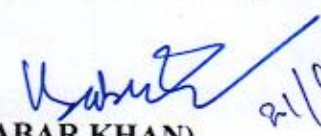
24.	<p>M/s Mehran International, 498/C Feroz Shah Mehta Road, Karachi</p> <p>ELI: 00351</p> <p>Evaluator AD-II (3526-P)</p>	<p>Legal Manufacturer:</p> <p>M/s Suzhou Laishi Transfusion Equipment Co., Ltd, Changsheng Road, Tongli Town 215217 Wujiang City, Jiangsu, Province China</p> <p>FSC: China</p> <p>Valid till: 22/04/2024</p> <p>FSC: Spain</p> <p>Date of issue: 19-10-2021</p>	<p>M.I Blood Bag CPDA-I (DC) 250 ML</p> <p>[Disposable Plastic Blood Bag, with Anticoagulant Citrate Phosphate Dextrose Adenine (CPDA)]</p> <p>Class-D</p> <p>Shelf Life: 36 months Fsc ok only DC, not cpda</p>	<p>The MDB after deliberation decided to DEFER the application The firm submitted letter dated 10th February 2023 wher in they submitted only copy of ISO 13485, Full quality assurance system only.</p> <p>Furthermore the Name of the blood bag is not aligned with the the original embassy attested copy FSC of China. Since CPDA and MI not mentioned in the FSC with the brand name.</p> <p>Notarised CE certification not provided from the CAB mentioned in the nando Data Base.</p> <p>Need stability studies clarification. Need clarification for the exporter name present in the LOA.</p>
125.	<p>Sure Bio-Diagnostics & Pharmaceuticals , EE-10, Defense View Phase-II, Near Iqra University Shaheed-e-Millat Express Way, Karachi (ELI-00084)</p> <p>Evaluator: AD-VI -4394-</p>	<p>Legal Manufacturer & mfg. site: Ortho-Legal Manufacturer & mfg. site: Clinical Diagnostics, Inc. Felindre Meadows, Pencoed, Bridgend, CF35 5PZ, United Kingdom</p> <p>FSC: UK</p> <p>Valid Till: 08-07-2023.</p>	<p>ORTHO-CLINICAL Diagnostics, Inc.</p> <ol style="list-style-type: none"> 1. ABD Confirmation (100 Pack) 2. ABD Confirmation RUM1 (100 Pack) 3. BioVue A/B/A+B/D/CDE/CTL (400 Pack) 4. BioVue A/B/D/CTL/REV DIL (100 Pack) Class D 5. BioVue C/E/SMC/SME/K/CTL (400 Pack) 6. BioVue C/E/SMC/SME/K/CTL (100 Pack) 7. BioVue Reverse Diluent (400 Pack) Class C 8. BioVue SYS ABODD GRP Cassette (100 Pack) class C 9. BioVue SYS Newborn Cassette (100 Pack) Class-D <p>Shelf life:08-months.</p>	<p>Deferred for further clarification from the firm for clustering as per MDR 2017.</p>
126.	<p>Sure Bio-Diagnostics & Pharmaceutical</p>	<p>TÜRKLAB TIBBİ MALZEMELER SAN. ve T-C. A.S</p>	<p>Class "B" Cluster Category "Virology" for</p> <ul style="list-style-type: none"> • TOYO® Dengue NS1: Cat 	<p>Deferred for submission of the following deficiencies:</p>

U/S

	s, EE-I0, Defense View Phase-II, Near Iqra University Shaheed-e- Millat Express Way. Karachi (ELI- 00084)	<ul style="list-style-type: none"> FSC Turkey valid Till 3-11-2022. ISO13485 Validity 21-12-2020 	No.TDG03 <ul style="list-style-type: none"> TOYO® Dengue IgG/IgM Cat No. TDG01 TOYO® Dengue NS1, IgG/IgM Cat No.TDG02 TOYO® SARS-CoV-2 IgM/IgG Ab: Cat No. TCV01 Shelf life: 24 Months. 	<ul style="list-style-type: none"> Valid and Original FSC in the country of origin Notarised CE certification from Nando data base or FSC of any reference regulatory authority Valid ISO 13485 Clarification of Stability studies and provide
127.	Sure Bio-Diagnostics & Pharmaceutical s, EE-I0, Defense View Phase-II, Near Iqra University Shaheed-e- Millat Express Way. Karachi (ELI- 00084)	TÜRKLAB TIBB- MALZEMELER SAN. ve T-C. A.S <ul style="list-style-type: none"> FSC Turkey valid Till 3-11-2022. ISO13485 Validity 21-12-2020 	Class "B" Cluster Category "Parasitology" for <ul style="list-style-type: none"> TOYO® Malaria Cat No. TML01 Shelf life: 24 Months. 	Deferred for submission of the following deficiencies: <ul style="list-style-type: none"> Valid and Original FSC in the country of origin Notarised CE certification from Nando data base or FSC of any reference regulatory authority Valid SIO 13485 Clarification of Stabilities studies and provide DOC
128.	Sure Bio-Diagnostics & Pharmaceutical s, EE-I0, Defense View Phase-II, Near Iqra University Shaheed-e- Millat Express Way. Karachi (ELI- 00084)	TÜRKLAB TIBB- MALZEMELER SAN. ve T-C. A.S <ul style="list-style-type: none"> FSC Turkey valid Till 3-11-2022. ISO13485 Validity 21-12-2020 	Class "B" Cluster Category "Bacteriology" <ul style="list-style-type: none"> TOYO®H. Pylori Ag Test Cat No. THP03 TOYO® H. Pylori Ab Test Cat o. THP02 Shelf life: 24 Months. 	Deferred for submission of the following deficiencies: <ul style="list-style-type: none"> Valid and Original FSC in the country of origin Notarised CE certification from Nando data base or FSC of any reference regulatory authority Valid SIO 13485 Clarification of Stabilities studies and provide DOC

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