

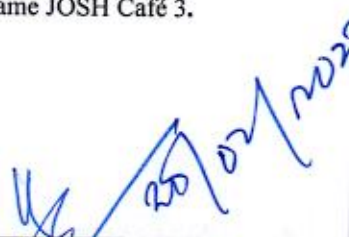


No.F.4-1/2023-MD (M-54)
Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
Drug Regulatory Authority of Pakistan

Islamabad the 20th February, 2023.

Subject:- **REGISTRATION/ENLISTMENT OF MEDICAL DEVICES FOR IMPORT -
DEFERRED CASES (SUBMISSION OF DEFICIENT INFORMATION/DOCUMENTS
THEREOF)**

The applications of following applicants were placed before Medical Device Board (MDB) in its 54th meeting held on 31st January, 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 Firm (s)	Name of Manufacturer	Name of Medical Devices.	Decision
1.	M/S TRI-TECH INTERNATIONAL 10-C, 6TH Sunset Commercial Lane, Phase 2 EXT, DHA, KARACHI, PAKISTAN. ELI-00247 142-C Evaluator: AD-III	Legal Manufacturer: M/S Jiangsu Yuyue Medical Equipment & Supply Co., Ltd No. 1 Baisheng Road, Development Zone, Danyang, Jiangsu, 212300 China. Manufacturing facilities: M/S Jiangsu Yuyue Medical Equipment & Supply Co., Ltd No. 1 Baisheng Road, Development Zone, Danyang, Jiangsu, 212300 China. and M/S Jiangsu Yuyue Medical Equipment & Supply Co., Ltd Yunyang Industrial Park, Danyang City, Jiangsu Province, CHINA FSC China validity 09-02-2024 FSC Germany issued 11-08-2021	Yuwell Electronic Blood Pressure Monitor Class-B Shelf life: 5 years Model: YE660D	Deferred for provision of original FSC of Germany duly attested by Embassy of Pakistan.
2.	DKT Pakistan (Pvt) Ltd. RJ Building, 4 th Floor, Plot No. 37-C, Stadium Lane No. 2, Stadium Commercial Area, Phase V, DHA Karachi.	Legal Manufacturer: M/s Thai Nippon Rubber Industry Public Company Limited. 789/ 139 Moo 1 Pinthong Industrial estate Nonkham, Sriracha, Chonburi 20110, Thailand. FSC Thailand validity 05-06-2024	Josh Condom (Male Latex Condom) Class-C Shelf life: Not provided Codes: JOSH Café'3	Deferred for clarification of name JOSH Café 3. 

Deferred Letters of 54th Meeting of MDB (31-01-2023)

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	(ELI-00515) 1220 Evaluator: AD-III		Josh Classic-144's Josh Classic 5's Josh Classic 4's Josh Neon 3's Josh Ultrathin 3's	
3.	DKT Pakistan (Pvt) Ltd. RJ Building, 4 th Floor, Plot No. 37-C, Stadium Lane No. 2, Stadium Commercial Area, Phase V, DHA Karachi. (ELI-00515) 1220 Evaluator: AD-III	Legal Manufacturer: M/s Thai Nippon Rubber Industry Public Company Limited. 789/ 139 Moo 1 Pinthong Industrial estate Nonkham, Sriracha, Chonburi 20110, Thailand. FSC Thailand validity 05-06- 2024	Josh Condom (Male Latex Condom) Class-C Shelf life: Not provided Codes: JOSH Café'3 Josh Classic-144's Josh Classic 5's Josh Classic 4's Josh Neon 3's Josh Ultrathin 3's	Deferred for clarification of name JOSH Café'3.
4.	DKT Pakistan (Pvt) Ltd. RJ Building, 4 th Floor, Plot No. 37-C, Stadium Lane No. 2, Stadium Commercial Area, Phase V, DHA Karachi. (ELI-00515) 1220 Evaluator: AD-III	Legal Manufacturer: M/s Thai Nippon Rubber Industry Public Company Limited. 789/ 139 Moo 1 Pinthong Industrial estate Nonkham, Sriracha, Chonburi 20110, Thailand. FSC Thailand validity 05-06-2024	Josh Condom (Male Latex Condom) Class-C Shelf life: Not provided Codes: JOSH Menthol 3's JOSH Menthol 4's JOSH Strawberry 3's JOSH Strawberry 4's	Deferred for further clarification use of flavourants.
5.	M/s Eastern Medical Care (Pvt) Ltd, 7-A, Block N, Model Town, Lahore (ELI: 00130) Evaluator AD-II (2622-P)	Legal Manufacturer: M/s Inofab Saglik Teknolojileri A.S, Universiteler Mah. Ihsan Dogramaci Blv. No. 17/115 Cankaya/Ankara, Turkey FSC: Turkey Date of Issue: 23.02.2021 Validity: 03 Years	Spirohome (Spirohome Personal Ultrasonic spirometer) Codes & Sizes: As per FSC Class-B Shelf Life: Not provided Fee: Rs. 5,000	Deferred for the provision of following; <ul style="list-style-type: none">Valid ISO-13485 certificate;Full Quality Assurance Certificate or equivalent as applicable duly notarized in the country of origin;Proposed MRP.
6.	M/s Eastern Medical Care (Pvt) Ltd, 7-A, Block N, Model Town, Lahore	Legal Manufacturer: M/s Inofab Saglik Teknolojileri A.S, Universiteler Mah. Ihsan Dogramaci Blv. No. 17/115	Spirohome (Spiroway reusable mouth piece)	Deferred for the provision of following; <ul style="list-style-type: none">Valid ISO-13485 certificate;Full Quality Assurance

	(ELI: 00130) EvaluatorAD-II (2623-P)	Cankaya/Ankara, Turkey FSC: Turkey Date of Issue: 23.02.2021 Validity: 03 Years	Codes & Sizes: As per FSC Class-B Shelf Life: No stability study (Battery life) Fee: Rs. 25,000	Certificate or equivalent as applicable duly notarized in the country of origin: • Proposed MRP.
7.	M/s Eastern Medical Care (Pvt) Ltd, 7-A, Block N, Model Town, Lahore (ELI: 00130) EvaluatorAD-II (2632-P)	Legal Manufacturer: M/s Inofab Saglik Teknolojileri A.S, Universiteler Mah. Ihsan Dogramaci Blv. No. 17/115 Cankaya/Ankara, Turkey FSC: Turkey Date of Issue: 23.02.2021 Validity: 03 Years	Spirohome (Spiroway disposable mouthpiece) Codes & Sizes: As per FSC Class-B Shelf Life: as per stability study Fee: Rs. 25,000	Deferred for the provision of following; • Valid ISO-13485 certificate; • Full Quality Assurance Certificate or equivalent as applicable duly notarized in the country of origin; • Proposed MRP.
8.	M/s Eastern Medical Care (Pvt) Ltd, 7-A, Block N, Model Town, Lahore (ELI: 00130) EvaluatorAD-II (2633-P)	Legal Manufacturer: M/s Inofab Saglik Teknolojileri A.S, Universiteler Mah. Ihsan Dogramaci Blv. No. 17/115 Cankaya/Ankara, Turkey FSC: Turkey Date of Issue: 23.02.2021	Spirohome (Spirohome clinic ultrasonic spirometer) Codes & Sizes: As per FSC Class-B Shelf Life: as per stability study Fee: Rs. 25,000	Deferred for the provision of following; • Valid ISO-13485 certificate; • Full Quality Assurance Certificate or equivalent as applicable duly notarized in the country of origin; • Proposed MRP.
9.	M/s Medilution Healthcare A- 322, First Floor, Gulshan-e-Iqbal, Block II, KDA Scheme 24, Karachi. (ELI: 00157) Evaluator: AD-II	Legal Manufacturer: M/s ME Medical AG. via Valresa 52C 6645 Brione sopra Minusio Switzerland. Contract Manufacturer: M/s Shanghai POVOS Electric Works Co. Ltd, No.99, East Wenxiang Road, Songjiang	ME Medical Professional Clipper Class: A Shelf Life: N/A Fee: Rs. 5,000	Deferred for provision of following; • Free sale certificate in the country of origin duly attested by Embassy of Pakistan; • Original Agency agreement/ Letter of Authorization from Manufacturer / Market Authorization Holder duly

	(191-C)	Shanghai, China. FSC: Switzerland Date of Issue: 11.03.2022		notarized from the country of origin; • Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized in the country of Origin.
10.	M/s Universal Dental Pvt. Ltd, 17-Mcleod Road, Lahore (ELI 00071) Evaluator: AD-II (3456-P)	Legal Manufacturer: M/s Associated Dental Products Ltd, Kemdent Works, Purton, Swindon, Wiltshire, SN5 AHT, United Kingdom FSC: UK Valid till: 21/12/2022	Zonalin (Zinc oxide eugenol Dental cement) Codes & Sizes: As per FSC Class-B Shelf Life: 3 years	Deferred for provision of following; • Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized in the country of origin; • Original Free sale certificate in the country of origin duly attested by Embassy of Pakistan; • Original Agency agreement / Letter of Authorization from Manufacturer / Market Authorization Holder duly notarized from the country of origin; • Full Quality Assurance Certificate or equivalent as applicable duly notarized in the country of origin; • Declaration of conformity (DoC), to be printed on the manufacturer's letterhead, filled and signed by the responsible person.
11.	M/s Universal Dental Pvt. Ltd, 17-Mcleod Road, Lahore (ELI 00071) Evaluator: AD-II (3415-P)	Legal Manufacturer: M/s Beviston GmbH Scharnstedter Weg 34-36 27639 Wurster, Nordseekuste Germany FSC: Germany Date of Issue: 07/12/2021	Bevistosept (Disinfectant for surfaces) Codes & Sizes: As per FSC Class-B Shelf Life: 3 years	Deferred for provision of following; • Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized in the country of origin; • Original Free sale certificate in the country of origin duly attested by Embassy of Pakistan; • Original Agency agreement / Letter of Authorization from

				<p>Manufacturer / Market Authorization Holder duly notarized from the country of origin:</p> <ul style="list-style-type: none"> • Full Quality Assurance Certificate or equivalent as applicable duly notarized in the country of origin: • Declaration of conformity (DoC), to be printed on the manufacturer's letterhead, filled and signed by the responsible person.
12.	<p>M/s Universal Dental Pvt. Ltd, 17-Mcleod Road, Lahore</p> <p>(ELI 00071)</p> <p>Evaluator: AD-II</p> <p>(3372-P)</p>	<p>Legal Manufacturer:</p> <p>M/s Produits Dentaires SA, Rue des Bosquets 18, 1800 vevey, Switzerland</p> <p>FSC: Switzerland</p> <p>Valid till: 02/10/2023</p>	<p>Eugenol</p> <p>(Dental cement)</p> <p>Codes & Sizes: As per FSC</p> <p>Class-B</p> <p>Shelf Life: 5 years</p>	<p>Deferred for provision of following;</p> <ul style="list-style-type: none"> • Original Free sale certificate in the country of origin duly attested by Embassy of Pakistan: • Declaration of conformity (DoC), to be printed on the manufacturer's letterhead, filled and signed by the responsible person.
13.	<p>M/s Universal Dental Pvt. Ltd, 17-Mcleod Road, Lahore</p> <p>(ELI 00071)</p> <p>Evaluator: AD-II</p> <p>(3374-P)</p>	<p>Legal Manufacturer:</p> <p>M/s Produits Dentaires SA, Rue des Bosquets 18, 1800 vevey, Switzerland</p> <p>FSC: Switzerland</p> <p>Valid till: 02/10/2023</p>	<p>EssenSeal</p> <p>(Root canal sealer)</p> <p>Codes & Sizes: As per FSC</p> <p>Class-B</p> <p>Shelf Life: 3 years</p>	<p>Deferred for provision of following;</p> <ul style="list-style-type: none"> • Original Free sale certificate in the country of origin duly attested by Embassy of Pakistan: • Declaration of conformity (DoC), to be printed on the manufacturer's letterhead, filled and signed by the responsible person.
14.	<p>M/s Universal Dental Pvt. Ltd, 17-Mcleod Road, Lahore</p> <p>(ELI 00071)</p> <p>Evaluator: AD-II</p> <p>(3373-P)</p>	<p>Legal Manufacturer:</p> <p>M/s Produits Dentaires SA, Rue des Bosquets 18, 1800 vevey, Switzerland</p> <p>FSC: Switzerland</p> <p>Valid till: 02/10/2023</p>	<p>Opacal</p> <p>(Calcium hydroxide paste for Root canal dressing)</p> <p>Codes & Sizes: As per FSC</p> <p>Class-B</p> <p>Shelf Life: 3 years</p>	<p>Deferred for provision of following;</p> <ul style="list-style-type: none"> • Original Free sale certificate in the country of origin duly attested by Embassy of Pakistan: • Declaration of conformity (DoC), to be printed on the manufacturer's letterhead, filled and signed by the responsible person.

15.	M/s Universal Dental Pvt. Ltd, 17-Mcleod Road, Lahore (ELI 00071) Evaluator: AD-II (3368-P)	Legal Manufacturer: M/s Produits Dentaires SA, Rue des Bosquets 18, 1800 vevey, Switzerland FSC: Switzerland Valid till: 02/10/2023	Eugenate Desobturator (Root canal cleaning and irrigation) Codes & Sizes: As per FSC Class-B Shelf Life: 5 years	Deferred for provision of following; • Original Free sale certificate in the country of origin duly attested by Embassy of Pakistan: • Declaration of conformity (DoC), to be printed on the manufacturer's letterhead, filled and signed by the responsible person.
16.	M/s Universal Dental Pvt. Ltd, 17-Mcleod Road, Lahore (ELI 00071) Evaluator: AD-II (3371-P)	Legal Manufacturer: M/s Produits Dentaires SA, Rue des Bosquets 18, 1800 vevey, Switzerland FSC: Switzerland Valid till: 02/10/2023	Zinc Oxide Dental Cement (Dental cement) Codes & Sizes: As per FSC Class-B Shelf Life: 5 years	Deferred for provision of following; • Original Free sale certificate in the country of origin duly attested by Embassy of Pakistan: • Declaration of conformity (DoC), to be printed on the manufacturer's letterhead, filled and signed by the responsible person.
17.	M/s Universal Dental Pvt. Ltd, 17-Mcleod Road, Lahore (ELI 00071) Evaluator: AD-II (3370-P)	Legal Manufacturer: M/s Produits Dentaires SA, Rue des Bosquets 18, 1800 vevey, Switzerland FSC: Switzerland Valid till: 02/10/2023	Root canal enlarger EDTA solution 17% (Chelating agent Root canal cleaning and irrigation) Codes & Sizes: As per FSC Class-B Shelf Life: 3 years	Deferred for provision of following; • Original Free sale certificate in the country of origin duly attested by Embassy of Pakistan: • Declaration of conformity (DoC), to be printed on the manufacturer's letterhead, filled and signed by the responsible person.
18.	M/s Universal Dental Pvt. Ltd, 17-Mcleod Road, Lahore (ELI 00071) Evaluator: AD-II (3369-P)	Legal Manufacturer: M/s Produits Dentaires SA, Rue des Bosquets 18, 1800 vevey, Switzerland FSC: Switzerland Valid till: 02/10/2023	PD MTA White (Endodontic cement) Codes & Sizes: As per FSC Class-B Shelf Life: 3 years	Deferred for provision of following; • Original Free sale certificate in the country of origin duly attested by Embassy of Pakistan: • Declaration of conformity (DoC), to be printed on the manufacturer's letterhead, filled and signed by the responsible person.

	<p>M/s Universal Dental Pvt. Ltd, 17-Mcleod Road, Lahore (ELI 00071)</p> <p>Evaluator: AD-II (3359-P)</p>	<p>Legal Manufacturer: M/s Cavex Holland BV, Fustweg 5, 2031CJ Haarlem, the Netherlands.</p> <p>FSC: Netherlands</p> <p>Valid till: 04.08.2022</p>	<p>Cavex Temporary Cement (Dental Cement)</p> <p>Codes & Sizes: As per FSC</p> <p>Class-B</p> <p>Shelf Life; 3 years</p>	<p>Deferred for provision of following;</p> <ul style="list-style-type: none"> • Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized in the country of origin; • Original Free sale certificate in the country of origin duly attested by Embassy of Pakistan; • Full Quality Assurance Certificate or equivalent as applicable duly notarized in the country of origin; • Declaration of conformity (DoC), to be printed on the manufacturer's letterhead, filled and signed by the responsible person.
20.	<p>M/s Universal Dental Pvt. Ltd, 17-Mcleod Road, Lahore (ELI 00071)</p> <p>Evaluator: AD-II (3360-P)</p>	<p>Legal Manufacturer: M/s Produits Dentaires SA, Rue des Bosquets 18, 1800 vevey, Switzerland</p> <p>FSC: Switzerland</p> <p>Valid till: 02/10/2023</p>	<p>Rosen Root Canal Cement (Zinc oxide based radiopaque Root canal sealer silver free)</p> <p>Codes & Sizes: As per FSC</p> <p>Class-B</p> <p>Shelf Life: 3 years</p>	<p>Deferred for provision of following;</p> <ul style="list-style-type: none"> • Original Free sale certificate in the country of origin duly attested by Embassy of Pakistan; • Declaration of conformity (DoC), to be printed on the manufacturer's letterhead, filled and signed by the responsible person.
21.	<p>M/s Universal Dental Pvt. Ltd, 17-Mcleod Road, Lahore (ELI 00071)</p> <p>Evaluator: AD-II (1914-P)</p>	<p>Legal Manufacturer: M/s Septodont 58 rue du Pont de Creteil 94107 saint-Maur-des-Fossess Cedex, France.</p> <p>FSC: France</p> <p>Date of issue: 30.04.2020</p>	<p>Endomethasone Liquid</p> <p>Codes & Sizez: As per FSC</p> <p>Class-B</p> <p>Shelf Life: 36 months</p>	<p>Deferred for provision of following;</p> <ul style="list-style-type: none"> • Original Free sale certificate in the country of origin duly attested by Embassy of Pakistan; • Original Full Quality Assurance Certificate or equivalent as applicable duly notarized in the country of origin; • Declaration of conformity (DoC), to be printed on the manufacturer's letterhead, filled and signed by the responsible person.


22.	<p>M/s Universal Dental Pvt. Ltd, 17-Mcleod Road, Lahore</p> <p>(ELI 00071)</p> <p>Evaluator: AD-II</p> <p>(1915-P)</p>	<p>Legal Manufacturer:</p> <p>M/s Septodont 58 rue du Pont de Creteil 94107 saint-Maur-des-Fosses Cedex, France.</p> <p>FSC: France</p> <p>Date of issue: 30.04.2020</p>	<p>Alveogyl</p> <p>Class-B</p> <p>Code & Size: As per FSC</p> <p>Shelf Life: 25 months</p>	<p>Deferred for provision of following;</p> <ul style="list-style-type: none"> • Original Free sale certificate in the country of origin duly attested by Embassy of Pakistan; • Original Full Quality Assurance Certificate or equivalent as applicable duly notarized in the country of origin; • Declaration of conformity (DoC), to be printed on the manufacturer's letterhead, filled and signed by the responsible person.
23.	<p>M/s Universal Dental Pvt. Ltd, 17-Mcleod Road, Lahore</p> <p>(ELI 00071)</p> <p>Evaluator: AD-II</p> <p>(2331-P)</p>	<p>Legal Manufacturer:</p> <p>M/s Cavex Holland BV, Fustweg 5, 2031CJ Haarlem, the Netherlands.</p> <p>FSC: Netherlands</p> <p>Valid till: 04.08.2022</p>	<p>Cavex Exsense</p> <p>(Dental Desensitizer Agent)</p> <p>Codes & Sizes: As per FSC</p> <p>Class-B</p> <p>Shelf Life: 3 years</p>	<p>Deferred for provision of the following;</p> <ul style="list-style-type: none"> • Original Free sale certificate in the country of origin duly attested by Embassy of Pakistan; • Valid Free Sale Certificate; • Valid ISO 13485 Certificate; • Valid Full Quality Assurance Certificate or equivalent.
24.	<p>M/s Hospital Solutions, H. No. 174-E Block 2, P.E.C.H.S Karachi.</p> <p>ELI No. 00250</p> <p>Evaluator: AD-II</p> <p>(221-C)</p>	<p>Legal Manufacturer:</p> <p>M/s Wuhan Snow Medical Disinfectant Co. Ltd, No. 18, Yinhu Science & Technology Industrial Park, Dongxiu District Wuhan Hubei, China 430040</p> <p>FSC China</p> <p>Issued on 28-01-2022</p> <p>Valid for 2 years</p>	<p>OPA Disinfectant Ortho Phthalaldehyde 0.5% Solution 5L & 1L</p> <p>Class B</p> <p>Shelf Life: 05 Years</p>	<p>Deferred for provision of FSC of any reference country or CE Marking Certificates.</p>
25.	<p>M/s Hospital Solutions, H. No. 174-E Block 2, P.E.C.H.S Karachi.</p> <p>ELI No. 00250</p> <p>Evaluator: AD-II</p> <p>(4811-P)</p>	<p>Legal Manufacturer:</p> <p>M/s Wuhan Snow Medical Disinfectant Co. Ltd, No. 18, Yinhu Science & Technology Industrial Park, Dongxiu District Wuhan Hubei, China 430040</p> <p>FSC China</p> <p>Issued on 28-01-2022</p> <p>Valid for 2 years</p>	<p>Snow Xue Huan Glutaraldehyde Solution</p> <p>(Glutaraldehyde 2%)</p> <p>Class D</p> <p>Shelf Life: 02 Years</p>	<p>Deferred for provision of FSC of any reference country or CE Marking Certificates.</p>

26.	Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi ELI-00109 2919-P Evaluator: AD-V	Legal Manufacturer: M/s BioMerieux SA 376 Chemin de l'Orme 69280 Marcy-l'Etoile France FSC: France Date of Issue: 15-10-2021	ARGENE ® COVID-19 R-GENE (SARS-COV-2 detection PCR kit) Code: 424017 Class-C Shelf Life: 12 months	Deferred for provision of valid and duly notarized Letter of Authorization and stability studies data for claimed shelf life of 12 months.
27.	Biosorin (Private) Limited, 19-Usman Block, Main Boulevard New Garden Town, Lahore ELI: 00186 2934-P Evaluator: AD-V	Legal Manufacturer: M/s William A. Cook Australia Pty Ltd, 95 Brandl Street Brisbane Technology Park Eight Mile Plains, Queensland 4113, Australia FSC: Australia Date of Issue: 19.08.2020	Ovum Aspiration Needle Double Lumen (Double Lumen Ovum Pick-up Needle) Codes & Sizes: K-OPSD-1630-B-L K-OPSD-1635-A-L K-OPSD-1635-B-L K-OPSD-1730-A-L K-OPSD-1735-A-L K-OPSD-1735-B-L Class-B Shelf Life: 3 years	Deferred for provision of valid & duly notarized Letter of Authorization.
28.	Hamza Trading Co., Office No. 302, 3rd Floor, Makkah Market, Katchi Gali No.1, Marriot Road, Densohall, Karachi. (ELI-00280) -4982-	M/s Huaina Tianda medical instruments co. ltd., 106, east songjiang road, huaiyin economical & technological development zone, huaiyan, jiangsu, china. FSC (Copy) valid till 27-10-2023.	National sterile surgical blade. Class: B Shelf life: 05-years. Codes and Sizes as per FSC.	Deferred for provision of FSC of any reference country or CE mark documents, Letter of Authorization and original FSC of country of origin.
29.	Hamza Trading Co., Office No. 302, 3rd Floor, Makkah Market, Katchi Gali No.1, Marriot Road, Densohall, Karachi (ELI-00280) -3227-	M/s Suzhou Health Medical Plastic Products Co., Ltd Donggu Road (Middle), Qiushe Industrial Park, Tongli Town, Wujiang Suzhou, 215216 Jinagsu China. FSC (China) valid until 14-03-2021.	National Three-way stopcock. Class: B Shelf life: 05-years. Codes and Sizes as per FSC	Deferred for provision of FSC of any reference country or CE mark documents, Letter of Authorization and original FSC of country of origin.
30.	Hamza Trading Co., Office No. 302, 3rd Floor, Makkah Market, Katchi Gali No.1, Marriot Road,	M/s Suzhou Health Medical Plastic Products Co., Ltd Donggu Road (Middle), Qiushe Industrial Park, Tongli Town, Wujiang Suzhou, 215216 Jinagsu China.	National IV-Flow Regulator. Class: B Shelf life: 05-years. Codes and Sizes as per FSC.	Deferred for provision of FSC of any reference country or CE mark documents, Letter of Authorization and original FSC of country of origin.

	Densohall, Karachi (ELI-00280) 3217	FSC (China) valid until 14-03-2021.				
31.	Hamza Trading Co., Office No. 302, 3rd Floor, Makkah Market, Katchi Gali No.1, Marriot Road, Densohall, Karachi (ELI-00280) 3216	M/s Suzhou Health Medical Plastic Products Co., Ltd Donggu Road (Middle), Qiushe Industrial Park, Tongli Town, Wujiang Suzhou, 215216 Jinagsu China FSC (China) valid until 14-03-2021.	National Heparin cap, Class: B Shelf life: 05-years. Codes and Sizes as per FSC	Deferred for provision of FSC of any reference country or CE mark documents, Letter of Authorization and original FSC of country of origin.		
32.	M/s Briogene Pvt Ltd, 196-A, Sindhi Muslim Cooperative Housing Society, Shahrah-e-Faisal, Karachi (ELI-00015) Evaluator : AD VI	Legal Manufacture M/s Thermo Fisher Scientific Oy, Ratastie 2, FI-01620 Vantaa, Finland. FSC: FINLAND DATE OF FSC: 24 Feb. 2021	INDIKO chemistry Analyzer. • Class -A • Claimed Shelf Life: N/A • Codes as per FSC.	Deferred for provision of FSC of any reference country or CE mark documents and valid Letter of Authorization.		
33.	M/s Briogene Pvt Ltd, 196-A, Sindhi Muslim Cooperative Housing Society, Shahrah-e-Faisal, Karachi (ELI-00015) Evaluator AD VI	Legal Manufacture M/s Xiamen Zeesan Pvt.Ltd Building 1#, 4F and include complete address, telephone number, fax number area 3F of Building 11#, No.3701 North and its official website: Xiang'an Road, (Xiang An) Industrial Area, Torch High-Tech Zoiie, Xiamen City, Fujian Province, 361101, P.R. China FSC: China DATE OF FSC: July 22, 2020.	Lab-Aid Virus RNA Extraction Kit • Class -B • Claimed Shelf life: 12 Months • Codes as per FSC • Code#606104	Deferred for provision of FSC of any reference country or CE mark documents, valid FSC of country of origin, valid ISO 13485 and valid Letter of Authorization.		
34.	M/s Briogene Pvt Ltd, 196-A, Sindhi Muslim Cooperative Housing Society, Shahrah-e-Faisal, Karachi (ELI-00015) Evaluator: AD VI	Legal Manufacture Thermo Fisher Scientific Oy, Ratastie 2,FI-01620 Vantaa, Finland. FSC: FINLAND Date of FSC: 13th June 2022	Clinical Chemistry (Anemia) Codes as per FSC: • Class -B • HS Codes 3822 00 00 • Claimed Shelf Life: 18- 24 Months <table><tr><td>ITEM</td><td>CODE</td></tr></table>	ITEM	CODE	Deferred for provision of FSC of any reference country or CE mark documents and valid Letter of Authorization.
ITEM	CODE					

			<table><tr><td>Iron 10 x 20 ml</td><td>981236</td></tr><tr><td>FERRITIN</td><td>981949</td></tr><tr><td>sTfR (Soluble Transferrin Receptor) 2 x 5 ml</td><td>981945</td></tr><tr><td>Transferrin 2 x 3 ml</td><td>981943</td></tr><tr><td>SpeciCal</td><td>980997</td></tr><tr><td>Ferritin Calibration</td><td>981874</td></tr><tr><td>Specitrol High 5 x 1</td><td>981799</td></tr><tr><td>uTrol 10 x 5 ml</td><td>981821</td></tr><tr><td>uTrol High 10 x 5 ml</td><td>981822</td></tr><tr><td>Ferritin Control 2 x 1 ml</td><td>981875</td></tr><tr><td>Ferritin Control High 2 x 1 ml</td><td>981875</td></tr><tr><td>sTfR Control 2 x 1 ml</td><td>981866</td></tr><tr><td>sTfR Control High 2 x 1 ml</td><td>981867</td></tr></table>	Iron 10 x 20 ml	981236	FERRITIN	981949	sTfR (Soluble Transferrin Receptor) 2 x 5 ml	981945	Transferrin 2 x 3 ml	981943	SpeciCal	980997	Ferritin Calibration	981874	Specitrol High 5 x 1	981799	uTrol 10 x 5 ml	981821	uTrol High 10 x 5 ml	981822	Ferritin Control 2 x 1 ml	981875	Ferritin Control High 2 x 1 ml	981875	sTfR Control 2 x 1 ml	981866	sTfR Control High 2 x 1 ml	981867	
Iron 10 x 20 ml	981236																													
FERRITIN	981949																													
sTfR (Soluble Transferrin Receptor) 2 x 5 ml	981945																													
Transferrin 2 x 3 ml	981943																													
SpeciCal	980997																													
Ferritin Calibration	981874																													
Specitrol High 5 x 1	981799																													
uTrol 10 x 5 ml	981821																													
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Ferritin Control 2 x 1 ml	981875																													
Ferritin Control High 2 x 1 ml	981875																													
sTfR Control 2 x 1 ml	981866																													
sTfR Control High 2 x 1 ml	981867																													
35.	M/s Briogene Pvt Ltd, 196-A, Sindhi Muslim Cooperative Housing Society, Shahrah-e-Faisal, Karachi (ELI-00015) Evaluator: AD VI	Legal Manufacture Thermo Fisher Scientific Oy, Ratastie 2, FI-01620 Vantaa, Finland. FSC: FINLAND DATE OF FSC: 13th June 2022	Clinical Chemistry (Complement Component) Generic Name: Clinical Chemistry (Complement Component) Codes as per FSC: <ul style="list-style-type: none">• Class -B• HS Codes 3822 00 00• Claimed Shelf Life: 18- 24 Months	Deferred for provision of FSC of any reference country or CE mark documents and valid Letter of Authorization.																										

			<table><tr><td>ITEM</td><td>CODE</td></tr><tr><td>Complement C3 2 x 3</td><td>981931</td></tr><tr><td>Complement C4</td><td>981932</td></tr></table>	ITEM	CODE	Complement C3 2 x 3	981931	Complement C4	981932									
ITEM	CODE																	
Complement C3 2 x 3	981931																	
Complement C4	981932																	
36.	M/s Briogene Pvt Ltd, 196-A, Sindhi Muslim Cooperative Housing Society, Shahrah-e-Faisal, Karachi (ELI-00015) Evaluator: AD VI	Name of Manufacturer/ Legal Manufacture Thermo Fisher Scientific Oy, Ratastie 2, FI-01620 Vantaa, Finland FSC: FINLAND DATE OF FSC: 13th June 2022	Clinical Chemistry (Diabetic Assay) Codes as per FSC: <ul style="list-style-type: none">• Class -B• HS Codes 3822 00 00• Claimed Shelf Life: 18- 24 Months <table><tr><td>ITEM</td><td>CODE</td></tr><tr><td>HbA1c Pretreatment Liquid 12 x20 ml</td><td>981948</td></tr><tr><td>HbA1c Pretreatment Liquid 12 x 20 ml</td><td>981924</td></tr><tr><td>HbA1c Calibrator or 3 x 2 ml</td><td>981863</td></tr><tr><td>HbA1c Control Normal 5 x 1 ml</td><td>981695</td></tr><tr><td>HbA1c Control Abnormal 5 x 1 ml</td><td>981696</td></tr><tr><td>HbA1c Reagent</td><td>981947</td></tr></table>	ITEM	CODE	HbA1c Pretreatment Liquid 12 x20 ml	981948	HbA1c Pretreatment Liquid 12 x 20 ml	981924	HbA1c Calibrator or 3 x 2 ml	981863	HbA1c Control Normal 5 x 1 ml	981695	HbA1c Control Abnormal 5 x 1 ml	981696	HbA1c Reagent	981947	Deferred for provision of FSC of any reference country or CE mark documents and valid Letter of Authorization.
ITEM	CODE																	
HbA1c Pretreatment Liquid 12 x20 ml	981948																	
HbA1c Pretreatment Liquid 12 x 20 ml	981924																	
HbA1c Calibrator or 3 x 2 ml	981863																	
HbA1c Control Normal 5 x 1 ml	981695																	
HbA1c Control Abnormal 5 x 1 ml	981696																	
HbA1c Reagent	981947																	

	<p>Briogene Pvt Ltd, 196-A, Sindhi Muslim Cooperative Housing Society, Shahrah-e-Faisal, Karachi</p> <p>(ELI-00015)</p> <p>Evaluator</p> <p>AD VI</p>	<p>Name of Manufacturer Legal Manufacture</p> <p>Thermo Fisher Scientific Oy, Ratastie 2,FI-01620 Vantaa, Finland</p> <p>FSC: FINLAND</p> <p>DATE OF FSC: 13th June 2022</p>	<p>Clinical Chemistry (Immunoglobulin) Codes as per FSC:</p> <ul style="list-style-type: none">• Class -B• HS Codes 3822 00 00• Claimed Shelf Life : 18- 24 Months <table><tr><th>ITEM</th><th>CODE</th></tr><tr><td>MMU NOGL OBUL IN M (IgM) 2 x 3 ml.</td><td>981938</td></tr><tr><td>IMMU NOGL OBUL IN A (IgA)</td><td>981936</td></tr><tr><td>IMMU NOGL OBUL IN G (IgG)</td><td>981937</td></tr></table>	ITEM	CODE	MMU NOGL OBUL IN M (IgM) 2 x 3 ml.	981938	IMMU NOGL OBUL IN A (IgA)	981936	IMMU NOGL OBUL IN G (IgG)	981937	<p>Deferred for provision of FSC of any reference country or CE mark documents and valid Letter of Authorization.</p>
ITEM	CODE											
MMU NOGL OBUL IN M (IgM) 2 x 3 ml.	981938											
IMMU NOGL OBUL IN A (IgA)	981936											
IMMU NOGL OBUL IN G (IgG)	981937											
38.	<p>Briogene Pvt Ltd, 196-A, Sindhi Muslim Cooperative Housing Society, Shahrah-e-Faisal, Karachi</p> <p>(ELI-00015)</p> <p>Evaluator</p> <p>AD VI</p>	<p>Legal Manufacture Thermo Fisher Scientific Oy, Ratastie 2,FI-01620 Vantaa, Finland</p> <p>FSC: FINLAND</p> <p>DATE OF FSC: 13th June 2022.</p>	<p>Clinical Chemistry Lipoprotein Clinical Chemistry Lipoprotein</p> <p>Codes as per FSC:</p> <ul style="list-style-type: none">• Class -B• HS Codes 3822 00 00• Claimed Shelf Life: 18- 24 Months <table><tr><th>ITEM</th><th>CODE</th></tr><tr><td>Apolipo protein A1</td><td>981929</td></tr><tr><td>Apolipo protein</td><td>981930</td></tr></table>	ITEM	CODE	Apolipo protein A1	981929	Apolipo protein	981930	<p>Deferred for provision of FSC of any reference country or CE mark documents and valid Letter of A uthorization.</p> 		
ITEM	CODE											
Apolipo protein A1	981929											
Apolipo protein	981930											
39.	<p>M/s Briogene Pvt Ltd, 196-A, Sindhi Muslim Cooperative</p>	<p>Legal Manufacture Thermo Fisher Scientific Oy, Ratastie 2,FI-01620 Vantaa, Finland</p>	<p>Clinical Chemistry Other Specific Proteins</p>	<p>Deferred for provision of FSC of any reference country or CE mark documents and valid Letter of Authorization.</p>								

	M/s Briogene Pvt Ltd, 196-A, Sindhi Muslim Cooperative Housing Society, Shahrah-e-Faisal, Karachi (ELI-00015) Evaluator: AD VI	Legal Manufacture Thermo Fisher Scientific Oy, Ratastie 2,FI-01620 Vantaa, Finland FSC: FINLAND DATE OF FSC: 13th June 2022	Clinical Chemistry Rheumatoid Marker Cluster Codes as per FSC: • Class -B • HS Codes 3822 00 00 • Claimed Shelf Life: 18- 24 Months <table><tr><th>ITEM</th><th>CODE</th></tr><tr><td>Rheumato id Factors 2 (RF 2) 2 x 6 ml</td><td>981920</td></tr><tr><td>Rheumato id Factors Control</td><td>981252</td></tr></table>	ITEM	CODE	Rheumato id Factors 2 (RF 2) 2 x 6 ml	981920	Rheumato id Factors Control	981252	Deferred for provision of FSC of any reference country or CE mark documents and valid Letter of Authorization.										
ITEM	CODE																			
Rheumato id Factors 2 (RF 2) 2 x 6 ml	981920																			
Rheumato id Factors Control	981252																			
41.	M/s Briogene Pvt Ltd, 196-A, Sindhi Muslim Cooperative Housing Society, Shahrah-e-Faisal, Karachi (ELI-00015) Evaluator: AD VI	Legal Manufacture Thermo Fisher Scientific Oy, Ratastie 2,FI-01620 Vantaa, Finland. FSC: FINLAND DATE OF FSC: 13th June 2022	Clinical Chemistry Cluster of Substrates- Calibrators and Controls. Codes as per FSC: • Class -B • HS Codes 3822 00 00 • Claimed Shelf Life: 18- 24 Months <table><tr><th>Item</th><th>Code</th></tr><tr><td>HDL / LDL CHOL. CALIBRA TOR</td><td>981657</td></tr><tr><td>NORTROL</td><td>981043</td></tr><tr><td>ABTROL</td><td>981044</td></tr><tr><td>LIPOTROL</td><td>981653</td></tr><tr><td>LIPOTROL HDL/LDL Abnormal</td><td>981907</td></tr><tr><td>Washing Solution</td><td>984030</td></tr><tr><td>ICE Calibrator</td><td>984032</td></tr></table>	Item	Code	HDL / LDL CHOL. CALIBRA TOR	981657	NORTROL	981043	ABTROL	981044	LIPOTROL	981653	LIPOTROL HDL/LDL Abnormal	981907	Washing Solution	984030	ICE Calibrator	984032	Deferred for provision of FSC of any reference country or CE mark documents and valid Letter of Authorization.
Item	Code																			
HDL / LDL CHOL. CALIBRA TOR	981657																			
NORTROL	981043																			
ABTROL	981044																			
LIPOTROL	981653																			
LIPOTROL HDL/LDL Abnormal	981907																			
Washing Solution	984030																			
ICE Calibrator	984032																			
42.	M/s A. Feroz & Co., Medicine Street No. 1, Marriot Road Karachi (ELI-00066)	A&D Company, Limited 1-243 Asahi, Kitamoto-shi Saitama-Ken, 364-8585, Japan Manufacturing site	A&D Multi-function Infrared Thermometer Class B	Deferred for provision of valid original and embassy attested FSC in the country of origin.																

	3171	<p>A & D Electronics (Shenzhen) Co., Ltd. 1-5/F, Building #4, Hengchangrong High Tech Industry Park, Shangnan East Road, Hongtian, Shajing, Bao'an District, Shenzhen, Guangdong, 518125, P.R.China</p> <p>Manufacturing site Radiant Innovation Inc IF, No.3, Industrial E. 9th Rd., Science-Based Industrial Park, HsinChu 300, Taiwan</p>		<p>Provide valid, original and notarized letter of Authorization, since the only unsigned copy is provided.</p> <p>Provide notarised and vlnid ISO 13485 Certificate of all sites.</p> <p>Provide Notarsied and valid FQA Certifaite, EC certificate and DOC.</p>				
43.	<p>Roche Pakistan Limited.</p> <p>1st Floor, 37-B, Block 6, P.E.C.H.S, Karachi.</p> <p>(ELI-00009)</p>	<p>Manufacturer: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany</p> <p>Manufacturing Site:</p> <table border="1"><tr><td>094085921 90</td><td>Roche Molecular Systems Inc., 1080US Highway 202 South Branchburg, NJ 08876, USA.</td></tr><tr><td>094088351 90</td><td></td></tr></table> <p>FSC Germany issue date: 08.09.2021</p>	094085921 90	Roche Molecular Systems Inc., 1080US Highway 202 South Branchburg, NJ 08876, USA.	094088351 90		<p>Cobas SARS-CoV-2 LIAT</p> <p>Class: C</p> <p>Shelf life: 12 M</p> <p>Fee submitted: Rs.50,000</p> <p>1)Code: 09408592190 Cobas SARS-CoV-2 Assay Kit Nucleic acid test for use on the cobas Liat Syatem Pack size: 20 Test</p> <p>2)Code: 09408835190 Cobas SARS-CoV-2 Quality Control Kit for use on the cobas Liat Syatem Pack size: 8 Test Shelf life: 12 M</p>	<p>Defrred for Clarificaton about the two kits applied under single application.</p> <p>Submit revise Form 7A as per barnd name given in FSC.</p> <p>Provide stability study for Cobas SARS-CoV-2 Quality Control Kit</p>
094085921 90	Roche Molecular Systems Inc., 1080US Highway 202 South Branchburg, NJ 08876, USA.							
094088351 90								
44.	<p>Roche Pakistan Limited, 1st Floor, 37-B, Block 6, P.E.C.H.S, Karachi.</p> <p>(ELI-00009)</p>	<p>Manufacturer: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany</p> <p>Manufacturing Site: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany</p> <p>FSC: 24-08-2022</p>	<p>Elecsys HCV Duo</p> <p>Class: D</p> <p>Fee submitted: Rs.50,000</p> <p>Shelf life: 12 months</p> <p>1)Code: 08110697190 Elecsys HCV Duo Pack size: 300 Tests</p>	<p>Defrred for provsiosn of Embassy attested original and valid FSC in the country of origin</p>				

			2)Code: 08335923190 Elecsys PreciControl HCV Duo Pack size: 10 x 1.0ml 5 x 2.0ml	
45.	M/s Tri-Tech International, 10-C, 6TH Sunset Commercial Lane, Phase 2 EXT, DHA, Karachi ELI-00247 144-C Evaluator: <u>AD-III</u>	Legal Manufacturer: M/S Jiangsu Yuyue Medical Equipment & Supply Co., Ltd No. 1 Baisheng Road, Development Zone, Danyang, Jiangsu, 212300 China. Manufacturing facilities: M/S Jiangsu Yuyue Medical Equipment & Supply Co., Ltd No. 1 Baisheng Road, Development Zone, Danyang, Jiangsu, 212300 China. and M/S Jiangsu Yuyue Medical Equipment & Supply Co., Ltd Yunyang Industrial Park, Danyang City, Jiangsu Province, CHINA FSC China validity 09-02-2024 FSC Germany issued 11-08-2021	Yuwell Oxygen Concentrator Class-B Shelf life: 3 years Model: 7F-B5	Deferred for provision of original legalized documents.
46.	M/s Tri-Tech International, 10-C, 6TH Sunset Commercial Lane, Phase 2 EXT, DHA, Karachi. ELI-00247 256-C Evaluator: AD-III	Legal Manufacturer: M/S Avrasyamed Medikal Tibbi Cihazlar ve Urunle Pazalama Sanayi ve Dis Tic. Ltd Sti. Esenyurt, Gokevler Mah.563 Sok. A Block No. 9/B Istanbul, Turkey FSC Turkey Original Validity 24 th Feb , 2025	Medione Automatic Tourniquet Device Class-B Shelf life: 5 years Model: TRQ-2020	Deferred for provision of FSC of any reference country or CE mark documents.
47.	M/s Tri-Tech International, 10-C, 6TH Sunset Commercial Lane, Phase 2 EXT, DHA, Karachi. ELI-00247 257-C Evaluator: AD-III	Legal Manufacturer: M/S Avrasyamed Medikal Tibbi Cihazlar ve Urunle Pazalama Sanayi ve Dis Tic. Ltd Sti. Esenyurt, Gokevler Mah.563 Sok. A Block No. 9/B Istanbul, Turkey FSC Turkey Original Validity 24 th Feb , 2025	Medione Automatic Tourniquet Device Class-B Shelf life: 5 years Model: RQ-2022	Deferred for provision of FSC of any reference country or CE mark documents.
48.	M/s Tri-Tech International, 10-C, 6TH Sunset Commercial Lane,	Legal Manufacturer: M/S Jiangsu Yuyue Medical Equipment & Supply Co., Ltd No. 1 Baisheng Road, Development	Yuwell Mesh Nebulizer Class-B	Deferred for provision of original legalized documents.

	<p>Phase 2 EXT, DHA, Karachi.</p> <p>ELI-00247 139-C</p> <p>Evaluator: AD-III</p>	<p>Zone, Danyang, Jiangsu, 212300 China.</p> <p><u>Manufacturing facilities:</u> M/S Jiangsu Yuyue Medical Equipment & Supply Co., Ltd No. 1 Baisheng Road, Development Zone, Danyang, Jiangsu, 212300 China.</p> <p>and M/S Jiangsu Yuyue Medical Equipment & Supply Co., Ltd Yunyang Industrial Park, Danyang City, Jiangsu Province, CHINA</p> <p>FSC China validity 09-02-2024 FSC Germany issued 11-08-2021</p>	<p>Shelf life: 5 years</p> <p>Model: M102</p>	
49.	<p>M/s Tri-Tech International, 10-C, 6TH Sunset Commercial Lane, Phase 2 EXT, DHA, Karachi.</p> <p>ELI-00247 140-C</p> <p>Evaluator: AD-III</p>	<p><u>Legal Manufacturer:</u> M/S Jiangsu Yuyue Medical Equipment & Supply Co., Ltd No. 1 Baisheng Road, Development Zone, Danyang, Jiangsu, 212300 China.</p> <p><u>Manufacturing facilities:</u> M/S Jiangsu Yuyue Medical Equipment & Supply Co., Ltd No. 1 Baisheng Road, Development Zone, Danyang, Jiangsu, 212300 China.</p> <p>and M/S Jiangsu Yuyue Medical Equipment & Supply Co., Ltd Yunyang Industrial Park, Danyang City, Jiangsu Province, CHINA</p> <p>FSC China validity 09-02-2024 FSC Germany issued 11-08-2021</p>	<p>Yuwell Non-Contact Infrared Thermometer</p> <p>Class-B</p> <p>Shelf life: 5 years</p> <p>Model: YT-2C</p>	Deferred for provision of original legalized documents.
50.	<p>M/s Tri-Tech International, 10-C, 6TH Sunset Commercial Lane, Phase 2 EXT, DHA, Karachi.</p> <p>ELI-00247 141-C</p> <p>Evaluator: AD-III</p>	<p><u>Legal Manufacturer:</u> M/S Jiangsu Yuyue Medical Equipment & Supply Co., Ltd No. 1 Baisheng Road, Development Zone, Danyang, Jiangsu, 212300 China.</p> <p><u>Manufacturing facilities:</u> M/S Jiangsu Yuyue Medical Equipment & Supply Co., Ltd No. 1 Baisheng Road, Development Zone, Danyang, Jiangsu, 212300 China.</p> <p>and M/S Jiangsu Yuyue Medical Equipment & Supply Co., Ltd</p>	<p>Yuwell Portable Phlegm Suction Unit</p> <p>Class-B</p> <p>Shelf life: 5 years</p> <p>Model: 7E-B5</p>	Deferred for provision of original legalized documents.

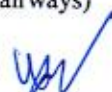
		Yunyang Industrial Park, Danyang City, Jiangsu Province, CHINA FSC China validity 09-02-2024 FSC Germany issued 11-08-2021		
51.	M/s Tri-Tech International, 10-C, 6 TH Sunset Commercial Lane, Phase 2 EXT, DHA, Karachi. ELI-00247 143-C Evaluator: AD-III	Legal Manufacturer: M/S Jiangsu Yuyue Medical Equipment & Supply Co., Ltd No. 1 Baisheng Road, Development Zone, Danyang, Jiangsu, 212300 China. Manufacturing facilities: M/S Jiangsu Yuyue Medical Equipment & Supply Co., Ltd No. 1 Baisheng Road, Development Zone, Danyang, Jiangsu, 212300 China. and M/S Jiangsu Yuyue Medical Equipment & Supply Co., Ltd Yunyang Industrial Park, Danyang City, Jiangsu Province, CHINA FSC China validity 09-02-2024 FSC Germany issued 11-08-2021	Yuwell Finger Pulse Oximeter Class-B Shelf life: 5 years Model: YX102	Deferred for provision of original legalized documents.
52.	M/s Tri-Tech International, 10-C, 6 TH Sunset Commercial Lane, Phase 2 EXT, DHA, Karachi. ELI-00247 138-C Evaluator: AD-III	Legal Manufacturer: M/S Jiangsu Yuyue Medical Equipment & Supply Co., Ltd No. 1 Baisheng Road, Development Zone, Danyang, Jiangsu, 212300 China. Manufacturing facilities: M/S Jiangsu Yuyue Medical Equipment & Supply Co., Ltd No. 1 Baisheng Road, Development Zone, Danyang, Jiangsu, 212300 China. and M/S Jiangsu Yuyue Medical Equipment & Supply Co., Ltd Yunyang Industrial Park, Danyang City, Jiangsu Province, CHINA FSC China validity 09-02-2024 FSC Germany issued 11-08-2021	Yuwell Infrared Ear Thermometer Class-B Shelf life: 5 years Model: YHT101	Deferred for provision of original legalized documents.
53.	M/s. Popular International (PVT) Ltd, House No. 141 Justice Inamullah Road, Block 7&8 K.M.C.H.S Near Hill Park Karachi.	Legal Manufacturer: M/s. Covidien LLC 15 Hamshire street Mansfield MA 02048, USA Manufacturing facility: M/s. Covidien Micheal Collins Road Mervue, Galway Ireland.	INVOS Cerebral/ Somatic Oximeter Class-B Shelf life/ Service life: 5 years	Deferred for provision of following: <ul style="list-style-type: none">• Stability studies supporting claimed Shelf life/ Service life.• DoC with clearly highlighted the Product applied with codes.

	Eli No.00091 172-C Evaluator: AD-III	FSC USFDA valid till 13-01-2023	Model as per FSC: 5100C	
54.	M/s. Popular International (PVT) Ltd, House No. 141 Justice Inamullah Road, Block 7&8 K.M.C.H.S Near Hill Park Karachi. Eli No.00091 174-C Evaluator: AD-III	Legal Manufacturer: M/s. COVIDIEN LLC 15 HAMSHIRE STREET, MANSFIELD MA 02048, USA, Manufacturing facility: M/s. Quasar Electronics Technology (Dongguan) Co., Ltd Bldg 8 of Guantai Biotech Technical Cooperation Centre Taoyuan 1st Rd Taiwan High Tech Park of High and New Tech Development Zone of Songshan Lake Dongguan, Guangdong CHINA 523808 FSC USFDA valid till 14-01-2023	CAPNOSTREAM CO ₂ Monitoring system Class-B Shelf life/ Service life: 5 years Codes: FSC submitted is expired and subject device is not mentioned	Deferred for provision of following: <ul style="list-style-type: none"> • Original and attested FSC clearly mentioning the model number/ codes. Also highlighted the codes of any component or accessory used within the system • Valid ISO 13485 of manufacturing facility • Stability studies supporting claimed Shelf life/ Service life. • DoC with clearly highlighted the Product applied with codes.
55.	M/s. Popular International (PVT) Ltd, House No. 141 Justice Inamullah Road, Block 7&8 K.M.C.H.S Near Hill Park Karachi. Eli No.00091 166-C Evaluator: AD-III	Legal Manufacturer: M/s. Covidien LLC 15 Hamshire street Mansfield MA 02048, USA Manufactured by M/s. Covidien LLC Boulevard Insurgentes 19030 Libramiento Tijuana, B.C. Mexico 22225 M/s. Covidien Avenue Henequen No. 1181 Park Industrial Salvarcar ciudad juarez, Chihuahua Mexico 32573 M/s. Jiangyin Sinbon Electronics Co ltd 288 Chengiang middle road Jiangyin, Jiangsu China 214400 M/s. Sanmina 202 Lorong Perusahaan Maju 9, Bukit Tengah Industrial Park perai, Pulau Pinang Malaysia 13600 FSC USFDA valid till 21-04-2024	Warmtouch™ Patients Warmth System Patient warming system Class-B Service life/ shelf life: 5 years Model: Not provided.	Deferred for provision of following: <ul style="list-style-type: none"> • Original and attested FSC clearly mentioning the model number/ codes. Also highlighted the codes of any component or accessory used within the system • Valid ISO 13485 of manufacturing facility • Stability studies supporting claimed Shelf life/ Service life. • DoC with clearly highlighted the Product applied with codes. • Clarification and complete details of manufacturing sites mentioned on form-7A are required.
56.	M/s. Popular International (PVT) Ltd, House No. 141 Justice Inamullah Road, Block 7&8 K.M.C.H.S Near Hill Park Karachi. Eli No.00091	Legal Manufacturer: M/s. COVIDIEN LLC 15 HAMSHIRE STREET, MANSFIELD MA 02048, USA, Manufactured by M/s. Jabil Circuit Singapore Pte LTD 16 Tampines Industrial	BIS Monitoring System Brain Activity Monitor Class-C Shelf life: N/A	Deferred for provision of following: <ul style="list-style-type: none"> • Original and attested FSC clearly mentioning the model number/ codes. Also highlighted the codes of any

	173-C Evaluator: AD-III	Crescent Singapore, central Singapore Singapore 528604 M/s. Celestica Electronics (S) PTE LTD 6 serangoon North Avenue 5 Singapore, Central Singapore Singapore 554910 M/s. Covidien 6135 Gunbarrel Ave Boulder, CO USA 80301 Covidien, Formerly Aspect Medical Systems 1 Upland Road Norwood, MA 02062 FSC USFDA 09-03-2024	Codes as per FSC	component or accessory used within the system • Valid ISO 13485 of manufacturing facility • Stability studies supporting claimed Shelf life/ Service life. • DoC with clearly highlighted the Product applied with codes. • Clarification and complete details of manufacturing sites mentioned on form-7A are required.
57.	M/s. Popular International (PVT) Ltd, House No. 141 Justice Inamullah Road, Block 7&8 K.M.C.H.S Near Hill Park Karachi. Eli No.00091 57-C Evaluator: AD-III	Legal Manufacturer: M/s. Covidien LLC Hamshire street, Mansfield MA 02048, USA. Manufactured by: M/s. Covidien LLC Boulevard Insurgentes 19030 Libramiento Tijuana, B.C., Mexico 22225 FSC USFDA valid till 23-10-2021	Nellcor Oximeter SPO2 Monitor SpO2 Monitoring system Class-B Shelf life: N/A Codes as per FSC	Deferred for provision of following: • Original and attested FSC clearly mentioning the model number/ codes. Also highlighted the codes of any component or accessory used within the system • Valid ISO 13485 of manufacturing facility • Service life studies supporting claimed Shelf life/ Service life. • DoC with clearly highlighted the Product applied with codes. • Manufacturing and QC tests details of applied product. • Undertaking on stamp paper.
58.	M/s. Popular International (PVT) Ltd, House No. 141 Justice Inamullah Road, Block 7&8 K.M.C.H.S Near Hill Park Karachi. Eli No.00091 54-C Evaluator: AD-III	Legal Manufacturer: M/s. Covidien LLC Hamshire street, Mansfield MA 02048, USA. Manufactured by: M/s. Covidien LLC Boulevard Insurgentes 19030 Libramiento Tijuana, B.C., Mexico 22225 FSC USFDA valid till 23-10-2021	Easycap Colorimetric Co2 Detector CO2 Gas Analyzer Class-B Shelf life: N/A Codes/models as per FSC	Deferred for provision of following: • Original and attested FSC clearly mentioning clearly mentioning the model number/ codes. • Valid ISO 13485 of manufacturing facility • Service life studies supporting claimed Shelf life/ Service life. • Manufacturing and QC tests details of applied product. • Undertaking on stamp paper. • Apply separately for Pedicap detector.
59.	M/s. Popular International (PVT) Ltd, House No. 141	Legal Manufacturer: M/s. Covidien LLC Hamshire street, Mansfield MA 02048, USA.	Shiley Oral / nasal Rae Endotracheal tubes	Deferred for provision of following: • Clarification of brand name.

	Justice Inamullah Road, Block 7&8 K.M.C.H.S Near Hill Park Karachi. Eli No.00091 55-C Evaluator: AD-III	Manufactured by: M/s. Covidien Avenue Henequen No. 1181 Park industrial Salvacar Ciudad Juarez, Chihuahua Mexico, 32573 FSC USFDA valid till 20-06-2024	Class-C Shelf life: not provided Codes as per FSC	<ul style="list-style-type: none"> FSC submitted is copy without attestation, submit original and attested FSC clearly mentioning the model number/ codes. Also highlighted the codes of any component or accessory used within the system ISO 13485 expired before the submission of file. Also provide the ISO 13485 of manufacturing sites. Shelf life studies supporting claimed Shelf life/ Service life. Submit revised DoC with clearly highlighted the Product applied with codes. Manufacturing and QC tests details of applied product. Undertaking on stamp paper
60.	M/s. Popular International (PVT) Ltd, House No. 141 Justice Inamullah Road, Block 7&8 K.M.C.H.S Near Hill Park Karachi. Eli No.00091 56-C Evaluator: AD-III	Legal Manufacturer: M/s. Covidien LLC Hamshire street, Mansfield MA 02048, USA. Manufactured by: Mallinckrodt Medical Cornamaddy, Athlone Co. Westmeath, Ireland. FSC Ireland validity 08-05-2023	Shilley Endotracheal Tube, Cuffed Class-C Shelf life: not provided Codes as per FSC	Deferred for provision of following: <ul style="list-style-type: none"> FSC submitted is copy without attestation, submit original and attested FSC clearly mentioning the model number/ codes. Also highlighted the codes of any component or accessory used within the system. ISO 13485 expired before the submission of file. Also provide the ISO 13485 of manufacturing sites. Shelf life studies supporting claimed Shelf life/ Service life. Submit revised DoC with clearly highlighted the Product applied with codes. Manufacturing and QC tests details of applied product. Undertaking on stamp paper.
61.	M/s. Popular International (PVT) Ltd, House No. 141 Justice Inamullah Road, Block 7&8 K.M.C.H.S Near Hill Park Karachi. Eli No.00091 242-C Evaluator: AD-III	Legal Manufacturer: M/s. HEBEI CHAORAN MEDICAL INSTRUMENTS CO., LTD Xiongan New Area, Beijing, China FSC China issued on 20-05-2020 valid for 2 years	Hebei Chaoran Viral Transport Media Disposable sampling test kit Class-A Shelf life: 3 years Codes: CR502-19C CR502-19D	Deferred for provision of following: <ul style="list-style-type: none"> Original and valid LOA and FSC. European type DoC. Undertaking on Stamp paper. Updated and notarized ISO 13485.

62.	<p>M/s. Popular International (PVT) Ltd, House No. 141 Justice Inamullah Road, Block 7&8 K.M.C.H.S Near Hill Park Karachi.</p> <p>Eli No.00091 243-C Evaluator: AD-III</p>	<p>Legal Manufacturer: ACRO BIOTECH, INC. 9500 7TH ST, UNIT M, RANCHO CUCAMONGA, CA 91730, U.S.A.</p> <p>Manufacturing facility: Hangzhou AllTest Biotech Co, Ltd, 550# Yinhai Street, Hangzhou Economic and Technological Peoples Republic of China</p> <p>FSC Germany issue on 17-10-2016</p>	<p>Basechek HBsAg Rapid Test Cassette</p> <p>Class-B</p> <p>Shelf life: 2 years</p> <p>Codes: List provided</p>	<p>Deferred for provision of following:</p> <ul style="list-style-type: none"> • Credentials submitted are without notarization. • Updated and notarized LOA is required. • FSC of Germany submitted is issued for Saudi Arabia and missing the subject device. Provide original, updated and attested FSC in the country of origin mentioning the subject device with codes need to be registered. • Complete details of the applied device. • Notarized ISO 13485. • Notarized FQA certificate mentioning the subject device. • DoC to be printed on manufacturer's letter head and duly filled and signed by responsible person. • Labels of all applied codes as per FSC. • Undertaking on stamp paper. • Apply separately for dipstick kit.
63.	<p>M/s. Popular International (PVT) Ltd, House No. 141 Justice Inamullah Road, Block 7&8 K.M.C.H.S Near Hill Park Karachi.</p> <p>Eli No.00091 244-C Evaluator: AD-III</p>	<p>Legal Manufacturer: ACRO BIOTECH, INC. 9500 7TH ST, UNIT M, RANCHO CUCAMONGA, CA 91730, U.S.A.</p> <p>Manufacturing facility: Hangzhou AllTest Biotech Co, Ltd, 550# Yinhai Street, Hangzhou Economic and Technological Peoples Republic of China</p> <p>FSC Germany issue on 17-10-2016</p>	<p>Basechek HCV Rapid Test Cassette</p> <p>Class-B</p> <p>Shelf life: 2 years</p> <p>Codes: List provided</p>	<p>Deferred for provision of following:</p> <ul style="list-style-type: none"> • Firm applied in Class-B whereas device falls in Class-C, so differential fee of Rs-25,000/- is required. • Credentials submitted are without notarization. • Updated and notarized LOA is required. • FSC of Germany submitted is issued for Saud Arabia and missing the subject device. Provide original, updated and attested FSC in the country of origin mentioning the subject device with codes need to be registered. • Complete details of the applied device. • Notarized ISO 13485.

				<ul style="list-style-type: none"> • Updated and notarized FQA certificate mentioning the subject device. • DoC to be printed on manufacturer's letter head and duly filled and signed by responsible person. • Labels of all applied codes as per FSC. • Undertaking on stamp paper. • Apply separately for dipstick kit
64.	<p>Popular International (Pvt) Ltd., House No. 141, Justice Inamullah Road, Block 7 & 8 KMCHS Near Hill Park, Karachi.</p> <p>(ELI-00091) 4964 Evaluator: AD-III</p>	<p>Legal Manufacturer: M/s Covidien LLC 15 Hampshire Street Mansfield, MA 02048, USA.</p> <p>Manufacturer Site: Mallinckrod DAR S.R.L., Via G. Bove 2/4/6/8, 41037 MIRANDOLA (MO) Italy.</p> <p>FSC HPRA issuance 18-02-2022</p>	<p>DAR Breathing Circuits (Breathing Circuits)</p> <p>Class-B</p> <p>Shelf life: 5 years</p> <p>Codes as per FSC</p>	<p>Deferred for provision of following:</p> <ul style="list-style-type: none"> • Clarification is required about the codes need to be registered. • Original Letter of Authorization as provided one is copy. • Provide original FSC with codes highlighted as provided one is copy. • Undertaking on Stamp
65.	<p>Popular International (Pvt) Ltd., House No. 141, Justice Inamullah Road, Block 7 & 8 KMCHS Near Hill Park, Karachi.</p> <p>(ELI-00091) 4962 Evaluator: AD-III</p>	<p>Legal Manufacturer: M/s Covidien LLC 15 Hampshire Street Mansfield, MA 02048, USA.</p> <p>Manufacturer Site: Mallinckrod DAR S.R.L., Via G. Bove 2/4/6/8, 41037 MIRANDOLA (MO) Italy.</p> <p>FSC HPRA issuance 18-02-2022</p>	<p>DAR Breathing Filters (filters/ HMEs)</p> <p>Class-B</p> <p>Shelf life: 5 years</p> <p>Codes as per FSC</p>	<p>Deferred for provision of following:</p> <ul style="list-style-type: none"> • Original Letter of Authorization as provided one is copy. • Provide original FSC with codes highlighted as provided one is copy. • Undertaking on Stamp • Shelf lie studies of the applied device for claimed shelf life.
66.	<p>Popular International (Pvt) Ltd., House No. 141, Justice Inamullah Road, Block 7 & 8 KMCHS Near Hill Park, Karachi.</p> <p>(ELI-00091) 4960 Evaluator: AD-III</p>	<p>Legal Manufacturer: M/s Covidien LLC 15 Hampshire Street Mansfield, MA 02048, USA.</p> <p>Manufacturer Site: Mallinckrod DAR S.R.L., Via G. Bove 2/4/6/8, 41037 MIRANDOLA (MO) Italy.</p> <p>FSC HPRA issuance 18-02-2022</p>	<p>DAR Airway System (Guedel airways)</p> <p>Class-B </p> <p>Shelf life: 5 years</p> <p>Codes as per FSC</p>	<p>Deferred for provision of following:</p> <ul style="list-style-type: none"> • Original Letter of Authorization as provided one is copy. • Provide original FSC with codes highlighted as provided one is copy. • Undertaking on Stamp • Shelf lie studies of the applied device for claimed shelf life.
67.	<p>Popular International (Pvt) Ltd., House No. 141, Justice Inamullah Road, Block 7 & 8 KMCHS</p>	<p>Legal Manufacturer: M/s Covidien LLC 15 Hampshire Street Mansfield, MA 02048, USA.</p> <p>Manufacturer Site:</p>	<p>DAR Breathing System kit</p> <p>Class-B</p>	<p>Deferred for provision of following:</p> <ul style="list-style-type: none"> • Generic name of the device is not mentioned on Form-7A. submit revised form mentioning

	Near Hill Park, Karachi. (ELI-00091) 4965 Evaluator: AD-III	Mallinckrod DAR S.R.L., Via G. Bove 2/4/6/8, 41037 MIRANDOLA (MO) Italy. FSC HPRA issuance 18-02-2022	Shelf life: 5 years Codes as per FSC	the name and codes of the device. • Provided LOA is copy LOA. • Original FSC is missing (copy provided). • Shelf lie studies of the applied device for claimed shelf life. • Undertaking on Stamp paper.
68.	Popular International (Pvt) Ltd., House No. 141, Justice Inamullah Road, Block 7 & 8 KMCHS Near Hill Park, Karachi. (ELI-00091) 4961 Evaluator: AD-III	Legal Manufacturer: M/s Covidien LLC 15 Hampshire Street Mansfield, MA 02048, USA. Manufacturer Site: Mallinckrod DAR S.R.L., Via G. Bove 2/4/6/8, 41037 MIRANDOLA (MO) Italy. FSC HPRA issuance 18-02-2022	DAR Airway Management kits Class-B Shelf life: 5 years Codes as per FSC	Deferred for provision of following: • Generic name of the device is not mentioned on Form-7A. submit revised form mentioning the name and codes of the device. • Provided LOA is copy LOA. • Original FSC is missing (copy provided). • Shelf lie studies of the applied device for claimed shelf life. • Undertaking on Stamp paper.
69.	Popular International (Pvt) Ltd., House No. 141, Justice Inamullah Road, Block 7 & 8 KMCHS Near Hill Park, Karachi. (ELI-00091) 4836 Evaluator: AD-III	Legal Manufacturer: M/s Covidien LLC 15 Hampshire Street Mansfield, MA 02048, USA. Manufacturer Site: Mallinckrod DAR S.R.L., Via G. Bove 2/4/6/8, 41037 MIRANDOLA (MO) Italy. FSC HPRA issuance 18-02-2022	Shiley Tracheostomy system Adult tracheostomy tube, cuffed Class-B Shelf life: 5 years Codes as per FSC	Deferred for provision of following: • Revised form mentioning the codes of the applied device. • LOA is copy, submit original LOA. • Original FSC as provided one is copy. • Shelf life studies of the applied device for claimed shelf life. • Labels of applied codes. • Undertaking on Stamp paper.
70.	Popular International (Pvt) Ltd., House No. 141, Justice Inamullah Road, Block 7 & 8 KMCHS Near Hill Park, Karachi. (ELI-00091) 4837 Evaluator: AD-III	Legal Manufacturer: M/s Covidien LLC 15 Hampshire Street Mansfield, MA 02048, USA. Manufacturer Site: Mallinckrod DAR S.R.L., Via G. Bove 2/4/6/8, 41037 MIRANDOLA (MO) Italy. FSC HPRA issuance 18-02-2022	Curity Endotracheal tube Class-B Shelf life: 5 years Codes as per FSC	Deferred for provision of following: • Provided LOA is copy, submit original LOA. • Original FSC is missing (copy provided). • Shelf life studies of the applied device for claimed shelf life. • Labels of applied codes. • Apply separately for uncuffed type. • Undertaking on Stamp paper.

71.	Popular International (Pvt) Ltd., House No. 141, Justice Inamullah Road, Block 7 & 8 KMCHS Near Hill Park, Karachi. (ELI-00091) 4966 Evaluator: AD-III	Legal Manufacturer: M/s Covidien LLC 15 Hampshire Street Mansfield, MA 02048, USA. Manufacturer Site: Mallinckrodt DAR S.R.L., Via G. Bove 2/4/6/8, 41037 MIRANDOLA (MO) Italy. FSC HPRA issuance 18-02-2022	DAR Breathing system ROH Class-B Shelf life: 5 years Codes as per FSC	Deferred for provision of following: <ul style="list-style-type: none"> • Generic name of the device is not mentioned on Form-7A. submit revised form mentioning the name, type and codes of the applied device. • Provided LOA is copy, submit original LOA. • Original FSC is missing (copy provided). • Shelf life studies of the applied device for claimed shelf life. • Labels of applied codes. • Undertaking on Stamp paper.
72.	Popular International (Pvt) Ltd., House No. 141, Justice Inamullah Road, Block 7 & 8 KMCHS Near Hill Park, Karachi. (ELI-00091) 4963 Evaluator: AD-III	Legal Manufacturer: M/s Covidien LLC 15 Hampshire Street Mansfield, MA 02048, USA. Manufacturer Site: Mallinckrodt DAR S.R.L., Via G. Bove 2/4/6/8, 41037 MIRANDOLA (MO) Italy. FSC HPRA issuance 18-02-2022	DAR Airway Management kits Class-B Shelf life: 5 years Codes as per FSC	Deferred for provision of following: <ul style="list-style-type: none"> • Generic name of the device is not mentioned on Form-7A. submit revised form mentioning the name, type and codes of the applied device. • Provided LOA is copy, submit original LOA. • Original FSC is missing (copy provided). • Shelf life studies of the applied device for claimed shelf life. • Labels of applied codes. • Undertaking on Stamp paper.
73.	ORIENT TRADERS INTERNATIONAL Commercial - 10, Block A, Kazimabad, Model Colony Karachi CM - 18, Block A, Kazimabad, Model Colony Karachi. (ELI-00621) 3702 Evaluator: AD-III	Legal Manufacturer: M/s CID Lines N.V./S. A Waterpoortstraat 2, 8900 Ieper, Belgium. FSC Belgium issuance 27-06-2017	VIROCID Disinfectant, Biocide Class-B Shelf life: 3 years Model/ code: Not provided	Deferred for provision of following: <ul style="list-style-type: none"> • The applied device is biocidal and FSC is issued by Ministry of Environment, Belgium. • The device is not CE marked and the manufacturer has not provided the ISO 13485.
74.	M/s Crystolite Pharmaceuticals Health Care Division, Plot No.7, Flat No.31, 3 rd Floor, Rehmat Centre, I-8 Markaz,	M/s Ovistech Co., Ltd., B-102, 40-Imi-ro, Uiwang-si, Gyeonggi-do Republic of Korea FSC: Korea	J-Lift (Sterile single use absorbable polydioxanone suture with needle) Codes & Sizes: As	Deferred for provision of following: <ul style="list-style-type: none"> • Original Agency agreement/Letter of Authorization from Manufacturer / Market

	Islamabad. (ELI: 00917) EvaluatorAD-II (397-C)	Date of Issue: 30.09.2022	per FSC Class-D Shelf Life: 01 Year Fee: Rs. 50,000	Authorization Holder duly notarized from the country of origin: • Original Free sale certificate in the country of origin duly attested by Embassy of Pakistan; • Original ISO-13485 certificate duly notarized from the country of origin.
75.	M/s Best-Med Traders Lower ground Suit No. 28 & 29 Resham Bazar, Main University Road, Gulshan-e-Iqbal Karachi. (ELI-00236) Evaluator: AD-II (3332)	M/s Hangzhou Fushan Medical Appliances Co., Ltd. No. 1288 South Jinxi Road, Linglong Industry Park, Linan Dsistrict Hangzhou City Zhejiang Province 311301 China. FSC: China Issue Date: 19-03-2019 Valid till: 18-03-2021	Silicone Stomach Tube 12FR, 14FR, 16FR & 18 FR Codes and Sizes as per FSC Class B Shelf life: N/A	Deferred for provision of following documents; • Credentials of manufacturer abroad as per format approved in 3 rd meeting of MDB, duly notarized. • Detail of Manufacturing and Quality Control processes; • Original notarized copy of LOA; • Declaration of conformity on company letterhead; • Original embassy attested and notarized copy of valid FSC (only photocopy of FSC is provided which expired on 18-03-2021); • Original embassy attested and notarized copy of valid FSC of the applied product in reference country, as claimed at clause xv of the application Form 7A; • Original embassy attested and notarized copy of valid ISO 13485 Certificate / GMP Certificate; • Original embassy attested and notarized copies of Full Quality Assurance certificates or equivalent; • Technical information of the product including indications, contraindications, warnings, usage / handling instructions, validation etc
76.	M/s Best-Med Traders , Lower ground Suit No. 28 & 29 Resham Bazar, Main University	M/s Vitamed Instrument Co., Ltd No.101 Nanmatou Rd, Pudong, Shanghai 200125 China.	Feeding Set Codes and sizes as per FSC	Deferred for provision of following documents; • Credentials of manufacturer abroad as per format approved


	Road, Gulshan-e-Iqbal Karachi. (ELI-00236) Evaluator: AD-II (3690)	FSC: China Issue Date: 06-11-2020 Valid till: 06-11-2022	Class B Shelf life: 5 Years	in 3 rd meeting of MDB, duly notarized. <ul style="list-style-type: none"> • Detail of Manufacturing and Quality Control processes; • Original notarized copy of LOA; • Declaration of conformity on company letterhead; • Original embassy attested and notarized copy of valid FSC (only photocopy of FSC is provided which expired on 06-11-2022); • Original embassy attested and notarized copy of valid ISO 13485 Certificate / GMP Certificate; • Original embassy attested and notarized copies of Full Quality Assurance certificates or equivalent; • Technical information of the product including indications, contraindications, warnings, usage / handling instructions, validation etc
77.	M/s Best-Med Traders, Lower ground Suit No. 28 & 29 Resham Bazar, Main University Road, Gulshan-e-Iqbal Karachi. (ELI-00236) Evaluator: AD-II (3740)	M/s Shunmei Medical Co. Ltd. R401 of building B. No.8 of 1st Jinglong Road, Baolong Industrial Zone, Long gang District, 518116 Shenzhen, Guangdong, China.	Shunmei Disposable Pressure Transducer Codes and sizes as per FSC Class B Shelf life: 3 Years	Deferred for provision of following documents; <ul style="list-style-type: none"> • Credentials of manufacturer abroad as per format approved in 3rd meeting of MDB, duly notarized. • Detail of Manufacturing and Quality Control processes; • Original notarized copy of LOA; • Declaration of conformity on company letterhead; • Original embassy attested and notarized copy of valid FSC (only photocopy of FSC is provided which expired on 18-03-2021); • Original embassy attested and notarized copy of valid FSC of the applied product in reference country, as claimed at clause xv of the application Form 7A; • Original embassy attested and notarized copy of valid ISO

				13485 Certificate / GMP Certificate; <ul style="list-style-type: none"> • Original embassy attested and notarized copies of Full Quality Assurance certificates or equivalent; • Technical information of the product including indications, contraindications, warnings, usage / handling instructions, validation etc
78.	M/s Decent Traders, KH 2312 Tape Road, Sheesh Mehal Lahore. (ELI-00516) Evaluator: AD-II	Legal Manufacturer: M/s Zhejiang Hongyu Medical Commodity Co., Ltd located at No.668 Chanhua Road, Fotang Town Industrial Functional Area, Yiwu City, 322002, Zhejiang Province, China. FSC: China Issue Date: 28-04-2022 Valid till: 16-05-2023	Protect pore by Smileplus (Self-Adhesive Non- woven wound Dressing) Class B Shelf Life: 03 Years	Deferred for provision of following documnts; <ul style="list-style-type: none"> • Product quality assurance certificate; • Evidence of availability of the applied product on free sale in any reference country.
79.	M/s Chemical House, 6-C Sikander Malhi Road, Canal Park, Gulberg II, Lahore Pakistan. ELI: 00156 Evaluator: AD-II (2249-P)	Legal Manufacturer: M/s Bio-Rad Laboratories, Inc, 9500 Jeronimo Road Irvine, CA 92618, U.S.A FSC: USA Valid till: 16.01.2021	Liquickek Spinal Fluid Control (Quality Control (Immunology/Protein Controls) Codes & Sizes: As per FSC Class-B Shelf Life: 2 years	Deferred for provision of following documnts; <ul style="list-style-type: none"> • Original Agency agreement/Letter of Authorization from Manufacturer /Market Authorization Holder duly notarized from the country of origin; • Original Free sale certificate in the country of origin duly attested by Embassy of Pakistan; • Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized in the country of origin; • Full Quality Assurance Certificate or equivalent as applicable duly notarized in the country of origin; • Declaration of conformity (DoC) to be printed on the manufacturer's letterhead, filled and signed by the responsible person.

80.	<p>M/s Chemical House, 6-C Sikander Malhi Road Gulberg-II, Lahore.</p> <p>(ELI:00156)</p> <p>Evaluator: AD-II</p> <p>(3157-P)</p>	<p><u>Legal Manufacturer:</u></p> <p>M/s Bio-Rad Laboratories, Inc, 9500 Jeronimo Road Irvine, CA 92618, U.S.A</p> <p>FSC: U.S.A Valid till: 20/08/2022</p>	<p>Lymphochek Specialty Immunoassay Control</p> <p>(Multiple Clinical Chemistry Protein IVD Control)</p> <p>Class-B</p> <p>Shelf Life: 3 years</p>	<p>Deferred for provision of following documnts;</p> <ul style="list-style-type: none"> • Original Agency agreement/Letter of Authorization from Manufacturer /Market Authorization Holder duly notarized from the country of origin: • Original Free sale certificate in the country of origin duly attested by Embassy of Pakistan: • Valid Production Quality Management System Certificate (ISO 13485): • Full Quality Assurance Certificate or equivalent as applicable duly notarized in the country of origin: • Declaration of conformity (DoC) to be printed on the manufacturer's letterhead, filled and signed by the responsible person.
81.	<p>M/s Chemical House, 6-C Sikander Malhi Road Gulberg-II, Lahore.</p> <p>(ELI:00156)</p> <p>Evaluator: AD-II</p> <p>(1805-P)</p>	<p><u>Legal Manufacturer:</u></p> <p>M/s Bio-Rad Laboratories, Inc, 9500 Jeronimo Road Irvine, CA 92618, U.S.A.</p> <p>FSC: USA Valid till: 16.01.2021</p>	<p>Liquichek Diabetes Controls</p> <p>(Quality Control)</p> <p>Class-B</p> <p>Shelf Life: 3 years</p>	<p>Deferred for provision of following documnts;</p> <ul style="list-style-type: none"> • Original Agency agreement/Letter of Authorization from Manufacturer /Market Authorization Holder duly notarized from the country of origin: • Original Free sale certificate in the country of origin duly attested by Embassy of Pakistan: • Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized in the country of origin: • Full Quality Assurance Certificate or equivalent as applicable duly notarized in the country of origin: • Declaration of conformity (DoC) to be printed on the manufacturer's letterhead,

				filled and signed by the responsible person.
82.	<p>M/s Chemical House, 6-C Sikander Malhi Road Gulberg-II, Lahore.</p> <p>(ELI:00156)</p> <p>Evaluator: AD-II (1802-P)</p>	<p><u>Legal Manufacturer:</u> M/s Bio-Rad Laboratories, Inc, 9500 Jeronimo Road Irvine, CA 92618, U.S.A.</p> <p>FSC: USA</p> <p>Valid till: 16.01.2021</p>	<p>Liquichek Immunology/ Protein Controls</p> <p>(Quality Control)</p> <p>Class-B</p> <p>Shelf Life: 720 Days</p>	<p>Deferred for provision of following documnts;</p> <ul style="list-style-type: none"> • Original Agency agreement/Letter of Authorization from Manufacturer /Market Authorization Holder duly notarized from the country of origin: • Original Free sale certificate in the country of origin duly attested by Embassy of Pakistan: • Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized in the country of origin: • Full Quality Assurance Certificate or equivalent as applicable duly notarized in the country of origin: • Declaration of conformity (DoC) to be printed on the manufacturer's letterhead, filled and signed by the responsible person.
83.	<p>M/s Chemical House, 6-C Sikander Malhi Road Gulberg-II, Lahore.</p> <p>(ELI:00156)</p> <p>Evaluator: AD-II (3067-P)</p>	<p><u>Legal Manufacturer:</u> M/s Bio-Rad Laboratories Inc. 4000 Alfred Nobel Drive Hercules, CA, USA.</p> <p><u>Manufacturing Site:</u> M/s Bio-Rad Laboratories Inc., 14620 NE North Woodinville Way, Woodinville, WA 98072, USA.</p> <p>FSC: U.S.A</p> <p>Valid till: 11.08.2022</p>	<p>Bioplex 2200 HSV-1 & HSV-2 1gG</p> <p>(Herpes simplex virus 1gG Antibody IVD kit)</p> <p>Codes & Sizes: As per FSC</p> <p>Class-C</p> <p>Shelf Life: As per stability study.</p>	<p>Deferred for rectification of following discrepancies in the submitted application;</p> <p>The name and address of the manufacturing site mentioned on FSC is M/s Bio-Rad Laboratories Inc., located at 14620 NE North Woodinville Way, Woodinville, WA 98072, USA whereas on Application Form 7A, ISO 13485 certificate, DoC and Full Quality Assurance Certificate, it is mentioned as M/s Bio-Rad Laboratories Inc. 4000 Alfred Nobel Drive Hercules, CA, USA and on LOA it is written as M/s Bio-Rad Laboratories Inc. 1000 Alfred Nobel Drive Hercules, CA, USA.</p>

84.	M/s Chemical House, 6-C Sikander Malhi Road Gulberg-II, Lahore. (ELI:00156) Evaluator: AD-II (3071-P)	<u>Legal Manufacturer:</u> M/s Bio-Rad Laboratories Inc. 4000 Alfred Nobel Drive Hercules, CA, U.S.A Original FSC: U.S.A Valid till: 03.02.2023	Bioplex 2200 MMV IgM (Measles, Mumps, Varicella Zoster IgM antibody IVD kit) Codes & Sizes: As per FSC Class-C Shelf Life: 18 months	Deferred for provision of the following; <ul style="list-style-type: none"> • Original Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized in the country of origin; • Original Full Quality Assurance Certificate or equivalent as applicable duly notarized in the country of origin; • Original Agency agreement/ Letter of Authorization from • Manufacturer/ Market Authorization Holder duly notarized from the country of origin.
85.	M/s Chemical House, 6-C Sikander Malhi Road Gulberg-II, Lahore. (ELI:00156) Evaluator: AD-II (3066-P)	<u>Legal Manufacturer:</u> M/s Bio-Rad Laboratories Inc. 4000 Alfred Nobel Drive Hercules, CA, USA. <u>Manufacturing Site:</u> M/s Bio-Rad Laboratories Inc., 14620 NE North Woodinville Way, Woodinville, WA 98072, USA. FSC: U.S.A Valid till:11.08.2022	Bioplex 2200 MMRV IgG (Measles, Mumps, Rubella, Varicella zoster virus 1 GG antibody IVD Kit) Codes & Sizes: As per FSC Class-C Shelf Life: As per stability study.	Deferred for rectification of following discrepancies in the submitted application; The name and address of the manufacturing site mentioned on FSC is M/s Bio-Rad Laboratories Inc., located at 14620 NE North Woodinville Way, Woodinville, WA 98072, USA whereas on Application Form 7A, ISO 13485 certificate, DoC and Full Quality Assurance Certificate, it is mentioned as M/s Bio-Rad Laboratories Inc. 4000 Alfred Nobel Drive Hercules, CA, USA and on LOA it is written as M/s Bio-Rad Laboratories Inc. 1000 Alfred Nobel Drive Hercules, CA, USA.
86.	M/s Chemical House, 6-C Sikander Malhi Road Gulberg-II, Lahore. (ELI:00156) Evaluator: AD-II (3073-P)	<u>Legal Manufacturer:</u> M/s Bio-Rad Laboratories Inc. 4000 Alfred Nobel Drive Hercules, CA 94547, U.S.A	Bioplex 2200 ToRC IgM (Toxoplasma IgM, Rubella IgM, CMV IgM) Codes & Sizes: As per FSC Class-C	Deferred for provision of the following; <ul style="list-style-type: none"> • Original Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized in the country of origin; • Original Full Quality Assurance Certificate or equivalent as applicable duly notarized in the country of

			Shelf Life: 15 months	<p>origin:</p> <ul style="list-style-type: none"> • Original Agency agreement/ Letter of Authorization from Manufacturer/Market Authorization Holder duly notarized from the country of origin: • Original Free sale certificate in the country of origin duly attested by Embassy of Pakistan.
87.	<p>M/s Chemical House, 6-C Sikander Malhi Road Gulberg-II, Lahore.</p> <p>(ELI:00156)</p> <p>Evaluator: AD-II</p> <p>(3157-P)</p>	<p>Legal Manufacturer:</p> <p>M/s Bio-Rad Laboratories, Inc, 9500 Jeronimo Road Irvine, CA 92618, U.S.A</p> <p>FSC: U.S.A Valid till: 20/08/2022</p>	<p>Liquichek Immunology Control</p> <p>(Multiple Clinical Chemistry Analyte IVD Control)</p> <p>Codes & Sizes: As per FSC</p> <p>Class-B</p> <p>Shelf Life: 2 years</p>	<p>Deferred for provision of the following;</p> <ul style="list-style-type: none"> • Valid ISO 13485 Certificate: • Original Full Quality Assurance Certificate or equivalent as applicable duly notarized in the country of origin: • Original Agency agreement/ Letter of Authorization from Manufacturer/Market Authorization Holder duly notarized from the country of origin.
88.	<p>M/s Chemical House, 6-C Sikander Malhi Road, Canal Park, Gulberg II, Lahore Pakistan.</p> <p>ELI: 00156</p> <p>Evaluator: AD-II</p> <p>(3065-P)</p>	<p><u>Legal Manufacturer:</u> M/s Bio-Rad Laboratories Inc. 4000 Alfred Nobel Drive Hercules, CA, USA.</p> <p><u>Manufacturing Site:</u> M/s Bio-Rad Laboratories Inc., 14620 NE North Woodinville Way, Woodinville, WA 98072, USA.</p> <p>Original FSC: U.S.A</p> <p>Valid till: 11.08.2022</p>	<p>Bioplex 2200 HIV Ag-Ab</p> <p>(HIV/HIV2 antigen/antibody IVD Kit)</p> <p>Codes & Sizes: As per FSC</p> <p>Class-C Shelf Life: As per stability study.</p> 	<p>Deferred for rectification of following discrepancies in the submitted application;</p> <p>The name and address of the manufacturing site mentioned on FSC is M/s Bio-Rad Laboratories Inc., located at 14620 NE North Woodinville Way, Woodinville, WA 98072, USA whereas on Application Form 7A, ISO 13485 certificate, DoC and Full Quality Assurance Certificate, it is mentioned as M/s Bio-Rad Laboratories Inc. 4000 Alfred Nobel Drive Hercules, CA, USA and on LOA it is written as M/s Bio-Rad Laboratories Inc. 1000 Alfred Nobel Drive Hercules, CA, USA:</p> <p>Clarification is required regarding classification of the applied device since according to the GHTF Guidelines, the</p>

				IVDs intended to detect presence of, or exposure to, a transmissible agent in blood, blood components, blood derivatives, cells, tissues or organs, should be classified as Class D.
89.	M/s Chemical House, 6-C Sikander Malhi Road Gulberg-II, Lahore ELI:00156 Evaluator: AD-II (3072-P)	Legal Manufacturer: M/s Bio-Rad Laboratories Inc. 4000 Alfred Nobel Drive Hercules, CA, U.S.A Manufacturing Site: M/s Bio-Rad Laboratories Inc., 14620 NE North Woodinville Way, Woodinville, WA 98072, USA. Original FSC: USA Valid till:11.08.2022	Bioplex 2200 Syphilis Total & RPR (Treponema pallidum total antibody and reagin antibody IVD kit) Codes & Sizes: As per FSC Class-C Shelf Life: 21 months	Deferred for rectification of following discrepancies in the submitted application; The name and address of the manufacturing site mentioned on FSC is M/s Bio-Rad Laboratories Inc., located at 14620 NE North Woodinville Way, Woodinville, WA 98072, USA whereas on Application Form 7A, ISO 13485 certificate, DoC and Full Quality Assurance Certificate, it is mentioned as M/s Bio-Rad Laboratories Inc. 4000 Alfred Nobel Drive Hercules, CA, USA and on LOA it is written as M/s Bio-Rad Laboratories Inc. 1000 Alfred Nobel Drive Hercules, CA, USA:
90.	M/s Chemical House, 6-C Sikander Malhi Road Gulberg-II, Lahore ELI:00156 Evaluator: AD-II (3169-P)	Legal Manufacturer: M/s Bio-Rad Laboratories, Inc. 9500 Jeronimo Road Irvine, CA 92618, USA FSC: U.S.A Valid till: 20/08/2022	Liquichek Elevated CRP Control (C-Reactive Protein (CRP) IVD Control) Codes & Sizes: As per FSC Class-B Shelf Life: 1080 days	Deferred for provision of the following; <ul style="list-style-type: none"> Valid ISO 13485 Certificate: Original Full Quality Assurance Certificate or equivalent as applicable duly notarized in the country of origin: Original Agency agreement/ Letter of Authorization from Manufacturer/Market Authorization Holder duly notarized from the country of origin: Declaration of conformity (DoC) to be printed on the manufacturer's letterhead, filled and signed by the responsible person.
91.	M/s Chemical House, 6-C Sikander Malhi Road, Canal Park,	Legal Manufacturer: M/s Bio-Rad Laboratories, Inc. 9500 Jeronimo Road Irvine, CA	Liquichek Multiple Cardiac Marker IVD Control	Deferred for provision of the following;

	<p>Gulberg II, Lahore Pakistan.</p> <p>ELI: 00156</p> <p>Evaluator: AD-II (3170-P)</p>	<p>92618, USA</p> <p>FSC: U.S.A</p> <p>Valid till: 20/08/2022</p>	<p>(Multiple Cardiac Marker IVD, Control)</p> <p>Codes & Sizes: As per FSC Class-B</p> <p>Shelf Life: 1080 days</p>	<ul style="list-style-type: none"> Valid ISO 13485 Certificate: Original Full Quality Assurance Certificate or equivalent as applicable duly notarized in the country of origin: Original Agency agreement/ Letter of Authorization from Manufacturer/Market Authorization Holder duly notarized from the country of origin: Declaration of conformity (DoC) to be printed on the manufacturer's letterhead, filled and signed by the responsible person.
92.	<p>M/s Chemical House, 6-C Sikander Malhi Road, Canal Park, Gulberg II, Lahore Pakistan.</p> <p>ELI: 00156</p> <p>Evaluator: AD-II (3156-P)</p>	<p>Legal Manufacturer: M/s Bio-Rad Laboratories, Inc. 9500 Jeronimo Road Irvine, CA 92618, USA</p> <p>Original FSC: U.S.A</p> <p>Valid till: 20/08/2022</p>	<p>Liquid Multiquant Clinical Chemistry</p> <p>(Multiple Clinical Chemistry Analyte IVD Control)</p> <p>Codes & Sizes: As per FSC Class-B</p> <p>Shelf Life: 3 years</p>	<p>Deferred for provision of the following;</p> <ul style="list-style-type: none"> Valid ISO 13485 Certificate: Original Full Quality Assurance Certificate or equivalent as applicable duly notarized in the country of origin: Original Agency agreement/ Letter of Authorization from Manufacturer/Market Authorization Holder duly notarized from the country of origin: Declaration of conformity (DoC) to be printed on the manufacturer's letterhead, filled and signed by the responsible person.
93.	<p>M/s Chemical House, 6-C Sikander Malhi Road, Canal Park, Gulberg II, Lahore Pakistan.</p> <p>ELI: 00156</p> <p>Evaluator: AD-II (3160-P)</p>	<p>Legal Manufacturer: M/s Bio-Rad Laboratories, Inc. 9500 Jeronimo Road Irvine, CA 92618, USA</p> <p>Original FSC: U.S.A</p> <p>Valid till: 20/08/2022</p>	<p>Liquichek Diabetes Control</p> <p>(Glycated Hemoglobin (HbA1c) IVD Control)</p> <p>Codes & Sizes: As per FSC Class-B</p> <p>Shelf Life: 3 years</p>	<p>Deferred for provision of the following;</p> <ul style="list-style-type: none"> Valid ISO 13485 Certificate: Original Full Quality Assurance Certificate or equivalent as applicable duly notarized in the country of origin: Original Agency agreement/ Letter of Authorization from Manufacturer/Market Authorization Holder duly notarized from the country of origin:


				<p>origin:</p> <ul style="list-style-type: none"> Declaration of conformity (DoC) to be printed on the manufacturer's letterhead, filled and signed by the responsible person.
94.	<p>M/s Chemical House, 6-C Sikander Malhi Road, Canal Park, Gulberg II, Lahore Pakistan.</p> <p>ELI: 00156</p> <p>Evaluator: AD-II (3158-P)</p>	<p><u>Legal Manufacturer:</u> M/s Bio-Rad Laboratories, Inc. 9500 Jeronimo Road Irvine, CA 92618, USA</p> <p>Original FSC: U.S.A</p> <p>Valid till: 20/08/2022</p>	<p>Liquichek Tumor Marker Control</p> <p>(Multiple Tissue-Associated Protein/Tumor Marker IVD Control)</p> <p>Codes & Sizes: As per FSC</p> <p>Class-B</p> <p>Shelf Life: 2 years</p>	<p>Deferred for provision of the following;</p> <ul style="list-style-type: none"> Valid ISO 13485 Certificate: Original Full Quality Assurance Certificate or equivalent as applicable duly notarized in the country of origin: Original Agency agreement/ Letter of Authorization from Manufacturer/Market Authorization Holder duly notarized from the country of origin: Declaration of conformity (DoC) to be printed on the manufacturer's letterhead, filled and signed by the responsible person.
95.	<p>M/s Chemical House, 6-C Sikander Malhi Road, Canal Park, Gulberg II, Lahore Pakistan.</p> <p>ELI: 00156</p> <p>Evaluator: AD-II (3159-P)</p>	<p><u>Legal Manufacturer:</u> M/s Bio-Rad Laboratories, Inc. 9500 Jeronimo Road Irvine, CA 92618, USA</p> <p>Original FSC: U.S.A</p> <p>Valid till: 20/08/2022</p>	<p>Liquichek Reticulocyte Control</p> <p>(Reticulocyte count IVD Control)</p> <p>Codes & Sizes: As per FSC</p> <p>Class-B</p> <p>Shelf Life: 2 years</p>	<p>Deferred for provision of the following;</p> <ul style="list-style-type: none"> Valid ISO 13485 Certificate: Original Full Quality Assurance Certificate or equivalent as applicable duly notarized in the country of origin: Original Agency agreement/ Letter of Authorization from Manufacturer/Market Authorization Holder duly notarized from the country of origin: Declaration of conformity (DoC) to be printed on the manufacturer's letterhead, filled and signed by the responsible person.
96.	<p>M/s Chemical House, 6-C Sikander Malhi Road, Canal Park, Gulberg II, Lahore Pakistan.</p>	<p><u>Legal Manufacturer:</u> M/s Bio-Rad Laboratories, Inc. 9500 Jeronimo Road Irvine, CA 92618, USA</p>	<p>Licquichek Immunoassay Control</p> <p>(Multiple Clinical</p>	<p>Deferred for provision of the following;</p> <ul style="list-style-type: none"> Valid ISO 13485 Certificate: Original Full Quality

	<p>ELI: 00156</p> <p>Evaluator: AD-II</p> <p>(2562-P)</p>	<p>Original FSC: U.S.A</p> <p>Valid till: 20/08/2022</p>	<p>Chemistry Protein IVD)</p> <p>Codes & Sizes: As per FSC Class-B</p> <p>Shelf Life: As per stability study</p>	<p>Assurance Certificate or equivalent as applicable duly notarized in the country of origin:</p> <ul style="list-style-type: none"> • Original Agency agreement/ Letter of Authorization from Manufacturer/Market Authorization Holder duly notarized from the country of origin: • Declaration of conformity (DoC) to be printed on the manufacturer's letterhead, filled and signed by the responsible person.
97.	<p>M/s Chemical House, 6-C Sikander Malhi Road, Canal Park, Gulberg II, Lahore Pakistan.</p> <p>ELI: 00156</p> <p>Evaluator: AD-II</p> <p>(3172-P)</p>	<p>Legal Manufacturer: M/s Bio-Rad Laboratories, Inc. 9500 Jeronimo Road Irvine, CA 92618, USA</p> <p>Original FSC: U.S.A</p> <p>Valid till: 20/08/2022</p>	<p>Liquichek Urine Toxicology Control</p> <p>(Multiple Therapeutic Drug/Drugs of Abuse IVD Control)</p> <p>Codes & Sizes: As per FSC Class-B</p> <p>Shelf Life: 36 months</p>	<p>Deferred for provision of the following;</p> <ul style="list-style-type: none"> • Valid ISO 13485 Certificate: • Original Full Quality Assurance Certificate or equivalent as applicable duly notarized in the country of origin: • Original Agency agreement/ Letter of Authorization from Manufacturer / Market Authorization Holder duly notarized from the country of origin: • Declaration of conformity (DoC) to be printed on the manufacturer's letterhead, filled and signed by the responsible person.
98.	<p>M/s Chemical House, 6-C Sikander Malhi Road, Canal Park, Gulberg II, Lahore Pakistan.</p> <p>ELI: 00156</p> <p>Evaluator: AD-II</p> <p>(2564-P)</p>	<p>Legal Manufacturer: M/s Bio-Rad Laboratories, Inc. 9500 Jeronimo Road Irvine, CA 92618, USA</p> <p>Original FSC: U.S.A</p> <p>Valid till: 20/08/2022</p>	<p>Lyphocheck Urine Chemistry Control</p> <p>(Multiple urine Analyte IVD Control)</p> <p>Codes & Sizes: As per FSC Class-B</p> <p>Shelf Life: 36 months</p>	<p>Deferred for provision of the following;</p> <ul style="list-style-type: none"> • Valid ISO 13485 Certificate: • Original Full Quality Assurance Certificate or equivalent as applicable duly notarized in the country of origin: • Original Agency agreement/ Letter of Authorization from Manufacturer/Market Authorization Holder duly notarized from the country of origin:

				<ul style="list-style-type: none"> Declaration of conformity (DoC) to be printed on the manufacturer's letterhead, filled and signed by the responsible person.
99.	M/s Chemical House, 6-C Sikander Malhi Road, Canal Park, Gulberg II, Lahore Pakistan. ELI: 00156 Evaluator: AD-II (2254-P)	<u>Legal Manufacturer:</u> M/s Bio-Rad Laboratories, Inc. 9500 Jeronimo Road Irvine, CA 92618, USA FSC: USA Valid till: 16.01.2021	Liquickek Cardiac Assessment Controls Codes & Sizes: As per FSC Class-B	Deferred for provision of the following; <ul style="list-style-type: none"> Valid ISO 13485 Certificate: Original Full Quality Assurance Certificate or equivalent as applicable duly notarized in the country of origin: Original Agency agreement/ Letter of Authorization from Manufacturer/Market Authorization Holder duly notarized from the country of origin: Declaration of conformity (DoC) to be printed on the manufacturer's letterhead, filled and signed by the responsible person.
100.	M/s Chemical House, 6-C Sikander Malhi Road, Canal Park, Gulberg II, Lahore Pakistan. ELI: 00156 Evaluator: AD-II (2251-P)	<u>Legal Manufacturer:</u> M/s Bio-Rad Laboratories, Inc. 9500 Jeronimo Road Irvine, CA 92618, USA FSC: USA Valid till: 16.01.2021	Meter Trax Control Trilevel (Quality Control (Diabetes/Hb Control) Codes & Sizes: As per FSC Class-B Shelf Life: 180 days	Deferred for provision of the following; <ul style="list-style-type: none"> Valid ISO 13485 Certificate: Original Full Quality Assurance Certificate or equivalent as applicable duly notarized in the country of origin: Original Agency agreement/ Letter of Authorization from Manufacturer/Market Authorization Holder duly notarized from the country of origin: Declaration of conformity (DoC) to be printed on the manufacturer's letterhead, filled and signed by the responsible person.
101.	M/s Chemical House , 6-C Sikander Malhi Road, Canal Park, Gulberg II, Lahore Pakistan.	<u>Legal Manufacturer:</u> M/s Bio-Rad Laboratories, Inc. 9500 Jeronimo Road Irvine, CA 92618, USA	Liquichek Specialty Immunoassay Control (Multiple Clinical	Deferred for provision of the following; <ul style="list-style-type: none"> Valid ISO 13485 Certificate: Original Full Quality

	<p>ELI: 00156</p> <p>Evaluator: AD-II</p> <p>(3475-P)</p>	<p>FSC: U.S.A</p> <p>Date of Issue: 20.08.2022</p>	<p>Chemistry Protein IVD Control)</p> <p>Codes & Sizes: As per FSC</p> <p>Class- B</p> <p>Shelf Life: As per stability study</p>	<p>Assurance Certificate or equivalent as applicable duly notarized in the country of origin:</p> <ul style="list-style-type: none"> • Original Agency agreement/ Letter of Authorization from Manufacturer/Market Authorization Holder duly notarized from the country of origin: • Declaration of conformity (DoC) to be printed on the manufacturer's letterhead, filled and signed by the responsible person.
102.	<p>M/s Chemical House, 6-C Sikander Malhi Road, Canal Park, Gulberg II, Lahore Pakistan.</p> <p>ELI: 00156</p> <p>Evaluator: AD-II</p> <p>(3469-P)</p>	<p><u>Legal Manufacturer:</u></p> <p>M/s Bio-Rad Laboratories, Inc. 9500 Jeronimo Road Irvine, CA 92618, USA</p> <p>FSC: U.S.A</p> <p>Date of Issue: 20.08.2022</p>	<p>Quantify Urinalysis Control</p> <p>(Multiple Urine Analyte IVD Control)</p> <p>Codes & Sizes: As per FSC</p> <p>Class- B</p> <p>Shelf Life: As per stability study</p>	<p>Deferred for provision of the following;</p> <ul style="list-style-type: none"> • Valid ISO 13485 Certificate: • Original Full Quality Assurance Certificate or equivalent as applicable duly notarized in the country of origin: • Original Agency agreement/ Letter of Authorization from Manufacturer/Market Authorization Holder duly notarized from the country of origin: • Declaration of conformity (DoC) to be printed on the manufacturer's letterhead, filled and signed by the responsible person.
103.	<p>M/s Chemical House, 6-C Sikander Malhi Road, Canal Park, Gulberg II, Lahore Pakistan.</p> <p>ELI: 00156</p> <p>Evaluator: AD-II</p> <p>(2572-P)</p>	<p><u>Legal Manufacturer:</u></p> <p>M/s Bio-Rad Laboratories, Inc. 9500 Jeronimo Road Irvine, CA 92618, USA</p> <p>FSC: U.S.A</p> <p>Date of Issue: 20.08.2022</p>	<p>Lyphochek Serum Chemistry Controls</p> <p>(Multiple Clinical Chemistry Analyte IVD Control)</p> <p>Codes & Sizes: As per FSC</p> <p>Class- B</p> <p>Shelf Life: As per stability study</p>	<p>Deferred for provision of the following;</p> <ul style="list-style-type: none"> • Valid ISO 13485 Certificate: • Original Full Quality Assurance Certificate or equivalent as applicable duly notarized in the country of origin: • Original Agency agreement/ Letter of Authorization from Manufacturer/Market Authorization Holder duly notarized from the country of origin: • Declaration of conformity

				(DoC) to be printed on the manufacturer's letterhead, filled and signed by the responsible person.
104.	M/s Chemical House, 6-C Sikander Malhi Road, Canal Park, Gulberg II, Lahore Pakistan. ELI: 00156 Evaluator: AD-II (2565-P)	<u>Legal Manufacturer:</u> M/s Bio-Rad Laboratories, Inc. 9500 Jeronimo Road Irvine, CA 92618, USA FSC: U.S.A Date of Issue: 20.08.2022	Lyphochek Multiple Therapy Therapeutic Drug Monitoring (TDM) IVD Control (Multiple Therapy Therapeutic Drug Monitoring (TDM) IVD Control) Codes & Sizes: As per FSC Class- B Shelf Life: As per stability study	Deferred for provision of the following; <ul style="list-style-type: none"> Valid ISO 13485 Certificate: Original Full Quality Assurance Certificate or equivalent as applicable duly notarized in the country of origin: Original Agency agreement/ Letter of Authorization from Manufacturer/Market Authorization Holder duly notarized from the country of origin: Declaration of conformity (DoC) to be printed on the manufacturer's letterhead, filled and signed by the responsible person.
105.	M/s Chemical House, 6-C Sikander Malhi Road, Canal Park, Gulberg II, Lahore Pakistan. ELI: 00156 Evaluator: AD-II (2568-P)	<u>Legal Manufacturer:</u> M/s Bio-Rad Laboratories, Inc. 9500 Jeronimo Road Irvine, CA 92618, USA FSC: U.S.A Date of Issue: 20.08.2022	Lyphochek Diabetes and Hemoglobin IVD Control (HbA 1c and HbA2 IVD Control) Codes & Sizes: As per FSC Class- B Shelf Life: As per stability study	Deferred for provision of the following; <ul style="list-style-type: none"> Valid ISO 13485 Certificate: Original Full Quality Assurance Certificate or equivalent as applicable duly notarized in the country of origin: Original Agency agreement/ Letter of Authorization from Manufacturer/Market Authorization Holder duly notarized from the country of origin: Declaration of conformity (DoC) to be printed on the manufacturer's letterhead, filled and signed by the responsible person.
106.	M/s Chemical House, 6-C Sikander Malhi Road, Canal Park, Gulberg II, Lahore Pakistan. ELI: 00156	<u>Legal Manufacturer:</u> M/s Bio-Rad Laboratories, Inc. 9500 Jeronimo Road Irvine, CA 92618, USA FSC: U.S.A	Lyphochek Immunology Plus Control (Multiple Clinical Chemistry Analyte IVD Control)	Deferred for provision of the following; <ul style="list-style-type: none"> Valid ISO 13485 Certificate: Original Full Quality Assurance Certificate or equivalent as applicable duly


	Evaluator: AD-II (2563-P)	Date of Issue: 20.08.2022	Codes & Sizes: As per FSC Class- B Shelf Life: As per stability study	notarized in the country of origin: <ul style="list-style-type: none"> Original Agency agreement/ Letter of Authorization from Manufacturer/Market Authorization Holder duly notarized from the country of origin: Declaration of conformity (DoC) to be printed on the manufacturer's letterhead, filled and signed by the responsible person.
107.	M/s Chemical House, 6-C Sikander Malhi Road, Canal Park, Gulberg II, Lahore Pakistan. ELI: 00156 Evaluator: AD-II (2561-P)	Legal Manufacturer: M/s Bio-Rad Laboratories, Inc. 9500 Jeronimo Road Irvine, CA 92618, USA Original FSC: U.S.A Valid till: 20/08/2022	Liquichek Multiple Therapy TDM IVD Control (Multiple Therapy Therapeutic Drug Monitoring (TDM) IVD Control) Codes & Sizes: As per FSC Class- B Shelf Life: As per stability study	Deferred for provision of the following: <ul style="list-style-type: none"> Valid ISO 13485 Certificate: Original Full Quality Assurance Certificate or equivalent as applicable duly notarized in the country of origin: Original Agency agreement/ Letter of Authorization from Manufacturer/Market Authorization Holder duly notarized from the country of origin: Declaration of conformity (DoC) to be printed on the manufacturer's letterhead, filled and signed by the responsible person.
108.	M/s Chemical House, 6-C Sikander Malhi Road, Canal Park, Gulberg II, Lahore Pakistan. ELI: 00156 Evaluator: AD-II (2571-P)	Legal Manufacturer: M/s Bio-Rad Laboratories, Inc. 9500 Jeronimo Road Irvine, CA 92618, USA Original FSC: U.S.A Valid till: 20/08/2022	LyphocheK Toxicology Control (Multiple Heavy Metal IVD Control) Codes & Sizes: As per FSC Class- B Shelf Life: As per stability study 	Deferred for provision of the following: <ul style="list-style-type: none"> Applied brand name is different then the name mentioned on FSC and other documents: Valid ISO 13485 Certificate: Original Full Quality Assurance Certificate or equivalent as applicable duly notarized in the country of origin: Original Agency agreement/ Letter of Authorization from Manufacturer/Market Authorization Holder duly notarized from the country of origin:

				<ul style="list-style-type: none"> Declaration of conformity (DoC) to be printed on the manufacturer's letterhead, filled and signed by the responsible person.
109.	M/s Chemical House, 6-C Sikander Malhi Road, Canal Park, Gulberg II, Lahore Pakistan. ELI: 00156 Evaluator: AD-II (2566-P)	<u>Legal Manufacturer:</u> M/s Bio-Rad Laboratories, Inc. 9500 Jeronimo Road Irvine, CA 92618, USA Original FSC: U.S.A Valid till: 20/08/2022	Lyphochek Multiple Coagulation Factor IVD Control (Multiple Coagulation Factor IVD Control) Codes & Sizes: As per FSC Class- B Shelf Life: As per stability study	Deferred for provision of the following; <ul style="list-style-type: none"> Valid ISO 13485 Certificate: Original Full Quality Assurance Certificate or equivalent as applicable duly notarized in the country of origin: Original Agency agreement/ Letter of Authorization from Manufacturer/Market Authorization Holder duly notarized from the country of origin: Declaration of conformity (DoC) to be printed on the manufacturer's letterhead, filled and signed by the responsible person.
110.	M/s Chemical House, 6-C Sikander Malhi Road, Canal Park, Gulberg II, Lahore Pakistan. ELI: 00156 Evaluator: AD-II (2567-P)	<u>Legal Manufacturer:</u> M/s Bio-Rad Laboratories, Inc. 9500 Jeronimo Road Irvine, CA 92618, USA Original FSC: U.S.A Valid till: 20/08/2022	Lyphochek Anemia Control (Multiple Anemia Related Analyte, IVD Control) Codes & Sizes: As per FSC Class- B Shelf Life: As per stability study	Deferred for provision of the following; <ul style="list-style-type: none"> Valid ISO 13485 Certificate: Original Full Quality Assurance Certificate or equivalent as applicable duly notarized in the country of origin: Original Agency agreement/ Letter of Authorization from Manufacturer/Market Authorization Holder duly notarized from the country of origin: Declaration of conformity (DoC) to be printed on the manufacturer's letterhead, filled and signed by the responsible person.
111.	M/s Chemical House, 6-C Sikander Malhi Road, Canal Park, Gulberg II, Lahore Pakistan. ELI: 00156	<u>Legal Manufacturer:</u> M/s Roboscreen GmbH, Hohmannstrasse 7, 04129 Leipzig, Germany FSC: Germany	Instant Virus RNA/DNA Kit (847-0259200602- 847-0259200603) Class-A	Deferred for provision of the following; <ul style="list-style-type: none"> Valid ISO 13485 Certificate: Original Full Quality Assurance Certificate or

	Evaluator: AD-II (428-P)	Date of issue: 29.10.2020	Shelf Life: 6 months	<p>equivalent as applicable duly notarized in the country of origin:</p> <ul style="list-style-type: none"> • Original Agency agreement/ Letter of Authorization from Manufacturer/Market Authorization Holder duly notarized from the country of origin: • Declaration of conformity (DoC) to be printed on the manufacturer's letterhead, filled and signed by the responsible person.
112.	<p>M/s Chemical House, 6-C Sikander Malhi Road, Canal Park, Gulberg II, Lahore Pakistan.</p> <p>ELI: 00156</p> <p>Evaluator: AD-II (498-P)</p>	<p>Legal Manufacturer: M/s Bio-Rad, 3 Boulevard Raymond Poincare, 92430 Marnes-la-Coquette, France</p> <p>Manufacturing Site: M/s Bio-Rad, 7 – Rue de Madrid – Espace Europeen de l'entreprise, 67300 Schiltigheim, France</p> <p>FSC: France Date of issue: 01.02.2018</p>	<p>PW40 Microplate Washer (Catalogue # 85499)</p> <p>Codes & Sizes: Class-A</p>	<p>Deferred for provision of the following;</p> <ul style="list-style-type: none"> • Valid ISO 13485 Certificate: • Original Full Quality Assurance Certificate or equivalent as applicable duly notarized in the country of origin: • Original Agency agreement/ Letter of Authorization from Manufacturer/Market Authorization Holder duly notarized from the country of origin: • Declaration of conformity (DoC) to be printed on the manufacturer's letterhead, filled and signed by the responsible person.
113.	<p>M/ Chemical House, 6-C Sikander Malhi Road Gulberg II Lahore, Pakistan</p> <p>(ELI: 00156)</p> <p>Evaluator: AD-II (347-P)</p>	<p>Legal Manufacturer M/s Bio-Rad France, 3 Boulevard Raymond Poincare 92430 Marnes-la- Coquette, France</p> <p>FSC: France Date of issue: 15.03.2019</p>	<p>PR4100 Reader (94196/91587)</p> <p>Class: A</p> <p>Shelf Life: Not applicable</p>	<p>Deferred for provision of the following;</p> <ul style="list-style-type: none"> • Valid ISO 13485 Certificate: • Original Full Quality Assurance Certificate or equivalent as applicable duly notarized in the country of origin: • Original Agency agreement/ Letter of Authorization from Manufacturer/Market Authorization Holder duly notarized from the country of origin: • Declaration of conformity (DoC) to be printed on the manufacturer's letterhead,

				filled and signed by the responsible person.
114.	M/s Chemical House, 6-C Sikander Malhi Road Gulberg-II, Lahore ELI:00156 Evaluator: AD-II (3517)	Legal Manufacturer: M/s Bio-Rad Laboratories Inc. 4000 Alfred Nobel Drive Hercules, CA, U.S.A Manufacturing Site: M/s Bio-Rad Laboratories Inc., 14620 NE North Woodinville Way, Woodinville, WA 98072, USA. Original FSC: U.S.A Valid till: 11.08.2022	Bioplex 2200 Syphilis Total & RPR (Treponema pallidum total antibody and reagin antibody IVD kit) Codes & Sizes: As per FSC Class-B Shelf Life: 24 months	Deferred for rectification of following discrepancies in the submitted application; The name and address of the manufacturing site mentioned on FSC is M/s Bio-Rad Laboratories Inc., located at 14620 NE North Woodinville Way, Woodinville, WA 98072, USA whereas on Application Form 7A, ISO 13485 certificate, DoC and Full Quality Assurance Certificate, it is mentioned as M/s Bio-Rad Laboratories Inc. 4000 Alfred Nobel Drive Hercules, CA, USA and on LOA it is written as M/s Bio-Rad Laboratories Inc. 1000 Alfred Nobel Drive Hercules, CA, USA.
115.	M/s Chemical House, 6-C Sikander Malhi Road Gulberg-II, Lahore ELI:00156 Evaluator: AD-II (708-P)	Legal Manufacturer: M/s Bio-Rad Laboratories Inc. 4000 Alfred Nobel Drive Hercules, CA, U.S.A Manufacturing Site: M/s Leica Biosystems Melbourne Pty Ltd, 495 Blackburn Road, Mount Waverley, Melbourne, Victoria, Australia 3149 Original FSC: U.S.A Valid till: 11.08.2022	Bioplex 2200 Instrument (Immunoassay analyzer) Codes & Sizes: As per FSC Class-A Shelf Life: As per stability study.	Deferred for rectification of following discrepancies in the submitted application; The name and address of the manufacturing site mentioned on FSC is M/s Leica Biosystems Melbourne Pty Ltd, 495 Blackburn Road, Mount Waverley, Melbourne, Victoria, Australia 3149, whereas on Application Form 7A, ISO 13485 certificate, DoC and Full Quality Assurance Certificate, it is mentioned as M/s Bio-Rad Laboratories Inc. 4000 Alfred Nobel Drive Hercules, CA, USA and on LOA it is written as M/s Bio-Rad Laboratories Inc. 1000 Alfred Nobel Drive Hercules, CA, USA.
116.	M/s Chemical House, 6-C Sikander Malhi Road Gulberg- II, Lahore ELI:00156	Legal Manufacturer: M/s Bio-Rad Laboratories Inc. 4000 Alfred Nobel Drive Hercules, CA, U.S.A Manufacturing Site:	Bioplex 25-OH Vitamin D (Chemiluminescent Immunoassay) Codes & Sizes: As	Deferred for rectification of following discrepancies in the submitted application; The name and address of the manufacturing site mentioned on FSC is M/s Bio-Rad

	Evaluator: AD-II (3511-P)	M/s Bio-Rad Laboratories Inc., 14620 NE North Woodinville Way, Woodinville, WA 98072, USA. Original FSC: USA Valid till: 11.08.2022	per FSC Class-B Shelf Life: 24 months	Laboratories Inc., located at 14620 NE North Woodinville Way, Woodinville, WA 98072, USA whereas on Application Form 7A, ISO 13485 certificate, DoC and Full Quality Assurance Certificate, it is mentioned as M/s Bio-Rad Laboratories Inc. 4000 Alfred Nobel Drive Hercules, CA, USA and on LOA it is written as M/s Bio-Rad Laboratories Inc. 1000 Alfred Nobel Drive Hercules, CA, USA; Provided ISO 13485 Certificate, Full Quality Assurance Certificate, LOA and FSC are photocopies.
117.	M/s Chemical House , 6-C Sikander Malhi Road Gulberg- II, Lahore ELI:00156 Evaluator: AD-II (3512-P)	Legal Manufacturer: M/s Bio-Rad Laboratories Inc. 4000 Alfred Nobel Drive Hercules, CA, U.S.A Manufacturing Site: M/s Bio-Rad Laboratories Inc., 14620 NE North Woodinville Way, Woodinville, WA 98072, USA. Original FSC: USA Valid till: 11.08.2022	Bioplex 2200 ANA Screen with MDSS (Multiple antinuclear antibody screening IVD) Class-B Shelf Life: 24 months	Deferred for rectification of following discrepancies in the submitted application; The name and address of the manufacturing site mentioned on FSC is M/s Bio-Rad Laboratories Inc., located at 14620 NE North Woodinville Way, Woodinville, WA 98072, USA whereas on Application Form 7A, ISO 13485 certificate, DoC and Full Quality Assurance Certificate, it is mentioned as M/s Bio-Rad Laboratories Inc. 4000 Alfred Nobel Drive Hercules, CA, USA and on LOA it is written as M/s Bio-Rad Laboratories Inc. 1000 Alfred Nobel Drive Hercules, CA, USA.
118.	M/s Chemical House , 6-C Sikander Malhi Road Gulberg- II, Lahore ELI:00156 Evaluator: AD-II (3513-P)	Legal Manufacturer: M/s Bio-Rad Laboratories Inc. 4000 Alfred Nobel Drive Hercules, CA, U.S.A Manufacturing Site: M/s Bio-Rad Laboratories Inc., 14620 NE North Woodinville Way, Woodinville, WA 98072, USA. Original FSC: USA Valid till: 1.08.2022	Bioplex 2200 APLS IgG, IgM, & IgA (Phospholipid antibody IVD Kit) Class-B Shelf Life: 24 months	Deferred for rectification of following discrepancies in the submitted application; The name and address of the manufacturing site mentioned on FSC is M/s Bio-Rad Laboratories Inc., located at 14620 NE North Woodinville Way, Woodinville, WA 98072, USA whereas on Application Form 7A, ISO 13485 certificate, DoC and Full Quality

				Assurance Certificate, it is mentioned as M/s Bio-Rad Laboratories Inc. 4000 Alfred Nobel Drive Hercules, CA, USA and on LOA it is written as M/s Bio-Rad Laboratories Inc. 1000 Alfred Nobel Drive Hercules, CA, USA.
119.	M/s Chemical House, 6-C Sikander Malhi Road Gulberg-II, Lahore ELI:00156 Evaluator: AD-II (3514-P)	Legal Manufacturer: M/s Bio-Rad Laboratories Inc. 4000 Alfred Nobel Drive Hercules, CA, U.S.A Manufacturing Site: M/s Bio-Rad Laboratories Inc., 14620 NE North Woodinville Way, Woodinville, WA 98072, USA. Original FSC: USA Valid till:11.08.2022	Bioplex 2200 Anti- CCP IVD (Cyclic citrulinated peptide antibody (Anti-CCP) IVD Kit) Class-B Shelf Life: 24 months	Deferred for rectification of following discrepancies in the submitted application; The name and address of the manufacturing site mentioned on FSC is M/s Bio-Rad Laboratories Inc., located at 14620 NE North Woodinville Way, Woodinville, WA 98072, USA whereas on Application Form 7A, ISO 13485 certificate, DoC and Full Quality Assurance Certificate, it is mentioned as M/s Bio-Rad Laboratories Inc. 4000 Alfred Nobel Drive Hercules, CA, USA and on LOA it is written as M/s Bio-Rad Laboratories Inc. 1000 Alfred Nobel Drive Hercules, CA, USA.
120.	M/s Chemical House, 6-C Sikander Malhi Road Gulberg-II, Lahore ELI:00156 Evaluator: AD-II (3515-P)	Legal Manufacturer: M/s Bio-Rad Laboratories Inc. 4000 Alfred Nobel Drive Hercules, CA, U.S.A Manufacturing Site: M/s Bio-Rad Laboratories Inc., 14620 NE North Woodinville Way, Woodinville, WA 98072, USA. Original FSC: USA Valid till:11.08.2022	Bioplex 2200 Vaculitis (Multiple vasculitis- associated antibody IVD kit)  Class-B Shelf Life: 24 months	Deferred for rectification of following discrepancies in the submitted application; The name and address of the manufacturing site mentioned on FSC is M/s Bio-Rad Laboratories Inc., located at 14620 NE North Woodinville Way, Woodinville, WA 98072, USA whereas on Application Form 7A, ISO 13485 certificate, DoC and Full Quality Assurance Certificate, it is mentioned as M/s Bio-Rad Laboratories Inc. 4000 Alfred Nobel Drive Hercules, CA, USA and on LOA it is written as M/s Bio-Rad Laboratories Inc. 1000 Alfred Nobel Drive Hercules, CA, USA.

121.	<p>M/s Chemical House, 6-C Sikander Malhi Road Gulberg-II, Lahore</p> <p>ELI:00156</p> <p>Evaluator: AD-II (3516-P)</p>	<p>Legal Manufacturer: M/s Bio-Rad Laboratories Inc. 4000 Alfred Nobel Drive Hercules, CA, U.S.A</p> <p>Manufacturing Site: M/s Bio-Rad Laboratories Inc., 14620 NE North Woodinville Way, Woodinville, WA 98072, USA.</p> <p>Original FSC: USA Valid till:11.08.2022</p>	<p>Bioplex 2200 Celiac IgG & IgA</p> <p>(Multiple coeliac disease associated antibody IVD Kit)</p> <p>Class-B</p> <p>Shelf Life: 24 months</p>	<p>Deferred for rectification of following discrepancies in the submitted application;</p> <p>The name and address of the manufacturing site mentioned on FSC is M/s Bio-Rad Laboratories Inc., located at 14620 NE North Woodinville Way, Woodinville, WA 98072, USA whereas on Application Form 7A, ISO 13485 certificate, DoC and Full Quality Assurance Certificate, it is mentioned as M/s Bio-Rad Laboratories Inc. 4000 Alfred Nobel Drive Hercules, CA, USA and on LOA it is written as M/s Bio-Rad Laboratories Inc. 1000 Alfred Nobel Drive Hercules, CA, USA.</p>
122.	<p>M/s Mehran International, 498/C Feroz Shah Mehta Road, Karachi</p> <p>ELI: 00351</p> <p>Evaluator: AD-II (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: Spain</p> <p>Date of issue: 19-10-2021</p>	<p>M.I Blood Bag CPDA-1 (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>Deferred for rectification of following discrepancies in the submitted application;</p> <p>The firm has provided copy of FSC issued by Spanish Agency for Medicines & Health Products (Certificate No. PS / CL V/MGCO/ 1196/ 2021- CLV), dated 19-10-2021. The verification method is mentioned on the said certificate and when it was verified through the given procedure, it is found that the Annex – I (Page 3) of the FSC is different than the actual document available on the Agency's online database. On the document provided by the company the name of manufacturer and authorized representatives are different then those mentioned on the document available on Agency's database.</p> <p>Full Quality Assurance System Certificate or equivalent is not provided;</p> <p>ISO 13485 Certificate is photocopy;</p>

				Clarification is required regarding class of applied medical device.
123.	M/s Mehran International, 498/C Feroz Shah Mehta Road, Karachi ELI: 00351 Evaluator: AD-II (3522-P)	<u>Legal Manufacturer:</u> M/s Suzhou Laishi Transfusion Equipment Co., Ltd, Changsheng Road, Tongli Town 215217 Wujiang City, Jiangsu, Province China FSC: China Valid till: 22/04/2024 FSC: Spain Date of issue: 19-10-2021	M.I Blood Bag CPDA-1 (TC) 250 ML [Disposable Plastic Blood Bag, with Anticoagulant Citrate Phosphate Dextrose Adenine (CPDA)] Class-D Shelf Life: 36 months	Deferred for rectification of following discrepancies in the submitted application; The firm has provided copy of FSC issued by Spanish Agency for Medicines & Health Products (Certificate No. PS / CL V/MGCO/ 1196/ 2021-CLV), dated 19-10-2021. The verification method is mentioned on the said certificate and when it was verified through the given procedure, it is found that the Annex – I (Page 3) of the FSC is different than the actual document available on the Agency's online database. On the document provided by the company the name of manufacturer and authorized representatives are different then those mentioned on the document available on Agency's database. Full Quality Assurance System Certificate or equivalent is not provided; ISO 13485 Certificate is photocopy; Clarification is required regarding class of applied medical device.
124.	M/s Mehran International, 498/C Feroz Shah Mehta Road, Karachi ELI: 00351 Evaluator: AD-II (3523-P)	<u>Legal Manufacturer:</u> M/s Suzhou Laishi Transfusion Equipment Co., Ltd, Changsheng Road, Tongli Town 215217 Wujiang City, Jiangsu, Province China FSC: China Valid till: 22/04/2024 FSC: Spain	M.I Blood Bag CPDA-1 (TC) 500 ML [Disposable Plastic Blood Bag, with Anticoagulant Citrate Phosphate Dextrose Adenine (CPDA)] Class-D Shelf Life: 36 months	Deferred for rectification of following discrepancies in the submitted application; The firm has provided copy of FSC issued by Spanish Agency for Medicines & Health Products (Certificate No. PS / CL V/MGCO/ 1196/ 2021-CLV), dated 19-10-2021. The verification method is mentioned on the said certificate and when it was verified through the given procedure, it is found that the Annex – I (Page

		Date of issue: 19-10-2021		<p>3) of the FSC is different than the actual document available on the Agency's online database. On the document provided by the company the name of manufacturer and authorized representatives are different then those mentioned on the document available on Agency's database.</p> <p>Full Quality Assurance System Certificate or equivalent is not provided;</p> <p>ISO 13485 Certificate is photocopy;</p> <p>Clarification is required regarding class of applied medical device.</p>
125.	<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: 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 (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</p>	<p>Deferred for rectification of following discrepancies in the submitted application;</p> <p>The firm has provided copy of FSC issued by Spanish Agency for Medicines & Health Products (Certificate No. PS / CL V/MGCO/ 1196/ 2021-CLV), dated 19-10-2021. The verification method is mentioned on the said certificate and when it was verified through the given procedure, it is found that the Annex – I (Page 3) of the FSC is different than the actual document available on the Agency's online database. On the document provided by the company the name of manufacturer and authorized representatives are different then those mentioned on the document available on Agency's database.</p> <p>Full Quality Assurance System Certificate or equivalent is not provided;</p> <p>ISO 13485 Certificate is photocopy;</p> <p>Clarification is required regarding class of applied medical device.</p>

126.	<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</p>	<p>Deferred for rectification of following discrepancies in the submitted application;</p> <p>The firm has provided copy of FSC issued by Spanish Agency for Medicines & Health Products (Certificate No. PS / CL V/MGCO/ 1196/ 2021-CLV), dated 19-10-2021. The verification method is mentioned on the said certificate and when it was verified through the given procedure, it is found that the Annex – I (Page 3) of the FSC is different than the actual document available on the Agency's online database. On the document provided by the company the name of manufacturer and authorized representatives are different then those mentioned on the document available on Agency's database. Full Quality Assurance System Certificate or equivalent is not provided;</p> <p>ISO 13485 Certificate is photocopy;</p> <p>Clarification is required regarding class of applied medical device.</p>
127.	<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-1 (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</p>	<p>Deferred for rectification of following discrepancies in the submitted application;</p> <p>The firm has provided copy of FSC issued by Spanish Agency for Medicines & Health Products (Certificate No. PS / CL V/MGCO/ 1196/ 2021-CLV), dated 19-10-2021. The verification method is mentioned on the said certificate and when it was verified through the given procedure, it is found that the Annex – I (Page 3) of the FSC is different than the actual document available on the Agency's online database. On the document</p>

				<p>provided by the company the name of manufacturer and authorized representatives are different then those mentioned on the document available on Agency's database.</p> <p>Full Quality Assurance System Certificate or equivalent is not provided;</p> <p>ISO 13485 Certificate is photocopy;</p> <p>Clarification is required regarding class of applied medical device.</p>
128.	<p>M/s Maqsood Brothers, Office No. 503-B, 5th Floor, Saima Trader Tower, I.I Chundrigar Road Karachi.</p> <p>(ELI-00282)</p> <p>Evaluator: AD-II (3878-P)</p>	<p>Legal Manufacturer: M/s Faramasino Pharmaceuticals (Jiangsu) Co., Ltd No. 9 Weidi Road, Nanjing, Jiangsu Province, Peoples Republic of China.</p> <p>FSC: China</p> <p>Issued: 8-6-2021</p>	<p>Life care Disposable Transfusion Set</p> <p>Class C</p> <p>Shelf Life: Not provided</p>	<p>Deferred for rectification of following discrepancies in the submitted application;</p> <ul style="list-style-type: none"> • Application Form-7A is not signed; • MRP is not provided; • Credentials of manufacturer are not notarized; • LOA is photocopy; • ISO 13485 Certificate is photocopy; • Production Quality Assurance System certificate is photocopy; • Full Quality Assurance System Certificate or equivalent is not provided; • Stability studies data not provided; • Justification of class of applied medical device is required. • Undertaking on notarized stamp paper is not provided.
129.	<p>M/s Maqsood Brothers, Office No. 503-B, 5th Floor, Saima Trader Tower, I.I Chundrigar Road Karachi.</p> <p>(ELI-00282)</p> <p>Evaluator: AD-II</p>	<p>Legal Manufacturer: M/s Faramasino Pharmaceuticals (Jiangsu) Co., Ltd No. 9 Weidi Road, Nanjing, Jiangsu Province, Peoples Republic of China.</p> <p>FSC: China</p> <p>Issued: 8-6-2021</p>	<p>Life care Disposable Plastic Blood Bag</p> <p>Class B</p> <p>Shelf Life: Not provided</p>	<p>Deferred for rectification of following discrepancies in the submitted application;</p> <ul style="list-style-type: none"> • Application Form-7A is not signed; • MRP is not provided; • Credentials of manufacturer are not notarized; • LOA is photocopy; • ISO 13485 Certificate is

	(3879-P)			<p>photocopy;</p> <ul style="list-style-type: none"> • Production Quality Assurance System certificate is photocopy; • Full Quality Assurance System Certificate or equivalent is not provided; • Stability studies data not provided; • Justification of class of applied medical device is required. • Undertaking on notarized stamp paper is not provided.
130.	<p>M/s Maqsood Brothers, Office No. 503-B, 5th Floor, Saima Trader Tower, I.I Chundrigar Road Karachi.</p> <p>(ELI-00282)</p> <p>Evaluator: AD-II</p> <p>(3771-P)</p>	<p>Legal Manufacturer: M/s Shandong Caremed Medical Products Co. Ltd, Yan Tai Industrial Park , Ding Tao County (The East of Zhanqian Road) Heze, Shandong Province, China</p> <p>FSC: China Valid till:27.02.2022</p>	<p>Life Care Plus Transfusion Set</p> <p>Class B</p> <p>Shelf life:</p>	<p>Deferred for provision of following documents;</p> <ul style="list-style-type: none"> • Valid free Sale Certificate: • Valid ISO 13485 Certificate: • Stability Studies Data: • Full Quality Assurance System Certificate or equivalent.
131.	<p>M/s Maqsood Brothers, Office No. 503-B, 5th Floor, Saima Trader Tower, I.I Chundrigar Road Karachi.</p> <p>(ELI-00282)</p> <p>Evaluator: AD-II</p> <p>(3767-P)</p>	<p>Legal Manufacturer: M/s Shandong Caremed Medical Products Co. Ltd, Yan Tai Industrial Park , Ding Tao County (The East of Zhanqian Road) Heze, Shandong Province, China</p> <p>FSC: China Valid till:27.02.2022</p>	<p>Life Care Plus Disposable Syringe</p> <p>(Disposable Syringe)</p> <p>Sizes: 10ml, 20ml, 50ml 100ml</p> <p>Class B</p> <p>Shelf life:</p>	<p>Deferred for provision of following documents;</p> <ul style="list-style-type: none"> • Valid Free Sale Certificate: • Valid ISO 13485 Certificate: • Stability Studies Data: • Full Quality Assurance System Certificate or equivalent. • Original Declaration of Conformity on manufacturer's letterhead, duly signed and stamped.
132.	<p>M/s Maqsood Brothers, Office No. 503-B, 5th Floor, Saima Trader Tower, I.I Chundrigar Road Karachi.</p> <p>(ELI-00282)</p> <p>Evaluator: AD-II</p> <p>(4134-P)</p>	<p>Legal Manufacturer: M/s Shandong Caremed Medical Products Co. Ltd, Yan Tai Industrial Park , Ding Tao County (The East of Zhanqian Road) Heze, Shandong Province, China</p> <p>FSC: China Valid till:27.02.2022</p>	<p>Life Care Plus Sterile Intravenous Needles / Scalp Vein Set for Single Use</p> <p>Class B</p> <p>Shelf Life: 05 Years</p>	<p>Deferred for provision of following documents;</p> <ul style="list-style-type: none"> • Valid Free Sale Certificate: • Valid ISO 13485 Certificate: • Stability Studies Data: • Full Quality Assurance System Certificate or equivalent. • Original Declaration of Conformity on manufacturer's letterhead, duly signed and stamped.

133.	M/s Maqsood Brothers, Office No. 503-B, 5th Floor, Saima Trader Tower, I.I Chundrigar Road Karachi. (ELI-00282) Evaluator: AD-II (4135-P)	Legal Manufacturer: M/s Shandong Caremed Medical Products Co. Ltd, Yan Tai Industrial Park , Ding Tao County (The East of Zhanqian Road) Heze, Shandong Province, China FSC: China Valid till:27.02.2022	Life Care Plus Sterile Foley Catheter for Single Use (Sterile Urethral Catheter) Class B Shelf Life: 05 Years	Deferred for provision of following documents; <ul style="list-style-type: none"> • Valid Free Sale Certificate: • Valid ISO 13485 Certificate: • Stability Studies Data: • Full Quality Assurance System Certificate or equivalent. • Original Declaration of Conformity on manufacturer's letterhead, duly signed and stamped.
134.	M/s Maqsood Brothers, Office No. 503-B, 5th Floor, Saima Trader Tower, I.I Chundrigar Road Karachi. (ELI-00282) Evaluator: AD-II (4137-P)	Legal Manufacturer: M/s Shandong Caremed Medical Products Co. Ltd, Yan Tai Industrial Park , Ding Tao County (The East of Zhanqian Road) Heze, Shandong Province, China FSC: China Valid till:27.02.2022	Life Care Plus Burette Type Infusion Sets for Single Use Sizes: 100ml, 150ml Class B Shelf Life: 05 Years	Deferred for provision of following documents; <ul style="list-style-type: none"> • Valid Free Sale Certificate: • Valid ISO 13485 Certificate: • Stability Studies Data: • Full Quality Assurance System Certificate or equivalent. • Original Declaration of Conformity on manufacturer's letterhead, duly signed and stamped.
135.	M/s Maqsood Brothers, Office No. 503-B, 5th Floor, Saima Trader Tower, I.I Chundrigar Road Karachi. (ELI-00282) Evaluator: AD-II (4863-P)	Legal Manufacturer: M/s Jiangsu Shuangsheng Medical Appliance Co. Ltd., Dandong Industrial Park, Danyang City, Jiangsu Province, China. FSC: China Valid till:17.04.2023	Life Care Plus Nebulizer Class B Shelf Life:	Deferred for provision of following documents; <ul style="list-style-type: none"> • Stability Studies Data: • Full Quality Assurance System Certificate or equivalent. • Original Declaration of Conformity on manufacturer's letterhead, duly signed and stamped.
136.	M/s Maqsood Brothers, Office No. 503-B, 5th Floor, Saima Trader Tower, I.I Chundrigar Road Karachi. (ELI-00282) Evaluator: AD-II (3429-P)	Legal Manufacturer: M/s Huaian Poly Medical technology Corporation No.5, West Huaqing Road 223002 Huaian City, China. FSC: China Valid till:17.02.2023	Life Cath I.V Cannula Class B Shelf Life:	Deferred for provision of following documents; <ul style="list-style-type: none"> • Valid ISO 13485 Certificate: • Stability Studies Data: • Full Quality Assurance System Certificate or equivalent.
137.	M/s Maqsood Brothers Office No. 503-B, 5th Floor, Saima Trader	Legal Manufacturer: M/s Xuzhou Yongkang Electronic Science Technology Co. Ltd., 4F Building C8, 40 Jingshan Road,	Life Care Multi-parameter Patient Monitor	Deferred for provision of following documents; <ul style="list-style-type: none"> • Valid Free Sale Certificate:

	<p>Tower, I.I Chundrigar Road Karachi.</p> <p>(ELI-00282)</p> <p>Evaluator: AD-II (4426-P)</p>	<p>Economic and Technological Development Zone, 221000 Xuzhou China.</p> <p>FSC: China</p> <p>Valid till: 28.08.2021</p>	<p>Class B</p> <p>Shelf Life: 05 Years</p>	<ul style="list-style-type: none"> Valid ISO 13485 Certificate: Stability Studies Data: Full Quality Assurance System Certificate or equivalent. Original Declaration of Conformity on manufacturer's letterhead, duly signed and stamped. Original Letter of Authorization, duly notarized in the country of origin.
138.	<p>Nisa Impex Pvt. Ltd. Office: Maxim Arcade Plot No. 13-14, Usman Block, Jaddah Town, Phase-I, Opp. DHA- II, G.T. Road, Islamabad.</p> <p>Godown: Office No. 2, 1st Floor Akbar Khan, Plaza Collage Road, Rawalpindi.</p> <p>[ELI-00064]</p> <p>-2393-</p> <p>Evaluator: AD-I</p>	<p>Chengdu Xinjin Shifeng Medical Apparatus & Instrument Co. Ltd. No. 46 7th Group Wanjie, Xinping Town, Xinjin County, Chengdu, China.</p> <p>FSC: China</p> <p>Valid Till: 26-07-2022</p>	<p>NISA Disposable Hemodialysis Blood Tubing Set</p> <p>Extracorporeal Blood Circuit for Hemodialysers</p> <p>Model/Specifications : BPC-A, BPC-B, BPC-C, BPC-D (As per provided FSC)</p> <p>Code: GXZZ-20173453302</p> <p>Class: B</p> <p>Shelf Life: 3 years</p> <p>Fee Slip No. 2068340 Rs. 25000/-</p>	<p>Deferred for the provision of following documents:</p> <ul style="list-style-type: none"> Original Agency Agreement from MAH duly notarized from country of origin Original and valid FCS duly attested by embassy of Pakistan FSC of RRA Declaration of Conformity ISO 13485 Certificate CE Certificate Full QA certificate Stability studies
139.	<p>Nisa Impex Pvt. Ltd. Office: Maxim Arcade Plot No. 13-14, Usman Block, Jaddah Town, Phase-I, Opp. DHA- II, G.T. Road, Islamabad.</p> <p>Godown: Office No. 2, 1st Floor Akbar Khan, Plaza Collage Road, Rawalpindi.</p> <p>[ELI-00064]</p> <p>-2392-</p> <p>Evaluator: AD-I</p>	<p>Chengdu Xinjin Shifeng Medical Apparatus & Instrument Co. Ltd. No. 46 7th Group Wanjie, Xinping Town, Xinjin County, Chengdu, China.</p> <p>FSC: China</p> <p>Valid Till: 26-07-2022</p>	<p>NISA Nasal Oxygen Tube</p> <p>Disposable Nasal Oxygen Tube</p> <p>Model: YG-Z, YG-T, YG-II</p> <p>Code: CXZZ-20172560244</p> <p>Class: B</p> <p>Shelf Life: 3 years</p> <p>Fee Slip No. 2068343 Rs. 25000/-</p>	<p>Deferred for the provision of following documents:</p> <ul style="list-style-type: none"> Original Agency Agreement from MAH duly notarized from country of origin Original and valid FCS duly attested by embassy of Pakistan FSC of RRA Declaration of Conformity ISO 13485 Certificate CE Certificate Full QA certificate Stability studies


140.	<p>Nisa Impex Pvt. Ltd. Office: Maxim Arcade Plot No. 13-14, Usman Block, Jaddah Town, Phase-I, Opp. DHA-II, G.T. Road, Islamabad. Godown: Office No. 2, 1st Floor Akbar Khan, Plaza Collage Road, Rawalpindi.</p> <p>[ELI-00064]</p> <p>-2391-</p> <p>Evaluator: AD-I</p>	<p>Chengdu Xinjin Shifeng Medical Apparatus & Instrument Co. Ltd. No. 46 7th Group Wanjie, Xinping Town, Xinjin County, Chengdu, China.</p> <p>FSC: China</p> <p>Valid Till: 26-07-2022</p>	<p>NISA Urine Bag</p> <p>Size: 1000 & 2000ml</p> <p>Code: CCDXB 20140035</p> <p>Class: B</p> <p>MRP: Rs. 140/-</p> <p>Shelf Life: 3 years</p> <p>Fee Slip No. 2068344 Rs. 25000/-</p>	<p>Deferred for the provision of following documents:</p> <ul style="list-style-type: none"> • Original Agency Agreement from MAH duly notarized from country of origin • Original and valid FCS duly attested by embassy of Pakistan • FSC of RRA • Declaration of Conformity • ISO 13485 Certificate • CE Certificate • Full QA certificate • Stability studies
141.	<p>Noor Brands, Plot # 09-M/18-49/A.M, Quaid e Azam, Industrial estate, K. Lakhpat, Lahore</p> <p>ELI:00822</p> <p>2917</p> <p>Evaluator: AD-V</p>	<p>Legal Manufacturer:</p> <p>Shandong Ming Yuan, Commodity Co., Ltd, Middle Licheng Road, Development zone of linyi country, 2515000 Dezhou City, Shandong China</p> <p>FSC: Not found</p>	<p>ROMEO (CONTRACEPTIVE)</p> <p>Class: C</p> <p>Shelf Life: 1 year claimed but supporting data not provide.</p>	<p>Deferred for submission of required documents as per MDR, 2017.</p>
142.	<p>Medical Equipment & Systems, 60/61 F.C.C Syed Maratib Ali Road Gulberg IV, Lahore</p> <p>ELI: 00554</p> <p>Evaluator: AD-V</p>	<p>Legal Manufacturer:</p> <p>Suzhou Zoll Medical Technology Co., Ltd, Room 102-1/ 102-2, Block 19, No.8 Jinmen Road Suzhou New District, 215163 Suzhou Jiangsu, P.R, China</p> <p>Original FSC: China</p> <p>Date of Issue: 11.09.2019</p>	<p>ZOLL M2 DEFEBRILLATOR (DEFEBRILLATOR)</p> <p>Codes & Sizes: As per FSC</p> <p>Class: C</p> <p>Shelf Life: 10 years</p>	<p>Deferred for provision of followings:-</p> <ul style="list-style-type: none"> • Legal Manufacturer of the product is Zoll Medical Corporation, USA. LoA is also given by the same Manufacturer but Credentials, ISO 13485, FQAS certificate, stability studies, EPSP, Details of Manufacturing and QC processes all are provided by Suzhou Zoll Medical Technologies Co., Ltd, China. • FSC of Netherland also bears the name of Suzhou Zoll Medical technologies Co., Ltd, China instead of legal manufacturer i.e. Zoll Medical Corporation, USA.

				<ul style="list-style-type: none"> FSC of Netherlands is required to be attested by the Embassy of Pakistan in Netherlands. Need clarification regarding the abovementioned ambiguities from the Firm.
143.	<p>Medical Equipment & Systems, 60/61 F.C.C Syed Maratib Ali Road Gulberg IV, Lahore</p> <p>ELI: 00554</p> <p>Evaluator: AD-V</p>	<p>Legal Manufacturer:</p> <p>ZOLL Medical Corporation 269 Mill Road Chelmsford, MA 01824</p> <p>Original FSC: China</p> <p>FSC: U.S.A</p> <p>Valid till: 06/07/2023</p>	<p>ZOLL R Series Defibrillator, BSL, with NIBP and ETCO2</p> <p>(Deferbrillator)</p> <p>Codes & Sizes: N/A</p> <p>Class-C</p> <p>Shelf Life: 10 years</p>	<p>Deferred for provision of followings:-</p> <ul style="list-style-type: none"> Evidence/report regarding 10 years service life is not provided. Copy of FSC of US FDA provided. Valid and Notarizes ISO 13485 not provided. Credentials from the Zoll Medical Corporation
144.	<p>Medical Equipment & Systems, 60/61 F.C.C Syed Maratib Ali Road Gulberg IV, Lahore</p> <p>ELI: 00554</p> <p>2940-P</p> <p>Evaluator: AD-V</p>	<p>Legal Manufacturer:</p> <p>ZOLL Medical Corporation 269 Mill Road Chelmsford, MA 01824</p> <p>FSC: U.S.FDA</p> <p>Valid till: 06/07/2023</p>	<p>ZOLL FULLY AUTOMATIC AED PLUS DEFEBRILLATOR (Automated External Defibrillator)</p> <p>Codes & Sizes: N/A</p> <p>Class-C</p> <p>Service Life: 10 years (Evidence/ report not provided)</p>	<p>Deferred for provision of followings:-</p> <ul style="list-style-type: none"> Evidence/report regarding 10 years service life is not provided. Copy of FSC of US FDA provided. Valid and Notarizes ISO 13485 not provided. Credentials from the Zoll Medical Corporation
145.	<p>Reaction Scientific Private Limited, 337, Street No. 17, Block-B, Sector-B, 17, Islamabad</p> <p>ELI: 00228</p> <p>3148-P</p> <p>Evaluator: AD-V</p>	<p>Legal Manufacturer:</p> <p>Human Gesellschaft fur Biochemica und Diagnostica MbH, Max-Planck-Ring 21, 65205, Wiesbaden, Germany</p> <p>Original FSC: Germany</p> <p>Date of Issue: 17/11/2021</p>	<p>HumaSRate 24PT</p> <p>(Erythrocyte sedimentation Rate (ESR) Analyzer</p> <p>Codes & Sizes: As per FSC</p> <p>Class-C</p> <p>Service Life: not mentioned</p>	<p>Deferred for provision of followings:-</p> <ul style="list-style-type: none"> Applied product i.e. HumaSRate24PT is not mentioned in the Letter of Authorization. ISO 13485 Expired. FQAS certificate not provided. Service Life not mentioned provide relevant study data and report
146.	<p>M/s Universal Dental Pvt. Ltd, 17-Mcleod Road, Lahore</p> <p>(ELI 00071)</p>	<p>Legal Manufacturer:</p> <p>M/s Produits Dentaires SA, Rue des Bosquets 18, 1800 vevey, Switzerland</p>	<p>Pella Transparent Crown Forms</p> <p>Odus pella transparent crown</p>	<p>Deferred for provision of following documents:</p> <ul style="list-style-type: none"> Original Agency agreement / Letter of Authorization from

	Evaluator:AD-II (669-P)	FSC: Switzerland Valid till: 02/10/2023	forms Codes & Sizes: As per FSC Class-A Shelf Life: 5 years	Manufacturer/Market Authorization Holder duly notarized from the country of origin: <ul style="list-style-type: none"> • Original Free Sale Certificate in the country of origin duly attested by Embassy of Pakistan. • Declaration of conformity (DoC) to be printed on the manufacturer's letterhead, filled and signed by the responsible person: • Original and valid Full Quality Assurance Certificate or equivalent as applicable duly notarized in the country of origin: • Original and valid ISO 13485 Certificate.
147.	M/s Universal Dental Pvt. Ltd, 17-Mcleod Road, Lahore. (ELI 00071) Evaluator: AD-II (507-P)	<u>Legal Manufacturer:</u> M/s Ivoclar Vivadent AG Benderstrasse 2 FL-9494 Schan Liechtenstein, Germany FSC: Liechtenstein, Germany Valid: 12.10.2021	Cavifil Injector (Non active instrument for dental material) Codes & Sizes: As per FSC Class-A	Deferred for provision of following documnts: <ul style="list-style-type: none"> • Valid Free Sale Certificate: • Declaration of conformity (DoC) to be printed on the manufacturer's letterhead, filled and signed by the responsible person: • Valid Full Quality Assurance Certificate: • Valid ISO 13485 Certificate.
148.	M/s Universal Dental Pvt. Ltd, 17-Mcleod Road, Lahore (ELI 00071) Evaluator: AD-II (655-P)	<u>Legal Manufacturer:</u> M/s Produits Dentaires SA , Rue des Bosquets 18, 1800 vevey, Switzerland FSC: Switzerland Valid till: 02/10/2023	Abrasive strips (Steel abrasive strips Diamond abrasive strips) Codes & Sizes: As per FSC Class-A Shelf Life: N/A	Deferred for provision of following documnts: <ul style="list-style-type: none"> • Original Agency agreement / Letter of Authorization from Manufacturer/Market Authorization Holder duly notarized from the country of origin: • Original Free Sale Certificate in the country of origin duly attested by Embassy of Pakistan. • Declaration of conformity (DoC) to be printed on the manufacturer's letterhead, filled and signed by the responsible person: • Original and valid Full Quality

				Assurance Certificate or equivalent as applicable duly notarized in the country of origin: • Original and valid ISO 13485 Certificate.
149.	M/s Universal Dental Pvt. Ltd, 17-Mcleod Road, Lahore (ELI 00071) Evaluator: AD-II (656-P)	<u>Legal Manufacturer:</u> M/s Produits Dentaires SA, Rue des Bosquets 18, 1800 vevey, Switzerland FSC: Switzerland Valid till: 02/10/2023	Tofflemire Matrix Bands (Tofflemirematrix bands Nystroem type 8 matrix retainers) Codes & Sizes: As per FSC Class-A Shelf Life: N/A	Deferred for provision of following documnts: • Original Agency agreement / Letter of Authorization from Manufacturer/Market Authorization Holder duly notarized from the country of origin: • Original Free Sale Certificate in the country of origin duly attested by Embassy of Pakistan. • Declaration of conformity (DoC) to be printed on the • manufacturer's letterhead, filled and signed by the responsible person: • Original and valid Full Quality Assurance Certificate or equivalent as applicable duly notarized in the country of origin: • Original and valid ISO 13485 Certificate
150.	M/s Universal Dental Pvt. Ltd, 17-Mcleod Road, Lahore (ELI 00071) Evaluator: AD-II (657-P)	<u>Legal Manufacturer:</u> M/s Produits Dentaires SA, Rue des Bosquets 18, 1800 vevey, Switzerland FSC: Switzerland Valid till: 02/10/2023	Transparent strips (PD transparent strips Odus transparent strips) Codes & Sizes: As per FSC Class-A Shelf Life: 5 years	Deferred for provision of following documnts: • Original Agency agreement / Letter of Authorization from Manufacturer/Market Authorization Holder duly notarized from the country of origin: • Original Free Sale Certificate in the country of origin duly attested by Embassy of Pakistan. • Declaration of conformity (DoC) to be printed on the manufacturer's letterhead, filled and signed by the responsible person: • Original and valid Full Quality Assurance Certificate or equivalent as applicable duly

				notarized in the country of origin: • Original and valid ISO 13485 Certificate.
151.	M/s Universal Dental Pvt. Ltd, 17-Mcleod Road, Lahore (ELI 00071) Evaluator: AD-II (658-P)	<u>Legal Manufacturer:</u> M/s Produits Dentaires SA , Rue des Bosquets 18, 1800 vevey, Switzerland FSC: Switzerland Valid till: 02/10/2023	Articulating Paper (Straight Articulating Paper Horseshoe Articulating Paper) Codes & Sizes: As per FSC Class-A Shelf Life: 10 years	Deferred for provision of following documnts: • Original Free Sale Certificate in the country of origin duly attested by Embassy of Pakistan. • Declaration of conformity (DoC) to be printed on the manufacturer's letterhead, filled and signed by the responsible person.
152.	M/s Universal Dental Pvt. Ltd, 17-Mcleod Road, Lahore (ELI 00071) Evaluator: AD-II (424-P)	<u>Legal Manufacturer:</u> M/s Cavex Holland BV , Fustweg 5, 2031CJ Haarlem, the Netherlands. FSC: Netherlands Valid till: 04.08.2022	Cavex Silicon A (Dental impression material) Codes & Sizes: As per FSC Class-A Shelf Life: 3 years	Deferred for provision of following documnts: • Original Free Sale Certificate in the country of origin duly attested by Embassy of Pakistan: • Original and valid Full Quality Assurance Certificate or equivalent as applicable duly notarized in the country of origin: • Valid ISO 13485 Certificate.
153.	M/s Universal Dental Pvt. Ltd, 17-Mcleod Road, Lahore (ELI 00071) Evaluator: AD-II (425-P)	<u>Legal Manufacturer:</u> M/s Cavex Holland BV , Fustweg 5, 2031CJ Haarlem, the Netherlands. FSC: Netherlands Valid till: 04.08.2022	Cavex Outline (Dental Impression materials- zinc oxide (non) eugenol) Codes & Sizes: As per FSC Class-A Shelf Life: 3 years	Deferred for provision of following documnts: • Valid Free Sale Certificate: • Valid Full Quality Assurance Certificate or equivalent as applicable: • Valid ISO 13485 Certificate.
154.	M/s Universal Dental Pvt. Ltd, 17-Mcleod Road, Lahore (ELI 00071) Evaluator: AD-II (426-P)	<u>Legal Manufacturer:</u> M/s Cavex Holland BV , Fustweg 5, 2031CJ Haarlem, the Netherlands. FSC: Netherlands Valid till: 04.08.2022	Cavex Set Up Wax (Dental modeling wax) Class-A Shelf Life: 5 years	Deferred for provision of following documnts: • Valid Free Sale Certificate: • Valid Full Quality Assurance Certificate or equivalent as applicable: • Valid ISO 13485 Certificate.

155.	M/s Universal Dental Pvt. Ltd, 17-Mcleod Road, Lahore (ELI 00071) Evaluator: AD-II (505-P)	<u>Legal Manufacturer:</u> M/s Ivoclar Vivadent AG, Benderstrasse 2 FL-9494 Schan Liechtenstein, Germany FSC: Liechtenstein, Germany Valid: 12.10.2021	OPTRA (Dental rubber dam and material applicator) Codes & Sizes: As per FSC Class-A Shelf Life: Optra Dam 36 months Optra Gate 42 months Optra Stick 21 months	Deferred for provision of following documnts: <ul style="list-style-type: none"> • Valid Free Sale Certificate: • Valid Full Quality Assurance Certificate or equivalent as applicable: • Valid ISO 13485 Certificate.
156.	M/s Universal Dental Pvt. Ltd, 17-Mcleod Road, Lahore (ELI 00071) Evaluator: AD-II (506-P)	<u>Legal Manufacturer:</u> M/s Septodont 58 rue du Pont de Creteil 94107 saint-Maur-des-Fossess Cedex, France. FSC: France Date of issue: 30.04.2020	Detartine (Dental paste for scaling and polishing) Codes & Sizes: As per FSC Class-A Shelf Life: 36 months	Deferred for provision of following documnts: <ul style="list-style-type: none"> • Valid Free Sale Certificate: • Valid Full Quality Assurance Certificate or equivalent as applicable: • Valid ISO 13485 Certificate. • Original Declaration of Conformity to be printed on company letterhead, duly signed and stamped.
157.	M/s Johnson & Johnson Pakistan (Pvt) Ltd., Office No.806, 8th Floor, Horizon Tower, Block 3, Scheme 5, Clifton, Karachi (ELI-00154) Evaluator: AD-II (369-P)	<u>Legal Manufacturer:</u> M/s Ethicon Endo-Surgery, LLC 475 Calle C Guaynabo, Puerto Rico, USA 00969 <u>Manufacturing Site:</u> M/s Linemaster Switch Corporation 29 Plaine Hill Road Woodstock, CT 06281 USA	Generator G11Footswitch (Generator Footswitch) Class A  Shelf Life: N/A	Deferred for provision of following documnts: <ul style="list-style-type: none"> • Valid ISO 13485 Certificate: • Original and notarized Letter of Authorization: • Original and valid Free Sale Certificate in the country of origin duly attested by Embassy of Pakistan: • Original and valid Full Quality Assurance System Certificate or equivalent: • Notarized copy of the credentials of manufacturer: • Declaration of Conformity, on company letterhead.


158.	<p>M/s Johnson & Johnson Pakistan (Pvt) Ltd., Office No.806, 8th Floor, Horizon Tower, Block 3, Scheme 5, Clifton, Karachi</p> <p>(ELI-00154)</p> <p>Evaluator: AD-II (2972-P)</p>	<p>Legal Manufacturer: M/s DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, Indiana, 46582, USA</p> <p>Manufacturing Sites: M/s DePuy Orthopaedics Inc. 325 Paramount Drive Raynham, MA 02767 USA.</p> <p>M/s DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, IN 46582 USA.</p> <p>M/s Johnson & Johnson Medical (Depuy-Suzhou) Ltd., No. 299, Changyang street, Suzhou Industrial park, SUZHOU, Jiangsu, China 215126</p> <p>FSC: USA</p> <p>Valid till:04.04.2021</p>	<p>Knee Stems</p> <p>Class: C</p> <p>Shelf life: 10 Years</p> <p>Codes: As per FSC</p>	<p>Deferred for provision of following documnts:</p> <ul style="list-style-type: none"> Valid ISO 13485 Certificate: Original and notarized Letter of Authorization: Original and valid Free Sale Certificate in the country of origin duly attested by Embassy of Pakistan: Original and valid Full Quality Assurance System Certificate or equivalent.
159.	<p>M/s Johnson & Johnson Pakistan (Pvt) Ltd., Office No.806, 8th Floor, Horizon Tower, Block 3, Scheme 5, Clifton, Karachi</p> <p>(ELI-00154)</p> <p>Evaluator: AD-II (2977-P)</p>	<p>Legal Manufacturer: M/s DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, Indiana, 46582, USA</p> <p>Manufacturing Sites: M/s DePuy Orthopaedics Inc. 325 Paramount Drive Raynham, MA 02767 USA.</p> <p>M/s DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, IN 46582 USA.</p>	<p>Knee Accessories</p> <p>Class: C</p> <p>Shelf life: 10 Years</p> <p>Codes: As per FSC</p>	<p>Deferred for provision of following documnts:</p> <ul style="list-style-type: none"> Valid ISO 13485 Certificate: Original and notarized Letter of Authorization: Original and valid Free Sale Certificate in the country of origin duly attested by Embassy of Pakistan: Original and valid Full Quality Assurance System Certificate or equivalent.
160.	<p>M/s Aglow Healthcare Pvt. Ltd Jinnah Street. DC. Road Gujranwala</p> <p>ELI:00876</p> <p>Evaluator AD-II (659-P)</p>	<p>Legal Manufacturer: M/s Jolea SDN. BHD (202001033369) (1389717-M) 42A-a, Pusat Komersil Equine, Jalan Equine IG, 43300 Seri Kembangan Selangor, Malayisa.</p> <p>FSC: Malaysia</p> <p>Valid till: 29/05/2022</p>	<p>Jolea Examination Gloves</p> <p>(Non Sterile Latex Powder Free Examination)</p> <p>Class-A</p> <p>Shelf Life: 5 years</p> <p>Codes & Sizes: As per FSC</p>	<p>Deferred for provision of following documents:</p> <ul style="list-style-type: none"> Original and valid Free Sale Certificate in the country of origin duly attested by Embassy of Pakistan: Full Quality Assurance System Certificate or equivalent, duly notarized in the country of origin: Product is from non reference country and firm has not provided any evidence of availability in any reference country.

161.	A.Feroz & Co., Medicine Street No. 1, Marriot Road Karachi (ELI-00066) 521	Molnlycke Healthcare AB. Box 13080 Gamlestadsvagen 3C SE-402 52 Goteborg, Sweden FSC Sweden copy expired	Mefix Non-Sterile Self-Adhesive Bandage/Fabric Class A Shelf life 03 years not applied	Deferred for provision of : <ul style="list-style-type: none"> Valid original and embassy attested FSC, since the firm has provided copy. Valid, original and notarized letter of Authorization, since only copy is provided Notarized ISO13485 certificate & Full quality assurance certificate Stability studies Embassy attested Original FSC of reference Regulatory Authority
162.	M/s Abbott Laboratories (Pakistan) Ltd. Opp. Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, Karachi (ELI-00019) Evaluator: AD-II -2453-	Legal Manufacturer: M/s Diatron MI Plc. H-1097, Budapest, Tablas u 39, Hungary. FSC Hungary Issuance Date (22-11-2019)	H 380 Hemo Control Low H 380 Hemo Control Medium H 380 Hemo Control High H 380 Hemo Control Kit H Hemo Calibrator Class B Shelf Life: H 380 Hemo Control (Low, Medium, High) 105 Days H Hemo Calibrator: 45 Days Codes & Sizes as per FSC	Deferred for provision of FSC of any reference country or CE mark documents.
163.	M/s Chemical House, 6-C Sikander Malhi Road, Canal Park, Gulberg II, Lahore Pakistan. ELI: 00156 Evaluator: AD-II (2961-P)	Legal Manufacturer: M/s Bio-Rad Laboratories, Inc. 9500 Jeronimo Road Irvine, CA 92618, USA Original FSC: U.S.A Valid till: 20/08/2022	Amplichek I (HIV-1/ Hepatitis C Virus/Hepatitis B Virus Nucleic Acid IVD Control) Codes and sizes: 12000527 (10 x 1.2ml), 12000528 (10 x 1.2ml), 12000529 (10 x 1.2ml), 12000530 (10 x 1.2ml), 12000531 (4 x 1.2ml) Class-C Shelf Life: 16 months	Deferred for provision of following documents; <ul style="list-style-type: none"> Original and valid letter of authorization (LOA), duly notarized in the country of origin: Valid ISO 13485 Certificate: Valid Full Quality Assurance System certificate or equivalent.

164.	M/s Excel Corporation 435 BYJ Society, Bahadurabad, Karachi.	Ultra For Medical Product (Ultra Med) Co (U.M.I.C)S.A.E. Part no (304;310) & part no (312)- industrial area arab el awamer – abanob-assiut Land Plot # 25 & 27 1 st industrial zone, Badr City, 11829 Cairo Governorate, Egypt	Flo-Cath IV Cannula CLASS: B Shelf life 5 years	Deffred for clarification of brand name and provision of Reference Regulatory Authority if any
165.	MHK ENTERPRISES, JALAL HEIGHTS, FLAT NO.201, PLOT NO.4 ST, AL-HILAL, CO-OPERATIVE HOUSING SOCIETY, KARACHI. 1039	ZYBIO INC. FLOOR 1 TO FLOOR 5,BUILDING 30, NO 6, OF TAIKANG ROAD BLOCK C OF JIANQIAO INDUSTRIAL PARK, DADUKOU DISTRICT,400082 CHONGQING, China	Probe Cleanser Cleanser for Hematology Analyzer Cass A Shelf life 13 months	Deferred for provision of valid original embassy attested FSC in the country of origin and any reference country as given under rule 67 of the MDR 2017. Provide CE marking certificate including FQA
166.	M/s Ali Gohar & Company (Pvt) Ltd., State life building 1-B, I.I Chundrigar Road, Karachi (ELI-00004) AD-VIII	M/s Smith Medical , 10 Bowman Drive, Keene New Hampshire 03431, USA FSC copy of MEHRA Issued in march 2017	Smith Line Draw, Dry Lithium –Pro Vent Class B Shelf life: 03 Years Codes & Sizes as per FSC	Deferred for provision of Brand name need clarification and Form 7A need to be revised for company name as well. Clarification required for weather the product is kit or otherwise. Stability study need clarification. Therefore, provide valid embassy attested FSC in the country of origin and reference country. Also provide notarized FQA and ISO 13485. The submitted are copies and expired Provide Notarized and Valid DOC
167.	M/s Zenith International, Room No 104, Tahir Plaza, A/20, Block 7 & 8, KCHSU, Karachi. (ELI-00090) 4853	M/s Bonree Medical Co., Ltd., 1 st Floor of No.2, No.4 Longzhu Garden, Nanlang Industrial Estate, Nanlang, Zhongshan Guangdong, China. Exported by: M/s Qingdao Uni-Blessings Medical Technology Co., Ltd., No.7 Siliuzhong Road, Licang District, Qingdao China	K&K Precision Disposable Endotracheal Tube, Sterile without Cuff Class B Shelf life: 05 years Codes & Sizes as per FSC	Deferred for clarification of brand name not found on FSC clarify or apply as per brand name given in the free sale certificate. The firm has provided valid notarized ISO 13485 certificate, now expired. So provide valid ISO 13485 certificate The product is from non reference country the firm has provided notarized EC certificate. Provide FQA certificate.

				<p>Clarify the relation of the M/s Qingdao Uni-Blessings Medical Technology Co., Ltd., No.7 Siliuzhong Road, Licang District, Qingdao China with the manufacturer, why not exporting by themselves.</p> <p>Provide FSC of RRA as per rule 67 o the MDR 2017. Provide stability study</p> <p>Clarify the issuing agency of the FSC</p>
168.	<p>M/s Zenith International, Room No 104, Tahir Plaza, A/20, Block 7 & 8, KCHSU, Karachi. (ELI-00090)</p> <p>4855</p>	<p>M/s Bonree Medical Co., Ltd., 1st Floor of No.2, No.4 Longzhu Garden, Nanlang Industrial Estate, Nanlang, Zhongshan Guangdong, China.</p> <p>Exported by: M/s Qingdao Uni-Blessings Medical Technology Co., Ltd., No.7 Siliuzhong Road, Licang District, Qingdao China</p>	<p>Precision Disposable Nasal Oxygen Cannula Sterile</p> <p>Class B</p> <p>Shelf life: 05 years</p> <p>Codes & Sizes as per FSC</p>	<p>Deferred for clarification and provision of the following</p> <p>The applied brand name not found on FSC clarify or apply as per brand name given in the free sale certificate</p> <p>The firm has provided valid notarized ISO 13485 certificate, now expired. So provide valid ISO 13485 certificate</p> <p>The product is from non reference country the firm has provided notarized EC certificate.</p> <p>Provide FQA certificate.</p> <p>Clarify the relation of the M/s Qingdao Uni-Blessings Medical Technology Co., Ltd., No.7 Siliuzhong Road, Licang District, Qingdao China with the manufacturer, why not exporting by themselves.</p> <p>Provide FSC of RRA as per rule 67 o the MDR 2017. Provide stability study</p> <p>Clarify the issuing agency of the FSC</p>
169.	<p>M/s Zenith International, Room No 104, Tahir Plaza, A/20, Block 7 & 8, KCHSU, Karachi. (ELI-00090)</p>	<p>M/s Bonree Medical Co., Ltd., 1st Floor of No.2, No.4 Longzhu Garden, Nanlang Industrial Estate, Nanlang, Zhongshan Guangdong, China.</p> <p>Exported by:</p>	<p>K&K Precision Disposable Endotracheal Tube, Sterile with Cuff</p> <p>Class B</p>	<p>Deferred for clarification and provision of the following:</p> <p>The applied brand name not found on FSC clarify or apply as per brand name given in the free sale certificate</p>

	4856	M/s Qingdao Uni-Blessings Medical Technology Co., Ltd., No.7 Siliuzhong Road, Licang District, Qingdao China	Shelf life: 05 years Codes & Sizes as per FSC	<p>The firm has provided valid notarized ISO 13485 certificate, now expired. So provide valid ISO 13485 certificate</p> <p>The product is from non reference country the firm has provided notarized EC certificate.</p> <p>Provide FQA certificate.</p> <p>Clarify the relation of the M/s Qingdao Uni-Blessings Medical Technology Co., Ltd., No.7 Siliuzhong Road, Licang District, Qingdao China with the manufacturer, why not exporting by themselves.</p> <p>Provide FSC of RRA as as per rule 67 o the MDR 2017. Provide stability study</p> <p>Clarify the issuing agency of the FSC</p>
170.	<p>M/s Zenith International, Room No 104, Tahir Plaza, A/20, Block 7 & 8, KCHSU, Karachi. (ELI-00090)</p> <p>4854</p>	<p>M/s Bonree Medical Co., Ltd., 1st Floor of No.2, No.4 Longzhu Garden, Nanlang Industrial Estate, Nanlang, Zhongshan Guangdong, China.</p> <p>Exported by: M/s Qingdao Uni-Blessings Medical Technology Co., Ltd., No.7 Siliuzhong Road, Licang District, Qingdao China</p>	<p>Precision Disposable Oxygen Mask, Sterile</p> <p>Class B</p> <p>Shelf life: 05 years</p> <p>Codes & Sizes as per FSC</p>	<p>Deferred for clarification and provision of the following:</p> <p>The applied brand name not found on FSC clarify or apply as per brand name given in the free sale certificate</p> <p>The firm has provided valid notarized ISO 13485 certificate, now expired. So provide valid ISO 13485 certificate</p> <p>The product is from non reference country the firm has provided notarized EC certificate.</p> <p>Provide FQA certificate.</p> <p>Clarify the relation of the M/s Qingdao Uni-Blessings Medical Technology Co., Ltd., No.7 Siliuzhong Road, Licang District, Qingdao China with the manufacturer, why not exporting by themselves.</p>

				<p>Provide FSC of RRA as per rule 67 of the MDR 2017.</p> <p>Clarify the issuing agency of the FSC</p>
171.	<p>M/s Zenith International, Room No 104, Tahir Plaza, A/20, Block 7 & 8, KCHSU, Karachi. (ELI-00090)</p> <p>4857</p>	<p>M/s Bonree Medical Co., Ltd., 1st Floor of No.2, No.4 Longzhu Garden, Nanlang Industrial Estate, Nanlang, Zhongshan Guangdong, China.</p> <p>Exported by: M/s Qingdao Uni-Blessings Medical Technology Co., Ltd., No.7 Siliuzhong Road, Licang District, Qingdao China</p> <p>FSC China valid till 9.05.2023</p>	<p>Precision Disposable Nebulizer Mask, Sterile</p> <p>Class B</p> <p>Shelf life: 05 years</p> <p>Codes & Sizes as per FSC</p>	<p>Deferred for clarification and provision of the following:</p> <p>The applied brand name not found on FSC clarify or apply as per brand name given in the free sale certificate</p> <p>The firm has provided valid notarized ISO 13485 certificate, now expired. So provide valid ISO 13485 certificate</p> <p>The product is from non reference country the firm has provided notarized EC certificate.</p> <p>Provide FQA certificate.</p> <p>Clarify the relation of the M/s Qingdao Uni-Blessings Medical Technology Co., Ltd., No.7 Siliuzhong Road, Licang District, Qingdao China with the manufacturer, why not exporting by themselves.</p> <p>Provide FSC of RRA as per rule 67 of the MDR 2017.</p> <p>Provide stability study.</p> <p>Clarify the issuing agency of the FSC</p>
172.	<p>M/s Pakistan Marketing Services , westridge 3 Rawalpindi.</p>	<p>M/s Viva check Biotech (Hangzhou) Co,Ltd , level 2 block 2 146 east chaofeng Rd yuhang Econonmy development Zone Hangzhou zhejiang province , china</p>	<p>Vivacheck Ino Blood Glucose Meter</p> <p>Class C . </p>	<p>Deferred for clarification and provision of the following:</p> <p>The brand name on the FORM 7A need to be clarified and applied as per FSC provided. And justify family /set as per MDR 2017.</p> <p>The firm submitted Original and valid and embassy attested FSC of China and US FDA. However, both are expired therefore</p>

				<p>provide Original and valid FSC of china and US FDA of all the applied products.</p> <p>The notarized and original is expired now therefore provide notarized original LOA from the principle manufacturer</p> <p>The notarized ISO 13485 certificate is expired therefore provide valid ISO 13485 certificate.</p> <p>Provide FQA .</p> <p>Provide Stability studies and DOC of all the medical Devices.</p>
173.	<p>M/s New Pakistan Traders, Office No. 306/I, Trade Tower, Altaf Hussain Road, New Challi, Karachi.</p> <p>(ELI-00161)</p> <p>Evaluator: AD – II</p> <p>(4931-P)</p>	<p>Legal Manufacturer:</p> <p>M/s Shanghai Kinmed Import & Export Co. Ltd, Suit L, 12th Floor, No.588 Yingkou Road, Shanghai, China</p> <p>FSC China</p> <p>Date Of Issuance 06-12-2021</p>	<p>KBM Disposable Infusion Set</p> <p>Class B</p> <p>Shelf life: 05 Years</p> <p>Codes & Sizes as per FSC</p>	<p>Deffered for provision of following documents:</p> <ul style="list-style-type: none"> • Original and valid Letter of Authorization, duly notarized in the country of origin; • Valid ISO 13485 Certificate, duly notarized in the country of origin; • Valid Full Quality Assurance certificate or equivalent, duly notarized in the country of origin; • Original and valid Free Sale Certificate, issued by the concerned regulatory authority in the country of origin, countersigned by Pakistan Embassy; • Evidence of availability of the applied product in any reference country.
174.	<p>M/s New Pakistan Traders, Office No. 306/I, Trade Tower, Altaf Hussain Road, New Challi, Karachi.</p> <p>(ELI-00161)</p> <p>Evaluator: AD – II</p> <p>(4932-P)</p>	<p>Legal Manufacturer:</p> <p>M/s Shanghai Kinmed Import & Export Co. Ltd, Suit L, 12th Floor, No.588 Yingkou Road, Shanghai, China</p> <p>FSC China</p> <p>Date of issuance 06-12-2021</p>	<p>KBM Scalp Vein Set</p> <p>Class B</p> <p>Shelf life: 05 Years</p> <p>Codes & Sizes as per FSC</p>	<p>Deffered for provision of following documents:</p> <ul style="list-style-type: none"> • Original and valid Letter of Authorization, duly notarized in the country of origin; • Valid ISO 13485 Certificate, duly notarized in the country of origin; • Valid Full Quality Assurance certificate or equivalent, duly notarized in the country of origin;


				<ul style="list-style-type: none"> • Original and valid Free Sale Certificate, issued by the concerned regulatory authority in the country of origin, countersigned by Pakistan Embassy; • Evidence of availability of the applied product in any reference country.
175.	<p>M/s New Pakistan Traders, Office No. 306/I, Trade Tower, Altaf Hussain Road, New Challi, Karachi.</p> <p>(ELI-00161)</p> <p>Evaluator: AD – II</p> <p>(4933-P)</p>	<p>Legal Manufacturer: M/s Shanghai Kinmed Import & Export Co. Ltd, Suit L, 12th Floor, No.588 Yingkou Road, Shanghai, China</p> <p>FSC China</p> <p>Date of Issuance 06-12-2021</p>	<p>KBM Disposable IV Cannula</p> <p>Class B</p> <p>Shelf life: 05 Years</p> <p>Codes & Sizes as per FSC</p>	<p>Deferred for provision of following documents:</p> <ul style="list-style-type: none"> • Original and valid Letter of Authorization, duly notarized in the country of origin; • Valid ISO 13485 Certificate, duly notarized in the country of origin; • Valid Full Quality Assurance certificate or equivalent, duly notarized in the country of origin; • Original and valid Free Sale Certificate, issued by the concerned regulatory authority in the country of origin, countersigned by Pakistan Embassy; • Evidence of availability of the applied product in any reference country.
176.	<p>M/s New Pakistan Traders, Office No. 306/I, Trade Tower, Altaf Hussain Road, New Challi, Karachi.</p> <p>(ELI-00161)</p> <p>Evaluator: AD – II</p> <p>(4934-P)</p>	<p>Legal Manufacturer: M/s Shanghai Kinmed Import & Export Co. Ltd, Suit L, 12th Floor, No.588 Yingkou Road, Shanghai, China</p> <p>FSC China</p> <p>Date of Issuance 06-12-2021</p>	<p>KBM Disposable Sterile Syringe</p> <p>Class B</p> <p>Shelf life: 05 Years</p> <p>1ml, 10ml, 20ml, 30ml, 50ml, 60ml</p> <p>Codes & Sizes as per FSC</p>	<p>Deferred for provision of following documents:</p> <ul style="list-style-type: none"> • Original and valid Letter of Authorization, duly notarized in the country of origin; • Valid ISO 13485 Certificate, duly notarized in the country of origin; • Valid Full Quality Assurance certificate or equivalent, duly notarized in the country of origin; • Original and valid Free Sale Certificate, issued by the concerned regulatory authority in the country of origin, countersigned by Pakistan Embassy;

				<ul style="list-style-type: none"> Evidence of availability of the applied product in any reference country.
177.	M/s Ferozsos Laboratories Limited, P.O Ferozsos, Amangarh, Nowshera (KPK) ELI: 00120 Evaluator: AD-II (3549-P)	Legal Manufacturer: M/s Apollo Endosurgery, Inc., 1120 South Capital of Texas Highway, Building 1, Suite 300, Austin, Texas 78746 USA FSC: Costa Rica Valid till: Not mentioned	ORBERA365 Intragastric Balloon System Codes & Sizes: As per FSC Class-C Shelf Life: Not provided	Deferred for rectification of following discrepancies in the submitted application; <ul style="list-style-type: none"> Credential of the manufacturer abroad, duly notarized in the country of origin, are not provided; Stability studies data is not provided; Proposed MRP is not provided; Storage conditions are not mentioned; LOA is not notarized from the country of origin; FSC is a photocopy which is of Costa Rican origin and not in English language, hence not readable; ISO 13485 certificate is photocopy; Full Quality Assurance System Certificate was expired at the time of submission of application; Undertaking on notarized stamp paper is not provided.
178.	M/s Ferozsos Laboratories Limited, P.O Ferozsos, Amangarh, Nowshera (KPK) ELI: 00120 Evaluator: AD-II (3551-P)	Legal Manufacturer: M/s Apollo Endosurgery, Inc., 1120 South Capital of Texas Highway, Building 1, Suite 300, Austin, Texas 78746 USA. FSC: USA Valid till: 25.05.2023	OverTube Endoscopic Access System Codes & Sizes: As per FSC Class-B Shelf Life: As per stability study.	Deferred for rectification of following discrepancies in the submitted application; <ul style="list-style-type: none"> Credential of the manufacturer abroad, duly notarized in the country of origin, are not provided; Stability studies data is not provided; Proposed MRP is not provided; Storage conditions are not mentioned; LOA is not notarized from the country of origin; FSC is a photocopy; ISO 13485 certificate is photocopy; Full Quality Assurance System Certificate was expired at the time of submission of

				application; • Undertaking on notarized stamp paper is not provided.
179.	M/s Ferozsons Laboratories Limited, P.O Ferozsons, Amangarh, Nowshera (KPK) ELI: 00120 Evaluator: AD – II (3551-P)	Legal Manufacturer: M/s Apollo Endosurgery, Inc., 1120 South Capital of Texas Highway, Building 1, Suite 300, Austin, Texas 78746 USA. FSC: Costa Rica Valid till: Not mentioned	BioEnterics Intragastric Balloon (BIB) System Codes & Sizes: As per FSC Class-C Shelf Life: As per stability study.	Deferred for rectification of following discrepancies in the submitted application; • Credential of the manufacturer abroad, duly notarized in the country of origin, are not provided; • Stability studies data is not provided; • Proposed MRP is not provided; • Storage conditions are not mentioned; • LOA is not notarized from the country of origin; • FSC is a photocopy which is of Costa Rican origin and not in English language, hence not readable; • ISO 13485 certificate is photocopy; • Full Quality Assurance System Certificate was expired at the time of submission of application; • Undertaking on notarized stamp paper is not provided.
180.	M/s Ferozsons Laboratories Limited, P.O Ferozsons, Amangarh, Nowshera (KPK) ELI: 00120 Evaluator: AD – II (3546-P)	Legal Manufacturer: M/s Apollo Endosurgery, Inc., 1120 South Capital of Texas Highway, Building 1, Suite 300, Austin, Texas 78746 USA. FSC: USA Valid till: 25.05.2023	XTACK Endoscopic HeliX Tacking System Codes & Sizes: As per FSC Class-C Shelf Life: 3 years	Deferred for rectification of following discrepancies in the submitted application; • Credential of the manufacturer abroad, duly notarized in the country of origin, are not provided; • Stability studies data is not provided; • Proposed MRP is not provided; • Storage conditions are not mentioned; • LOA is not notarized from the country of origin; • FSC is a photocopy; • ISO 13485 certificate is photocopy; • Full Quality Assurance System Certificate was expired at the

				time of submission of application; • Undertaking on notarized stamp paper is not provided.
181.	M/s Ferozsans Laboratories Limited, P.O Ferozsans, Amangarh, Nowshera (KPK) ELI: 00120 Evaluator: AD – II (3548-P)	Legal Manufacturer: M/s Apollo Endosurgery, Inc., 1120 South Capital of Texas Highway, Building 1, Suite 300, Austin, Texas 78746 USA. FSC: USA Valid till: 25.05.2023	OverStitch & OverStitch Sx Endoscopic Suturing System Codes & Sizes: As per FSC Class-C Shelf Life: 03 years	Deferred for rectification of following discrepancies in the submitted application; • Credential of the manufacturer abroad, duly notarized in the country of origin, are not provided; • Stability studies data is not provided; • Proposed MRP is not provided; • Storage conditions are not mentioned; • LOA is not notarized from the country of origin; • FSC is a photocopy; • ISO 13485 certificate is photocopy; • Full Quality Assurance System Certificate was expired at the time of submission of application; • Undertaking on notarized stamp paper is not provided.
182.	M/s Ferozsans Laboratories Limited, P.O Ferozsans, Amangarh, Nowshera (KPK) ELI: 00120 Evaluator: AD – II (3550-P)	Legal Manufacturer: M/s Prince Medical ZA, La Sente du Moulin, 60530 Ercuis-France FSC: France Date of Issue: 20/12/2021	Drainage Needle/ Needle Aspirator & Extraction Forceps/Wire Grasper Codes & Sizes: As per FSC Class-B Shelf Life: As per stability study.	Deferred for rectification of following discrepancies in the submitted application; • Credential of the manufacturer abroad, duly notarized in the country of origin, are not provided; • Stability studies data is not provided; • Proposed MRP is not provided; • Storage conditions are not mentioned; • LOA is photocopy and the address of the importer mentioned on LOA is different than the licensed address; • FSC is a photocopy; • ISO 13485 certificate is photocopy; • Full Quality Assurance System Certificate is not provided; • Production Quality Assurance

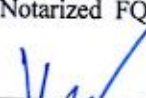
				System Certificate is photocopy; • Undertaking on notarized stamp paper is not provided.
183.	M/s Medtronic Pakistan (Pvt) Ltd. Ocean Tower, 21st Floor, Plot # G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi.	Legal Manufacturer: Medtronic Inc 710 Medtronic Pkwy Minneapolis MN USA 55432 Manufacturing Site: Medtronic Singapore Operations Pte Ltd 49 Changi South Avenue 2, Nasaco Tech Centre Singapore 486056 Free sale certificate: Free sale certificate Singapore Date of issuance: 17 May 2021	Attest S DR MRI SureScan (ATDRS1) Shelf Life: 3 years Class: D	Deferred for valid original & embassy attested FSC of RRA or WHO PQ or CE certification as per MDR, 2017
184.	M/s. Ocusurg Co. Pharma and Surgical Shareef Chamber, 68-Mozang Road, Lahore. ELI-00682 419-C	Legal Manufacturer: M/s. Cristalens Industrie, 4 Rue Louis De Broglie 22300 Lannion France. FSC France issuance 28-05-2021	CLARE Monofocal Hydrophilic Intraocular lenses Class-C Shelf life: 3 years Reference: Clare	Deferred for provision of following: • Provide credentials of manufacturer abroad, duly notarized. • Provide stability studies in details for the claimed shelf life. • Submitted LOA is missing the name of importer, submit agency agreement for Pakistan, duly notarized with clearly mentioning the validity of agreement. • Notarized ISO 13485, Full and Product quality assurance certificates. • Provide Essential Principle checklist • Provide Declaration of Conformity to be printed on manufacturer's letter head duly signed and stamped by responsible person, mentioning the name, classification, models/codes and certifications of the manufacturer.
185.	M/s. Ocusurg Co. Pharma and Surgical	Legal Manufacturer: M/s. Cristalens Industrie, 4 Rue Louis De Broglie 22300 Lannion France.	CRISTAL Monofocal Hydrophilic Intraocular lenses	Deferred for provision of following: • Provide credentials of

	Shareef Chamber, 68-Mozang Road, Lahore. ELI-00682 473-C	FSC France issuance 28-05-2021	Class-C Shelf life: 3 years Reference: Cristal	<p>manufacturer abroad, duly notarized.</p> <ul style="list-style-type: none"> • Provide stability studies in details for the claimed shelf life. • Submitted LOA is missing the name of importer, submit agency agreement for Pakistan, duly notarized with clearly mentioning the validity of agreement. • Notarized ISO 13485, Full and Product quality assurance certificates. • Provide Essential Principle checklist • Provide Declaration of Conformity to be printed on manufacturer's letter head duly signed and stamped by responsible person, mentioning the name, classification, models/codes and certifications of the manufacturer.
186.	M/s. Ocusurg Co. Pharma and Surgical Shareef Chamber, 68-Mozang Road, Lahore. ELI-00682 419-C (part)	<p>Legal Manufacturer: M/s. Cristalens Industrie, 4 Rue Louis De Broglie 22300 Lannion France.</p> <p>FSC France issuance 28-05-2021</p>	<p>EAZ-Y, Monofocal Intraocular lenses (Sterile Preloaded hydrophobic IOL)</p> <p>Class-C </p> <p>Shelf life: 3 years</p> <p>Reference: EAZ-Y</p>	<p>Deferred for provision of following:</p> <ul style="list-style-type: none"> • Provide credentials of manufacturer abroad, duly notarized. • Provide stability studies in details for the claimed shelf life. • Submitted LOA is missing the name of importer, submit agency agreement for Pakistan, duly notarized with clearly mentioning the validity of agreement. • Notarized ISO 13485, Full and Product quality assurance certificates. • Provide Essential Principle checklist • Provide Declaration of Conformity to be printed on manufacturer's letter head duly signed and stamped by responsible person, mentioning the name, classification, models/codes and certifications of the manufacturer.

187.	M/s. Ocusurg Co. and Pharma Surgical Shareef Chamber, 68-Mozang Road, Lahore. ELI-00682 419-C (part)	Legal Manufacturer: M/s. Cristalens Industrie, 4 Rue Louis De Broglie 22300 Lannion France. FSC France issuance 28-05-2021	ARTIS Toric, Monofocal Intraocular lenses (Sterile Preloaded hydrophobic IOL) Class-C Shelf life: 3 years Reference: ARTIS T PL E	Deferred for provision of following: <ul style="list-style-type: none"> • Provide credentials of manufacturer abroad, duly notarized. • Provide stability studies in details for the claimed shelf life. • Submitted LOA is missing the name of importer, submit agency agreement for Pakistan, duly notarized with clearly mentioning the validity of agreement. • Notarized ISO 13485, Full and Product quality assurance certificates. • Provide Essential Principle checklist • Provide Declaration of Conformity to be printed on manufacturer's letter head duly signed and stamped by responsible person, mentioning the name, classification, models/codes and certifications of the manufacturer.
188.	M/s. Ocusurg Co. and Pharma Surgical Shareef Chamber, 68-Mozang Road, Lahore. ELI-00682 419-C (part)	Legal Manufacturer: M/s. Cristalens Industrie, 4 Rue Louis De Broglie 22300 Lannion France. FSC France issuance 28-05-2021	ARTIS PL, Monofocal Intraocular lenses (Sterile Preloaded hydrophobic IOL) Class-C Shelf life: 3 years Reference: ARTIS PL E	Deferred for provision of following: <ul style="list-style-type: none"> • Provide credentials of manufacturer abroad, duly notarized. • Provide stability studies in details for the claimed shelf life. • Submitted LOA is missing the name of importer, submit agency agreement for Pakistan, duly notarized with clearly mentioning the validity of agreement. • Notarized ISO 13485, Full and Product quality assurance certificates. • Provide Essential Principle checklist • Provide Declaration of Conformity to be printed on manufacturer's letter head duly signed and stamped by responsible person, mentioning the name, classification, models/codes and certifications of the manufacturer.

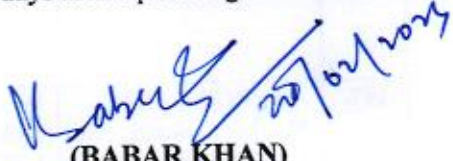
189.	Rech International, M-10, Block-6, PECHS, Near Hotel Faran, Off Shahrah-e-Faisal, Karachi. (ELI-00257) [2735]	Legal Manufacturer: M/s SERF, 85 Avenue des Bruyeres 69150 Decines Charpieu, France. FSC France Issuance Date (27-08-2018)	Sunfit TH Dual Mobility Cups Class-D Shelf life: 5 years Codes as per FSC.	Deferred for provision of following: <ul style="list-style-type: none">• Copy of FSC provided, provide valid and embassy attested original FSC in the country of origin.• Provide claimed shelf life/ service life validation protocols /studies.• ISO 13485, FQA and design Examination certificates are expired but valid upon submission.• Valid and notarized Authorization letter, the firm has provided photocopy which is expired.• Provide Manufacturing method.• Undertaking on stamp paper.• Apply separately for other Brands.
190.	3M Pakistan (Pvt) Ltd., Islamic Chamber of Commerce of Commerce Building, Street No.2/A, Block 9, KDA Scheme 5, Clifton, Karachi. (ELI-00259) 4655	Legal Manufacturer: 3M Company, 2510 Conway Ave St. Paul MN 55144, USA Manufacturing site: 3M Brookings Plant 601 22nd Avenue South Brookings, South Dakota 57006 FDA Establishment Reg. No. 1717046	3M Tegaderm + Pad Film dressing with Non-Adherent Pad Class-B Shelf life: 3 years Codes: 3582, 3584, 3586, 3587, 3588, 3589, 3590, 3591, 3593	Deferred for provision of following: <ul style="list-style-type: none">• Valid Free Sale Certificate• Valid ISO 13485.• Original Letter of Authorization
191.	M/s. Musaji Adam & Sons, C-285, Block 10, Federal B Area Karachi Eli 00239 286-C	Legal manufacturer: M/s. Oxoid limited Wade Road, Basingstoke, Hampshire, RG24 8PW, United Kingdom. FSC MHRA valid till 04-05-2027	Antimicrobial Susceptibility Testing Class-B Shelf life: Codes as per FSC	Deferred for provision of following: <ul style="list-style-type: none">• Submit properly filled Form-7A with all the information, brand name, generic name including analytes, codes required and detail of components included with their shelf life.• Valid LOA.• Labels of applied codes.• FQA certificate.• Linkup letter between Oxoid limited and Thermo fischer, UK.

192.	M/s. Musaji Adam & Sons, C-285, Block 10, Federal B Area Karachi Eli 00239 287-C	Legal manufacturer: M/s. Oxoid limited Wade Road, Basingstoke, Hampshire, RG24 8PW, United Kingdom. FSC MHRA valid till 04-05-2027	Dehydrated Culture Media and Supplements Class-B Shelf life: Codes as per FSC	Deferred for provision of following: <ul style="list-style-type: none"> • Submit properly filled Form-7A with all the information, brand name, generic name including analytes, codes required and detail of components included with their shelf life. • Valid LOA. • Labels of applied codes. • FQA certificate.
193.	M/s Musaji Adam & Sons, C-285, Block 10, Federal B Area Karachi Eli 00239 288-C	Legal manufacturer: M/s. Oxoid limited Wade Road, Basingstoke, Hampshire, RG24 8PW, United Kingdom. FSC MHRA valid till 04-05-2027	Oxoid Signal Blood Culture system Class-B Shelf life: 24 Months Codes as per FSC	Deferred for provision of following: <ul style="list-style-type: none"> • Submit properly filled Form-7A with all the information, brand name, generic name including analytes, codes required and detail of components included with their shelf life. • State difference where it is a blood culture system or atmosphere generation system • Valid LOA. • Labels of applied codes. • FQA certificate.
194.	M/s. Musaji Adam & Sons, C-285, Block 10, Federal B Area Karachi Eli 00239 289-C	Legal manufacturer: M/s. Oxoid limited Wade Road, Basingstoke, Hampshire, RG24 8PW, United Kingdom. FSC MHRA valid till 04-05-2027	Bacterial infection Immunology Class-B Shelf life: Codes as per FSC	Deferred for provision of following: <ul style="list-style-type: none"> • Submit properly filled Form-7A with all the information, brand name, generic name including analytes, codes required and detail of components included with their shelf life. • Valid LOA. • Labels of applied codes. • FQA certificate.
195.	M/s. Musaji Adam & Sons, C-285, Block 10, Federal B Area Karachi Eli 00239 290-C	Legal manufacturer: M/s. Oxoid limited Wade Road, Basingstoke, Hampshire, RG24 8PW, United Kingdom. FSC MHRA valid till 04-05-2027	Biochemical Identification Class-B Shelf life: 24 Months Codes as per FSC	Deferred for provision of following: <ul style="list-style-type: none"> • Submit properly filled Form-7A with all the information, brand name, generic name including analytes, codes required and detail of components included with their shelf life. • Valid LOA. • Labels of applied codes. • FQA certificate.

196.	M/s. Musaji Adam & Sons C-285, Block 10, Federal B Area Karachi Eli 00239 292-C	Legal manufacturer: M/s. Oxoid limited Wade Road, Basingstoke, Hampshire, RG24 8PW, United Kingdom. FSC MHRA valid till 04-05-2027	Serological identification test Class-B Shelf life: 24 Months Codes as per FSC	Deferred for provision of following: <ul style="list-style-type: none"> • Submit properly filled Form-7A with all the information, brand name, generic name including analytes, codes required and detail of components included with their shelf life. • Valid LOA . • Labels of applied codes. • FQA certificate.
197.	A.FEROZ & CO. Medicine Street No. 1, Marriot Road, Karachi	WUXI MEDICAL INSTRUMENT FACTORY CO., LTD. No.43 Xixin Road, Zhangjing, Xibei Town, Wuxi City, Jiangsu, 214194 China	Safety Clinical Thermometer CLASS: A	Deferred for pfovision of following: <ul style="list-style-type: none"> • Original and embassy attested FSC, since the firm has provided copy. • Provide valid, original and notarized letter of Authorizaion, since only copy is provided • Provide notarized ISO13485 certificate & Full quality assurance certificate and Credential. • Provide Embassy attested Original FSC of reference Regulatory Authority
198.	M/s United Healthcare, Plot No. 330/B Second Floor, DMCHS, Bahadurabad, Karachi	WENZHOU BOKANG INSTRUMENTS CO., LTD No.1500 Haining Road Haibin, Longwan 325024 Wenzhou China	Senior Aneroid Sphygmomanometer CLASS: A SHELF LIFE: N/A MODELS: BK2002	Deferred for pfovision of following: <ul style="list-style-type: none"> • Valid and original FSC. • Valid and notarized ISO 13485 and • Notarized FQA
199.	M/S United Healthcare, Plot No. 330/B Second Floor, DMCHS, Bahadurabad, Karachi	WENZHOU BOKANG INSTRUMENTS CO., LTD No.1500 Haining Road Haibin, Longwan 325024 Wenzhou China	Senior Stethoscope CLASS: A SHELF LIFE: N/A MODELS: BK3001, BK3002, BK3003, BK3004, BK3005, BK3006, BK3007, BK3008, BK3009, BK3012, BK3013	Deferred for pfovision of following: <ul style="list-style-type: none"> • Valid and original FSC. • Valid and notarized ISO 13485 and • Notarized FQA 

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 within 20 days after uploading of this letter on official website of DRAP.


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