Implant Kit | 24 Months

No.F.4-5/2022-MD (M-49)
Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
Drug Regulatory Authority of Pakistan
*****

Islamabad the 16th September, 2022.

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

The applications of following applicants were placed before the Medical Device Board (MDB) in its 49th meeting held on 23rd June, 2022 and the same have been deferred 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
(I)	(II)	(III)	(IV)	(V)
1.	M/s Alam Medix, 9/1 Hannan Plaza Mayo Hospital Road, Lahore ELI: 00033 Evaluator AD-VIII 2373	Legal Manufacturer: M/s Metran Co., Ltd 2-12-18 Kawaguchi-shi Saitama, 332-0015 Japan FSC: Japan Date of issue: 01.05.2020	Humming Vue (Piston HFO / IMV Ventilator for Neonatal and Pediatric Patients) Codes & Sizes: As per FSC Class-C Shelf Life: 10 years	**Deferred** for provision of following documents: - i. Submit properly filled application form since many required fields are left blank e.g. grouping, MRP etc. ii. Credentials not attached with application. Provide the credentials of manufacturer abroad duly notarized from the country of origin. iii. Provide stability studies/validation studies/service life studies. iv. Provided photocopy of LOA is expired now. Provide original and valid Letter of Authorization. v. Provided un-attested photocopy of Free Sale Certificate having Date of Issue: May – 1, 2020. Provide Original Embassy attested Free Sale Certificate in the country of origin. vi. FQA not attached with application. Provide valid FQA duly notarized in the country of origin. vii. Description or complete list of the various configurations/ codes of the medical device to be registered. Furthermore, clarify that whether the provided list of configurations/ codes will be the part of import package at the time of import or otherwise these configurations / codes will be imported separately and if separately, under what name? viii. Provide label (as approved in the country of origin) and its packaging, promotion material and brochure. ix. Provide Essential Principle of Safety and Performance / Essential Requirements / Essential Checklist as per EU Directive 93/42/EEC.
2.	M/s Total Technologies Pvt. Ltd 696, J-2, Johar	Legal Manufacturer:	STEELCO	**Deferred** for provision of following documents:-

	Town, Lahore, Pakistan. ELI- 00129 Evaluator AD-VIII 1462	STEELCO S.p.A Via Baleganate 27, 31039 Riese Pio X (TV) , Italy FSC: Italy Date of Issue: 30-07-2018	(Hydrogen Peroxide Sterilizer:) Code & Sizes: as per FSC Class: C Shelf Life: 12 months	i. Provide stability studies to justify the claimed shelf life of applied medical device. ii. The applied medical device is a sterilizer using 58% Hydrogen Peroxide solution as sterilizing agent, provide studies that applied medical device achieve Sterility Assurance level SAL (1x10-6) by using 58% H2O2. iii. Highlight the scope under which the Notified Body is authorized to carryout assessment of Steelco (Hydrogen Peroxide Sterilizer) under EU 93/42/EEC, where the body is authorized to assess "sterilization". iv. Firm submitted photocopy of letter of authorization dated April 30, 2019 where validity of authorization is not given. Therefore, provide original, valid LOA duly notarized in the country of origin, otherwise justify. v. Provided expired copy of FSC at the time of application submission. Provide original valid Free Sale Certificate duly attested by the embassy of Pakistan covering the applied medical device. vi. Provide its manual, packaging, promotion material and brochure containing the description of device, IFU, etc. vii. Provided ISO 13485 & FQA are expired now. Provide valid certificates..
3.	-do- Evaluator AD-VIII 1457	Legal Manufacturer: STEELCO S.p.A Via Baleganate 27, 31039 Riese Pio X (TV), Italy FSC: Italy Date of Issue: 30-07-2018	Steeclo Pro PL (58% Hyderogen Peroxide Sterilizing Agent) Code & Sizes: as per FSC Class-C Shelf life: 12 months	**Deferred** for provision of following documents:- i. Provide stability studies to justify the claimed shelf life of applied medical device. ii. The applied medical device is a sterilizing agent comprising of Hydrogen Peroxide, provide studies that 58% H2O2 will achieve SAL (1x10-6) with this Medical Device. iii. Highlight the scope under which the Notified Body is authorized to carryout assessment of Steelco (Hydrogen Peroxide Sterilizing Agent) under EU 93/42/EEC, where Body is authorized to assess "sterilization". iv. Clarify the discrepancy between brand name, as word "STEELCO" is mentioned against brand name while "STEELCO PRO PL" on description of medical device. Accordingly submit correctly filled application form. v. Firm submitted photocopy of letter of authorization dated April 30, 2019 where validity of authorization is not given. Therefore, provide original, valid LOA duly notarized in the country of origin, otherwise justify. vi. Provided expired copy of FSC at the time of application submission. Provide original valid Free Sale Certificate duly attested by the embassy of Pakistan covering the applied medical device. vii. Provided ISO 13485 & FQA are expired now. Provide valid certificates .
4.	M/s Fresenius Medical Care Pakistan Pvt. Ltd,: TAMC, First Floor, 27C III, M.M. Alam Road Gulberg III, Lahore 54660, Pakistan	Legal Manufacturer: M/s Fresenius Medical Care AG & Co. KGaA, 61346 Bad Homburg Germany	MULTIFILTRATE Kit 4 CVVHDF 600 (Therapy sets for acute dialysis treatment) multiFiltrate cassette Code: 5016801	**Deferred** for provision of following documents:- i. Provide original valid LOA duly notarized in the country of origin. ii. The firm has applied medical device with brand name "MULTIFILTRATE Kit 4 CVVHDF 600" however this name "MULTIFILTRATE Kit 4 CVVHDF 600" is not mentioned on

	ELI-00315 Evaluator AD-VIII 1652 (P)	Manufacturer Site: M/s Nova Med GmbH Antalya Serbest Bolgesi Merkez Subesi No: 16, Liman Serbest Bolgesi Mahallesi 07070 Antalya, Turkey. (for multiFiltrate cassette Code: 5016801; substituteate system multiFiltrate Code: 5016761; Dialysate System multiFiltrate Code: 5016751) M/s Fresenius Medical Care Deutschland GmbH St. Wendel Plant Frankfurter StraBe 6 – 8 66606 St. Wendel Germany (for Ultraflux® AV 600S code: 5007361) FSC: Germany Date of Issue: 14.06.1993	substituteate system multiFiltrate Code: 5016761 Dialysate System multiFiltrate Code: 5016751 Ultraflux® AV 600S (code: 5007361) Class: C Shelf Life: 3 Years	provided FSC, DoC, ISO-13485, FQA, need clarification. iii. Explain the grouping of "MULTIFILTRATE Kit 4 CVVHDF 600", in detail also provide documentary evidence in this regard. Furthermore, Ultraflux® AV 600S (code: 5007361) has already been approved subject to provision of ISO 13485 certificate. Now the same has been applied as component of MULTIFILTRATE Kit 4 CVVHDF 600. iv. Provide photocopy of FSCs issued on July 08, 2019 & Jun 28, 2019. Provide Original valid FSCs duly attested by embassy of Pakistan in the country of origin. v. Provided ISO certificate and Full Quality Assurance certificates are expired now. Provide valid certificates. vi. Provide its packaging, promotion material and brochure containing the description of device, IFU, component's usage etc. vii. Provided DoC is expired now, provide the Declaration of conformity (DoC) to be printed on manufacturer letterhead, filled and duly signed by responsible person.
5.	-do- Evaluator AD-VIII 1531 (P)	Legal manufacturer Fresenius Medical Care AG & Co. KGaA 61346 Bad Homburg Germany Manufacturing Site : Fresenius Medical Care Deutschland GmbH Frankfurter Straße 6 - 8 66606 St. Wendel Germany FSC: Germany Date of issue: 06-05-2016	Ultraflux AV Paed (Dialysers/Filters) Code: 5008231 Class-C Shelf Life: 3 years	**Deferred** for provision of following documents:- i. Provide original valid LOA duly notarized in the country of origin. ii. Provided ISO certificate and Full Quality Assurance certificates are expired now. Provide valid certificates. iii. Provide its packaging, promotion material and brochure containing the description of device, IFU, component's usage etc. iv. Provide photocopy of FSC issued on May 06, 2016. Provide Original valid FSCs duly attested by embassy of Pakistan in the country of origin. v. Provided DoC is expired now, provide the Declaration of conformity (DoC) to be printed on manufacturer letterhead, filled and duly signed by responsible person.
6.	Martin Dow Marker Specialities (Pvt) Ltd., D-7, Parveen Building Shaheed Millat Road Karachi, Pakistan (ELI-00160) Evaluator	Legal Manufacturer: M/s ELITech Clinical Systems SAS 4 Rue Auguste Motin, Zone Industrielle, 61500 Sees France. FSC: France Date of issue:	CK-MB SL (Enzymes for Heart Profile) Codes and Sizes: CMSL – 230 CMSL – 0410 CMSL – 0430 Class-C	**Deferred** for provision of following documents:- i. Provided photocopy of LOA doesn't mention the validity period, please clarify. Provide original LOA. ii. Provided un-attested Photocopy of FSC dated 30 July 2020 . Provide original, valid FSC duly attested by the Embassy of Pakistan in the country of origin. iii. The same medical device (CK-MB SL) has already been registered by MDB in its 40th

	AD-VIII 2334	30 July 2020	Claimed Shelf life: 14 months	Meeting form the same manufacturer (M/s ELITech Clinical Systems SAS 4 Rue Auguste Motin, Zone Industrielle, 61500 Sees France) in favor of M/s Hoora Pharma (Pvt) Ltd., Address: WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi (ELI-00037), clarification is required. iv. It cannot be ascertained that whether the Submitted checklist of essential requirements is of applied medical device i.e. CK-MB SL. v. Explain the difference between variants of CK-MB SL w.r.t. CMSL codes of "KIT" and "Vials", duly supported by documentary evidence. Manual, brochure, IFU etc.
7.	-do- Evaluator AD-VIII 3402	Legal Manufacturer: M/s ELITech Clinical Systems SAS 4 Rue Auguste Motin, Zone Industrielle, 61500 Sees France. FSC: France Date of issue: 30 July 2020	CK-MB Control Codes and Sizes CKMB-0900 Class-C Claimed Shelf life: 14 Months	**Deferred** for provision of following documents:- i. Provided photocopy of LOA doesn't mention the validity period, please clarify. Provide original LOA. ii. Provided un-attested Photocopy of FSC dated 30 July 2020 . Provide original, valid FSC duly attested by the Embassy of Pakistan in the country of origin. iii. The same medical device (CK-MB Control) has already been registered by MDB in its 40th Meeting form the same manufacturer (M/s ELITech Clinical Systems SAS 4 Rue Auguste Motin, Zone Industrielle, 61500 Sees France) in favor of M/s Hoora Pharma (Pvt) Ltd., Address: WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi (ELI-00037), clarification is required. iv. It cannot be ascertained that whether the Submitted checklist of essential requirements is of applied medical device i.e. CK-MB Control.
8.	M/s Medilution Healthcare A-322 (First Floor), Gulshan-e-iqbal Block 2, KDA Scheme No. 24, Karachi Evaluator: AD-VIII 17515	Legal Manufacturer: Pharmaplast SAE Amria Free Zone, 23512 Alexandria Egypt FSC: Egypt Date of issue: 23 Sep 2019 FSC: Spain Validity: Not given	Pharmacoll, Pharmacoll comfort, Pharmacoll Thin, Pharmacoll Basic Codes & Sizes as per FSC Class- C Claimed Shelf life: 5 Years	**Deferred** for provision of following documents: - i. The firm submitted only tabulated results of stability studies however the detailed stability protocol and discussion on results are not attached with application. ii. Provide difference in the manufacturing methods in detail of applied variant. iii. Clarify that the sterilization of applied medical devices is done by the "Pharmaplast SAE, Amria Free Zone, 23512 Alexandria Egypt" or otherwise this step is outsourced. If outsourced, then provide certification of site being used for sterilization. iv. Photocopy of FSC (Spain) neither mentions the validity nor the issue date. Provide Original, Valid FSC of RRA duly attested by embassy of Pakistan in the country of origin. v. Provide labels (as approved in the country of origin) of all the codes applied and its packaging, promotion material and brochure. Explain the difference between variants of hydrocolloid dressing and their respective codes duly supported by documentary evidence. Manual, brochure, IFU etc. vi. Justify that the how different type variants of applied medical device can be registered as a "Family" in the light of Schedule-B read with

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<td>Chapter-III - Rule 11 of MDR, 2017 with special focus on "design & manufacturing process; and variations that are within the scope of the permissible variants"
vii. EC certificate of Full Quality Assurance issued by GMED doesn't cover "Pharmacoll Basic", Need clarification
viii. Provided ISO 13485 is expired now. Provide valid certificate.
ix. Clarification is required regarding European Representative. That as per label the Authorized Representative for European Community is "M Devices Group / EC Rep Ltd, Portland Street, Southport, PR8 1HU, UK" However, on Declaration of Conformity, the address of authorized representative is "EC Rep Ltd, 5 Fitzwilliam Square East, Dublin 2, D02 R744, Ireland."</td>
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<td>9.</td>
<td>M/s. Princess Scientific Services Plot No, 67/62 , ADAM-JEE Road 1st Floor DEEN Plaza Saddar Cantonment Rawalpindi

(ELI-00215)

Evaluator:
AD-VIII
1527</td>
<td>Legal Manufacturer:

M/s. Helena Biosciences Europe Queensway South Team Valley Trading Estate Gateshead Tyne and Wear NE11 OSD UK

FSC: UK
Valid till:
26.11.2024</td>
<td>HELENA BIOSCIENCES MANUAL D-DIMER

Codes:

<table>
<tr><th></th><th>Ref 5250</th><th>Ref 5250H</th></tr>
<tr><td>Manual D-Dimer Latex</td><td>1x 1.7 mL</td><td>1x 0.85mL</td></tr>
<tr><td>Positive control Plasma</td><td>1x 1mL</td><td>1x 1mL</td></tr>
<tr><td>Negative control Plasma</td><td>1x 1mL</td><td>1x 1mL</td></tr>
<tr><td>Saline Solution</td><td>2x 8mL</td><td>1x 8mL</td></tr>
<tr><td>Test cards</td><td>16 x 6 sample</td><td>8 x 6 sample</td></tr>
<tr><td>Mixing sticks</td><td>50</td><td>25</td></tr>
</table>

Class-C
Shelf Life:
24 months</td>
<td>Deferred for provision of following documents:-

i. Incomplete credentials are attached with application. Provide complete credentials of manufacturer.
ii. Firm attached photocopy of LOA which is expired now, it doesn't contain complete address of manufacturer. Furthermore, the applicant is only authorized regarding "coagulation reagents", but product list is not provided. Provide Original valid LOA mentioning the product list.
iii. Provided unattested photocopy of MHRA. Provide Original FSC.
iv. Provided ISO certificate is incomplete and expired now. Provide valid and complete ISO certificate.</td>
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<td>10.</td>
<td>-do-

Evaluator:
AD-VIII</td>
<td>Legal Manufacturer:

M/s. Helena Biosciences Europe Queensway South Team Valley</td>
<td>HELENA BIOSCIENCES

(THROMBOPLASTIN L)

Codes:
5265L (8x5mL)</td>
<td>Deferred for provision of following documents:-

i. Incomplete credentials are attached with application. Provide complete credentials of manufacturer.</td>
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	1525	Trading Estate Gateshead Tyne and Wear NE11 OSD UK FSC: UK Valid till: 26.11.2024	5267L (10x10mL) Class: C Shelf Life: 2 years	ii. Firm attached photocopy of LOA which is expired now, it doesn't contain complete address of manufacturer. Furthermore, the applicant is only authorized regarding "coagulation reagents", but product list is not provided. Provide Original valid LOA mentioning the product list. iii. Provided unattested photocopy of MHRA. Provide Original FSC. iv. Provided ISO certificate is incomplete and expired now. Provide valid and complete ISO certificate.
11.	-do- 1526-P Evaluator: AD-IX	Legal Manufacturer: M/s Helena Laboratories UK ltd., Trading as Helena Biosciences Europe Queensway south team valley trading estate gateshead tyne and wear NE11 osd UK. FSC:.	APPT Si L Minus Codes & Sizes: 5558SLQ, 5559SLQ, 5560SLQ, 5562SLQ Class-C Shelf Life: 2 years	**Deferred** for submission of original, legalized and valid Free Sale Certificate.
12.	M/s Ferozsons Laboratories Limited P.O Ferozsons, Amangarh, Nowshera (KPK) ELI-00120 Evaluator AD-VIII 1543(P)	Legal Manufacturer M/s. Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA Manufacturing Site: Boston Scientific Limited Ballybrit Business Park Galway, Ireland FSC: FDA U.S FOOD & DRUG Date of issue 10-10-2019 Valid till 09-10-2021	Ultraflex™ Esophageal NG Stent System (Polymer-metal oesphageal stent, non-sterile; bare-Metal oesophageal Stent, non-sterile) Codes: M00513700 08714729716129 Uncovered Distal 18 mm x 23 mm x 70 mm M00513710 08714729716136 Uncovered Distal 18 mm x 23 mm x 100 mm M00513720 08714729716143 Uncovered Distal 18 mm x 23 mm x 150 mm M00513800 08714729716174 Uncovered Proximal 18 mm x 23 mm x	**Deferred** for provision of following documents:- i. The firm claimed that Original credentials are attached in file for registration of medical device vide letter # PDFLL-510419081, dated 14-09-2018 i.e. Wallstent-UniTM Endoprosthesis Self Expanding Stent. ii. Provided ISO 13485 certificate is expired now. Provide valid certificate. iii. Provided photocopy of FSC is expired now. Provide valid original FSC certificate. iv. Provided LOA is expired now provide original valid LOA. v. Clarify/justify with documentary evidence regarding grouping of medical device in the light of Schedule-B read with Chapter-III - Rule 11 of MDR, 2017. Since, the firm has specified grouping as a "Single" medical device on the application form. However, the firm has applied different types/variants/ codes of UltraflexTM Esophageal NG Stent System like covered; uncovered; polymer-metal; bare-metal; proximal and distal.

			70 mm M00513810 08714729716181 Uncovered Proximal 18 mm x 23 mm x 100 mm M00513820 08714729716198 Uncovered Proximal 18 mm x 23 mm x 120 mm M00513830 08714729716204 Uncovered Proximal 18 mm x 23 mm x 150 mm M00513840 08714729716099 Covered Proximal 18 mm x 23 mm x 100 mm, 70 mm M00513850 08714729716075 Covered Proximal 18 mm x 23 mm x 120 mm, 90 mm Class : C M00513860 08714729716082 Covered Proximal 18 mm x 23 mm x 150 mm, 120 mm Shelf Life: 2 years	
13.	-do- Evaluator AD-VIII 1516	Legal Manufacturer: Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA Manufacturing Site: Boston Scientific Corporation 780 Brookside Drive Spencer, indiana USA FSC: USFDA Valid Till: 02-04.2021	Percutaneous Access Set (Catheter, Nephrostomy) Code: M0064201100 M0064201110 M0064201120 Class- C Shelf Life: 4 years	**Deferred** for provision of following documents:- i. The firm has applied "Percutaneous Access Set" in Class-B under MDR, 2017, therefore submitted Rs.:25000/- as registration fee vide challan no. 0835682 dated 19 March 2020. The DoC bears Statement regarding Classification that All the devices, with the exception of the Percuteneous Access Set (M0064201100 – Class IIa) are Class IIb. Therefore, the firm is required to submit differential fee of 25000/- for further processing and of Registration application in Class-C. ii. Provided LOA is expired on 31st December, 2020, therefore provide valid original LOA. iii. Provided photocopy of FSC is expired on April 02, 2020. Therefore, provide original, valid FSC. iv. Provided ISO 13485 and FQA certificates are expired on 1st September 2020 and 25th September, 20, respectively. Therefore, provide valid ISO certificate and FQA certificates.
14.	-do- Evaluator	Legal Manufacturer: Boston Scientific Corporation	Radial Jaw 4 Single-Use Standard Capacity Biopsy Forceps	**Deferred** for provision of following documents:- i. The firm claimed that Original FSC is attached in application submitted for registration of

	AD-VIII 1519	300, Boston Scientific Way, Marlborough, MA 01752 USA Manufacturing Site: Boston Scientific Corporation de Costa Rica, S.R.L. 2546 First Street, Propark El Coyol Alajuela Costa Rica 20904. FSC: USFDA Valid till: 15-04-2021	(with or without Needle) UPN Code: M00513381 M00513382 M00513383 M00513391 M00513392 M00513393 M00513401 M00513402 M00513403 M00513411 M00513412 M00513413 M00513414 M00513394 M00513404 M00513384 Class- B Shelf Life: 3 years	medical device vide letter # PDFLL-799411191, dated 14 November, 2019 i.e. SpyBite Biopsy Forceps. ii. Provided LOA is expired on 31st December, 2020, therefore provide valid original LOA. iii. Provided photocopy of FSC is expired on April 15, 2021. Therefore, provide original, valid FSC. iv. Provided ISO 13485 and FQA certificates are expired on 1st September 2020 and 25th September, 20, respectively. Therefore, provide valid ISO certificate and FQA certificates. v. The firm provided "Direction for Use" of Radial JawTM 4 MultibiteTM. Provide IFU of RJ4 Standard Capacity Biopsy Forceps specifying the target biopsy site(s) / tissue(s).
15.	-do- Evaluator AD-VIII 1517	Legal Manufacturer: Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA Manufacturing Site: Boston Scientific Limited Business and Technology Park Model Farm Road Cork Ireland FSC: Ireland Valid Till: 28-06-2021	Occluder™ Occlusion Balloon Catheter (Ureteropelvic Balloon Catheter) Code: as per FSC Class- B Shelf Life: 18 months Fee Submitted: Rs.25000/-	**Deferred** for provision of following documents:- i. Provided LOA is expired on 31st December, 2020, therefore provide valid original LOA. ii. The Provided Original embassy attested FSC is expired on 28th Jun 2021. Therefore, provide Original Valid FSC. iii. The provide ISO 13485 certificate is expired on 23 March 2021. Provide valid certificate.
16.	-do- Evaluator AD-VIII 1786	Legal Manufacturer: Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA. Manufacturing Site: Boston Scientific Corporation 780 Brookside Drive Spencer, IN USA FSC: US-FDA Valid till: 27.01.2022	Advanix Biliary Stent with Naviflex™ RX Delivery System - Preloaded Duodenal Bend (Polymeric Biliary Stent, non-bioabsorbable) codes & Sizes: M00534200 M00534210 M00534220 M00534230 M00534240 M00534250 M00534260 M00534270 M00534280 M00534290	**Deferred** for provision of following documents:- i. The label (M00534200 to M00534250 & M00534320 to M00534370) bears CE Mark No. 0086 however the label of (M00534260 to M00534310) are marked with CE2797. The firm didn't provide any EC certificate duly issued by body no. 2797. Therefore, provide EC certificate duly issue by notified body no. 2797. ii. Provided LOA is expired on 31st December, 2020, therefore provide valid original LOA. iii. Provided ISO 13485 and FQA certificates are expired on 1st September 2020 and 25th September, 20, respectively. Therefore, provide valid ISO certificate and FQA certificates. iv. The provided un-attested photocopy of FSC is expired on 27 Jan 2022. Therefore, provide valid original FSC duly attested by Embassy of Pakistan.

			M00534300 M00534310 M00534320 M00534330 M00534340 M00534350 M00534360 M00534370 Class-C Shelf Life: 2 years	
17.	M/s BAIN Medical SMC-Pvt) Ltd, Shop No. 2, Ground Floor, Plot 58-C, Street No. 24, Touheed Commercial Area, phase 5 DHA karachi (ELI-00614) Evaluator: AD-VIII 3730	Vital Healthcare SDN. BHD., Lot 3, Jalan Sultan Mohamed 3, Bandar Sultan Sulaiman, 42000 Pelabuhan Klang, Selangor Darul Ehsan, Malaysia FSC: Malaysia Validity: 08 Nov 2022 FSC: Germany Validity: 02 Jun 2021	Hemodialysis Bicarbonate / Vital Codes and sizes: HB001 650g cartridge HB002 720g cartridge HB003 750g cartridge HB004 760g cartridge HB005 650g bag HB006 700g bag Class-C Shelf life: 2 Years	**Deferred** for clarification/ provision of following documents:- i. Clarify/ justify with documentary evidence regarding grouping of medical device in the light of Schedule-B read with Chapter-III - Rule 11 of MDR, 2017. Special focus on different type of constituent-components of different codes/model of the medical device that are grouped together e.g. HB001 650g cartridge; HB002 720g cartridge; HB003 750g cartridge; HB004 760g cartridge; HB005 650g bag; & HB006 700g bag. Furthermore, the IFUs for HB001 to HB004 is different from HB005 & HB006. ii. Clarify that why the Free Sale Certificate (Germany) have been issued by the Ministry of Environment and consumer Protection. The provided FSC (Germany) is expired on 02 Jun 2021 and doesn't contain applied product i.e. Hemodialysis Bicarbonate / Vital. Provide Original Valid FSC duly attested by embassy of Pakistan containing Hemodialysis Bicarbonate / Vital. iii. The provided ISO 13485 certificate is expired even upon submission. Provide valid certificate duly notarized in country of origin as per law.
18.	-do- Evaluator: AD-VIII 3727	M/s Giant Medical Equipment (Guangzhou) Co., Ltd., No.10 Juncheng Road, Eastern Area, Economic and Technological Devolpment District, Guangzhou 510760, PR. China FSC: Validity	GMKey HEMODIALYSIS CATHETER KITS - Double Lumen (straight extension, curved extension) Identifier: GMH-211515-S GMH-211520-S, GMH-21215, GMH-21215-S, GMH-21216 List of main components of Kit: Part: Hemo-dialysis Catheter Model: Double lumen, 12Frx16cm, Straight extension legs	**Deferfed** for provision of following documents: - i. Provide ISO certificate for Sterilization agency Bain Medical Equipment (Guangzhou) Co., Ltd., No.10 Juncheng Road, Eastern Area, Economic and Technological Devolpment District, Guangzhou 510760, PR. China ii. The firm is authorized by manufacturer to register and distribute their products under "GMKey brand". iii. The provided country specific German FSC is issued for "India". iv. Clarify that why the Free Sale Certificate (Germany) have been issued by the Ministry of Environment and consumer Protection. The provided FSC (Germany) is expired on 19 Feb 2021 and doesn't cover following codes GMH-21215 & GMH-21216. Provide Original Valid FSC duly attested by embassy of Pakistan covering all codes of applied medical device or justify with documentary evidence. v. It cannot be ascertained that whether the Submitted checklist of essential requirements is of applied medical device. vi. Explain the difference in codes of dialysis catheter to be registered (as per form 7A) used in

			<table><tr><td>Vessel Dilator</td><td>10FrX15cm 12FrX15cm</td></tr><tr><td>Guidewire</td><td>0.038"x 60cm, Nitinol</td></tr><tr><td>Introducer Needle</td><td>17Gx7cm</td></tr><tr><td>Blue Hollow Syringe</td><td>5ml</td></tr><tr><td>Disposable Syringe</td><td>7#</td></tr><tr><td>Heparin Cap</td><td>Octagonal</td></tr><tr><td>Plastic scalpel</td><td>11#</td></tr><tr><td>Blister packing</td><td>HC</td></tr></table> Codes and sizes as per FSC Class-C Shelf Life: 3 Years	Germany as per FSC (GMH-211515-S; GMH-211520-S, GMH-21215-S-W, GMH-21215-S, & GMH-21216-S-W) and China as per FSC (GMH-211515-S; GMH-211520-S, GMH-21215, GMH-21215-S, & GMH-21216). vii. Explain difference in specifications of components of KITs like Vessel Dilator; Guidewire; Introducer Needle; Blue Hollow Syringe; Disposable Syringe; Heparin Cap; Plastic scalpel; Blister packing. viii. Provide label (as approved in the country of origin) of complete KIT for each code/model applied for registration alongwith promotion material, brochures etc.
19.	M/s Optisurg, 17/C-1, Valencia Town, Lahore (ELI: 00305) Evaluator AD-VIII 3432	Legal Manufacturer: M/s Oertli Instruments AG Hafnerwisenstrasse 4 9442- Bernec Switzerland FSC: Switzerland Date of Issue: 14 March, 2020	Oertli Diathermy Instruments Reusable (Handpiece short for Diathermy TIP Cable 3M, Floating Connector) (A accessory to Oertli CatRhex 3 Ophthalmic Surgery System) Article No. VE201712 Class: C Shelf Life: Not Mentioned	**Deferred** for provision of following documents:- i. Provided photocopy of LOA. Therefore, provide original valid LOA duly notarized in the country of origin. ii. As per document provided in attachment #1(Technical Datasheet), & 5 (EC-FQA) the applied product is classified as IIb however as per attachment# 8 (DoC) the product is classified as IIa, need clarification. Furthermore, Justify Class-C under MDR 2017 for applied product. iii. Provided ISO certificate is expired now. Provide valid certificate. iv. Provide the shelf-life & storage conditions, i.e., justified with stability studies.
20.	M/s. Medequips SMC Pvt Ltd, 30 Shahrah-e-Quaid-e-Azam Lahore. ELI-00362 Evaluator: AD-VIII	Legal Manufacturer Canon Medical System Corporation, 1385 Shimoishigami, Otwara Shi Tochigi 324-8550, Japan. FSC: JAPAN Date of issue: 07 Mar 2018, 14 Jun 2018, 20 Jun 2018 & 26 Feb 2019	Aquilion System (Computed Tomography system) TSX -304A TSX-305A TSX-303B TSX-036A TSX-035A TSX-037A TSX-201A Constituents-Components: ECG Gating System SIM Manuals Phantoms Computer Monitor Console Couch Gantry	**Deferfed** for provision of following documents: - i. Provided photocopy of LOA which is expired now. Provide original valid LOA duly notarized. ii. Each device has different trade name therefore all of the applied models (TSX -304A, TSX-305A, TSX-303B, TSX-036A, TSX-035A, TSX-037A, TSX-201A) cannot be registered against single application. Hence apply individually for each model. iii. Provided photocopy of FSC (Japan) for TSX 0304A model therefore provide original, valid FSC duly attested by Embassy of Pakistan. iv. Justify that the how different type models of applied medical device can be registered as a "Family" in the light of Schedule-B read with Chapter-III - Rule 11 of MDR, 2017 with special focus on "Trade name difference, design & manufacturing processes; and variations that are within the scope of the permissible variants" v. Provided FQA certificate is expired now. Provide valid FQA.

			Class-C Shelf Life: N/A as per Application form	vi. Provide label of all applied model Family as approved in the country of origin. vii. The provide label template bears CE Marking of 2797, need clarification. Since the did not provide EC certificates duly issued by 2797 Notified Body. viii. It cannot be ascertained that whether the Submitted checklist of essential requirements is of applied medical devices. ix. Clarify that why DoCs have been issue separately for each model, that have been applied to be registered as a family.
21.	M/s Roche Pakistan Limited. 1st Floor, 37-B, Block 6, P.E.C.H.S Karachi (ELI-0009) Evaluator: AD-VIII 3410	Roche Diagnostics GmbH Sandhofer Strasse 116 68305 Mannheim, Germany FSC (A): Germany Date of Issue: 19 Sep 2016 FSC (B): Germany Date of Issue: 31 Aug 2020	TINA-QUANT MYOGLOBIN GEN 2 (MYO2) Codes and sizes as per FSC Class-C 1. Tina-quant Myoglobin Gen.2 (MYO2) Code: 4580010 Pack Size: 100 Tests Shelf Life: 24 Months 2. Tina-quant Myoglobin Gen.2 (MYO2) Code: 8252629 Pack Size: 200 Tests Shelf Life: 24 Months 3. C.f.a.s. Myoglobin Code: 4580044 Pack Size: 3x 1mL Shelf Life: 18 Months 4. Myoglobin Control Set Code: 11730835 Pack Size: 4 x 3mL Shelf Life: 24 Months	**Deferfed** for provision of following documents: - i. The firm claimed that Original has been submitted along with the letter Ref. # RA/SU/024. ii. The firm claimed that Original FSC (A) was submitted in Dossier # 0001. iii. The firm claimed that Original FSC (B) was submitted in dossier # 0116. iv. The firm has applied Class-C in-vitro cluster however, as per MDR, 2017 – "An in-vitro medical device shall be grouped as in-vitro diagnostic cluster if it comprises of a number of in-vitro diagnostic reagents or articles that are within risk classification A or B". Need Clarification. v. The provided photocopy of FSC is expired now. Provide Original valid FSC duly attested by embassy of Pakistan. vi. The "TINA-QUANT MYOGLOBIN GEN 2" is not mentioned on provided FSC only "MYO2" is mentioned, need clarification. vii. Only Myoglobin Control Set is mentioned on FSC however there is no bifurcation in Level I and Level II as mentioned on Package Insert & label, please clarify. viii. As per package insert of "Tina-quant Myoglobin Gen 2 (MYO2) Code: 8252629" having Pack Size of 200 tests is "for use in the USA only", please clarify. ix. Provided ISO is expired now provide valid certificate. x. Provide the Full Quality Assurance of the applied IVD medical Device or otherwise justify.
22.	M/s Physiomed Pvt Ltd, 268/3 Kamal Road Saddar, Rawalpindi ELI: 00199 Evaluator: AD-VIII	Legal Manufacturer: Avanos Medical Inc., 5405 Windward Parkway Alpharetta, GA USA Manufacturing Site: Avent S. de R.L. de. C.V Carretera Internacional Salida Norte No. 1053 Magdalena, Sonora Mexico CP 84160	COOLIEF COOLED RADIOFREQUENCY PROBE (Radiofrequency Ablation device) Model No.: CRP-17-50 CRP-17-75 CRP-17-100 CRP-17-150 Codes & Sizes: As per FSC Class-C	**Deferfed** for provision of following documents: - i. Provide valid, Original LOA, duly notarized in the country of Origin. ii. Provided unattested photocopy of FSC (USFDA) is expired now. Provide original valid FSC duly attested by the Embassy of Pakistan. iii. The provided FQA is expired even upon submission. Provide valid FQA duly notarized. iv. Difference in "stability" and "limited warranty" as given in IFU. v. Provide label/ brochure/ promotion material etc. as approved in the country of origin for CRP-17-50; CRP-17-75; CRP-17-100 & CRP-17-150.

		Sterilization Site: Isomedix Operations Inc. 1435 Isomedix Place, El Paso, Texas 79936, USA FSC: U.S.A Valid till: 14.04.2022	Shelf Life: 4 years Warranty period: 90 days	
23.	M/s Radiant Medical (Pvt) Ltd 06-Sher Shah Block, New Garden Town, Lahore. ELI: 00135 Evaluator: AD-VII	Legal Manufacturer: SiMAD S.r.L-Via Benedetto Zallone, 25-40066 Pieve di Cento (BO) Italy FSC: Italy Date of issue: 18.12.2019	Simad (Image Intensifier (C-Arm) Moonray series Codes & Sizes: As per FSC Class-C Shelf Life: 10 years	**Deferfed** for provision of following documents: - i. Provide Original letter of Authorization the submitted is expired after submission . ii. Provide Service life / shelf life studies. iii. Provide DOC having name and class of the product iv. Name of the manufacturer on Form7-A is M/s Carestream Health Inc, newyork, however all documents provide is of Simad Srl, Italy. Therefore, revise Form-7A.
24.	M/s AA Enterprises, 57,15-16 First floor Mobi Plaza Haider Road, Saddar, Rawalpindi ELI: 00525 Evaluator: AD-VII 1438	Legal manufacturer Sie AG, Surgical Instrument Engineering Allmendstrasse II, 2562 Port Switzerland FSC: Switzerland 23-12-2019	FEMTO LDV Z8 FEMTO LDV Z6 FEMTO LDV Z4 FEMTO LDV Z2 Class C Shelf Life: 3 years	**Deferfed** for provision of following documents: - i. Provide valid , embassy attested FSC in the country of origin , the firm has provided only a copy. ii. Provide valid and notarized ISO 13485 certificate and FQA certificate, the firm has provided only copies. iii. Provide original letter of clarification / relation regarding Sie AG, Surgical Instrument Engineering Allmendstrasse II, 2562 Port Switzerland And Ziemer Opthalmic System AG , awitaerland
25.	M/s Chemical House, 6-C Sikander Malhi Road, Canal Park, Gulberg II, Lahore Pakistan. ELI: 00156 Evaluator: AD-VII	Legal Manufacturer: Bio-Rad Laboratories 9500 Jeronimo Rd Irvine, CA USA 92618 FSC: FDA U.S FOOD & DRUG Valid till: 16.01.2021	Liquichek Cardiac Markers Controls (Multiple Cardiac Marker IVD Controls Class-C Shelf Life: 3 years	**Deferfed** for provision of following documents: - i. Provide valid and original FSC in the country of origin , the original and embassy attested FSC submitted had been expired after submission. ii. The grouping of device is not clear on FORM 7A. Several codes of various brands written under one name in Form-7A. Therefore, Justify for Family system/ grouping under MDR 2017 or revise Form-7A with clear brand name as present in FSC. iii. The name of manufacturer on Form-7A is Bio-Rad Laboratories , USA however, the firm is authorized by the Bio Rad Eurape Gmbh, basel Switzerland, Clarification letter in original is required from the legal manufacturer mentioning different sites and names representaive / manufacturing sites if any. iv. Provide valid and notarized ISO 13485 certificate the submitted has been expired.

				Provide Full Quality Assurance Certificate, the firm has not provided . v. Provide DOC mentioning the class of the medical device.
26.	-do- Evaluator: AD-VII	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 (Multiple Clinical Chemistry Protein IVD Control (Immunoassay Controls) Codes & Sizes: As per FSC Class- C Shelf Life: As per stability study	**Deferfed** for provision of following documents: - i. Provide valid original and embassy attested FSC in the country of origin, the firm has provided only a copy. ii. The grouping of device is not clear on FORM 7A. Several codes of various brands written under one name in Form-7A. Therefore, Justify for Family system/ grouping under MDR 2017 or revise Form-7A with clear brand name as present in FSC. iii. The name of manufacturer on Form-7A is Bio-Rad Laboratories Inc , USA however, the firm is authorized by the Bio Rad Eurape Gmbh, basel Switzerland, Clarification letter in original is required from the legal manufacturer mentioning different sites and names of the firm/ manufacturer if any. iv. Provide valid and notarized ISO 13485 certificate the submitted has been expired now. v. Provide Full Quality Assurance Certificate, only copy submitted which is expired.
27.	M/s MedOptics, Flat No. 3, 3rd Floor, Hafiz Plaza, M-Block, Model Town, Lahore ELI: 00615 Evaluator: AD-VII	Legal Manufacturer: M/s Aaren Scientific Inc. 1040 S. Vintage Ave. Bldg.A Ontario, CA 91761 USA FSC: France Date of Issue: 21/02/2019	AQUA SIY (Posterior chamber intraocular lens) Codes & Sizes: As per FSC Class- C Shelf Life: 5 years 3007	**Deferfed** for provision of following documents: - i. Provide valid embassy attested FSC in the country of origin , the firm has provide only a copy. ii. Provide valid and notarized ISO 13485 certificate for USA site. Also Provide Full Quality Assurance Certificate, the firm has not provided. iii. Provide Stability studies. iv. First Part of Form-7A not printed and filled, Therefore, properly fill Form-7A and write both manufacturing sites as mentioned in credential and EPSP..
28.	M/s Siemens Healthcare (Pvt) Ltd 4th Floor, State Life Building, 15-A, Sir Agha Khan Road, Lahore ELI: 00146 Evaluator: AD-VII [2185]	Legal Manufacturer: M/s Siemens Healthcare GmbH Henkestr, 127 91052 Erlangen Germany FSC: Germany	Polymobil Plus (Polymobile Plus) Class-C Shelf Life: 10 years	**Deferred** for provision of following documents:- i. Provide valid, embassy attested FSC in the country of origin issued by the regulatory authority of Germany, the firm has provided only a copy and is not clear whether issued by regulatory authority of Germany or otherwise. ii. Provide valid and notarized ISO 13485 certificate and Full Quality Assurance Certificate, the firm has provided only copies. iii. Provide service life claim/ studies iv. Provide Notarized and original letter of Authorization.
29.	M/s Latif Instruments (Pvt),	Legal Manufacturer:	VISULAS GREEN	**Deferred** for provision of following documents:-

	Ltd., 14 Commercial Buildings Shahrah-e-Quaid-Azam Lahore Head Office & Godown same as above ELI: 00118 Evaluator: AD-VII [2320]	M/s Carl Zeiss Meditec AG, GoeschwitzerStrasse 51-52, 07745 Jena, Germany FSC: Germany Date of Issue: 27.11.2020	(Ophthalmic Laser) Codes & Sizes: As per FSC Class: C Shelf Life: As per stability study	• Provide valid, embassy attested original FSC in the country of origin having name and codes of the product. The FSC provided does not have the exact name of the product. • Provide valid and notarized ISO 13485 certificate and Full Quality Assurance Certificate, the firm has provided only copies. • Provide service life claim/ studies • Provide Notarized and original letter of Authorization
30.	M/s Azad Scientific 3-B/2 Mouj Darya Road, Lahore ELI: 00349 Evaluator: AD-VII [2270]	Legal Manufactaurer: M/s Dia-pro-Diagnostics Bioprobes Srl, Via Giosue Carducci, 27, 20099 Sesto San Giovanni Milano (MI), Italy FSC: Italy Date of Issue: 27.03.2020	HEV IgG ELISA Kit 96 Test Evg.Ce Codes & Sizes: As per FSC Class- C Shelf Life: 15 months	**Deferred** for provision of following documents:- • Provide valid, embassy attested FSC in the country of origin. Only copy provided • Provide valid and notarized ISO 13485 certificate and Full Quality Assurance Certificate issued by CABS having scope and listed in Nando data base website, the firm has provided only copies. • Provide Notarized and original letter of Authorization • The Fee slip contain the name of "biological drug registration" instead of the brand name of the kit. Provide calrification.
31.	M/s Alam Medix, 9/1 Hannan Plaza Mayo Hospital Road, Lahore ELI: 00033 Evaluator: AD-VII [2372]	Legal Manufacturer: M/s Shenzhen Browiner Tech Co., Ltd located at 7F Building C, Longjing Jingu Pioneer Parkm Tayuan Street, Nanshan District, 518055 Shenzhen, Peoples s Republic of China FSC: China Valid till: 21.03.2021	Mobile Sparkler E&S (X-Ray) Codes & Sizes: As per FSC Class-C Shelf Life: 8 years	**Deferred** for provision of following documents:- • As per online DRAP Fee window , the *Fee has been expired*. Therefore, submit / clarify about fee of the product. • Provide valid, embassy attested FSC in the country of origin having name and codes of the product. The firm has provide a copy only. • Copy of FSC Germany provided but does not confirm whether the FSC issued by the regulatory authority or otherwise. Provide clarification. • Provide valid and notarized ISO 13485 certificate and Full Quality Assurance Certificate, the firm has provided only copies. • Provide Notarized and original letter of Authorization
32.	M/s Optisurg, 17/C-1, Valencia Town, Lahore ELI: 00305 Evaluator: AD-VII	Legal Manufacturer: Medicontur Medical Engineering Ltd., Herceghalmi Road 1, 2072 Zsambek, Hungary	Medicontur Bi-Flex 677AD (Aspheric hydrophilic acrylic IOL for Implantation into the capsular bag) Codes & Sizes: As per FSC	**Deferred** for provision of following documents:- • The product is from non-reference regulatory authority. Therefore Provide embassy attested original and valid FSC of any reference regulatory authority. • Provide valid and notarized all CE marking certificates issued by the Cabe present in the

	[2103]	FSC: Hungary Date of issue: 24.09.2020	Class- C Shelf Life: 5 years	Nando data base having scope of CE certification. • FQA expired after submission, therefore provide valid FQA certificate
33.	Rech International, M-10, Block-6, PECHS, Near Hotel Faran, Off Shahrah-e-Faisal, Karachi (ELI-00257) Evaluator: AD-VII [2741]	Legal Manufacturer: M/s SERF , 85 Avenue des Bruyeres 69150 Decines Charpieu, France FSC France Issuance Date (27-08-2018)	Reinforcement Cross KE Shelf life 5 years Class C	**Deferred** for provision of following documents:- • Copy of FSC provided, therefore provide valid and embassy attested original FSC in the country of origin. • Provide codes/sizes of the component / accessories to be present with the product. • Provide claimed shelf life/ service life validation protocols /studies • Provide valid and notarized ISO 13485 certificate, the firm has provided expired copy. Also provide valid and notarized full quality assurance certificate. • Provide Valid and notarized Authorization letter, the firm has provided photocopy which is expired • Provide Manufacturing method and DOC
34.	B.Braun Pakistan (Pvt) Ltd., The Forum, Suite 216, Khayaban-e-Jami, Block No.9, Clifton, Karachi (ELI-00006) Evaluator: AD-VII [1306-K]	Legal Manufacturer: M/s. B. Braun Melsungen AG. Carl-Braun-Strasse 1, 34212 Melsungen, Germany. Phone: +49 30 568207-230 Fax: +49 30 568207-123 Web: www.bbraun.com Manufacturing Site: Aesculap Chifa Sp, z. o. o. ul. Tysiaclecia 14, 64-300 Nowy Tomysl, Poland. FSC: Germany Date of issue: 14-03-2019	Intradyn Arterial Codes: 5210763, 5210771, 5210780, 5210704, 5210712, 5210720, 5210739 Class : B Shelf Life : 3 Years	**Deferred** for provision of valid notarized Letter of Authorization and valid notarized Full Quality Assurance certificate.
35.	-do- Evaluator: AD-VII	Legal Manufacturer: M/s. B. Braun Melsungen AG. Carl-Braun-Strasse 1, 34212 Melsungen, Germany.	Angiodyn High Pressure Tubes Codes: 5011507, 5011515, 5011523, 5011531, 5016002, 5014824, 5014875, 5018196, 5018200, 5018218,	**Deferred** for provision of valid notarized Letter of Authorization valid notarized Full quality Assurance certificate.

		Phone: +49 30 568207-230 Fax: +49 30 568207-123 Web: www.bbraun.com Manufacturing Site : Aesculap Chifa Sp, z. o. o. ul. Tysiaclecia 14, 64-300 Nowy Tomysl, Poland FSC: Germany Date of issue: 14-03-2019	5018233, 5011957, 5011965, 5011973, 5011938, 5018580, 5218088 Class : B Shelf Life : 3 Years	
36.	-do- Evaluator: AD-VII	Legal Manufacturer: M/s. B. Braun Melsungen AG. Carl-Braun-Strasse 1, 34212 Melsungen, Germany. Phone: +49 30 568207-230 Fax: +49 30 568207-123 Web: www.bbraun.com Manufacturing Site : Aesculap Chifa Sp, z. o. o. ul. Tysiaclecia 14, 64-300 Nowy Tomysl, Poland FSC: Germany Date of issue: 14-03-2019	Intradyn Introducer Needle (Puncture Needle) Codes: 5208505 Class : B Shelf Life : 3 Years	**Deferred** for provision of valid notarized Letter of Authorization valid notarized Full quality Assurance certificate.
37.	-do- Evaluator: AD-VII [1294-K]	Legal Manufacturer: M/s. B. Braun Melsungen AG. Carl-Braun-Strasse 1, 34212 Melsungen, Germany.	VascuFlex® Multi-LOC Codes: 5506650, 5506651, 5506652, 5506653, 5506654, 5506655, 5506656, 5506657 Class : C	**Deferred** for provision of following documents:- • Valid and notarized ISO 13485 certificate of the production facility i.e, Medicut Stent Technology GmbH, Christinstasse 15,75177 Pforzheim, Germany. • Also provide notarized and valid Full Quality assurance certificate.

		Manufacturing Site: Medicut Stent Technology GmbH, Christinstasse 15, 75177 Pforzheim, Germany. FSC: Germany Date of issue: 5-11-2018	Shelf Life : 3 Years	• Valid and notarized Authorization letter for this product.
38.	-do- Evaluator: AD-VII	Legal Manufacturer: M/s. B. Braun Melsungen AG. Carl-Braun-Strasse 1, 34212 Melsungen, Germany. Web: www.bbraun.com Manufacturing Site: Aesculap Chifa Sp, z. o. o. ul. Tysiaclecia 14, 64-300 Nowy Tomysl, Poland. M/s. B. Braun Medical (Suzhou) Co., Ltd. No 128 Changyang Street, Suzhou Industry Park, 215024 Suzhou, People's Republic of China. FSC: Germany Date of issue: 29-07-2019	Manifold kit Pakistan (Individually pre-assembled kit for angiography) Codes: 5014652 Class : B Shelf Life : 3.5 Years	**Deferred** for provision of following documents:- • Stability studies provided carry the brand name "customised kit", provide clarification. • Provide valid and notarized ISO 13485 certificate of both production sites including china, also provide valid and notarized full quality assurance certificate the firm has provided copies. • Valid and notarized Authorization letter, the firm has provided photocopy
39.	-do- Evaluator: AD-VII [1299-K]	M/s. B. Braun Melsungen AG. Carl-Braun-Strasse 1, 34212 Melsungen, Germany. Manufacturing Site:	Combidyn PVC Pressure Tubing (PRESSURE TUBING FOR TRANSMISSION OF PHYSIOLOGICAL PRESSURE)	**Deferred** for provision of following documents:- • Provide valid and notarized ISO 13485 certificate of both production sites including Czech republic, also provide valid and notarized Full Quality Assurance Certificate the firm has provided copies. • Valid and notarized Authorization letter, the firm has provided photocopy

		MPH Medical Devices s.r.o. Pardubicka 1571, 535 01 Prelouc, Czech Republic. FSC: Germany Date of issue: 05-11-2018	Codes: 5204976, 5204984, 5204992, 5205000, 5205018, 5205026, 5205034, 5205042, 5205050, 5205255, 5205263, 5205271, 5208000, 5208020, 5208080, 5208090. 5208599, 5211280 Class : B Shelf Life : 3 Years	
40.	M/s. Cardiac Care, 848-C, Shadman-1, Lahore 54610, Pakistan ELI: 00070 Evaluator: AD-VII [1503-P]	Legal Manufacturer: Vygon GmbH &Co KG 100 Prager Ring 100, 52070 Aachen Germany FSC: Germany Date of Issue: : 29-03-2019	Trilysecath Code: 1139 Class-B Shelf Life: 5 years	**Deferred** for provision of following documents:- • Firm applied in Class-B for Hemodialysis, whereas the MDB registered the Central Venous catheters in Class-D/C. • Copy of FSC provided, therefore, provide valid and embassy attested original FSC in the country of origin having the product names/codes present. • Provide claimed shelf life studies. • Provide valid and notarized ISO 13485 certificate and full quality assurance certificate the firm has provided copies. • Provide Valid and notarized Authorization letter, the firm has provided photocopy • Provide Notarized copy of Declaration of Conformity. • Differential Fee of Rs.25,000/-
41.	M/s Care and Cure International, 65-B Satellite Town, Rahim Yar Khan ELI: 00192 Evaluator: AD-VII [2206]	Legal Manufacturer: M/s Shandong Chengwu Medical Products Factory, Southern end of Huxin Road Chengwu Country Heze City, Shandong Provice, P.R.C FSC: China Valid until: 09.03.2022	Cure IV set Disposable Infusion Set (Disposable Infusion set with Y port) Codes & Sizes: As per FSC Class-B shelf Life: 5 years	**Deferred** for provision of following documents:- • Valid and embassy attested original FSC in the country of origin having the exact product names/codes present. Clarify the name. furthermore, the copy of FSC provided has written "to be Manufactured and exported in china" • Provide claimed shelf life studies, the firm has not provided stability studies. • The product is from non-reference country therefore Provide valid and notarized all CE marking certificates issued by the Cabe present in the Nando data base having scope of CE certification or provide reference regulatory authority FSC. • Provide valid and notarized ISO 13485 Certificate. The firm has provided copy. • Provide Valid and notarized and original Authorization letter. • Credential the firm has provided photocopy • Provide notarized DOC.
42.	-do- Evaluator: AD-VII [2207]	**Legal Manufacturer:**	Cure IV Burette 100 ml and 150 ml	**Deferred** for provision of following documents:- • Valid and embassy attested original FSC in the country of origin having the exact product

		M/s Shandong Chengwu Medical Products Factory, Southern end of Huxin Road Chengwu Country Heze City, Shandong Provice, P.R.C FSC: China Valid until : 09.03.2022	Codes & Sizes: As per FSC Class-B shelf Life: 5 years	names/codes present. Clarify the name. furthermore, the copy of FSC provided has written "to be Manufactured and exported in china" • Provide claimed shelf life studies, the firm has not provided stability studies. • The product is from non-reference country therefore Provide valid and notarized all CE marking certificates issued by the CAB present in the NANDO data base having scope of CE certification • Provide reference regulatory authority FSC. • Provide valid and notarized ISO 13485 Certificate. The firm has provided copy. • Provide Valid and notarized and original Credential the firm has provided photocopy. Also provide notarized DOC
43.	M/s Shafia Enterprises, Shafia Enterprises 2nd Floor, Nigar Centre, Patiala Ground Link Meleod Road, Lahore ELI:00766 Evaluator: AD-VII [2758]	Legal Manufacaturer: M/s Haiyan Kangyuan Medical Instrument Co., Ltd, Songpodong Road, Shendang Town, Haiyan, Zhejiang China FSC: China Date of Issue: 23.04.2019	Foley catheter (Urinary Catheter for single use : Latex Silicon Coated two Way) Sizes: 6Fr, 8Fr, 10Fr, 12Fr, 16Fr, 18Fr, 20Fr, 22Fr, 24Fr, 26Fr, 28Fr. Class-C Shelf Life: As per stability study	**Deferred** for provision of following documents:- • Copy of Certificate of exportation provided therefore, provide valid and embassy attested original FSC in the country of origin having the product names/codes present. • Provide claimed shelf life studies, the firm has not provided stability studies. • The product is from non-reference country therefore Provide valid and notarized all CE marking certificates issued by the Cabe present in the Nando data base having scope of CE certification. Provide original and embassy attested Reference Regulatory Authority FSC. • Provide valid and notarized ISO 13485 Certificate. The firm has provided copy. • Provide Valid and notarized Authorization letter, Credential. The firm has provided photocopy
44.	M/s Uniplan Trade International Private Ltd 132/2 Quaid-e-Azam Industrial estate, Kot, Lakhpat Lahore. ELI: 00132 Evaluator: AD-VII [1759-P]	Legal Manufacturer: M/s Chengdu OCI Medical Devices Co., Ltd No. 2401, west Port Avenue, Southwest Airport Economic Development Zone, Shuangliu District Chengdu, Sichuan Province, China FSC: Valid until : 20.02.2021	Polyethersulfone Hollow Fiber Hemodialyzer Code & Sizes: As per FSC Class: C Shelf Life: 3 years	**Deferred** for provision of following documents:- • Certificate for exportation of Medical Products provided was valid upon submission now expired, therefore, provide valid and notarized FSC in the country of origin having the product names/codes present. • The grouping of the MD is not clear provide valid grouping under the MDR 2017 • Provide claimed shelf life studies for low flux Polyethersulfone Hollow Fiber Hemodialyzer. The firm has provided for Hiflux Polyethersulfone Hollow Fiber Hemodialyzer • The product is from non-reference country therefore, Provide valid and notarized all CE marking certificates issued by the Cabe present in the Nando data base having scope of CE certification. Provide reference regulatory authority FSC. • Provide Valid and notarized credential of the firm which has not been provided.

				• Provide valid and notarized ISO 13485 Certificate of the sterilization sites including Zhngjin Irradioation chendu co Ltd
45.	Mana & Co. Office # 401, 4th Floor, Masood Chamber, Shahrah-e-Liaqut, Karachi (ELI-00098) Evaluator: AD-VII [2679]	Legal Manufacturer: Promisemed Hangzhou Meditech Co., Ltd No. 12 Longtan Road, Cangqian Street, Yuhan District, Hangzhou City, 311121 Zhejhiang, China FSC valid until 7-10-2021	Medicare Insulin Pen Needles Class B Shelf life 5 years Codes & Sizes as per FSC	**Deferred** for provision of following documents:- • Copy of Certificate for exportation of Medical Products provided was valid upon submission now expired, therefore, provide valid and notarized FSC in the country of origin • The grouping of the MD is not clear provide valid grouping under the MDR 2017. • Provide claimed shelf life studies (real time studies) • The product is from non-reference country therefore, Provide valid and notarized all CE marking certificates issued by the Cabe present in the Nando data base having scope of CE certification. Provide original and embassy attested reference regulatory authority FSC. • Provide Valid and notarized LOA, DOC and credential of the firm. In the authorization letter Promisemed Medical Devices Inc , Canada written, however the same is not found on other documents submitted including DOC, FSC, ISO etc. Clarify? • Provide valid and notarized ISO 13485. The firm has provided photocopy.
46.	SK Surgical 60C Mezannie floor, 111th Commercial Street DHA Phase II Ext Karachi Pakistan Evaluator: AD-VII [2632]	Legal Manufacturer: Canwell Medical Co Ltd No. 466 South Xianhua Street Jinhua 321000 Zhejiang China	Canwell Metal Bone Plates Class C Shelf life 5 years Codes & Sizes as per FSC FSC valid until 29.11.2019	**Deferred** for provision of following documents:- • Expired Certificate for exportation of Medical Products provided therefore, provide valid original and embassy attested FSC in the country of origin having the product names/codes present. • Provide claimed shelf life studies particularly for sterilization. • The product is from non-reference country therefore, Provide valid and notarized all CE marking certificates issued by the Cabe present in the Nando data base having scope of CE certification. Provide reference regulatory authority FSC.(FQA provided). • Provide valid LOA the already submitted has been expired after submission. • Provide valid and notarized ISO 13485 Certificate. The certificate was valid upon submission, however expired now.
47.	M/s Al-Amin Associates, 125-Habitat Flats, Shadman-II, Lahore ELI: 00104 Evaluator: AD-VII [3014]	Legal Manufacturer: M/s Quantel Medical, 11 rue du Bois. Joil, CS 40015 63808 Cournon D' Auvergne Cedex France FSC: France Date of issue: 09/07/2021	Vitra Multispot 532nm Laser (Ophthalmologic Multispot Photocoagulator laser) Codes & Sizes: As per FSC Class-C Shelf Life: 5 years	**Deferred** for provision of following documents:- • Brand name on LOA not present provide Clarification or provide Original and Notarized LOA having name of the product. • Provide Stability studies/ service life protocol of the product. The firm has not provided these. • Provide Notarized Credential of the company.

48.	-do- Evaluator: AD-VII [3015]	Legal Manufacturer: M/s Quantel Medical, 11 rue du Bois. Joil, CS 40015 63808 Cournon D' Auvergne Cedex France FSC: France Date of issue: 09/07/2021	Vitra2 (Retinal Photocoagulator Laser) Codes & Sizes: As per FSC Class-C Shelf Life: 5 years	**Deferred** for provision of following documents:- • Provide Stability studies/ service life protocol of the product. The firm has not provided these. • Provide Notarized Credential of the company.
49.	-do- Evaluator: AD-VII [3016]	Legal Manufacturer: M/s Quantel Medical, 11 rue du Bois. Joil, CS 40015 63808 Cournon D' Auvergne Cedex France FSC: France Date of issue: 09/07/2021	Vitra 810 (Retinal Photocoagulator Laser) Codes & Sizes: As per FSC Class-C Shelf Life: 5 years	**Deferred** for provision of following documents:- • Provide Stability studies/ service life protocol of the product. The firm has not provided these. • Provide Notarized Credential of the company.
50.	-do- Evaluator: AD-VII [3017]	Legal Manufacturer: M/s Quantel Medical, 11 rue du Bois. Joil, CS 40015 63808 Cournon D' Auvergne Cedex France FSC: France Date of issue: 09/07/2021	EASY RET 577 nm Laser (Ophthalmologic Photocoagulator laser) Codes & Sizes: As per FSC Class-C Shelf Life: 5 years	**Deferred** for provision of following documents:- • Provide Stability studies/ service life protocol of the product. The firm has not provided these. • Provide Notarized Credential of the company.
51.	M/s Shaad Traders, 2nd Floor, Ehsan Tower, Near Abaseen Flour Mill, Dalazak Road Peshawar ELI: 00809 Evaluator: AD-VII	Legal Manufacturer: M/s Pleasure Latex Products Sdn Bhd, Lot 5322 15th Miles, Jalan Padang Gajah 48500 Heram, Selangor, Malaysia FSC: Malaysia Valid Till: 30/06/2022	MIXFUN (Natural rubber Latex male condom Codes & Sizes: As per FSC Class-C Shelf Life: 5 years	**Deferred** for provision of following documents:- • Provide Original embassy attested FSC in the country of origin. • Provide valid and notarised ISO 13485 certificate. • Provide Notarised and valid Full Quality assurance certificate. • Provide valid, original and notarized letter of Authorization,since the provided is a copy. • Provide DOC and Essential principles of safety and performance of the product.
52.	M/s Muaaz Medical Traders, Office No. 401-402, 6th Floor, saith center 10-syed Moj Darya Road, Lahore ELI: 00574 Evaluator: AD-VII [2902]	Legal Manufacturer: M/s Changsha Sinocare Inc. No. 265, Guyuan Road, Hi- Tech Zone, Changsha, Hunan Province 410205, People's Republic of China FSC: China	Safe AQ UG (Blood Glucose and Uric Acid Monitoring System) Codes & Sizes: As per FSC Class-C Shelf Life: 5 year	**Deferred** for provision of following documents:- • Provide valid original and embassy attested FSC having name of the product , since the firm has provided expired FSC. • The product is from non-reference regulatory authority. Therefore Provide embassy attested original and valid FSC of Germany. The firm has provided a copy. Or Provide valid and notarized all CE marking certificates issued by the Cabe present in the Nando data base having scope of CE certification. • Stability studies / Service life studies not provided

		Valid till 16.06.2021		• Provide valid and notarised ISO 13485 certificate, the original and notarized submitted has been expired • Provide Notarised and valid Full Quality assurance certificate, the submitted is copy. • Provide valid, original and notarized letter of Authorization, since the only copy is provided. • Provide Essential principle of safety and performance.
53.	-do- Evaluator: AD-VII []	Legal Manufacturer: M/s Changsha Sinocare Inc. No. 265, Guyuan Road, Hi- Tech Zone, Changsha, Hunan Province 410205, People's Republic of China FSC: China Valid till: 16.06.2021 FSC Germany issued on 13.09.2019	Safe AQ Blood Glucose Test Strips (Blood Glucose strip) Codes & Sizes: As per FSC Class-C Shelf Life:24 months	**Deferred** for provision of following documents:- • Provide valid original and embassy attested FSC having name of the product, the firm has provided expired FSC. • The product is from non-reference regulatory authority. Therefore Provide embassy attested original and valid FSC of Germany. The firm has provided a copy. Or Provide valid and notarized all CE marking certificates issued by the Cabe present in the Nando data base having scope of CE certification. • The model *Safe AQ Blood Glucose Test Strips* not present in both FSCs. Provide clarification. • Provide valid and notarised ISO 13485 certificate, the submitted has been expired • Provide Notarised and valid Full Quality assurance certificate, the submitted is copy. • Provide valid, original and notarized letter of Authorization, since the only copy is provided. • Provide Essential principle of safety and performance.
54.	-do- Evaluator: AD-VII	Legal Manufacturer: M/s Changsha Sinocare Inc. No. 265, Guyuan Road, Hi- Tech Zone, Changsha, Human Province 410205, People's Republic of China FSC: China Valid till: 16.06.2021	Safe AQ Voice (Blood Glucose Monitoring System) Codes & Sizes: As per FSC Class-C Shelf Life: meter 10 years	**Deferred** for provision of following documents:- • Provide valid original and embassy attested FSC having name of the product, the firm has provided expired FSC. • The product is from non-reference regulatory authority. Therefore Provide embassy attested original and valid FSC of Germany. The firm has provided a copy. Or Provide valid and notarized all CE marking certificates issued by the Cabe present in the Nando data base having scope of CE certification. • The model *Safe AQ voice* not present in China FSC. Provide clarification. • Stability studies / Service life studies not provided • Provide valid and notarised ISO 13485 certificate, submitted has been expired • Provide Notarised and valid FQA certificate, the submitted is copy. • Provide valid, original and notarized letter of Authorization, since the only copy is provided. • Provide Essential principle of safety and performance
55.	-do- Evaluator: AD-VII	Legal Manufacturer: M/s Changsha Sinocare Inc. No. 265, Guyuan Road, Hi- Tech Zone, Changsha, Human Province 410205,	Safe AQ UG (Blood Glucose and Uric Acid Monitoring System) Codes & Sizes: As per FSC Class-C	**Deferred** for provision of following documents:- • Provide valid original and embassy attested FSC having name of the product , the firm has provided expired FSC. • The product is from non-reference regulatory authority. Therefore, Provide embassy attested original and valid FSC of Germany. The firm has

		People's Republic of China FSC: China Valid till: 16.06.2021	Shelf Life: meter 5 years Glucose Strip 24 months Uric acid strip 12 ,moths	provided a copy. Or Provide valid and notarized all CE marking certificates issued by the Cabe present in the Nando data base having scope of CE certification. • Stability studies of glucose strips / Service life studies of the meter not provided • Provide valid and notarised ISO 13485 certificate, the submitted has been expired • Provide Notarised and valid FQA certificate, the submitted is copy. • Provide valid, original and notarized letter of Authorization, since the only copy is provided. • Provide Essential principle of safety and performance
56.	IBL Healthcare Limited 9th Floor NICL Building, Abbasi Shaheed Road Karachi (ELI-00119) Evaluator: AD-VII	G&G Contact Lens (Beommul-dong), 401,402,502,701,802, 93 Beoman-ro, Suseong-gu, Daegu, Korea FSC: Korea (Original) Issued: 3-5-2021	Lacelle Tri-Kolor Soft Contact Lens Class B Shelf life 5 years	**Deferred** for provision of following documents:- • The product is from non-reference country therefore, Provide valid and notarized all CE marking certificates issued by the Cabe present in the Nando data base having scope of CE certification. Provide original, valid and embassy attested FSC of any reference regulatory authority. • Provide valid and notarized ISO 13485, notarized provided but expired after submission.
57.	M/s Medical Equipment and Systems, 60/61 F.C.C Syed Maratib Ali road, Gulberg IV, Lahore. ELI: 00554 2957-P Evaluator: AD-IX	Legal Manufacturer: M/s Atom Medical Corporation 18-15, Hongo 3-Chome, Bunkyo-ku, Tokyo, 113-0033 Japan. FSC:	Air Incu i (Infant Incubator) Models/Codes/Sizes: Class-C Shelf Life: months Storage conditions: 2-8°C	**Deferred** for provision of following documents:- • notarized Letter of Authorization mentioning complete name and address of the applicant and the applied product. • MRP of the product since it is not mentioned in Form 7A. • original, legalized and valid Free Sale Certificate. • Notarized and valid ISO-13485 and Full Quality Assurance Certificate. • service life of the applied product along with the supporting data.
58.	M/s Optimus Entrepot, 194-F/1 Block Johar Town, Lahore. ELI: 00125 2962-P Evaluator: AD-IX	Legal Manufacturer: M/s Alsanza Meizintechnik und Pharma GmbH Hermann-Gurlhradt Str. 3 D-72793, Pfullingen, Germany. FSC: Germany (No. Leg.Reg.Nr.70/2021) issued on 27/01/2021.	Alsee (Opthalmic Viscosurgical Device) Model: M061 Diopter Range: - Class-C Shelf Life: 2 years	**Deferred** for provision of following documents:- • Valid distribution agreement/ letter of authorization mentioning the name of the applied product. • dioptric range of the applied medical device.
59.	-do- 2968-P Evaluator: AD-IX	Legal Manufacturer: M/s Alsanza Meizintechnik und Pharma GmbH Hermann-Gurlhradt Str. 3 D-72793, Pfullingen, Germany. FSC: Germany (No. Leg.Reg.Nr.70/2021	Alsiol (Posterior Chamber Intraocular Lens) Model: M035 Diopter Range: -20D to +45D with 0.5D increment Class-C Shelf Life: 5 years	**Deferred** for provision of following documents:- • The submitted stability studies data does not cover all the applied lenses of dioptric powders, therefore, submit stability studies supporting the claimed shelf life of 5 years for the applied lenses. • Valid distribution agreement/ letter of authorization mentioning the name of the applied product.

		) issued on 27/01/2021.		
60.	-do- 2968-P Evaluator: AD-IX	Legal Manufacturer: M/s Alsanza Meizintechnik und Pharma GmbH Hermann-Gurlhradt Str. 3 D-72793, Pfullingen, Germany. FSC: Germany (No. Leg.Reg.Nr.70/2021) issued on 27/01/2021.	Alsacell 2% (Opthalmic Viscosurgical Device) Model: MV032 Class-C Shelf Life: 2 years	**Deferred** for provision of Valid distribution agreement/ letter of authorization mentioning the name of the applied product.
61.	-do- 2965-P Evaluator: AD-IX	Legal Manufacturer: M/s Alsanza Meizintechnik und Pharma GmbH Hermann-Gurlhradt Str. 3 D-72793, Pfullingen, Germany. FSC: Germany (No. Leg.Reg.Nr.70/2021) issued on 27/01/2021.	Alsafit Fourier (Posterior Chamber Intraocular Lens) Diopter Range: -20D to +45D Model: M073 Class-C Shelf Life: 3 years	**Deferred** for provision of following documents: - • The submitted stability studies data does not cover all the applied lenses of dioptric powders, therefore, submit stability studies supporting the claimed shelf life of 5 years for the applied lenses. • Valid distribution agreement/ letter of authorization mentioning the name of the applied product.
62.	-do- 2964-P Evaluator: AD-IX	Legal Manufacturer: M/s SAV-IOL SA Route des Falaises 74 2000 Neuchatal, Switzerland. FSC: Switzerland, (No. FSC-17-22317) valid till 22/10/2020.	Eden Toric (Posterior Chamber Intraocular Lens) Diopter Range: +5D to +30D with n increment of 0.5D Model: 108MT/10.8mm & 124MT/12.4mm Class-C Shelf Life: 5 years	**Deferred** for provision of following documents:- • valid and notarized ISO-13485 certificate. • original, legalized and valid Free Sale Certificate since the submitted copy is expired. • Two models/Sizes (108MT/10.8mm & 124MT/12.4mm) are applied against one registration application while registration of one model/size will be granted against one application. Please select one model/size so that your application may be processed. • The brand name on the submitted label, free sale certificate and DOC is different from the brand name mentioned in Form 7A and full quality assurance certificate.
63.	-do- 2963-P Evaluator: AD-IX	Legal Manufacturer: M/s SAV-IOL SA Route des Falaises 74 2000 Neuchatal, Switzerland. FSC: Switzerland, (No. 0008777) valid till 11/01/2024.	Lucidis Toric (Posterior Chamber Intraocular Lens) Diopter Range: Model: 108MT/10.8mm & 124MT/12.4mm Class-C Shelf Life: 5 years	**Deferred** for provision of following documents:- • Notarized ISO-13485 certificate. • original, legalized and valid Free Sale Certificate since the submitted copy is expired. • Two models/Sizes (108MT/10.8mm & 124MT/12.4mm) are applied against one registration application while registration of one model/size will be granted against one application. Please select one model/size so that your application may be processed. • The brand name on the submitted label, free sale certificate and DOC is different from the brand name mentioned in Form 7A and full quality assurance certificate. • dioptric range for the applied lens. • stability studies supporting the claimed shelf life of the product.

64.	M/s Optisurg, 17/C-1, Valancia town, Lahore ELI: 00305 2915-P Evaluator: AD-IX	Legal Manufacturer: M/s Hoya Medical Singapore Pte Ltd, 455A, Jalan Ahmad Ibrahim, Singapore. Manufacturing facility: M/s Hoya Lamphun Ltd., 75/2 MOO 4, Tambol Banklang, Amphur Muang, Lamphun 51000, Thailand. FSC: • Singapore, (FSC/3360/2021) issued on 22/11/2021. • Thailand (No.1-1-03-02-21-01797) issued on 08/11/2021. • Germany (No.56-53o12(085-00079) issued on 26/11/2021.	HOYA Nanex™ Multisert+™ (Preloaded Intraocular Lens) Codes & Sizes: NY1-SP (+6D to +30D with an increment of 0.5) NC1-SP (+6D to +30D with an increment of 0.5) Class-C Shelf Life: 3 years	**Deferred** for provision of following documents:- • Two models/ Sizes (NY1-SP & NC1-SP) are applied against one registration application while registration of one model/size will be granted against one application. Please select one model/size so that your application may be processed. • label of the applied medical device
65.	M/s Sind Medical Stores,13-B, block 6, PECHS, Shahrah e Faisal, Karachi, 75400, Pakistan. ELI: 00010 4455 Evaluator: AD-IX	Legal Manufacturer: M/s Bio-Rad Medical Diagnostics GmbH IndustriesStrasse.1, 63303 Dreieich, Germany. FSC: Germany (No. 56-53o12(012-00059) issued on 14/05/2021.	Polyspecific Anti-Human Globulin Complement IVD Models/Codes/Sizes: Anti-Human-Globulin 10mL (804020) Anti-Human-Globulin Color 10×10mL (804115) Anti-Human-Globulin Color 10mL (804120) Anti-Human-Globulin Color 50mL (804130) Class-D Shelf Life: 27 months Storage conditions: 2-8°C	**Deferred** for provision of following documents:- • Notarized and valid design examination certificate and full quality assurance certificate mentioning the name of the applied medical device. • Explaination regarding the difference between Anti-human globulin colors with codes 804115, 804120 & 804130 in term of their usage.
66.	-do- 4454 Evaluator: AD-IX	Legal Manufacturer: M/s Bio-Rad Medical Diagnostics GmbH IndustriesStrasse.1, 63303 Dreieich, Germany. FSC: Germany (No. 56-53o12(012-00059) issued on 14/05/2021.	Rare Red Blood Cells Grouping IVD-Antibody (Diagnostic Reagent for In-Vitro Use) Models/Codes/Sizes: Seraclone Anti-C (RH2) 802280 (5mL), 802282 (10mL), Seraclone Anti-C (RH4) 802346 (5mL), 802348 (10mL) Seraclone Anti-E (RH3) 802330 (5mL), 802331 (10mL), Seraclone Anti-E (RH5) 802370 (5mL), 802372 (10mL)	**Deferred** for provision of following documents:- • Notarized & valid design examination certificate and full quality assurance certificate mentioning the name of the applied medical device. • Notarized and valid IsO-13485 certificate is also required. • The grouping of the applied medical device is not clear. The submitted application is for Seraclone Anti-C (RH2), Seraclone Anti-C (RH4), Seraclone Anti-E (RH3), Seraclone Anti-E (RH5), Seraclone Anti-CDE (RH2,1,3), Seraclone Anti-K (KEL1), Seraclone Anti-Fy^{a} (FY1), Seraclone Anti-FY^{b} (FY2), Seraclone Anti-JK^{a} (JK1) and Seraclone Anti-JK^{b} (JK2) one IVD or set of IVDs used for the determination of same antigen from the above mentioned IVDs for

			Seraclone Anti-CDE (RH2,1,3) 802080 (10mL), Seraclone Anti-K (KEL1) 808090 (5mL), Seraclone Anti-Fy^a (FY1) 808188 (2mL), Seraclone Anti-FY^b (FY2) 808191 (2mL), Seraclone Anti-JK^a (JK1) 808179 (2mL), Seraclone Anti-JK^b (JK2) 808184 (2mL) Class-D Shelf Life: 15 months with storage condition of 2-8°C.	consideration of registration against the submitted application Since registration for all the above mentioned IVDs cannot be granted against one application or otherwise justified. • notarized Declaration of Conformity and design examination certificate of the applied device accordingly.
67.	-do- 4453 Evaluator: AD-IX	Legal Manufacturer: M/s Bio-Rad Medical Diagnostics GmbH IndustriesStrasse.1, 63303 Dreieich, Germany. FSC: Germany (No. 56-53o12(012-00059) issued on 14/05/2021.	Rare Blood Cells Grouping IVD Antibody (Rare Red Blood Cells Grouping IVD) Models/Codes/Sizes: Seraclone Anti-C (RH8) 802155 (5mL), Seraclone Anti-K (KEL2) 808126 (2mL), Seraclone Anti-M (MNS1) 808410 (2mL), Seraclone Anti-N (MNS2) 808415 (2mL), Seraclone Anti-S (MNS3) 808052 (2mL), Seraclone Anti-s (MNS4) 808068 (2mL), Seraclone Anti-P1 (P1) 808158 (2mL), Seraclone Anti-Le^b (LE2) 808423 (2mL), Seraclone Anti-Lu^b (LU2) 808227 (2mL), Seraclone Anti-Le^a (LE1) 808404 (2mL) Seraclone Anti-Kp^a (KEL3) 808131 (2mL), Seraclone Anti-Kp^b (KEL4) 808141 (2mL) Seraclone Anti-Lu^a (LU1) 808216 (2mL), Seraclone Anti-Wr^a (DI3) 808260 (2mL) Class-D Shelf Life: 9 months with storage condition of 2-8°C.	**Deferred** for provision of following documents: • notarized full quality assurance certificate mentioning the name of the applied medical device. Moreover, notarized and valid ISO-13485 certificate is also required. • The grouping of the applied medical device is not clear. The submitted application is for Seraclone Anti-C (RH8), Seraclone Anti-K (KEL2), Seraclone Anti-M (MNS1), Seraclone Anti-N (MNS2), Seraclone Anti-S (MNS3), Seraclone Anti-s (MNS4), Seraclone Anti-P1 (P1), Seraclone Anti-Le^b (LE2), Seraclone Anti-Lu^b (LU2), Seraclone Anti-Le^a (LE1), Seraclone Anti-Kp^a (KEL3), Seraclone Anti-Kp^b (KEL4), Seraclone Anti-Lu^a (LU1), Seraclone Anti-Wr^a (DI3). Therefore you are required to select one IVD or set of IVDs used for the determination of same antigen from the above mentioned IVDs for consideration of registration against the submitted application Since registration for all the above mentioned IVDs cannot be granted against one application or otherwise justified. Moreover, provide notarized Declaration of Conformity and design examination certificate of the applied device accordingly.
68.	-do- 4452 Evaluator: AD-IX	Legal Manufacturer: M/s Bio-Rad Medical Diagnostics GmbH IndustriesStrasse.1, 63303 Dreieich, Germany.	ABO/Rh (D) Blood Grouping IVD-Antibody Models/Codes/Sizes: Seraclone Anti-A (ABO1) 801320 (10mL), Seraclone Anti-A (ABO1) 801325 (10×10mL),	**Deferred** for provision of following documnetns: • notarized & valid full quality assurance certificate mentioning the name of the applied medical device. Moreover, notarized and valid ISO-13485 certificate is also required.

		FSC: Germany, (No. 56-53o12(012-00059) issued on 14/05/2021.	Seraclone Anti-B (ABO2) 801345 (10mL), Seraclone Anti-B (ABO2) 801350 (10×10mL), Seraclone Anti-AB (ABO3) 801370 (10mL), Seraclone Anti-AB (ABO3) 801375 (10×10mL), Seraclone Anti-D (RHI) 226 802039 (10mL), Seraclone Anti-D (RH1) 226 802042 (10×10mL), Seraclone Anti-D (RH1) 232 802054 (10mL), Seraclone Anti-D (RH1) 802032 (10mL) Seraclone Anti-D (RH1) 802033 (10×10mL) Class-D Shelf Life: 24 months with storage condition of 2-8°C.	▪ The grouping of the applied medical device is not clear. The submitted application is for Seraclone Anti-A (ABO1), Seraclone Anti-A (ABO1), Seraclone Anti-B (ABO2), Seraclone Anti-B (ABO2), Seraclone Anti-AB (ABO3), Seraclone Anti-AB (ABO3), Seraclone Anti-D (RHI) 226, Seraclone Anti-D (RH1) 226, Seraclone Anti-D (RH1) 232, Seraclone Anti-D (RH1), Seraclone Anti-D (RH1). Therefore, you are required to select one IVD or set of IVDs used for the determination of same antigen from the above mentioned IVDs for consideration of registration against the submitted application Since registration for all the above mentioned IVDs cannot be granted against one application or otherwise justified. Moreover, provide notarized Declaration of Conformity of the applied device accordingly.
69.	M/s Lab Links, 14-Khan Arcade, 16-Mouj Darya Road, Lahore ELI: 00573 [2348-P] Evaluator AD-II	Legal Manufacturer/Site: Dia.Pro Diagnostic Bioprobes S.r.l, Via G, Carducci No. 27, 20099 Sesto San Giovanni (MI) Italy FSC (scanned copy): Italy Date of issue: 27.03.2020	HEV IgM (Enzyme Linked Immunoassay (ELISA) for the Determination of IgM antibodies to Hepatitis E Virus in Human Serum and Plasma) Codes & Sizes: EVG.CE (96 tests) Class: C Shelf Life: 15 months	**Deferred** for provision of following documents:- ▪ Brand name of applied MD since HEV IgM from the same legal manufacturer has also been applied by M/s Azad Scientific, Lahore for registration ▪ Original FSC duly attested by embassy of Pakistan since scanned copy is provided. ▪ Credentials of manufacturer abroad as per format approved in 3rd meeting of MDB. ▪ Form 7A is not duly signed and stamped. ▪ Original LoA duly notarized by the country of origin ▪ Valid ISO 13485 certificate duly notarized by the country of origin ▪ FQA certificate duly notarized by the country of origin. ▪ The grouping of MD in line with MDR 2017 ▪ Declaration on stamp paper as per form 7A
70.	-do- [2369-P] Evaluator AD-II	Legal Manufacturer: Dia.Pro Diagnostic Bioprobes S.r.l, Via G, Carducci No. 27, 20099 Sesto San Giovanni (MI) Italy FSC (copy): Italy Date of issue: 27.03.2020	HAV IgM (Enzyme Linked Immunoassay (ELISA) for the Determination IgM antibodies to Hepatitis A virus in Human Serum and Plasma) Codes & Sizes: AVM.CE (96 tests) Class-C Shelf Life: 15 months	**Deferred** for provision of following documents:- ▪ Brand name of MD ▪ Original FSC duly attested by embassy of Pakistan since scanned copy is provided. ▪ Credentials of manufacturer abroad as per format approved in 3rd meeting of MDB. ▪ Form 7A is not duly signed and stamped. ▪ Original LoA duly notarized by the country of origin ▪ ISO 13485 certificate duly notarized by the country of origin ▪ FQA certificate duly notarized by the country of origin. ▪ Grouping of MD in line with MDR 2017 ▪ Declaration on stamp paper as per form 7A
71.	M/s Azad Scientific Office No. 3/B Mouj	Legal Manufacturer M/s Dia.pro-	HEV IgM ELISA Kit 96 Test	**Deferred** for provision of following documents:- ▪ The firm has deposited fee Rs. 50,000/- for

	Darya Road, Near AG Office, Lahore ELI: 00349 2255-P Evaluator AD-II	Diagnostics Bioprobes srl, Via Giosue Carducci, 27 20099 Sesto San Giovanni Milano (MI) Italy FSC: Italy (original embassy attested) Date of issue: 27.03.2020	Codes: EVM.CE Class-C Shelf Life: 15 months	registration under the head 1428 (Biological drugs registration fee) instead of 1424 (MDMC registration fee). ▪ Brand name of applied MD ▪ Original FSC duly attested by embassy of Pakistan ▪ FQA certificate duly notarized by the country of origin. ▪ The grouping of MD in line with MDR 2017 ▪ Credentials of manufacturer abroad as per format approved in 3rd meeting of MDB. ▪ original LoA duly notarized by the country of origin ▪ Valid ISO 13485 certificate duly notarized by the country of origin. ▪ FQA certificate duly notarized by the country of origin. ▪ The grouping of MD in line with MDR 2017
72.	M/s SES Associates, 148-Ejaz Park, Model Town Link Road, Lahore ELI: 00041 2502 Evaluator AD-II	Legal Manufacturer: M/s AndraTec GmbH Simmerner Str. 70 D-56075 Koblenz, Germany FSC: Germany Date of issue: 11.02.2021	Optimus-CVS PTFE-Covered Stent (Stent, Vascular) Codes & Sizes: As per FSC Class- C Shelf Life: 4 years	**Deferred** for provision of following documents:- • Differential fee Rs.25,000/- is required, since the firm has applied in Class-B but as per DOC the applied MD belongs to class IIb. • Original FSC duly attested by embassy of Pakistan or reference of dossier where original FSC is attached. The provided FSC is copy originally attested by embassy of Pakistan. • FQA certificate originally notarized from the country of origin. • Credentials of manufacturer abroad duly notarized from the country of origin. • Original Agency agreement or letter of authorization from manufacturer (legal) / owner or market authorization holder (MAH) or its authorized distributer, containing name and complete address of manufacturer, product or category of medical device(s), validity of agreement, duly notarized by the country of origin • Stability studies data supporting claimed shelf life. • Provided manual in German language, submit the document with English translation duly notarized. • Valid ISO 13485 certificate duly notarized by the country of origin.
73.	Tri-Tech International 10-C, 6th Sunset Commercial Lane, Phase 2 Ext, DHA, Karachi. ELI-00247 2841	Legal manufacturer M/s BISTOS CO., Ltd 7th Fl., A Bldg., Woolim Lions Valley 5-Cha, 302, Galmachi-ro, Jungwon-gu, Seongnam-si,	BISTOS (Patient Monitor) Codes: BT-720 BT-740 BT-770 Class-C	**Deferred** for provision of following documents:- ▪ Original and valid free sale certificate of any RRA, as per rule 67, duly attested by embassy of Pakistan or CE certification or WHO pre-qualification in the light of Rule 67 of rules ibid. ▪ Documentation on software validation studies to verify the correctness of software in medical

	Evaluator AD-II	Gyeonggi-d0, KOREA FSC: Korea (original in dossier No. 2845) Date of issuance: 21-01-2020	Shelf life: 5 years	device. The document shall include the results of all verification, validation and testing performed prior to final release. ▪ Original valid LOA duly notarized by country of origin. ▪ Original valid ISO 13485 certificate duly notarized by country of origin.
74.	-do- 2848 Evaluator AD-II	Legal manufacturer M/s BISTOS CO., Ltd 7th Fl., A Bldg., Woolim Lions Valley 5-Cha, 302, Galmachi-ro, Jungwon-gu, Seongnam-si, Gyeonggi-d0, KOREA FSC: Korea (original in dossier No. 2845) Date of issuance: 21-01-2020	BISTOS (PULSE OXIMETER) Code: BT-700 Class-C Shelf life: 5 years	**Deferred** for provision of following documents:- ▪ Original and valid free sale certificate of any RRA, as per rule 67, duly attested by embassy of Pakistan or CE certification or WHO pre-qualification in the light of Rule 67 of rules ibid. ▪ Documentation on software validation studies to verify the correctness of software in medical device. The document shall include the results of all verification, validation and testing performed prior to final release. ▪ Original valid LOA duly notarized by country of origin. ▪ Valid ISO 13485 certificate duly notarized by country of origin
75.	-do- 2845 Evaluator AD-II	Legal manufacturer M/s BISTOS CO., Ltd 7th Fl., A Bldg., Woolim Lions Valley 5-Cha, 302, Galmachi-ro, Jungwon-gu, Seongnam-si, Gyeonggi-d0, KOREA FSC: Korea (original, embassy attested) Date of issuance: 21-01-2020	BISTOS (INFANT INCUBATOR) Code: BT-500 Class-C Shelf life: 2 years	**Deferred** for provision of following documents:- ▪ Original and valid free sale certificate of any RRA, as per rule 67, duly attested by embassy of Pakistan or CE certification or WHO pre-qualification in the light of Rule 67 of rules ibid. ▪ Documentation on software validation studies to verify the correctness of software in medical device. The document shall include the results of all verification, validation and testing performed prior to final release. ▪ Original valid LOA duly notarized by country of origin. ▪ valid ISO 13485 certificate duly notarized by country of origin. ▪ Stability studies data supporting the claimed shelf-life.
76.	-do- 2795 Evaluator AD-II	Legal manufacturer M/s BISTOS CO., Ltd 7th Fl., A Bldg., Woolim Lions Valley 5-cha, 302, Galmachi-ro, Jungwon-gu, Seongnam-si, Gyeonggi-do, KOREA FSC: Korea (original in dossier No. 2845)	BISTOS (Infant Warmer) Codes:BT-550 Class-C Shelf life: 2 years	**Deferred** for provision of following documents:- ▪ Original and valid free sale certificate of any RRA, as per rule 67, duly attested by embassy of Pakistan or CE certification or WHO pre-qualification in the light of Rule 67 of rules ibid. ▪ Documentation on software validation studies to verify the correctness of software in medical device. The document shall include the results of all verification, validation and testing performed prior to final release. ▪ Original valid LOA duly notarized by country of origin. ▪ Provide valid ISO 13485 certificate.

		Date of issuance: 21-01-2020		▪ Provide stability studies data supporting the claimed shelf-life.
77.	-do- 3552 Evaluator AD-II	Legal manufacturer and manufacturing site: M/s Elltec Co., Ltd., Shirakawa No. 6 Bldg., 2-18-5, Nishiki Naka-ku, Nagoya, Aichi, Japan FSC: Japan Date of issuance: 05-08-2020 (Original embassy attested)	ELLTEC Blood/infusion warmer Codes: ANIMEC AM-301-4AF ANIMEC AM-301-5AF Class-C Service life: 5 years	**Deferred** for provision of following documents:- ▪ Original valid Letter of Authorization duly notarized by the country of origin. ▪ Valid ISO 13485 certificate duly notarized by the country of origin. ▪ Valid Full Quality Asurance certificate duly notarized by the country of origin. ▪ Details of QC processes.
78.	-do- 3732 Evaluator AD-II	M/s Jiangsu Yuyue Medical Equipment & Supply Co., Ltd, Yunyang Industrial Park, Danyang City, Jiangsu Province, China. FSC: Germany Date of issuance: 12-10-2020	Yuwell Blood Glucose Monitoring System Model: 710 Class-C Shelf-life: not mentioned	**Deferred** for provision of following documents:- ▪ FSC of country of origin and any RRA duly attested by embassy of Pakistan. ▪ Original valid LoA duly notarized by the country of origin. ▪ Credentials of manufacturer abroad, and ISO 13485 certificate duly notarized by country of origin. ▪ The provided DoC does not cover all the components of glucose monitoring system (only glucose meter is mentioned on DoC) ▪ Details of QC processes.
79.	M/s Hospital Supply Corporation 42 Darul Aman Housing Society, Block 7 & 8, Karachi (ELI-00005) 3327 Evaluator AD-II	Toray Medical (Qingdao) Co., Ltd No. 63 Kongquehe 4 Road, Garment Industrial Zone, Jimo, Qingdao, Shandong Province, 266200 China FSC: China Validity: 30-03-2019	TORAY (Single Patient Dialysis Machine) Model: TQS-88 Class-C Shelf life: 7 years	**Deferred** for provision of following documents:- ▪ Valid original FSC of country of origin & any RRA or CE certification or WHO pre-qualification in the light of Rule 71 of rules ibid. ▪ Stability studies data supporting claimed shelf life. ▪ Credentials of manufacturer abroad duly notarized from the country of origin. ▪ Valid ISO 13485 certificate duly notarized by the country of origin. ▪ FQA certificate or equivalent duly notarized by the country of origin.
80.	Abbott Laboratories (Pakistan) Ltd. Opp. Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, Karachi (ELI-00019) 3365 Evaluator AD-II	Legal manufacturer: Abbott Laboratories Diagnostics Division, Abbott Park, IL 60064 USA Manufacturing sites: Fujirebio Diagnostics, Inc. 201 Great Valley Parkway Malvern, PA USA 19355 Fujirebio Diagnostics, Inc. 940 Crossroads Blvd. Seguin, TX 78155, USA FSC: USA (copy) Validity: 18-05-2022	Alinity i Tacrolimus Reagent Kit Alinity i Tacrolimus Calibrators Alinity i Tacrolimus Whole Blood Precipitation Reagent Codes: as per FSC Class-C Shelf life: 18 months	**Deferred** for provision of following documents:- ▪ Copies of credentials of manufacturer abroad, LOA, FSC, ISO 13845 certificate is provided. ▪ Original Valid FSC of USA duly attested by embassy of Pakistan. ▪ Valid ISO 13485 certificate duly notarized by country of origin

81.	M/s Physiomed Pvt Ltd, 268/3 Kamal Road Saddar, Rawalpindi ELI: 00199 2376 Evaluator AD-II	Legal Manufacturer: Avanos Medical Inc., 5405 Windward Parkway Alpharetta, GA USA Manufacturing Site: Avent S. de R.L. de. C.V Carretera International Salida Norte No. 1053 Magdalena, Sonora Mexico CP 84160 Sterilization Site: Isomedix Operations Inc. 1435 Isomedix Place, El Paso, Texas 79936, USA FSC: US FDA Valid till: 25.03.2022 (unattested copy)	Coolief* Cooled Radiofrequency Fluid Delivery Introducer (Radiofrequency Ablation device) Sterile, single use Codes & Sizes: As per FSC Class-C Shelf Life: 4 years	**Deferred** for provision of following documents:- ▪ Valid, Original LOA, duly notarized in the country of Origin. ▪ Valid and Embassy attested FSC of USFDA. ▪ Valid FQA certificate duly notarized. ▪ Clarify difference in "claimed shelf life" and "limited warranty" as given in IFU. ▪ Notarized copies of ISO 13485 certificate and credentials of manufacturer abroad. ▪ Clarification is required since the sterilization site has not been described by Free Sale certificate. ▪ Price has not been proposed in the submitted dossier, therefore, you are required to provide MRP of the applied product. ▪ Declaration of Conformity to be printed on manufacturer letterhead, filled and duly signed by responsible person. ▪ Label/ brochure/ promotion material etc. as approved in the country of origin for each configuration of the applied MD
82.	M/s Roche Pakistan Limited. 1st Floor, 37-B, Block 6, P.E.C.H.S Karachi (ELI-0009) 3814 Evaluator AD-II	Legal manufacturer and manufacturing site: M/s Roche Diagnostics GmbH Sandhofer Strasse 116 68305 Mannheim, Germany FSC: Germany Date of issuance: 15-03-2017	ACCUTREND PLUS KIT mg/dl Codes: 5050472 Size: 1 unit Class-C Shelf Life: N/A	**Deferred** for provision of following documents:- ▪ Original valid FSC attested by embassy of Pakistan ▪ Original agency agreement with new approved address of distributor, duly notarized by country of origin. ▪ Valid ISO 13485 certificate duly notarized by the country of origin. ▪ FQA certificate duly notarized by the country of origin. ▪ Original duly notarized credentials of manufacturer abroad ▪ Details of quality control processes. ▪ Clarification is required since as per DoC, the applied meter is used for measurement of 4 blood parameters while in form 7-A and package insert 2 parameters is mentioned.
83.	M/s Global Clinical Cura Pvt Ltd., House No. 18, Mian Iqbal Road, Westridge-1 Rawalpindi, Pakistan ELI: 00196 1239 Evaluator AD-II	Legal Manufacturer and manufacturing site: Humasis Co., Ltd Rm 114, 502,504,604,604-1, B03-1, B03-2, 88 Jeonpa-ro, Dongan-gu, Anyang-si Gyeonggi-do, Republic of Korea FSC (original embassy attested): Korea Date of issue: 13.02.2017	Hubi cardiac duo (Tnl/CK-MB) Tnl, CK-MB Determination kinase –MB) ACDC-8025 Class: C Shelf Life: 12 months	**Deferred** for provision of following documents:- ▪ Original and valid FSC of any RRA as per rule 67 duly attested by Embassy of Pakistan ▪ Valid, original LOA duly notarized by the country of origin, the provided scanned copy is expired now but valid upon submission. ▪ GMP and FQA certificates for the applied device, duly notarized by the country of origin. ▪ Valid ISO 13485 certificate duly notarized by the country of origin.

84.	M/s F.W Distributors, Opposite Poonch House, Adamjee Road, Saddar, Rawalpindi ELI: 00221 [2897-P] Evaluator AD-II	Legal Manufacturer: M/s Coloplast A/S Holtedam 1 3050 Humlebaek, Denmark Manufacturing Site: i. M/s Coloplast Manufacturing France SAS 9 Avenue Edmond Rostand CS 70218 24206 Sarlat- la-Caneda Cedax, France ii. M/s Coloplast Manufacturing France SAS ZAC du Clotais 2b, Route du Chemin Blanc 91 160 champlan France. iii. M/s Coloplast Hungary KFT Buzavirag ut 15 2800 Tatabanya Hungary FSC: Denmark (original embassy attested) Valid till: 05.07.2023	Coloplast Biosoft® Duo Multi Length Hydro - Coated Double Loop Ureteral Stent Kit Codes & Sizes: BNGA58 BNGA68 BNGA78 Class-C Shelf Life: 05 years	**Deferred** for provision of following documents:- ▪ ISO 13485/ GMP Certificate duly notarized by the country of origin. ▪ Form 7A is not signed and stamped. ▪ Detail of manufacturing and QC processes. ▪ The Grouping of medical devices in line with MDR 2017 ▪ Complete description with intended use, Key functional elements, formulation & composition with functionality
85.	M/s J.F International, 4th Floor, 10-C, 6th Sunset Commercial Lane Phase 2 Ext, DHA Karachi ELI-00246 2702 Evaluator AD-II	Legal Manufacturer: BIONET CO., LTD 5F, 61 Digital-r0 31 gil, Guro-gu, Seoul, Republic of KOREA Manufacturing Site: Bionet Co., Ltd. 903 Shinil IT UTO, 13 LS-ro, Gunpo-si, Gyeonggi-do 15843 Republic of Korea. FSC: Korea (scanned copy, originally attested) Date of issuance: 17-01-2020	BIONET Fetal Monitor Class: C Codes FC 1400 Service life: 4 years	**Deferred** for provision of following documents:- ▪ Original and valid FSC of any RRA as per rule 67 duly attested by Embassy of Pakistan ▪ Valid FQA and ISO 13485 certificates duly notarized by the country of origin. ▪ Valid Full Quality Assurance certificate duly notarized by the country of origin. ▪ Original valid LOA duly notarized by the country of origin.
86.	M/s S.Ejazuddin & Co., P.O Box 5629 Zia Plaza Altaf Hussain Road Karachi-Pakistan ELI: 00078 [1380-K] Evaluator	Legal Manufacturer and Manufacturing Site: Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-Straße 76 35041 Marburg Germany	Berichrom ® F XIII Berichrom F XIII Code: OWSUII CLASS-C Shelf Life: 24 months	**Deferred** for provision of following documents:- ▪ Only code for Berichrom ® F XIII will be considered in this application, separate applications for Plasma control N, Plasma control P and Standard human plasma need be submitted. ▪ Valid and Original LOA and ISO 13485 certificate duly notarized.

	AD-II	FSC (scanned copy): Germany Date of issue: 29-04-2019		▪ Original FSC duly attested by embassy of Pakistan. ▪ FQA certificate duly notarized by the country of origin. ▪ Declaration (on stamp paper) as per Form-7A.
87.	-do- [1233-K] Evaluator AD-II	Legal Manufacturer and Manufacturing Site: Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-Straβe 76 35041 Marburg Germany FSC (scanned copy): Germany Date of issue: 29-04-2019	Coagulation Factor IX Deficient Plasma (Coagulation Factor IX Deficient Plasma) Code: OTXX17 Class- C Shelf Life: 24 months	**Deferred** for provision of following documents:- ▪ Only code for Coagulation Factor IX Deficient Plasma will be considered in this application, separate applications for Plasma control N, Plasma control P, Standard human plasma, Dade Owren's Veronal buffer, Imidazole Buffer solution and Calcium chloride solution need be submitted. ▪ Original and valid LOA and ISO 13485 certificate duly notarized. ▪ Original FSC duly attested by embassy of Pakistan. ▪ FQA certificate duly notarized by the country of origin. ▪ Declaration (on stamp paper) as per Form-7A.
88.	-do- [1234-K] Evaluator AD-II	Legal Manufacturer and Manufacturing Site: Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-Straβe 76 35041 Marburg Germany FSC (scanned copy): Germany Date of issue: 29-04-2019	Coagulation Factor VIII Deficient Plasma (Coagulation Factor VIII Deficient Plasma) Code: OTXW17 Class- C Shelf Life: 24 months	**Deferred** for provision of following documents:- ▪ Only code for Coagulation Factor VIII Deficient Plasma will be considered in this application, separate applications for Plasma control N, Plasma control P, Standard human plasma, Dade Owren's Veronal buffer, Imidazole Buffer solution and Calcium chloride solution need be submitted. ▪ Original LOA and ISO 13485 certificate duly notarized ▪ Original FSC (scan copy provided). ▪ FQA certificate duly notarized by the country of origin. ▪ Declaration (on stamp paper) as per Form-7A.
89.	-do- [1232-K] Evaluator AD-II	Legal Manufacturer and Manufacturing Site: Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-Straβe 76 35041 Marburg Germany FSC (scanned copy): Germany Date of issue: 29-04-2019	Coagulation Factor II Deficient Plasma Code: OSGR13 CLASS- C Shelf life: 24 months	**Deferred** for provision of following documents:- ▪ Only code for Coagulation Factor II Deficient Plasma will be considered in this application, separate applications for Plasma control N, Plasma control P, Standard human plasma, Dade Owren's Veronal buffer and Imidazole Buffer solution need be submitted. ▪ Original and valid LOA and ISO 13485 certificate duly notarized. ▪ Original FSC duly attested by embassy of Pakistan ▪ FQA certificate duly notarized by the country of origin. ▪ Declaration (on stamp paper) as per Form-7A.
90.	-do- [1236-K] Evaluator AD-II	Legal Manufacturer and Manufacturing Site: Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-Straβe 76 35041	Coagulation Factor V Deficient Plasma Code: ORSM19 Class-C Shelf Life: 18th months	**Deferred** for provision of following documents: - ▪ Only code for Coagulation Factor V Deficient Plasma will be considered in this application, separate applications for Plasma control N, Plasma control P, Standard human plasma, Dade Owren's Veronal buffer and Imidazole Buffer solution need be submitted.

		Marburg Germany FSC (scanned copy): Germany Date of issue: 29-04-2019		▪ Original and valid LOA and ISO 13485 certificate duly notarized. ▪ Providd original FSC duly attested by embassy of Pakistan ▪ FQA certificate duly notarized by the country of origin. ▪ Declaration (on stamp paper) as per Form-7A.
91.	-do- [1309-K] Evaluator AD-II	Legal Manufacturer and Manufacturing Site: Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-Straβe 76 35041 Marburg Germany FSC (scanned copy): Germany Date of issue: 29-04-2019	Coagulation Factor X Deficient Plasma Code: OTXY13 Class: C Shelf Life 24 months	**Deferred** for provision of following documents: - ▪ Only code for Coagulation Factor X Deficient Plasma will be considered in this application, separate applications for Plasma control N, Plasma control P, Dade Owren's Veronal buffer and Imidazole Buffer solution need be submitted. ▪ Original and valid LOA and ISO 13485 certificate duly notarized. ▪ Provide original FSC duly attested by embassy of Pakistan ▪ FQA certificate duly notarized by the country of origin. ▪ Declaration (on stamp paper) as per Form-7A.
92.	-do- [1381-K] Evaluator AD-II	Legal Manufacturer and Manufacturing Site: Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-Straβe 76 35041 Marburg Germany FSC (scanned copy): Germany Date of issue: 29-04-2019	Pathromtin ® SL Reagent Code: OQGS29 OQGS35 Class: C Shelf Life: 24 months	**Deferred** for provision of following documents: - ▪ Only codes for Pathromtin ® SL Reagent will be considered in this application, separate applications for Plasma control N, Plasma control P, Dade Ci-Trol 1, Dade Ci-Trol 2, Dade Ci-Trol 3, and Calcium chloride solution need be submitted. ▪ Original and valid LOA and ISO 13485 certificate duly notarized. ▪ Original FSC duly attested by embassy of Pakistan. ▪ FQA certificate duly notarized by the country of origin. ▪ Declaration (on stamp paper) as per Form-7A.
93.	-do- [1313-K] Evaluator AD-II	Legal Manufacturer and Manufacturing Site: Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-Straβe 76 35041 Marburg Germany FSC (scanned copy): Germany Date of issue: 29-04-2019	BC von Willebrand Reagent Code: OUBD37 Class: C Shelf Life: 24 months	**Deferred** for provision of following documents: - ▪ Only code for BC von Willebrand reagent will be considered in this application, separate applications for Plasma control N, Plasma control P and Standard human plasma need be submitted. ▪ Original and valid LOA and ISO 13485 certificate duly notarized. ▪ Original FSC duly attested by embassy of Pakistan. ▪ FQA certificate duly notarized by the country of origin. ▪ Declaration (on stamp paper) as per Form-7A.
94.	-do- [1181-K] Evaluator AD-II	Legal Manufacturer and Manufacturing Site: Siemens Healthcare Diagnostics	Thromborel® S Reagent Human Thromboplastin containing calcium	**Deferred** for provision of following documents: - ▪ Only code for Thromborel® S reagent will be considered in this application, separate applications for Plasma control N, Plasma control P, Standard human plasma, PT-Multi Calibrator,

		Products GmbH Emil-von-Behring-Straße 76 35041 Marburg Germany FSC (scanned copy): Germany Date of issue: 29-04-2019	Codes: OUHP29 OUHP49 Class-C Shelf life: OUHP29: 24 months	Dade Ci-Trol 1, Dade Ci-Trol 2, Dade Ci-Trol 3, and Imidazole Buffer solution need be submitted. ▪ Original and valid LOA and ISO 13485 certificate duly notarized. ▪ Original FSC duly attested by embassy of Pakistan. ▪ FQA certificate duly notarized by the country of origin. ▪ Declaration (on stamp paper) as per Form-7A.
95.	-do- [1308-K] Evaluator AD-II	Legal Manufacturer and Manufacturing Site: Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-Straße 76 35041 Marburg Germany FSC (scanned copy): Germany Date of issue: 29-04-2019	Test Thrombin Reagent Code: OWHM13 Class-C Shelf Life: 24 months	**Deferred** for provision of following documents: - ▪ Justify the grouping of the applied device in a kit also clarify whether the medical device would be imported as a single packing unit or the diluents will be imported separately? ▪ Original and valid LOA and ISO 13485 certificate duly notarized. ▪ FQA certificate duly notarized by the country of origin. ▪ Declaration (on stamp paper) as per Form-7A.
96.	B.Braun Pakistan (Pvt) Ltd., The Forum, Suite 216, Khayaban-e-Jami, Block No.9, Clifton, Karachi ELI-00006 [136] Renewal Evaluator AD-II	Legal Manufacturer: B.Braun Melsungen AG Carl-Braun-Straße 1 34212 Melsungen Germany Manufacturing Site: B.Braun Melsungen AG Vascular Systems, Sieversufer 8, 12359, Berlin Germany FSC: Germany Issued: 18-10-2016	Coroflex ISAR NEO Sirolimus-Eluting Coronary Stent System Codes & Sizes: As per FSC Class-D Shelf Life: 02 years	**Deferred** for provision of following documents: - ▪ Provide all the original legal documents duly attested and notarized. ▪ Scope of submitted LoA covers only SeQuent Neo balloon catheter. ▪ Valid FSC and Design Examination certificate duly notarized by the country of origin ▪ Declaration of Conformity
97.	M/s Reaction Scientific Private (Ltd), 337, Street No. 17, Sector B-17, Block-B, Islamabad. ELI: 00228 2885 Evaluator AD-II	Legal Manufacturer: M/s Spinreact, S.A.U. Carretera Santa Coloma, 7. 17176. Sant Esteve de Bas. Girona, Spain FSC: Spain	Salmonella Typhi O Bacterial Antigen Serology Test Kit (100 tests) Codes: 1205081 Class-C Shelf Life: 30 months	**Deferred** for provision of following documents: - ▪ Provide original legal documents or reference to the dossier where original documents are attached. ▪ Provided IFU is in Spanish language, submit the document with English translation. ▪ Provide valid and notarized ISO 13485 certificate. ▪ Provide valid and notarized FQA certificate. ▪ Provide Essential principle checklist.
98.	-do- 2888 Evaluator AD-II	Legal Manufacturer: M/s Spinreact, S.A.U. Carretera Santa Coloma, 7. 17176. Sant Esteve	Salmonella Paratyphi BH (Bacterial Antigen Serology Test Kit (100 tests)-Art # 1205031)	**Deferred** for provision of following documents: - ▪ Provide original legal documents or reference to the dossier where original documents are attached. ▪ Provided IFU is in Spanish language, submit the document with English translation.

<table>
<tr><td></td><td></td><td>de Bas. Girona, Spain

FSC: Spain</td><td>Codes & sizes: As per FSC

Class-C

Shelf Life: 30 months</td><td>▪ Provide valid and notarized ISO 13485 certificate.
▪ Provide valid and notarized FQA certificate.
▪ Provide Essential principle checklist.</td></tr>
<tr><td>99.</td><td>M/s Siemens Healthcare (Pvt) Ltd 4th Floor, State Life Building, 15-A, Sir Agha Khan Road, Lahore

ELI: 00146 2461

Evaluator AD-II</td><td>Legal Manufacturer:

M/s Siemens Healthcare GmbH Henkestr, 127 91052 Erlangen Germany

FSC: Germany

Date of issuance: 03-12-2018</td><td>Mammomat Family

Mammomat Fusion
Mammomat Inspiration
Mammomat Revelation

(Mammography X-Ray System)

Codes & Sizes: As per FSC

Class-C

Shelf Life: 10 years
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<tr><td colspan="5">Mammomat Family</td></tr>
<tr><td colspan="5">Siemens Healthineers</td></tr>
<tr><td rowspan="2">SN</td><td rowspan="2">FEATURE DESCRIPTION</td><td colspan="3">Mammomat variants of Digital Mammography</td></tr>
<tr><td>Mammomat Fusion</td><td>Mammomat Inspiration</td><td>Mammomat Revelation</td></tr>
<tr><td>1</td><td>Digital Mammography Machine</td><td>Yes</td><td>Yes</td><td>Yes</td></tr>
<tr><td>2</td><td>Stereotactic Breast Biopsy</td><td>Yes</td><td>Yes</td><td>Yes</td></tr>
<tr><td>3</td><td>Breast Tomosynthesis</td><td>No</td><td>Yes</td><td>Yes</td></tr>
<tr><td>4</td><td>Contrast En</td><td>No</td><td>No</td><td>Yes</td></tr>
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			hanced Mammography	
100.	M/s Medichem Enterprises, 331/C Block 3, Alamgir Road, DMCHS, Karachi (ELI-00252) Evaluator: AD-IV [4088]	Manufacturer: Nanjing Hong An Medical Appliances Co. Ltd No. 26, Hengguang Road, Nanjing Economic and Technological Development District, Nanjing China FSC UK Issued on 1-4-2019	Promed Feeding Tube Class B Shelf life: 5 years Sizes and codes: Not mentioned	**Deferred** for provision of following documents:- •On form it is mentioned that the applied product is feeding tube/NG tube and in application of stomach tube also the product mentioned is stomach tube/NG tube. Clearly state the difference between stomach tube and feeding tube and are they both nasogastric tubes? Explanation is required from manufacturer abroad. •Incomplete copy of Free Sale Certificate of reference country is attached in this dossier. •Form not properly filled and most fields are left blank. Provide completely and properly filled Form 7A for the applied product and each page duly signed and stamped by owner. In case of authorized person, provide Authority letter from owner. At this stage it is not clear who has signed the cover letter and form and under whose authority and those signatures are also scanned and not original. •Sizes/codes and types of applied product are not mentioned on form. Clearly state the types and their sizes/codes required for the applied product and they should be present on reference country Free Sale Certificate and CE mark documents and provide the pictures of actual product labels of all these types, sizes and codes and not specimen label. •MRP not provided. •Stability studies not signed and stamped. Provide stability studies for the applied product duly signed and stamped by responsible personnel of the manufacturer. •Credentials of manufactured abroad and not notarized. Provide original notarized credentials. •ISO13485 expired now. Provide valid certificate. •CE marking documents (Full QA certificate/Production QA certificate expired even upon submission and Declaration of Conformity is not provided). Provide valid notarized certificates. •Provide complete CE technical file of the applied product including manufacturing, QC etc as the provided documents are incomplete. •Provide Instructions For Use (IFU) for the applied product. •It cannot be established that the provided essential principles of safety and performance (EPSP) document is for the applied product as it has no title etc. Provide relevant EPSP. •The registration is applied on the claim that the product is CE marked so provide written, original,

				notarized Undertaking from the manufacturer abroad that same product Promed Feeding Tube with same specifications will be supplied to Pakistan as claimed for CE marking of Europe on the letterhead signed and stamped by responsible personnel.
101.	-do- Evaluator: AD-IV [4089]	Manufacturer: Nanjing Hong An Medical Appliances Co. Ltd No. 26, Hengguang Road, Nanjing Economic and Technological Development District, Nanjing China FSC UK Issued on 1-4-2019	Promed Reinforced Endotracheal Tube Class B Shelf life: 5 years Sizes and codes: Not mentioned	**Deferred** for provision of following documents:- • Incomplete copy of Free Sale Certificate of reference country is attached in this dossier. • CE marking documents (Full QA certificate/Production QA certificate and Declaration of Conformity) not provided. Provide valid notarized certificates. • Form not properly filled and most fields are left blank. Provide completely and properly filled Form 7A for the applied product and each page duly signed and stamped by owner. In case of authorized person, provide Authority letter from owner. At this stage it is not clear who has signed the cover letter and form and under whose authority and those signatures are also scanned and not original. • Sizes/codes and types of applied product are not mentioned on form. Clearly state the types and their sizes/codes required for the applied product and they should be present on reference country Free Sale Certificate and CE mark documents and provide the pictures of actual product labels of all these types, sizes and codes and not specimen label. • MRP not provided. • Stability studies not signed and stamped. Provide stability studies for the applied product duly signed and stamped by responsible personnel of the manufacturer. • Credentials of manufactured abroad and not notarized. Provide original notarized credentials. • ISO13485 expired now. Provide valid certificate. • Provide complete CE technical file of the applied product including manufacturing, QC etc as the provided documents are incomplete. • Provide Instructions For Use (IFU) for the applied product • It cannot be established that the provided essential principles of safety and performance (EPSP) document is for the applied product as it has no title etc. Provide relevant EPSP. • The registration is applied on the claim that the product is CE marked so provide written, original, notarized Undertaking from the manufacturer abroad that same product Promed Reinforced Endotracheal Tube with same specifications will be supplied to Pakistan as claimed for CE marking of Europe on the letterhead signed and stamped by responsible personnel.
102.	-do- Evaluator: AD-IV [4090]	Manufacturer: Nanjing Hong An Medical Appliances Co. Ltd No. 26, Hengguang Road, Nanjing Economic and Technological	Promed Nasopharyngeal Airways Class B Shelf life: 5 years	**Deferred** for provision of following documents:- • CE marking documents (Full QA certificate/Production QA certificate and Declaration of Conformity) not provided. Provide valid notarized certificates • Form not properly filled and most fields are left

		Development District, Nanjing China FSC UK Issued on 1-4-2019	Sizes and codes: Not mentioned	blank. Provide completely and properly filled Form 7A for the applied product and each page duly signed and stamped by owner. In case of authorized person, provide Authority letter from owner. At this stage it is not clear who has signed the cover letter and form and under whose authority and those signatures are also scanned and not original. • Sizes/codes and types of applied product are not mentioned on form. Clearly state the types and their sizes/codes required for the applied product and they should be present on reference country Free Sale Certificate and CE mark documents and provide the pictures of actual product labels of all these types, sizes and codes and not specimen label. • MRP not provided. • Stability studies not signed and stamped. Provide stability studies for the applied product duly signed and stamped by responsible personnel of the manufacturer. • Credentials of manufactured abroad and not notarized. Provide original notarized credentials. • ISO13485 expired now. Provide valid certificate. • Provide complete CE technical file of the applied product including manufacturing, QC etc as the provided documents are incomplete. • Provide Instructions For Use (IFU) for the applied product. • It cannot be established that the provided essential principles of safety and performance (EPSP) document is for the applied product as it has no title etc. Provide relevant EPSP. • The registration is applied on the claim that the product is CE marked so provide written, original, notarized Undertaking from the manufacturer abroad that same product Promed Nasopharyngeal Airways with same specifications will be supplied to Pakistan as claimed for CE marking of Europe on the letterhead signed and stamped by responsible personnel.
103.	-do- Evaluator: AD-IV [4092]	Manufacturer: Nanjing Hong An Medical Appliances Co. Ltd, No. 26, Hengguang Road, Nanjing Economic and Technological Development District, Nanjing China FSC UK Issued on 1-4-2019	Promed ETT RAE Tube Class B Shelf life: 5 years Sizes and codes: Not mentioned	**Deferred** for provision of following documents:- • Product not present in reference country Free Sale Certificate (FSC). Provide original, valid and Embassy attested FSC for the applied product from one of the reference countries specified in rule 67 of the Medical Devices Rules, 2017. • CE marking documents (Full QA certificate/Production QA certificate and Declaration of Conformity) not provided. Provide valid notarized certificates . • Form not properly filled and most fields are left blank. Provide completely and properly filled Form 7A for the applied product and each page duly signed and stamped by owner. In case of authorized person, provide Authority letter from owner. At this stage it is not clear who has signed the cover letter and form and under whose authority and those signatures are also scanned and not original. • Sizes/codes and types of applied product are not mentioned on form. Clearly state the types and their sizes/codes required for the applied product

				and they should be present on reference country Free Sale Certificate and CE mark documents and provide the pictures of actual product labels of all these types, sizes and codes and not specimen label. • MRP not provided. • Stability studies not signed and stamped. Provide stability studies for the applied product duly signed and stamped by responsible personnel of the manufacturer. • Credentials of manufactured abroad and not notarized. Provide original notarized credentials. • ISO13485 expired now. Provide valid certificate. • Provide complete CE technical file of the applied product including manufacturing, QC etc as the provided documents are incomplete. • Provide Instructions For Use (IFU) for the applied product. • It cannot be established that the provided essential principles of safety and performance (EPSP) document is for the applied product as it has no title etc. Provide relevant EPSP. • The registration is applied on the claim that the product is CE marked so provide written, original, notarized Undertaking from the manufacturer abroad that same product Promed ETT RAE Tube with same specifications will be supplied to Pakistan as claimed for CE marking of Europe on the letterhead signed and stamped by responsible personnel.
104.	-do- Evaluator: AD-IV [4093]	Manufacturer: Nanjing Hong An Medical Appliances Co. Ltd No. 26, Hengguang Road, Nanjing Economic and Technological Development District, Nanjing China FSC UK Issued on 1-4-2019	Promed Nelation Catheter Class B Shelf life: 5 years Sizes and codes: Not mentioned	**Deferred** for provision of following documents:- • Form not properly filled and most fields are left blank. Provide completely and properly filled Form 7A for the applied product and each page duly signed and stamped by owner. In case of authorized person, provide Authority letter from owner. At this stage it is not clear who has signed the cover letter and form and under whose authority and those signatures are also scanned and not original. • Sizes/codes and types of applied product are not mentioned on form. Clearly state the types and their sizes/codes required for the applied product and they should be present on reference country Free Sale Certificate and CE mark documents and provide the pictures of actual product labels of all these types, sizes and codes and not specimen label. • MRP not provided. • Stability studies not signed and stamped. Provide stability studies for the applied product duly signed and stamped by responsible personnel of the manufacturer. • Credentials of manufactured abroad and not notarized. Provide original notarized credentials. • ISO13485 expired now. Provide valid certificate. • CE marking documents (Full QA certificate/Production QA certificate and Declaration of Conformity) not provided. Provide valid notarized certificates . • Provide complete CE technical file of the applied

				product including manufacturing, QC etc as the provided documents are incomplete. • Provide Instructions For Use (IFU) for the applied product. • It cannot be established that the provided essential principles of safety and performance (EPSP) document is for the applied product as it has no title etc. Provide relevant EPSP. • The registration is applied on the claim that the product is CE marked so provide written, original, notarized Undertaking from the manufacturer abroad that same product Promed Nelation Catheter with same specifications will be supplied to Pakistan as claimed for CE marking of Europe on the letterhead signed and stamped by responsible personnel.
105.	-do- Evaluator: AD-IV [4094]	Manufacturer: Nanjing Hong An Medical Appliances Co. Ltd No. 26, Hengguang Road, Nanjing Economic and Technological Development District, Nanjing China FSC UK Issued on 1-4-2019	Promed Suction Catheter Class B Shelf life: 5 years Sizes and codes: Not mentioned	**Deferred** for provision of following documents:- • Form not properly filled and most fields are left blank. Provide completely and properly filled Form 7A for the applied product and each page duly signed and stamped by owner. In case of authorized person, provide Authority letter from owner. At this stage it is not clear who has signed the cover letter and form and under whose authority and those signatures are also scanned and not original. • Sizes/codes and types of applied product are not mentioned on form. Clearly state the types and their sizes/codes required for the applied product and they should be present on reference country Free Sale Certificate and CE mark documents and provide the pictures of actual product labels of all these types, sizes and codes and not specimen label. • MRP not provided. • Stability studies not signed and stamped. Provide stability studies for the applied product duly signed and stamped by responsible personnel of the manufacturer. • Credentials of manufactured abroad and not notarized. Provide original notarized credentials. • ISO13485 expired now. Provide valid certificate. • CE marking documents (Full QA certificate/Production QA certificate and Declaration of Conformity) not provided. Provide valid notarized certificates. • Provide complete CE technical file of the applied product including manufacturing, QC etc as the provided documents are incomplete. • Provide Instructions For Use (IFU) for the applied product. • It cannot be established that the provided essential principles of safety and performance (EPSP) document is for the applied product as it has no title etc. Provide relevant EPSP. • The registration is applied on the claim that the product is CE marked so provide written, original, notarized Undertaking from the manufacturer abroad that same product Promed Suction Catheter with same specifications will be supplied to Pakistan as claimed for CE marking of Europe on the letterhead signed and stamped by responsible personnel.

106.	-do- Evaluator: AD-IV [4095]	Manufacturer: Nanjing Hong An Medical Appliances Co. Ltd No. 26, Hengguang Road, Nanjing Economic and Technological Development District, Nanjing China FSC UK Issued on 1-4-2019	Promed Stomach Tube Class B Shelf life: 5 years Sizes and codes: Not mentioned	**Deferred** for provision of following documents:- • On form it is mentioned that the applied product is feeding tube/NG tube and in application of stomach tube also the product mentioned is stomach tube/ NG tube. Clearly state the difference between stomach tube and feeding tube and are they both nasogastric tubes? Explanation is required from manufacturer abroad. • Form not properly filled and most fields are left blank. Provide completely and properly filled Form 7A for the applied product and each page duly signed and stamped by owner. In case of authorized person, provide Authority letter from owner. At this stage it is not clear who has signed the cover letter and form and under whose authority and those signatures are also scanned and not original. • Sizes/codes and types of applied product are not mentioned on form. Clearly state the types and their sizes/codes required for the applied product and they should be present on reference country Free Sale Certificate and CE mark documents and provide the pictures of actual product labels of all these types, sizes and codes and not specimen label. • MRP not provided. • Stability studies not signed and stamped. Provide stability studies for the applied product duly signed and stamped by responsible personnel of the manufacturer. • Credentials of manufactured abroad and not notarized. Provide original notarized credentials. • ISO13485 expired now. Provide valid certificate. • CE marking documents (Full QA certificate/Production QA certificate and Declaration of Conformity) not provided. Provide valid notarized certificates . • Provide complete CE technical file of the applied product including manufacturing, QC etc as the provided documents are incomplete. • Provide Instructions For Use (IFU) for the applied product. • It cannot be established that the provided essential principles of safety and performance (EPSP) document is for the applied product as it has no title etc. Provide relevant EPSP. • The registration is applied on the claim that the product is CE marked so provide written, original, notarized Undertaking from the manufacturer abroad that same product Promed Stomach Tube with same specifications will be supplied to Pakistan as claimed for CE marking of Europe on the letterhead signed and stamped by responsible personnel.
107.	-do- Evaluator: AD-IV [4096]	Manufacturer: Nanjing Hong An Medical Appliances Co. Ltd No. 26, Hengguang Road, Nanjing Economic and Technological	Promed Endotracheal Tube Class B Shelf life: 5 years Sizes and codes: Not mentioned	**Deferred** for provision of following documents:- • Form not properly filled and most fields are left blank. Provide completely and properly filled Form 7A for the applied product and each page duly signed and stamped by owner. In case of authorized person, provide Authority letter from

		Development District, Nanjing China FSC UK Issued on 1-4-2019		owner. At this stage it is not clear who has signed the cover letter and form and under whose authority and those signatures are also scanned and not original. • Sizes/codes and types of applied product are not mentioned on form. Clearly state the types and their sizes/codes required for the applied product and they should be present on reference country Free Sale Certificate and CE mark documents and provide the pictures of actual product labels of all these types, sizes and codes and not specimen label. • MRP not provided. • Stability studies not signed and stamped. Provide stability studies for the applied product duly signed and stamped by responsible personnel of the manufacturer. • Credentials of manufactured abroad and not notarized. Provide original notarized credentials. • ISO13485 expired now. Provide valid certificate. • CE marking documents (Full QA certificate/Production QA certificate and Declaration of Conformity) not provided. Provide valid notarized certificates. • Provide complete CE technical file of the applied product including manufacturing, QC etc as the provided documents are incomplete. • Provide Instructions For Use (IFU) for the applied product. • It cannot be established that the provided essential principles of safety and performance (EPSP) document is for the applied product as it has no title etc. Provide relevant EPSP. • The registration is applied on the claim that the product is CE marked so provide written, original, notarized Undertaking from the manufacturer abroad that same product Promed Endotracheal Tube with same specifications will be supplied to Pakistan as claimed for CE marking of Europe on the letterhead signed and stamped by responsible personnel.
108.	M/s Waseem Brothers, B-45, Block 5, Gulshan-e-Iqbal. Karachi. (ELI-00342) 3997 Evaluator: AD-III	Legal Manufacturer: ZHEJIANG JINHUA HUATONG MEDICAL APPLICANCE CO. LTD 5th Floor, Building C.D. No. 818 Jidao Street, Wucheng Area Jinhua 321016 Zhejiang China FSC: China Valid Till: 23-8-2021	WASCO Disposable Electrosurgical Electrodes (Electrosurgical Pencils) Class-C Shelf life: 3 years Models as per FSC	**Deferred** for provision of following documents:- • Provide the Establishment license copy. • Provide the MRP of the device. • Provided Agency agreement is the color copy, submit the original Agency agreement, duly notarized. • Provide original and valid FSC in the country of origin, duly attested, the submitted FSC is expired at the time of submission of your application. • In Form-7A, you have mentioned the FSC of Reference country of UK, MHRA, whereas the document is missing in the file, submit the original, valid and attested FSC of refence country. • Provide the complete description of the device, with its intended use. • Provide valid and notarized ISO 13485, the submitted certificate is expired.

				• Provide labels of all applied models as per FSC approved in the country of origin. • Provide information on validation for medical device applied. • Provide the IFU, contraindications and warnings to inform specific risk or hazard to use medical device. • Provide undertaking on stamp paper.
109.	-do- 3998 Evaluator: AD-III	Legal Manufacturer: ZHEJIANG JINHUA HUATONG MEDICAL APPLICANCE CO. LTD 5th Floor, Building C.D. No. 818 Jidao Street, Wucheng Area Jinhua 321016 Zhejiang China FSC: China Valid Till: 23-8-2021	WASCO Disposable Electrosurgical Neutral Electrodes (Electrosurgical Plates for single use Class-C Shelf life: 2 years Models as per FSC	**Deferred** for provision of following documents:- • Provide the Establishment license copy. • Provide the MRP of the device. • Provided Agency agreement is the color copy, submit the original Agency agreement, duly notarized. • Provide original and valid FSC in the country of origin, duly attested, the submitted FSC is expired at the time of submission of your application. • In Form-7A, you have mentioned the FSC of Reference country of UK, MHRA, whereas the document is missing in the file, submit the original, valid and attested FSC of refence country. • Provide the complete description of the device, with its intended use. • Provide valid and notarized ISO 13485, the submitted certificate is expired. • Provide labels of all applied models as per FSC approved in the country of origin. • Provide information on validation for medical device applied. • Provide the IFU, contraindications and warnings to inform specific risk or hazard to use medical device. • Provide undertaking on stamp paper.
110.	Sure Bio-Diagnostics & Pharmaceuticals, EE-10, Defense View Phase-II, Near Iqra University Shaheed-e-Miliat Express Way, Karachi. (ELI-00084) 3571 Evaluator: AD-III	Legal Manufacturer: Terumo BCT Inc. 10811 West Collins Ave., Lakewood, Colorado, 80215, USA. FSC Belgium issuance 03-07-2020	Reveos Automated Blood processing System (Platelet Pooling Set) Class-C Shelf life: 24 Months Codes and sizes as per FSC	**Deferred** for provision of following documents:- • The applied device is grouped as system, whereas two sets of devices are applied which has difference in term of intended use as the additive solution is used in Reveos platelet pooling set. So, submit your priority on this application and apply separately for the other device. • Provided Agency agreement is copy without notarization, submit the original Agency agreement, duly notarized. • Provide valid and notarized ISO 13485, the submitted certificate is expired and without notarization.
111.	-do- 3573	**Legal Manufacturer:** Terumo BCT Inc. 10811 West Collins	Reveos Automated Blood processing System (Reveos LR Set)	**Deferred** for provision of following documents:- • Justify the grouping of device in System whereas

	Evaluator: AD-III	Ave., Lakewood, Colorado, 80215, USA. FSC Belgium issuance 03-07-2020	Class-C Shelf life: 24 Months Codes and sizes as per FSC	the device applied is grouped as set. Also, specify the difference between the two. • Provided Agency agreement is copy without notarization, submit the original Agency agreement, duly notarized. • Provide valid and notarized ISO 13485, the submitted certificate is expired and without notarization. • The DoC is provided for only one model which is different from the model number mentioned on FSC, give clarification.
112.	-do- 3574 Evaluator: AD-III	Legal Manufacturer: Terumo BCT, Ltd, Old Belfast Road, Millbrook, Larne, Co., Antrim, BT40 2SH, UK Manufacturing Site: Terumo BCT Inc. 10811 West Collins Ave., Lakewood, Colorado, 80215, USA. FSC US FDA validity 06-02-2019 to 05-02-2021	Terumo BCT Inc. Anticoagulant Citrate Dextrose Solution Class-C Shelf life: 24 months Code: 750ml Cat# 40818	**Deferred** for provision of following documents:- • Provided Agency agreement is copy without notarization, submit the original Agency agreement, duly notarized. • Provided FSC of US FDA is copy without attestation and expired at the time of submission, submit the original and valid FSC of US FDA, duly attested. • The file with catalogue no. 40818 missing the DoC, submit the required document.
113.	-do- 3575 Evaluator: AD-III	Legal Manufacturer: Terumo BCT, Ltd, Old Belfast Road, Millbrook, Larne, Co., Antrim, BT40 2SH, UK Manufacturing Site: Terumo BCT Inc. 10811 West Collins Ave., Lakewood, Colorado, 80215, USA. FSC US FDA validity 06-02-2019 to 05-02-2021	Terumo BCT Inc. Anticoagulant Citrate Dextrose Solution Class-C Shelf life: 24 months Code: 750ml Cat# 40800	**Deferred** for provision of following documents:- • Provided Agency agreement is copy without notarization, submit the original Agency agreement, duly notarized. • Provided FSC of US FDA is copy without attestation and expired at the time of submission, submit the original and valid FSC of US FDA, duly attested. • The file with catalogue no. 40818 missing the DoC, submit the required document.
114.	M/s UDL Distribution Pvt Ltd. I-D-13, Sector 30, Korangi Industrial Area Karachi (ELI-00073) 3471 Evaluator: AD-III	KAREX INDUSTRIES SDN. BHD.LOT 2244, BATU 39 1/2 PONTIAN BESAR, 8200, PONTIAN THOHOR MALAYSIA	Pulse-3 in 1 Class-C Shelf life: 5 Codes and sizes as per FSC	**Deferred** for provision of FSC of MHRA with specific brand (provided FSC of MHRA shows brand name "Happy Life" with different modelas).

115.	-do- 3472 Evaluator: AD-III	KAREX INDUSTRIES SDN. BHD.LOT 2244, BATU 39 1/2 PONTIAN BESAR, 8200, PONTIAN THOHOR MALAYSIA	Pulse - Dotted Class-C Shelf life: 5 Codes and sizes as per FSC	**Deferred** for provision of FSC of MHRA with specific brand (provided FSC of MHRA shows brand name "Happy Life" with different modelas).
116.	-do- 3473 Evaluator: AD-III	KAREX INDUSTRIES SDN. BHD.LOT 2244, BATU 39 1/2 PONTIAN BESAR, 8200, PONTIAN THOHOR MALAYSIA	Pulse - Delay Class-C Shelf life: 5 Codes and sizes as per FSC	**Deferred** for provision of FSC of MHRA with specific brand (provided FSC of MHRA shows brand name "Happy Life" with different modelas).
117.	-do- 3470 Evaluator: AD-III	KAREX INDUSTRIES SDN. BHD.LOT 2244, BATU 39 1/2 PONTIAN BESAR, 8200, PONTIAN THOHOR MALAYSIA	Pulse - Ultra thin Class-C Shelf life: 5 Codes and sizes as per FSC	**Deferred** for provision of FSC of MHRA with specific brand (provided FSC of MHRA shows brand name "Happy Life" with different modelas).
118.	K.S. Agencies Office 210, 2nd Floor, Business Arcade, Main University Road, Karachi. (ELI-00382) 2686 Evaluator: AD-III	Legal Manufacturer: Huaiyin Medical instruments Company Limited No. 8 West Ming Yuan Road, 223003, Huaian, China. FSC China validity 17-01-2021	Gly-Steel Sutures (stain-less steel non-absorbable surgical suture) Class-C Shelf life: 5 years Codes & Sizes as per FSC	**Deferred** for provision of following documents:- • Provide Credentials of manufacturer's abroad as per format approved in 3rd meeting of MDB, duly notarized. • Provide manufacturing process in detail. • Provide stability studies for the claimed shelf life. • Provided LOA is copy without notarization, submit original and notarized document. • Provide original and updated FSC in the country of origin, duly attested. • As the device is from Non-reference country, submit the original and valid FSC of any reference country, duly attested. • Provided ISO 13485 and FQA certificates are copies without notarization, submit notarized documents. • Provide labels of required sizes as per FSC approved in the country of origin. • Provided declaration of conformity is without notarization, submit notarized document (both Production quality assurance and Product quality assurance certificates). • Is the name Gly Steel brand name made for importer in Pakistan on OEM basis or is it brand of the manufacturer? Clarify it. Provide relevant labels of all the codes required on this application along with product brochure.
119.	-do- 2686 Evaluator: AD-III	Legal Manufacturer: Shandong Haidike Medical Products Company Limited Plant No. 1, Science and Technology Enterprise Incubator Park, Shan County, Heze City, Shandong Province, China.	SuperSilk Sutures (Braided Silk) Class: C Shelf life: 5years Codes & Sizes provided in certificate of Export	**Deferred** for provision of following documents:- • Provide Credentials of manufacturer's abroad as per format approved in 3rd meeting of MDB, duly notarized. • Provide manufacturing process in detail. • Provide stability studies for the claimed shelf life. • Provided LOA is copy without notarization, submit original and notarized document. • Provide original and updated FSC in the country of origin, duly attested.

		Export only certificate of China validity 27-08-2021		• As the device is from Non-reference country, submit the original and valid FSC of any reference country, duly attested. • Provided ISO 13485 and FQA certificates are copies without notarization, submit notarized documents. • Provide labels of required sizes as per FSC approved in the country of origin. • Provided declaration of conformity is without notarization, submit notarized document (both Production quality assurance and Product quality assurance certificates). • Is the name Gly Steel brand name made for importer in Pakistan on OEM basis or is it brand of the manufacturer? Clarify it. Provide relevant labels of all the codes required on this application along with product brochure.
120.	M/s. Biotech Pakistan, Suite# 301 3rd Floor, Tahir Plaza KCHS Karachi (ELI-00424) -3969- Evaluator: AD-VI	Legal Manufacturer & mfg. site: Erbe Elektromedizin GmbH. Waldhornlestr. 17 72072 Tubingen Germany FSC: Germanny Issue date: 13-11-2019	ERBEJET Hydro-surgical Unit. Class-C Shelf Life: 07-years Codes & Sizes as per FSC.	**Deferred** for provision of following documents:- • Valid ISO-13485 & Full QA certificates; • Original and Valid Letter of authorization. (Provided one expired). • Justifiable stability / validation/ service life study data with protocols of applied products.
121.	-do- -3970- Evaluator: AD-VI	Legal Manufacturer & mfg. site: Erbe Elektromedizin GmbH. Waldhornlestr. 17 72072 Tubingen Germany FSC: Germanny Issue date: 13-11-2019	APC-Argon Plasma Coagulation Unit. Class-C Shelf Life: 07-years Codes & Sizes as per FSC.	**Deferred** for provision of following documents:- • Valid ISO-13485 & Full QA certificates; • Original and Valid Letter of authorization. (Provided one expired). • Justifiable stability / validation/ service life study data with protocols of applied products.
122.	-do- -3971- Evaluator: AD-VI	Legal Manufacturer & mfg. site: Erbe Elektromedizin GmbH. Waldhornlestr. 17 72072 Tubingen Germany FSC: Germanny Issue date: 13-11-2019.	VIO200S Electro-surgical Unit. Class-C Shelf Life: 07-years Codes & Sizes as per FSC.	**Deferred** for provision of following documents:- • Valid ISO-13485 & Full QA certificates; • Original and Valid Letter of authorization. (Provided one expired). • Justifiable stability / validation/ service life study data with protocols of applied products. • Apply separately for different variants.
123.	Meher Traders, Office A21-22 First Floor, Zeenat Medicine Market, North Napier Road, Karachi (ELI-00128) -4436- Evaluator: AD-VI	Legal Manufacturer & mfg. site: Huaian Pingan Medical Instrument Co., Ltd No. 128 West Meigo Road, Huaian Jinagsu China. FSC(copy): Spain Issued: 16-2-2021.	PAAMIDE (Nylon Monofilament Suture) Shelf Life: 60-Months Class-D Codes & Sizes as per FSC.	**Deferred** for provision of following documents:- • Original and Valid FSC of country of origin & any RRA and Letter of authorization. • Labels of the product; • valid ISO-13485 Certificate of all manufacturing sites; • Justifiable stability study data with protocols.
124.	-do- -4437- Evaluator:	Legal Manufacturer & mfg. site: Huaian Pingan Medical Instrument	PAXANONE (Polydioxanone Suture) Shelf Life: 36-Months	**Deferred** for provision of following documents:- • Original and Valid FSC of country of origin & any

	AD-VI	Co., Ltd No. 128 West Meigo Road, Huaian Jinagsu China. FSC(copy): Spain Issued: 16-2-2021.	Class-D Codes & Sizes as per FSC.	RRA and Letter of authorization. • Labels of the product; • valid ISO-13485 Certificate of all manufacturing sites; • Justifiable stability study data with protocols.
125.	-do- -4438- Evaluator: AD-VI	Legal Manufacturer & mfg. site: Huaian Pingan Medical Instrument Co., Ltd No. 128 West Meigo Road, Huaian Jinagsu China. FSC(copy): Spain Issued: 16-2-2021.	PABOND Polyester Braided Suture. Shelf Life: 60-Months Class- B Codes & Sizes as per FSC.	**Deferred** for provision of following documents:- • Original and Valid FSC of country of origin & any RRA and Letter of authorization. • Labels of the product; • valid ISO-13485 Certificate of all manufacturing sites; • Justifiable stability study data with protocols.
126.	M/s Claris Medical Unit No. 27, Twin City Plaza, 1-8 Markez, Islamabad. ELI: 00269 -1855- Evaluator: AD-VI	Legal Manufacturer & mfg. site: M/s MEDISTIM ASA Okernveien 94 No-0579 Oslo, Norway. Manufacturing Site: Bromsveien 17 3183 Horten, Norway. FSC (copy): Norway Date of issue: 02.03.2020.	MEDISTIM Doppler Probe. (Doppler Probes to Measure Blood Flow Velocity) Class-B Shelf Life: ------- Codes and Sizes as per FSC.	**Deferred** for provision of following documents:- • Differential fee as the product fall in class-C, while firm applied in class-B. • Original and Valid FSC of country of origin & any RRA. • Original and valid Letter of authorization. • Valid ISO-13485 Certificate of all manufacturing sites; • Justifiable stability study data with protocols.
127.	Ghazi Brothers Ghazi House, D-35, K.D.A Scheme No. 1, Miran Muhammad Shah Road Karachi - 75350, Pakistan (ELI-00002) Evaluator: AD-VI	Legal Manufacturer & mfg. site: H&O Equipment nv/sa 1 rue des Journaliers 7822 Ghislenghien Belgium. FSC: Belgium	Cryopen XP Class-C Shelf Life: ------- Codes and Sizes as per FSC.	**Deferred** for provision of following documents: - • valid ISO-13485 Certificate; • Justifiable stability study data with protocols. • Apply separately for different variants.
128.	M/s Medisurg Innovatives Health Care, 1/6-N, Block-6, PECHS, Main Nursery, Shahrah e Faisal, Karachi. ELI: 00242. -1388- Evaluator: AD-VI	Legal Manufacturer & mfg. site: The Legal MFG: Contract Medical International GmbH Lauensteiner Strasse 37 01277 Dresden, Germany The actual MFG: Contract Medical International spol S.r.o Vazni 848 500 03 Haradec Kralove Czech Republic 2. Merit Medical Systems, Inc, 1600 West Merit Parkway, South Jordan, Utah, 84095, USA Manucaturer of critical component Steris AST CZ s.t.o Proumyslova zona, Kosikov 80, 59 501	FORTRESS Introducer Sheath System. Codes and Sizes as per FSC. Class: D Shelf Life: 3 years.	**Deferred** for provision of original and valid Agency Agreement, ISO 13485 and undertaking on stamp paper.

		Velka Bites Czech, Republic sterilization. FSC: Germany Date of issue: 14.05.2019.		
129.	Johnson & Johnson Pakistan (Pvt) Ltd., Office No.806, 8th Floor, Horizon Tower, Block 3, Scheme 5, Clifton, Karachi (ELI-00154) Evaluator: AD-VI	Legal Manufacturer & mfg. site: SERF-85 Avenue des Bruyeres-69150 Decines-Charpieu-France.	Bi-Mentum (Hip Osteoarticular prosthesis) Codes & Sizes as per FSC. Class: D Shelf Life: ---------.	**Deferred** for provision of original and valid Agency Agreement stability studies or validation studies of the product.
130.	-do- Evaluator: AD-VI	Legal Manufacturer & mfg. site: Depuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, IN 46582 USA FSC: US FDA	Sigma HP Partial Knee System Codes & Sizes as per FSC. Class: D Shelf Life: ---------.	**Deferred** for provision of original and valid FSC, ISO 13485 andFall Quality Assurance Certificate.
131.	M/s Treu-Dynamic International (Pvt), Ltd, Office No. C-206, 2nd Floor, City Towers, Main Boulevard Gulberg, Lahore. ELI: 00175 Evaluator: AD-VI	Legal Manufacturer & mfg. site: ANTON HIPP GmbH Annastrasse 25/1 78567 Frindingen/ Germany. FSC: Germany (copy) Date of issue: 1st Dec.2017	MAXILLOFACIAL Osteosynthesis System GMDN 16056. Class C Shelf Life: ---------- Codes & Sizes as per FSC	**Deferred** for provision of following documents:- • Original FSC, ISO-13485 and DoC. • Justifiable validation and quality details. • Provide brand name as 'MAXILLOFACIAL' While on fee slip it is mentioned as CRANIOFACIAL, clarification required in this regard.
132.	M/S Akram Brothers and Co., 89-D Jail Road, Lahore. ELI-00324 1523-P Evaluator: AD-III	Legal Manufacturer: FFOOSIN MEDICAL SUPPLIES Inc.Ltd Np.20 Xingshan Road, Weihai Torch Hi-Tech Science Park, Shandong China. FSC China Valid till: 07.05.2020	WEGO Plain Gut Sutures (Sterile Absorbable surgical suture) Class-D Shelf Life: 5 years Code & Sizes: List provided	**Deferred** for provision of following documents: - • Valid Free Sale Certificate. • Valid ISO 13485. • FSC of any Reference country or CE mark documents. • Design Examination Certificate. • Labels.

2. In the light of decision of MDB in its 37th meeting wherein the 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 without Notarization/Embassy attested.

3. It is requested to furnish the requisite information/documents within 20 days after uploading of this letter on official website of DRAP.

16-09-2022

(BABAR KHAN)
Additional Director (MDMC)/
Secretary MDB
Tele: 051-9107402