No.F.4-4/2022-MD (M-48)
Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
Drug Regulatory Authority of Pakistan
*****

Islamabad the 14th July, 2022.

Subject:- **REGISTRATION OF MEDICAL DEVICES FOR IMPORT - SUBMISSION OF DEFICIENT INFORMATION/DOCUMENTS.**

The applications of following applicants were placed before the Medical Device Board (MDB) in its 48th meeting held on 31st May, 2022 and the same have been deferred being deficient of the information / documents as specified in column (5) of the Table below.

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

S.#	Name of Firm (s)	Name of Manufacturer	Name of Medical Devices.	Decision
1.	M/s AA Enterprises 57, 15-16 first floor mobi plaza, Haider road, Saddar, Karachi. ELI: 00525 **Evaluator**: 1809-P AD-IX	Legal Manufacturer: D.O.R.C. Dutch Opthalmic Research Center (International) B.V. Kerkweg 47e, 3214 VC Zuidland, Netherlands. Manufacturing facility: Scheijdelveweg 2 3214 VN Zuidland, the Netherlands. FSC: Date of Issue: 16.02.2020	EVA Consumables and Accessories (Phaco-Vitrectomy System) Codes & Sizes: As per FSC Class-D Shelf Life: 3 years	**Deferred for:** • Clarification since the registration application is submitted for registration of EVA (consumables and Accessories) without specifying the exact device to be considered against the submitted application. Therefore, the firm should specify the medical device for which registration application is submitted and provide relevant documents as specified in Form 7A. • Calrification since there are multiple manufacturing sites, the role of each manufacturing facility involved in the manufacturing process is required • Provision of following notarized and valid certificates for the applied product: Full Quality assurance certificate Design examination certificate Declaration of conformity ISO 13485 certificate Letter of authorization Credentials of manufacturer • Provision of original, legalized and valid free sale certificate mentioning the detail of applied product.
2.	-do- **Evaluator**: 1808-P AD-IX	**Legal Manufacturer:** Schwinf eye-tech-solutions GmbH Mainparkstrasse 6-10 63801	Schwind Amaris with models Schwind Amaris 500E Schwind Amaris 750S	**Deferred For:** • Provision of following notarized and valid certificates for the applied product: Full Quality assurance certificate Design examination certificate Declaration of conformity

		Kleinostheim Germany. FSC: Germany Date of Issue: 16.02.2020	Schwind Amaris 1050RS (Laser Equipment for Opthalmology for corneal tissue ablation in refractive and therapeutic surgery) Codes & Sizes: As per FSC Class-C Shelf life: not applicable	ISO 13485 certificate Letter of authorization Credentials of manufacturer • Provision of original, legalized and valid free sale certificate mentioning the detail of applied product. • The technical information regarding the applied product is provided in another language, please provide the relevant information in English.
3.	M/s Ali Gohar & company (private) ltd., State life building 1-B, I.I. Chundrigar road, Karachi. ELI: 00004 **Evaluator**: 4338-K AD-IX	Legal Manufacturer: M/s Osarth GmbH Lagerstrasse 11-15, 64807, Dieburg, Germany. (form 7A-legal manufacturer and FSC manufacturing gfacility) M/s Osartis GmbH Auf der Beune 101 64839 Munster Germany. (FSC) (mfg+legal mfg as per ISO, MFG as per Full Q). FSC: Germany, issued on 09/03/2021.	Hi-Fatigue Bone Cement Hi-Fatigue G Bone Cement Codes & Sizes: as per FSC Class-D Shelf Life: 3 years	**Deferred for:** • Clarification along with the supported documents are required since the name and address of legal manufacturer mentioned in Form 7A, ISO 13485 and Free Sale Certificate are different. Furthermore, provide detailed information regarding the manufacturing site of the applied product. • Submission of notarized and valid letter of authorization. Please not the legal manufacturer should issue the letter of authorization. • Since Hi-Fatigue bone cement and Hi-Fatigue G Bone Cement cannot be grouped as family. separate applications for getting the registration of the applied cement should be submitted.
4.	-do- Evaluator [AD-VIII] 4086	**Legal manufacturer:** Smiths Medical ASD inc, 6000 Nathan Lane N. Minneapolis, MN 55442 **Manufacturing site:** Smiths Healthcare Manufacturing SA de CV Carretera Miguel Aleman km 21.7 Parque Industrial Monterrey Apoda NL, CP66603 Mexico. **EU representative:** Smith Medical Czech Republic a.s. Olomoucka 306, Hranice 1 – Misto, 753 01 Hranice, Czech Republic.	**PORTEX ECHOGLO (Nerve Block Needle Single Shot)** Codes & Sizes: Not given on application form Class-C Shelf Life: 3 Year	**Deferred** for the provision of deficient document / clarification: i. Discrepancy in name of applied medical device i.e. Portex Echoglo Single Shot Nerve Block Needle **OR** peripheral Nerve Block needle – Single Shot. ii. Details of QC-processes. iii. Codes/sizes not mentioned on application. iv. The firm submitted stability study bearing title "ECHOGLO REPORT FOR LUER (NEEDLE) 594 VERIFICATION TESTING", clarify that whether the same is applicable to Portex Echoglo Nerve Block Needle: Single Shot. v. FSC was not attached with the application. Therefore, provide the FSC of country of origin and any RRA as per rule 67(2) of MDR-2017. vi. Provide English Translated label of all codes & sizes of applied medical device (as approved in the country of origin) vii. Furthermore, highlight the applied medical product on FQA.

		FSC: Not Attached		viii. The label states Smiths Medical Minneapolis, MN 55442, USA is manufacturer and this product is assembled in Mexico. However, the application form and FQA states that the manufacturer is Smiths Healthcare Manufacturing SA de CV Carretera Miguel Aleman km 21.7 Parque Industrial Monterrey Apodaca NL, CP66603 Mexico. Therefore, provide the label as approved in the country of origin or clarify. ix. Provide the DECLARATION (on stamp paper) as per Form-7A.
5.	-do- Evaluator [AD-VIII] 4086	**Legal manufacturer:** Smiths Medical ASD inc, 6000 Nathan Lane N. Minneapolis, MN 55442 **Manufacturing site:** Smiths Healthcare Manufacturing SA de CV Carretera Miguel Aleman km 21.7 Parque Industrial Monterrey Apodaca NL, CP66603 Mexico. **EU representative:** Smith Medical Czech Republic a.s. Olomoucka 306, Hranice 1 – Misto, 753 01 Hranice, Czech Republic. FSC: Not Attached	**PORTEX ECHOGLO NERVE BLOCK NEEDLE: CONTINUOUS NERVE BLOCK SYSTEM** Codes & Sizes: Not given on application form. Class-C Shelf Life: 3 Year	**Deferred** for the provision of deficient document / clarification: i. Discrepancy in name of applied medical device i.e. Portex Echoglo Continuous Nerve Block System OR peripheral Nerve Block needle – Continuous Nerve Block System. ii. Details of manufacturing & QC-processes. iii. Mention codes/sizes of applied medical device and submit revised application form. iv. The firm submitted stability study bearing title "ECHOGLO REPORT FOR LUER (NEEDLE) 594 VERIFICATION TESTING", clarify that whether the same is applicable to Portex Echoglo Nerve Block Needle: Continuous Nerve Block System. v. FSC was not attached with the application. Therefore, provide the FSC of country of origin and any RRA as per rule 67(2) of MDR-2017. vi. Provide English Translated label of all codes & sizes of applied medical device (as approved in the country of origin) vii. Provide FQA duly notarized by the country of origin. Provided one is un-notarized valid scanned copy. Furthermore, highlight the applied medical product. viii. The label states Smiths Medical Minneapolis, MN 55442, USA is manufacturer and this product is assembled in Mexico. However, the application form and FQA states that the manufacturer is Smiths Healthcare Manufacturing SA de CV Carretera Miguel Aleman km 21.7 Parque Industrial Monterrey Apodaca NL, CP66603 Mexico. Therefore, provide the label as approved in the country of origin or clarify. ix. Provide the DECLARATION (on stamp paper) as per Form-7A..
6.	M/s A.J Mirza Pharma (pvt) Ltd., 1st floor, Shafi court, Civil Lines, Merewether road, Karachi.	Legal Manufacturer: M/s Asahi Kasei Transfusion Technology Co.,	Leucolite ™	**Deferred for:**

	ELI: 00321 3642-K **Evaluator**: AD-IX	Ltd., Hongmeng road Shanbei village, Jingang town, Zhangjiagang City, Jiangsu province 215632 China. FSC: China , (No. SSSYTXC20190407) valid till 02/07/2021.	(Leucocyte reduction filters for single use) Codes & Sizes: JM-RF Series: Non-bag (100), Single-bag (200), Double-bag (300), Triple-bag (400) Class-C Shelf Life: 2 years	• Provision of original, valid and legalized Free Sale Certificate (FSC) since the submitted FSC is expired. Moreover, the FSC is from China which is not our reference country, therefore, the firm is required to submit original, legalized and valid FSC from a reference country as specified in Rule 67 of Medical Devices Regulations. • Submission of stability study data supporting claimed shelf life of 2 years. • Provision of instructions for use and information on validation with sterile function for the applied medical device.
7.	M/s Allmed solutions, A21/3, KDA Scheme 1, Ext Opposite National Stadium Karachi. ELI: 00029 3665-K **Evaluator**: AD-IX	Legal Manufacturer: M/s Hocer (Tianjin) Medical Technologies Co., Ltd., A1-01 east, building No. 17, Haiyun street No. 80, TEDA economic development area, Tianjin, China. FSC: China, (No. 20200207) valid till 20/08/2022.	Iscalpel Ultrasound Activated Scalpel System (Generator, Hand Piece, Shear) Codes & Sizes: As per FSC Class-C Shelf Life: 5 years	**Deferred for:** • Provision of valid and notarized ISO-13485 and Full Quality Assurance certificates since the submitted certificates are expired. • Since the free sale certificate (FSC) is from China which is not our reference country. Therefore, FSC from any reference country as specified in Rule 67, Medical Devices Regulations is required.
8.	M/s Assuza Incorporation, 17-Rabbani Road, Old Anarkali, Lahore. ELI: 00546 2834-P **Evaluator**: AD-IX	Legal Manufacturer: M/s Ningbo Hi-Tech Unicmed Imp. & Exp. Co. Ltd. 11/F, Green Town Lvyuan Tower, 588 Canghai Road, Ningbo, 31504 China. FSC: China, (copy) valid till 07/06/2023. (Certificate No. 2021YB1191). Original certificate is attached in Disposable Urine Bag. FSC:	Silicone Foley Catheter (Urethral Catheter) Codes & Sizes: As per FSC Class-B Shelf Life: 5 years	**Deferred for:** • Clarification since as per Form 7A, the applied product is Silicone Foley Catheter while submitted IFU and Essential principles of safety and performance • are for Urethral Catheters. Moreover, the submitted copy of full quality assurance certificate is for Urethral Catheters as well as for Silicone Foley Catheter. Therefore, you are required to clarify the applied product as well as the relevant documents should be submitted. • Provision of IFU and Essential principles of safety and performance for the applied product. • Provision of notarized and Valid full quality assurance certificate • Provision of information on validation for medical devices with sterile or with measuring function. • Since the submitted Free Sale Certificate is from China which is not reference regulatory authority, therefore, the firm is required to submit original, legalized and valid free sale certificate from any reference regulatory authority. • Provision of MRP for the applied product.
9.	M/s Bain Medical (SMC-Pvt) Ltd Shop No. 2, Ground floor, Plot 58-C, Street No. 24, Touheed Commercial area, phase 5, and DHA Karachi.	Legal Manufacturer: M/s Guangzhoue Phoenix Medical Equipment Co., Ltd. 10 Juncheng road, Huangpu district, Guangzhou.	Haemodialysis Machine / BAIN Codes & Sizes: DORA-6000 Class-	**Deferred for:** • Provision of notarized Declaration of Conformity from the manufacturer for the applied product.

	ELI: 00614 3703-P **Evaluator**: AD-IX	FSC: China, (No. 20210015) valid till 03/07/2022.	Service Life: 8 years	• Since the product is manufactured and sold in China as per submitted certificate while the product should be available for free sale in any of the reference country as specified in Medical Devices Regulations. Therefore, submission of FSC from a reference country is required.
10.	M/s Fresenius Medical Care Pakistan Pvt. Ltd. TAMC, First Floor, 27C III, M.M Alam road Gulberg III, Lahore. ELI: 00315 1650-P **Evaluator**: AD-IX	Legal Manufacturer: M/s Fresenius Medical Care AG & Co. KGaA, 61346, Bad Homburg, Germany. Manufacturing of procedure packs: Fresenius Medical Care Deuschland GmbH, OberErlenbach plant, Steinmuhlstrasse 24 61352 Bad Homburg Germany. Manufacturing of component: M/s Nova Med GmbH, Antalya Serbest Bolgesi Merkez Subesi No:16, Liman Serbest Bolgesi Mahallesi 07070 Antalya Turkey. (Multifiltrate cassette, Substituate system mulitfiltrate, Dialysate system multifiltrate) FSC: Germany (35.3-53 I 437.02 (063b-01601-2) issued on 18/07/2019.	Multifiltrate Kit 8 CVVHDF 1000 (therapy sets for acute dialysis treatments) Codes & Sizes: 5038871 Class-C Shelf Life: 3 year	**Deferred for:** • Justification since the claimed shelf life of the applied kit along with the supporting documents/data. • Clarification is required since as per Form 7A the manufacturer for components is M/s Nova Med GmbH and the manufacturer for procedure pack is M/s Fresenius Medical Care Deutschland GmbH while as per the submited Free Sale Certificate, the manufacturer of Multifiltrate Kit is M/s Nova Med GmbH. • Submission of valid and notarized full quality assurance certificate mentioning the name of the applied device and the manufacturer. • Submission of valid and notarized ISO-13485 is required. • Provision essential principles of safety and performance of the applied product.
11.	-do- Evaluator [AD-VIII] 2877	Legal Manufacturer: M/s Fresenius Medical Care AG & Co. KGaA, 61346 Bad Homburg Germany Manufacturer Site: M/s Fresenius Medical Care Japan K.K. Buzen City Plant, 92-7 Ohaza Kaimo, Buzen City, Fukuoka Pre. 828-0045 Japan.	FX 60 Classic, FX 80 Classix & FX 100 Classix (Dialysers/ Filters) Coes & sizes: As per FSC Class-C Shelf Life: 3 years	**Deferred** for the provision of deficient document / clarification: Differential fee of 12500/- is required regarding manufacturing site addition in already registered product MDIR-0000799. The firm has paid 12500/- vide challan no. 96613729181. Provide DoC of applied medical product mentioning the manufacturing site to be added i.e. M/s Fresenius Medical Care Japan K.K Buzen Plant, 92-7 Ohaza Kaimo, Buzen City, Fukuoka Pref. 828-0045, Japan. The provided one is old and does not cover the same.

		FSC: Japan. Date of Issue: 18.01.2021		Provide valid ISO 13485 certificate since the provided one is expired now but valid upon submission.
12.	-do- Evaluator [AD-VIII] 2878	Legal Manufacturer: M/s Fresenius Medical Care AG & Co. KGaA, 61346 Bad Homburg Germany Manufacturer Site: M/s Fresenius Medical Care Japan K.K Buzen Plant, 92-7 Ohaza Kaimo, Buzen City, Fukuoka Pref. 828-0045, Japan Original FSC: Germany Date of Issue: 18.01.2021	FX5, FX8, FX10 (Dialysers/Filters) Coes & sizes: As per FSC Class-C Shelf Life: 3 years Fee Submitted: 12500/- for site addition.	**Deferred** for the provision of deficient document / clarification: Differential fee of 12500/- is required regarding manufacturing site addition in already registered product MDIR-0000799. The firm has paid 12500/- vide challan no. 96613729181. Provide DoC of applied medical product mentioning the manufacturing site to be added i.e. M/s Fresenius Medical Care Japan K.K Buzen Plant, 92-7 Ohaza Kaimo, Buzen City, Fukuoka Pref. 828-0045, Japan. The provided one is old and does not cover the same. Provide valid ISO 13485 certificate since the provided one is expired now but valid upon submission.
13.	-do- Evaluator [AD-VIII] 2879	Legal Manufacturer: M/s Fresenius Medical Care AG & Co. KGaA, 61346 Bad Homburg Germany Manufacturer Site: M/s Fresenius Medical Care Japan K.K Buzen Plant, 92-7 Ohaza Kaimo, Buzen City, Fukuoka Pref. 828-0045, Japan Original FSC: Germany Date of Issue: 18.01.2021	FX CorDiax 40, FX CorDiax 50, FX CorDiax 60, FX CorDiax 80 & FX CorDiax 100 (Dialysers/ Filters) Coes & sizes: As per FSC Class-C Shelf Life: 3 years Fee Submitted: 12500/- for site addition.	**Deferred** for the provision of deficient document / clarification: Differential fee of 12500/- is required regarding manufacturing site addition in already registered product MDIR-0000990. The firm has paid 12500/- vide challan no. 649264184580. Provide DoC of applied medical product mentioning the manufacturing site to be added i.e. M/s Fresenius Medical Care Japan K.K Buzen Plant, 92-7 Ohaza Kaimo, Buzen City, Fukuoka Pref. 828-0045, Japan. The provided one is old and does not cover the same. Provide valid ISO 13485 certificate since the provided one is expired now but valid upon submission.
14.	-do- **Evaluator:** AD-IV [1844-P]	Legal Manufacturer: M/s Fresenius Medical Care AG& Co. KGaA, 61346 Bad Homburg Germany Manufacturing site: M/s Fresenius Medical Care Deutschland GmbH, Obererlenbach Plant Steinmuhlstrasse 24, 61352 Bad Homburg, Germany FSC Germany	multiFiltrate Kit paed CRRT/SCUF (Therapy sets for acute dialysis treatment) Code: 5039051 Class C Shelf life: 3 year	**Deferred** for provision of following documents: - • Valid ISO13485. • Valid and notarized Full QA Certificate. • EU DOC for each component in this procedure pack on manufacturer's letter head signed and stamped by the responsible personnel • Label of this procedure pack is not readable • Credentials not notarized. Provide notarized credentials • Instructions for use (IFU) not provided. Provide IFU for procedure pack applied or of each component and then also clearly state the purpose of this applied

		issued on 20.05.2020		product • QC details of each component of this procedure pack not provided • Clearly state the shelf life of each component in the procedure pack and provide clear conclusive stability studies of each component and then state the shelf life of this pack based on the component with the shortest shelf life
15.	-do- **Evaluator:** AD-IV [1845-P]	Legal Manufacturer: M/s Fresenius Medical Care AG& Co. KGaA, 61346 Bad Homburg Germany Manufacturing site: M/s Fresenius Medical Care Deutschland GmbH, Obererlenbach Plant Steinmuhlstrasse 24, 61352 Bad Homburg, Germany FSC Germany issued on 20.05.2020	multiFiltrate Kit MIDI CVVHDF 400 (Therapy sets for acute dialysis treatments) Code: F00003317 Class C Shelf life: 3 year	**Deferred** for provision of following documents:- • Valid and notarized ISO13485. • Label of this procedure pack is not readable • Instructions for use (IFU) not provided. Provide IFU for procedure pack applied or of each component and then also clearly state the purpose of this applied product • QC details of each component of this procedure pack not provided • Clearly state the shelf life of each component in the procedure pack and provide clear conclusive stability studies of each component and then state the shelf life of this pack based on the component with the shortest shelf life
16.	M/s Fresenius Kabi Pakistan Private Limited, First floor, Tanwir Ahmad medical center (TAMC, MM Alam road, 27-C/3, Gulberg III, Lahore. ELI: 00266 1590-P **Evaluator:** AD-IX	Legal Manufacturer: M/s Fresenius Kabi AG 61346 Bad Homburg, Germany. Manufacturing facility: M/s Fresenius Kabi (Nanchang) Co., Ltd., Qin Lan road, Nanchang economic & technological development zone 330013 Nanchang, Jiangxi province, China. FSC: Germany, Issued on 30/01/2020.	Infusia Infusion Pump (Infusion pump) Codes/Models: INFVP7S-PK-ED3 Class-C Shelf Life: 7 years	**Deferred** for provision of following documents:- • Notarized and valid ISO-13485 certificate. • Justification regarding the service life of 7 years for the applied device along with the supporting documents. • Essential Principles of Safety and Performance for the applied device.
17.	M/s Humayun Dental Supplies 43, Mozang road, Lahore. ELI: 00063 2434-P **Evaluator:** AD-IX	Legal Manufacturer: M/s GC Corporation 76-1 Hasunuma-Cho, Itabashi-ku, Tokyo, 174-8585, Japan. Manufacturing facility: M/s GC Corporation Fuji Oyama Factory 584-1, Nakahinata, Oyama-Cho, Sunto-	Elite Cement 100 Asia 1-1 PKG (Dental Zinc Phosphate Cement) Codes & Sizes: 000033 Class-B Shelf Life: 36 months	**Deferred** for provision of following documents:- • Notarized and valid ISO-13485 certificate. • Noptarized and valid production quality assurance certificate. • Stability study data supporting the claimed shelf life of 3 years for liquid and the powder. • Provision of complete composition of the applied product.

		Gun, Shizoukz-Ken, 410-1307 Japan FSC: Japan, (No. KYS.02.B) issued on 09/0/2020		
18.	-do- 1624-P **Evaluator**: AD-IX	Legal Manufacturer: M/s Dr.Schumacher GmbH, Am Roggenfeld 3, 34323 Malsfeld, Germany. FSC: Germany (No. 35.3-53i437.02(05-00094)) issued on 17/06/2019.	Perfektan Extra (pre-disinfectant cleaner for instruments) Codes & Sizes: 250mL (00-144-0025EXP) 2L (00-144-020EXP) 5L (00-144-050EXP) Class-C Shelf Life: 36 months	**Deferred** for provision of following documents:- • stability study data supporting the shelf life of 3 years of the applied medical device. • Valid and notarized ISO-13485.
19.	M/s Health Care International, First floor, 210/J-2. Johar Town, Lahore. ELI: 00141 2898-P **Evaluator**: AD-IX	Legal Manufacturer: M/s Sunny Medical Device (Shenzen) Co., Ltd., 1/F and 401, Zhongtianxin Building B, Longgang District, Shenzen, Guangdong, 518172 China. FSC: Spain, issued on 06/09/2021. (Certificate No. PS/CLV/MGCO/0966/2021-CLV) FSC: China valid till 23/02/2023 (certificate No. 20211034)	Sunmed Guide Wires (Sterilized Guide Wires) Codes & Sizes: As per FSC Class-B Shelf Life: 3 years	**Deferred for:** • Clarification since as per submitted documents, the applied product falls under the category of class IIa (B) while the product is categorized the device as Class D. • Provision of valid and notarized ISO 13485.
20.	M/s Hoora Pharma (pvt) Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi. ELI: 00037 1248-k **Evaluator**: AD-IX	Legal manufacturer: M/s Siemens Healthcare Diagnostic Inc., 511 Benedict ave, Tarrytown, NY 10591, USA. M/s Siemens Healthcare Diagnostics Inc. Glyn Rhonwy, Llanberis, Gwynedd, LL55 4EL, United Kingdom. (mfg and legal mfg as per free sale)	Immulite / Immulite 1000 Myoglobin (Myoglobin Kit) Codes & Sizes: As per FSC Class-C Shelf Life: 1 years	**Deferred for:** • Submission of notarized and valid ISO 13485 is expired. • Clarification is required since as per Form 7A the legal manufacturer is M/s Siemens Healthcare Diagnostic Inc., 511 Benedict ave, Tarrytown, NY 10591, USA while as per the other documents such as DOC, free sale certificate the legal manufacturer is M/s Siemens Healthcare Diagnostics Inc. Glyn Rhonwy, Llanberis, Caernarfon, LL55 4EL, United Kingdom which is the manufacturer of the applied product, please. Moreover, the address of manufacturing facility mentioned in Form A is not in-line with the address mentioned in free sale certificate.

		FSC: UK (copy), valid till 16/10/2020.		• Provision of notarized and valid letter of authorization from legal manufacturer. The submitted copy of letter of authorization is from another firm located in Germany.
21.	-do- 1247-k **Evaluator**: AD-IX	Legal manufacturer: M/s Siemens Healthcare Diagnostic Inc., 511 Benedict ave, Tarrytown, NY 10591, USA. M/s Siemens Healthcare Diagnostics Inc. Glyn Rhonwy, Llanberis, Gwynedd, LL55 4EL, United Kingdom. (mfg and legal mfg as per free sale) FSC: UK (copy), valid till 16/10/2020.	Immulite / Immulite 1000 Turbo NT-Pro BNP Codes & Sizes: As per FSC Class-C Shelf Life: 1 years	**Deferred for:** • Clarification is required since as per Form 7A the legal manufacturer is M/s Siemens Healthcare Diagnostic Inc., 511 Benedict ave, Tarrytown, NY 10591, USA while as per the other documents such as DOC, free sale certificate the legal manufacturer is M/s Siemens Healthcare Diagnostics Inc. Glyn Rhonwy, Llanberis, Caernarfon, LL55 4EL, United Kingdom which is the manufacturer of the applied product, please. Moreover, the address of manufacturing facility mentioned in Form A is not in-line with the address mentioned in free sale certificate. • Provision of stability report of the applied product since stability report of another product is attached in the submitted dossier. • Provision of valid and notarized ISO 13485 certificate mentioning the name and complete address of manufacturing facility since the submitted copy is expired. • Provision of original, legalized and valid Free Sale Certificate since the submitted copy is expired.
22.	-do- 1259-k **Evaluator**: AD-IX	Legal manufacturer: M/s Siemens Healthcare Diagnostic Inc., 511 Benedict ave, Tarrytown, NY 10591, USA. M/s Siemens Healthcare Diagnostics Inc. 333 Coney street east Walpole, MA, 02032, USA. FSC: UK (copy), valid till 31/12/2020.	Advia Centaur Myoglobin (10329242) Advia Centaur Myoglobin (10310277) Advia Centaur Calibrator U (10309996) Advia Centaur Multi Diluent 10 (10310280) Advia Centaur Multi Diluent 10 (10310033) Codes & Sizes: As per FSC Class-C Shelf Life: 10 months	**Deferred for:** • Clarification regarding the grouping for the applied product and theuse of multi diluent whether it would be used with the applied kit only or it can be used with other diagnostic kits. Furthermore, clarify the difference between the two multi diluents and their intended use. • Provision of valid and notarized ISO 13485 certificate mentioning the correct name and complete address of manufacturing facility since the submitted copy of the certificate is expired. • Provision of detail of manufacturing and Quality Control procedures. • Provision of original, legalized and valid Free Sale Certificate since the submitted copy is expired. • Provision of legalized and valid letter of authorization mentioning the name of the applied product since the submitted copy does not contain the relevant information related to manufacturing facility and the applied product. • Provision of stability studies for the applied product including all the codes. • Provision of original, legalized and valid free sale certificate since you have submitted copy of FSC.

				• Provision of Declaration of Conformity for the applied codes of Diluent.
23.	-do- 1240-k **Evaluator**: AD-IX	Legal manufacturer: M/s Siemens Healthcare Diagnostic Inc., 511 Benedict ave, Tarrytown, NY 10591, USA. M/s Siemens Healthcare Diagnostics Inc. 700 GBC Drive Newark DE 19702 Glasgow, Delaware, USA. FSC: UK (copy), valid till 03/05/2023	Dimension Creatine Kinase Flex reagent cartridge Dimension CKI/MBI Calibrator (Creatine Kinase Kit) Codes & Sizes: As per FSC Class-C Shelf Life: 1 years	**Deferred for:** • Provision of valid and notarized ISO 13485 certificate mentioning the name and complete address of manufacturing facility. • Clarification is required since as per Form 7A the legal manufacturer is M/s Siemens Healthcare Diagnostic Inc., 511 Benedict ave, Tarrytown, NY 10591, USA while as per the other documents such as DOC, free sale certificate the legal manufacturer is M/s Siemens Healthcare Diagnostics Inc. 500 GBC driveMailstop 514, PO box 6101, Newark, DE, 19714, United States. Moreover, the address of manufacturing facility mentioned in Form 7A is not in-line with the address mentioned in DoC. • Provision of notarized and valid letter of authorization mentioning the name of the applied product.
24.	-do- 3245-k **Evaluator**: AD-IX	Legal manufacturer: M/s Siemens Healthcare Diagnostic Inc., 511 Benedict ave, Tarrytown, NY 10591, USA. Manufacturing facility; M/s Siemens Healthcare Diagnostics Inc. 333 Coney street East Walpole, MA, 02032, USA. FSC:	Atellica IM Cyclosporine (109955548) Atellica IM Cyclosporine Calibrator (10995549) Atellica IM Multi-Diluent 12 (10995550) Atellica IM Cyclosporine Pretreatment Reagent (10995552) Codes & Sizes: As stated above Class-C Shelf Life: 05 months	**Deferred for:** • Provision of valid and notarized ISO 13485 certificate mentioning the name and complete address of manufacturing facility since the submitted copy is expired. • Provision of valid and notarized letter of authorization. • Submission of notarized and valid production/full quality assurance certificate. • Clarification is required since the name and address of manufacturing facility is different in Form 7A and DoC/FSC. • Provision of notarized and valid letter of authorization mentioning the name of the applied product. • Clarification of the grouping for the applied product. Moreover, state clearly the use of multi diluent whether it would be used with the applied kit only or it can be used with other diagnostic kits. Furthermore, State difference between Atellica IM multi-diluent 12 and Atellica IM Cyclosporin Pretreatment Reagent in terms of their use. • Provision of original, legalized and valid Free Sale Certificate since the submitted copy is expired. • Provision of stability study data supporting the claimed shelf life of at least 05 months for Atellica IM Cyclosporine (109955548), Atellica IM Cyclosporine Calibrator (10995549), Atellica IM Multi-Diluent 12 (10995550), Atellica IM Cyclosporine Pretreatment Reagent (10995552).
25.	-do- 1245-k **Evaluator**: AD-IX	Legal manufacturer: M/s Siemens Healthcare Diagnostic Inc., 511 Benedict ave,	Atellica IM Trop TNI Ultra (10995696) Atellica IM Trop TNI Ultra (10995697)	**Deferred for:** • Provision of stability report of the applied product since stability report of another product is attached in the submitted dossier.

		Tarrytown, NY 10591, USA. Manufacturing facility; M/s Siemens Healthcare Diagnostics Inc. 333 Coney street East Walpole, MA, 02032, USA. FSC: UK (copy), valid till 31/12/2020	Atellica IM Multi-Diluent 11 (10995642) Atellica IM Multi-Diluent 11 (10995641) (Troponin Kit) Codes & Sizes: As per FSC Class-C Shelf Life: 11 months	• Provision of valid and notarized ISO 13485 certificate mentioning the name and complete address of manufacturing facility since the submitted copy is expired. • Provision of detail of manufacturing and Quality Control procedures. • Clarification is required since the name and address of manufacturing facility is different in Form 7A and DoC/FSC., • Please provide notarized and valid letter of authorization mentioning the name of the applied product. • Clarification of the grouping for the applied product. Moreover, state clearly the use of multi diluent whether it would be used with the applied kit only or it can be used with other diagnostic kits. Furthermore, clarification is required regarding the difference between the two multi diluents and their intended use. • Provision of original, legalized and valid Free Sale Certificate since the submitted copy is expired.
26.	-do- 1262-k **Evaluator:** AD-IX	Legal manufacturer: M/s Siemens Healthcare Diagnostic Inc., 511 Benedict ave, Tarrytown, NY 10591, USA. Manufacturing facility; M/s Randox Laboratories Limited, 55 Diamond road Crumlin County Antrium, BT29 4QY, United Kingdom. FSC: UK (copy), valid till 31/12/2020	Advia Chemistry Cardio Phase High Sensitivity C-Reactive Protein Reagents (10283282) Advia Chemistry Cardio Phase High Sensitivity C-Reactive Protein Calibrator (10335897) Codes & Sizes: As per FSC Class-C Shelf Life: 18 months	**Deferred for:** • Provision of valid and notarized ISO 13485 certificate mentioning the name and complete address of manufacturing facility since the submitted copy of the certificate is expired. • Provide detail of manufacturing and Quality Control procedures. • Provision of original, legalized and valid Free Sale Certificate since the submitted copy is expired. • Provision of legalized and valid letter of authorization mentioning the name of the applied product since the submitted copy does contain the relevant information related to manufacturing facility and the applied product.
27.	-do- 1250-k **Evaluator:** AD-IX	Legal manufacturer: M/s Siemens Healthcare Diagnostic Inc., 511 Benedict ave, Tarrytown, NY 10591, USA. Manufacturing facility; M/s Siemens Healthcare Diagnostics Inc. Glyn Rhonwy, Llanberis, Gwynedd, LL55 4EL, United Kingdom.	Immulite 2000 CK-MB (10381033) Immulite 2000 Multi Diluent 2 sample Diluent (10283031) Codes & Sizes: As per FSC Class-C Shelf Life: 12 months	**Deferred for:** • Provision of valid and notarized ISO 13485 certificate mentioning the name and complete address of manufacturing facility since the submitted copy of the certificate is expired. • Provision of detail of manufacturing and Quality Control procedures. • Provision of original, legalized and valid Free Sale Certificate since the submitted copy is expired. • Provide legalized and valid letter of authorization mentioning the name of the applied product since the submitted copy does not contain the relevant information related to manufacturing facility and the applied product.

		FSC: UK (copy), valid till 16/10/2020		• Clarification is required since as per Form 7A the legal manufacturer is M/s Siemens Healthcare Diagnostic Inc., 511 Benedict ave, Tarrytown, NY 10591, USA while as per the other documents such as DOC the legal manufacturer is M/s Siemens Healthcare Diagnostics Inc. Glyn Rhonwy, Llanberis, Caernarfon, LL55 4EL, United Kingdom which is the manufacturer of the applied product as well.
28.	-do- 1243-k **Evaluator**: AD-IX	Legal manufacturer: M/s Siemens Healthcare Diagnostic Inc., 511 Benedict ave, Tarrytown, NY 10591, USA. Manufacturing facility; M/s Siemens Healthcare Diagnostics Inc. 333 Coney street east Walpole, MA, 02032, USA FSC: UK (copy), valid till 31/112/2020	Advia Centaur BNP (10309045) Advia Centaur BNP (10309044) Advia Cetaur BNP Calibrator (10309047) Advia Centaur BNP 1,2,3 Quality Control Material (10309046) Codes & Sizes: As per FSC Class-C Shelf Life: 12 months	**Deferred for:** • Provision of valid and notarized ISO 13485 certificate mentioning the name and complete address of manufacturing facility since the submitted copy of the certificate is expired. • Provision of detail of manufacturing and Quality Control procedures. • Provision of original, legalized and valid Free Sale Certificate since the submitted copy is expired. • Provision of legalized and valid letter of authorization mentioning the name of the applied product since the submitted copy does not contain the relevant information related to manufacturing facility and the applied product.
29.	-do- 3249-k **Evaluator**: AD-IX	Legal manufacturer: M/s Siemens Healthcare Diagnostic Inc., 511 Benedict ave, Tarrytown, NY 10591, USA. Manufacturing facility; M/s Siemens Healthcare Diagnostics Inc. 700 GBC Drive Newark DE 19702 Glasgow, Delware USA. FSC: UK (copy), valid till 03/05/2023.	Dimension Mycophenolic Acid Flex Reagent Cartridge (10464329/DF115) Dimension Mycophenolic Acid Calibrator (10445527/DC115) Codes & Sizes: As stated above Class-C Shelf Life: 12 months (with storage conditions 2-8°C)	**Deferred for:** • Clarification regarding the name and address of manufacturing facility since the address mentioned in DoC/FSC is M/s siemens Healthcare Diagnostics inc. 500 GBC drive, mailstop 514, p.O. box 6101 Newark, DE, 19714, USA while the address mentioned in Form 7A is M/s Siemens Healthcare Diagnostics Inc. 700 GBC Drive Newark DE 19702 Glasgow, Delware USA. • Provision of valid and notarized ISO 13485 certificate mentioning the correct name and complete address of manufacturing facility since the submitted copy of the certificate is expired and it does not contain the name and address of the manufacturing facility. • Provide original, legalized and valid Free Sale Certificate since the submitted copy is expired. • Provision of legalized and valid letter of authorization mentioning the name of the applied product. • Provision of valid and notarized production/full quality assurance certificate is required. • Submission of stability report supporting the claimed shelf life of 12 months for Dimension Mycophenolic Acid Flex Reagent Cartridge (10464329/DF115).
30.	-do-	Legal manufacturer:	Dimension Tacrolimus Flex	**Deferred for:**

	3248-k **Evaluator**: AD-IX	M/s Siemens Healthcare Diagnostic Inc., 511 Benedict ave, Tarrytown, NY 10591, USA. Manufacturing facility; M/s Siemens Healthcare Diagnostics Inc. 700 GBC Drive Newark DE 19702 Glasgow, Delware USA. FSC: UK (copy), valid till 03/05/2023.	Reagent Cartridge (10700795/DF207) Dimension Tacrolimus Calibrator (10700796/DC207) Codes & Sizes: As stated above Class-C Shelf Life: 09 months (with storage conditions 2-8°C)	• Clarification regarding the name and address of manufacturing facility since the address mentioned in DoC/FSC is M/s siemens Healthcare Diagnostics inc. 500 GBC drive, mailstop 514, p.O. box 6101 Newark, DE, 19714, USA while the address mentioned in Form 7A is M/s Siemens Healthcare Diagnostics Inc. 700 GBC Drive Newark DE 19702 Glasgow, Delware USA. • Provision of valid and notarized ISO 13485 certificate mentioning the correct name and complete address of manufacturing facility since the submitted copy of the certificate is expired and it does not contain the name and address of the manufacturing facility. • Provision of original, legalized and valid Free Sale Certificate since the submitted copy is expired. • Provision of legalized and valid letter of authorization mentioning the name of the applied product. • Provision of valid and notarized production/full quality assurance certificate is required. • Submission of stability report supporting the claimed shelf life of 09months for Dimension Tacrolimus Calibrator (10700796/DC207).
31.	-do- 3250-k **Evaluator**: AD-IX	Legal manufacturer: M/s Siemens Healthcare Diagnostic Inc., 511 Benedict ave, Tarrytown, NY 10591, USA. Manufacturing facility; M/s Siemens Healthcare Diagnostics Inc. 700 GBC Drive Newark DE 19702 Glasgow, Delware USA. FSC: UK (copy), valid till 03/05/2023.	Dimension Sirolimus Flex Reagent Cartridge (10464331/DF306) Dimension Sirolimus Calibrator (10464327/DC306) Codes & Sizes: As stated above Class-C Shelf Life: 06 months (with storage conditions 2-8°C)	**Deferred for:** • Clarification regarding the name and address of manufacturing facility since the address mentioned in DoC/FSC is M/s siemens Healthcare Diagnostics inc. 500 GBC drive, mailstop 514, p.O. box 6101 Newark, DE, 19714, USA while the address mentioned in Form 7A is M/s Siemens Healthcare Diagnostics Inc. 700 GBC Drive Newark DE 19702 Glasgow, Delware USA. • Provision of valid and notarized ISO 13485 certificate mentioning the correct name and complete address of manufacturing facility since the submitted copy of the certificate is expired and it does not contain the name and address of the manufacturing facility. • Provision of original, legalized and valid Free Sale Certificate since the submitted copy is expired. • Provision of legalized and valid letter of authorization mentioning the name of the applied product. • Provision of valid and notarized production/full quality assurance certificate is required. • Submission of stability report supporting the claimed shelf life of 06 months for Dimension Sirolimus Flex Reagent Cartridge (10464331/DF306) Dimension Sirolimus Calibrator (10464327/DC306).

32.	-do- 3246-k **Evaluator:** AD-IX	Legal manufacturer: M/s Siemens Healthcare Diagnostic Inc., 511 Benedict ave, Tarrytown, NY 10591, USA. Manufacturing facility; M/s Siemens Healthcare Diagnostics Inc. 700 GBC Drive Newark DE 19702 Glasgow, Delware USA. FSC: UK (copy), valid till 03/05/2023.	Dimension Cyclosporine Flex Reagent Cartridge (10285193/DF89A) Dimension Cyclosporine Calibrator (10445001/DC89) Codes & Sizes: As stated above Class-C Shelf Life: 12 months (with storage conditions 2-8°C)	**Deferred for:** • Clarification regarding the name and address of manufacturing facility since the address mentioned in DoC/FSC is M/s siemens Healthcare Diagnostics inc. 500 GBC drive, mailstop 514, p.O. box 6101 Newark, DE, 19714, USA while the address mentioned in Form 7A is M/s Siemens Healthcare Diagnostics Inc. 700 GBC Drive Newark DE 19702 Glasgow, Delware USA. • Provision of valid and notarized ISO 13485 certificate mentioning the correct name and complete address of manufacturing facility since the submitted copy of the certificate is expired and it does not contain the name and address of the manufacturing facility. • Provision of original, legalized and valid Free Sale Certificate since the submitted copy is expired. • Provide legalized and valid letter of authorization mentioning the name of the applied product. • Provision of Valid and notarized production/full quality assurance certificate is required. • Submission of stability report supporting the claimed shelf life of 12 months for Dimension Cyclosporine Flex Reagent Cartridge (10285193/DF89A) Dimension Cyclosporine Calibrator (10445001/DC89).
33.	-do- 3247-k **Evaluator:** AD-IX	Legal manufacturer: M/s Siemens Healthcare Diagnostic Inc., 511 Benedict ave, Tarrytown, NY 10591, USA. Manufacturing facility; M/s Siemens Healthcare Diagnostics Inc. 700 GBC Drive Newark DE 19702 Glasgow, Delware USA. FSC: UK (copy), valid till 03/05/2023.	Dimension Cyclosporin, Extended Range Flex Reagent Cartridge (10444934/DF108) Dimension Cyclosporine Extended Range Calibrator (10445004/DC108A) Codes & Sizes: As stated above Class-C Shelf Life: 12 months (with storage conditions 2-8°C)	**Deferred for:** • Clarification regarding the name and address of manufacturing facility since the address mentioned in DoC/FSC is M/s siemens Healthcare Diagnostics inc. 500 GBC drive, mailstop 514, p.O. box 6101 Newark, DE, 19714, USA while the address mentioned in Form 7A is M/s Siemens Healthcare Diagnostics Inc. 700 GBC Drive Newark DE 19702 Glasgow, Delware USA. • Provision of valid and notarized ISO 13485 certificate mentioning the correct name and complete address of manufacturing facility since the submitted copy of the certificate is expired and it does not contain the name and address of the manufacturing facility. • Provision of original, legalized and valid Free Sale Certificate since the submitted copy is expired. • Provision of legalized and valid letter of authorization mentioning the name of the applied product. • Provision of valid and notarized production/full quality assurance certificate is required. • Submission of stability report supporting the claimed shelf life of 12 months for Dimension Cyclosporin, Extended Range

				Flex Reagent Cartridge (10444934/DF108).
34.	-do- 1246-k **Evaluator**: AD-IX	Legal manufacturer: M/s Siemens Healthcare Diagnostic Inc., 511 Benedict ave, Tarrytown, NY 10591, USA. Manufacturing facility; M/s Siemens Healthcare Diagnostics Inc. 700 GBC Drive Newark DE 19702 Glasgow, Delware USA. FSC: UK (copy), valid till 03/05/2023.	Dimension N-terminal Pro-Brain Natriuretic Peptide Flex Reagent Cartridge (10444900) Dimension N-terminal Pro-Brain Natriuretic Peptide Flex Reagent Cartridge (10444901) Dimension N-terminal Pro-Brain Natriuretic Peptide Flex Calibrator (10445008) Codes & Sizes: As per FSC Class-C Shelf Life: 12 months	**Deferred for:** • Clarification regarding the name and address of manufacturing facility since the address mentioned in DoC is M/s siemens Healthcare Diagnostics inc. 500 GBC drive, mailstop 514, p.O. box 6101 Newark, DE, 19714, USA while the address mentioned in Form 7A is M/s Siemens Healthcare Diagnostics Inc. 700 GBC Drive Newark DE 19702 Glasgow, Delware USA. • Provision of valid and notarized ISO 13485 certificate mentioning the correct name and complete address of manufacturing facility since the submitted copy of the certificate is expired and it does not contain the name and address of the manufacturing facility. • Provision of detail of manufacturing and Quality Control procedures. • Provision of original, legalized and valid Free Sale Certificate since the submitted copy is expired. • Provision of legalized and valid letter of authorization mentioning the name of the applied product since the submitted copy does not contain the relevant information related to manufacturing facility and the applied product.
35.	-do- 1244-k **Evaluator**: AD-IX	Legal manufacturer: M/s Siemens Healthcare Diagnostic Inc., 511 Benedict ave, Tarrytown, NY 10591, USA. Manufacturing facility; M/s Siemens Healthcare Diagnostics Inc. 333 Coney street east Walpole, MA, 02032, USA. FSC: UK (copy), valid till 31/12/2020.	Advia Centaur CKMB (10326496) Advia Centaur CKMB (10309982) Advia Centaur CKMB Calibrator (10311570) Advia Centaur CKMB Calibrator (10311572) Advia Centaur CKMB Diluent (10309951) Advia Centaur CKMB Diluent (10311592) Codes & Sizes: As per FSC Class-C Shelf Life: 12 months	**Deferred for:** • Provision of Declaration of Conformity (DoC) for Advia Centaur CKMB Diluent (10311592) along with the explanation regarding the difference between the two diluents. • Provision of valid and notarized ISO 13485 certificate mentioning the correct name and complete address of manufacturing facility since the submitted copy of the certificate is expired. • Provision of detail of manufacturing and Quality Control procedures. • Provision of original, legalized and valid Free Sale Certificate since the submitted copy is expired. • Provision of legalized and valid letter of authorization mentioning the name of the applied product since the submitted copy does not contain the relevant information related to manufacturing facility and the applied product. • Provision of stability studies for Advia Centaur CKMB, Advia Centaur CKMB Calibrator and Advia Centaur CKMB Diluent including all the codes applied. • Provision of original, legalized and valid free sale certificate since you have submitted copy of FSC.

36.	-do- 3251-k **Evaluator**: AD-IX	Legal manufacturer: M/s Siemens Healthcare Diagnostic Inc., 511 Benedict ave, Tarrytown, NY 10591, USA. Manufacturing facility; M/s Siemens Healthcare Diagnostics Inc. 333 Coney street east Walpole, MA, 02032, USA. FSC:	Advia Centaur Cyclosporine (10335448) Advia Centaur Cyclosporine Calibrator (10335454) Advia Centaur Multi-diluent 12 (10335692) Advia Centaur Cyclosporin pretreatment reagent (10335653) Codes & Sizes: as mentioned above Class-C Shelf Life: 05 months	**Deferred for:** • Provision of notarized Declaration of Conformity for the applied medical device for all the components. • Provision of valid and notarized ISO 13485 certificate mentioning the correct name and complete address of manufacturing facility since the submitted copy of the certificate is expired. • Provision of notarized and valid letter of authorization mentioning the name of the applied product. • Provision of notarized and valid production/full quality assurance certificate. • Provision of stability study data of all the components of the applied medical device supporting the claimed shelf life. • Provision of original, legalized and valid free sale certificate since you have submitted copy of FSC.
37.	-do- **Evaluator**: AD-VII	Legal Manufacturer: Siemens Healthcare Diagnostics Inc. 500 GBC Dr. mailstop 514 Newark DE 19714 U.SA". Manufacturer Site: Siemens Healthcare Diagnostics Inc. 500 GBC Dr. mailstop 514 Newark DE 19714 U.SA". FSC: U.K Valid till: 03.05.2023	SIMENS Dimension Creatine Kinase MB Flex reagent cartridge Simens Dimension CKI/MBI Calibrator] In Vitro Diagnostic Kit DF32 /10464510 DC-32/10464508 Class: C Shelf Life: 12 months	**Deferred** for provsiosn of the following documents: • Valid Notarised and embassy attested original FSC in the country of Origin, since only copy of FSC provided. • Provide valid Full Quality Assurance certificate. • Provide valid notarized, QMS 13485 certificate, for the manufacturing site "500 GBC Dr. mailstop 514 Newark DE 19714 U.SA". the already submitted is expired after submission and does not have the address of the manufacturing site. Furthermore, manufacturing site and legal manufacturer on Form-7 A is different than that present on the DOC and FSC. Provide clarification.
38.	-do- **Evaluator**: AD-VII	**Legal Manufacturer:** Siemens Healthcare Diagnostics Inc. **Address:**511 Benedict Ave. Tarrytown, NY 10591, USA FSC UK Valid Till 31.12.2020	**Atellica IM Creatine Kinase MB** **Class-C** **1. Atellica IM Creatine Kinase MB Kit** Size: 100 Tests Codes: 10995530 Shelf Life: 12 months **2. Atellica IM Creatine Kinase MB Kit**	**Deferred** for provsiosn of the following documents :- • Valid Notarised and embassy attested original FSC in the country of Origin, since only copy of FSC provided. • Provide valid Full Quality Assurance certificate. • Provide valid notarized, QMS 13485 certificate, the already submitted is expired after submission. • The stability study provided is for ADVIA Centaur System CKMB assay, different from the product name and codes of the product, provide clarification.

			Size: 500 Tests Codes: 10995531 Shelf Life: 12 months **3. Atellica IM Creatine Kinase MB Calibrator (CKMB CAL)** Size: 2 x 2 mL Codes: 10995532 Shelf Life: 12 months **4. Atellica IM Creatine Kinase MB Diluent (CKMB DIL)** Size: 2 x 2 mL Codes: 10995533 Shelf Life: 15 months Medical Generic Name: CK-MB KIT	
39.	-do- **Evaluator**: AD-VII	**Legal Manufacturer:** Siemens Healthcare Diagnostics Inc. **Address:**511 Benedict Ave. Tarrytown, NY 10591, USA **Manufacturing Site:** Name: Randox Laboratories Limited Address:55 Diamond Road Crumlin County Antrium, BT29 4QY, United Kingdom FSC UK Expirey date 31 Dec-2020	**1. ADVIA Chemistry Myoglobin Reagents Kit** Size: 200 Tests Codes: 10361939 Shelf Life: 18 months **2. ADVIA Chemistry Myoglobin Calibrator** Size: 4 x 1.0mL Codes: 10285682 Shelf Life: 12 months Class C	**Deferred** for provsiosn of the following documents:- • Valid Notarised and embassy attested original FSC in the country of Origin, since only copy of FSC provided. • Provide valid Full Quality Assurance certificate. • Provide valid notarized, QMS 13485 certificate, for the manufacturing site Randox Laboratories LimitedAddress:55 Diamond Road Crumlin County Antrium, BT29 4QY, United Kingdom the already submitted is expired after submission and does not have the address of the manufacturing site.

40.	-do- **Evaluator**: AD-VII	**Legal Manufacturer:** Siemens Healthcare Diagnostics Inc. **Address:**511 Benedict Ave. Tarrytown, NY 10591, USA **Manufacturing Site:** Name: Siemens Healthcare Diagnostics Inc. Address: 500 GBC Dr. mailstop 514 Newark DE 19714 U.SA FSC UK Valid Till 03.05.2023	**1. Dimension N-terminal Pro-Brain Natriuretic Peptide Flex reagent cartridge Kit** Size: 72 Tests Codes: RF723/10464338 Shelf Life: 13 months **2. Dimension N-terminal Pro-Brain Natriuretic Peptide Flex reagent cartridge Kit** Size: 120 Tests Codes: RF623 / 10464526 Shelf Life: 13 months **3. Dimension LOCI N-Terminal Pro-Brain Natriuretic Peptide Calibrator** Size: 10x 1.0mL Codes: RC623/ 10464529 Shelf Life: 12 months **Class-C**	**Deferred** for provsiosn of the following documents:- • Valid Notarised and embassy attested original FSC in the country of Origin, since only copy of FSC provided. • Provide valid Full Quality Assurance certificate. • Provide valid notarized, QMS 13485 certificate, for the manufacturing site "500 GBC Dr. mailstop 514 Newark DE 19714 U.SA". the already submitted is expired after submission and does not have the address of the manufacturing site. Furthermore, manufacturing site and legal manufacturer on Form-7 A is different than that present on the DOC and FSC. • The stability study provided is for EXL NTP/LNTP , different from the brand name provide clarification.
41.	-do- **Evaluator**: AD-VII	**Legal Manufacturer:** Siemens Healthcare Diagnostics Inc. **Address:**511 Benedict Ave. Tarrytown, NY 10591, USA **Manufacturing Site:** Name: Siemens Healthcare Diagnostics Inc. Glyn Rhony Llanberis,	**IMMULITE / IMMULITE 1000 TURBO Myoglobin Kit** Size: 100 Tests Codes: 10381020/LSKMY1 Shelf Life: 12 months **Class-C**	**Deferred** for provsiosn of the following documents:- • Valid Notarised and embassy attested original FSC in the country of Origin, since only copy of FSC provided. • Provide valid Full Quality Assurance certificate. • Provide valid notarized, QMS 13485 certificate, the already submitted is expired after submission

		Gwynedd, LL55 4EL, UK FSC UK Valid Till 16.10.2020		
42.	-do- **Evaluator**: AD-VII	**Legal Manufacturer:** Siemens Healthcare Diagnostics Inc. **Address:**511 Benedict Ave. Tarrytown, NY 10591, USA **Manufacturing Site:** Name: Siemens Healthcare Diagnostics Inc. **Address:**511 Benedict Ave. Tarrytown, NY 10591, USA FSC UK Valid Till 31.12.2020	**Atellica IM NT-proBNP (PBNP)) Class-C** **1. Atellica IM NT-proBNP (PBNP) Kit** Size: 100 Tests Codes: 11200588 Shelf Life: 18 months **2. Atellica IM NT-proBNP (PBNP) Kit** Size: 500 Tests Codes: 11200589 Shelf Life: 18 months **3. Atellica IM Multi-Diluent 1** Size: 2 Ready Pack Codes: 10995637 Shelf Life: 15 months **4. Atellica IM Multi-Diluent 1** Size: 6 Ready Pack Codes: 10995638 Shelf Life: 15 months **5. Atellica IM Multi-Diluent 1** Size: 50.0 mL/vial Codes: 10995639 Shelf Life: 15 months	**Deferred** for provsiosn of the following documents:- • Valid Notarised and embassy attested original FSC in the country of Origin, since only copy of FSC provided. • Provide valid Full Quality Assurance certificate. • Provide valid notarized, QMS 13485 certificate, the already submitted is expired after submission • The stability studies not provided. Provide stability studies
43.	-do- **Evaluator**: AD-VII	**Legal Manufacturer:** Siemens Healthcare Diagnostics Inc. **Address:**511 Benedict Ave.	**1. Atellica IM Myoglobin Kit** Size: 50 Tests Codes: 10995649 Shelf Life: 13 months	**Deferred** for provsiosn of the following documents:- • Valid Notarised and embassy attested original FSC in the country of Origin, since only copy of FSC provided. • Provide valid Full Quality Assurance certificate.

		Tarrytown, NY 10591, USA **Manufacturing Site:** Name: Siemens Healthcare Diagnostics Inc. **Address:**511 Benedict Ave. Tarrytown, NY 10591, USA FSC UK Valid Till 31.12.2020	**2. Atellica IM Myoglobin Kit** Size: 250 Tests Codes: 10995648 Shelf Life: 13 months **3. Atellica IM Calibrator U** Size: 2 x2.0mL Codes: 10995519 Shelf Life: 10 months **4. Atellica IM Multi-Diluent 10** Size: 5 mL/pk Codes: 10995640 Shelf Life: 12 months **Class C**	Provide valid notarized, QMS 13485 certificate, the already submitted is expired after submission
44.	-do- **Evaluator**: AD-VII	**Legal Manufacturer:** Siemens Healthcare Diagnostics Inc. **Address:**511 Benedict Ave. Tarrytown, NY 10591, USA **Manufacturing Site:** Siemens Healthcare Diagnostics Inc. **Address:** 333 Coney Street East Walpole, MA, 02032, USA FSC UK Valid Till 31.12.2020	**1. ADVIA Centaur TnI-Ultra Kit** Size: 500 Tests Codes: 10317709 Shelf Life: 12 months **2. ADVIA Centaur TnI-Ultra Kit** Size: 100 Tests Codes: 10317708 Shelf Life: 12 months **3. ADVIA Centaur Multi-Diluent 11** Size: 2 x 5 mL Codes: 10310281 Shelf Life: 11 months **4. ADVIA Centaur Multi-Diluent 11** Size: 10 mL/Vial Codes: 10309999	**Deferred** for provsiosn of the following documents:- • Valid Notarised and embassy attested original FSC in the country of Origin, since only copy of FSC provided. • Provide valid Full Quality Assurance certificate. • Provide valid notarized, QMS 13485 certificate, the already submitted is expired after submission

			Shelf Life: 11 months	
45.	-do- **Evaluator**: AD-VII	**Legal Manufacturer:** Siemens Healthcare Diagnostics Inc. **Address:**511 Benedict Ave. Tarrytown, NY 10591, USA **Manufacturing Site:** Name: Siemens Healthcare Diagnostics Inc. Address: Glyn Rhony Llanberis, Gwynedd, LL55 4EL, UK FSC UK Valid Till 16.10.2020	**1. IMMULITE 2000 Myoglobin Kit** Size: 200 Tests Codes: 10381031/L2KMY2 Shelf Life: 12 months **IMMULITE 2000 Multi Diluent 2 Sample Diluent** Size: 25 mL Codes: 10283031 /L2M2Z Shelf Life: 36 months **Class-C**	**Deferred** for provsiosn of the following documents:- • Valid Notarised and embassy attested original FSC in the country of Origin, since only copy of FSC provided wherein IMMULITE 2000 Multi Diluent 2 Sample Diluent name not found • Provide valid Full Quality Assurance certificate. • Provide valid notarized, QMS 13485 certificate, the already submitted is expired after submission. • Provide The DOC and stability study of the IMMULITE 2000 Multi Diluent 2 Sample Diluent.
46.	-do- **Evaluator**: AD-VII	**Legal Manufacturer:** Siemens Healthcare Diagnostics Inc. **Address:**511 Benedict Ave. Tarrytown, NY 10591, USA **Manufacturing Site:** Name: Siemens Healthcare Diagnostics Inc. **Address:**511 Benedict Ave. Tarrytown, NY 10591, USA FSC UK Valid Till 31.12.2020	**1. Atellica IM B-type Natriuretic Peptide (BNP) Kit** Size: 100 Tests Codes: 10995471 Shelf Life: 18 months **2. Atellica IM B-type Natriuretic Peptide (BNP)Kit** Size: 500 Tests Codes: 10995472 Shelf Life: 18 months **3. Atellica IM B-type Natriuretic Peptide Calibrator** Size: 2 x 2 mL Codes: 10995473 Shelf Life: 20 months **4. Atellica IM B-type Natriuretic**	**Deferred** for provsiosn of the following documents:- • Valid Notarised and embassy attested original FSC in the country of Origin, since only copy of FSC provided. • Provide valid Full Quality Assurance certificate. • Provide valid notarized, QMS 13485 certificate, the already submitted is expired after submission • The stability study provided is of Centaur Systems BNP, real Time Stability(52 months or 13 months) and Advia cetuar Systems B-Type natriuretic Peptide(20 months), brand name on stability doc is different then applied , provide clarification or provide stability studies.

			Peptide Quality Control Size: 3 x 2 mL Codes: 10995475 Shelf Life: 20 months **Class- C**	
47.	-do- **Evaluator:** AD-IV [1249-K]	Legal Manufacturer: M/s Siemens Healthcare Diagnostics Inc. 511 Benedict Ave. Tarrytown, NY 10591, USA Manufacturing site: 333 Coney Street East Walpole, MA, 02032, USA FSC UK MHRA valid till 30-12-2020	ADVIA Centaur NT-proBNP (Kit) Class C 1) ADVIA Centaur NT-proBNP Code: 10699449 Size: 100 Tests Shelf life: 12 Months 2) ADVIA Centaur NT-proBNP Code: 10699450 Size: 500 Tests Shelf life: 12 Months ADVIA Centaur Multi-Diluent 1 Code: 10311571 Size: 50mL/vial Shelf life: 12 Months ADVIA Centaur Multi-Diluent 1 Code: 10309941 Size: 2 x 25mL/Pack Shelf life: 12 Months ADVIA Centaur Multi-Diluent 1 Code: 10309942 Size: 50mL/vial Shelf life: 12 Months	**Deferred** for submission of clarification and provision of following documents:- • Grouping not clear. Three Multidiluent are applied on this application. Are these Multidiluent used specifically with the applied kit **ADVIA Centaur NT-proBNP** or they are used with other kits also? Clarify this and provide supporting evidence if these diluents are only used specifically for the applied reagent kit and if used in other kits also. • Details of manufacturing of the applied codes. • Shelf life studies are not provided for codes 10699450 and 10309942, Please provide. • Valid FSC. • Valid ISO 13485. • EPSP provided are not of the applied product ADVIA Centaur NT-proBNP and EPSP of multidiluent also not provided • IFU of three applied multidiluent. • Labels of all 5 codes applied which shall be readable
48.	-do- **Evaluator:** AD-IV [1258-K]	Legal Manufacturer: Siemens Healthcare Diagnostics Inc. 500 GBC Drive, Mailstop 514, P.O . Box 6101, Newark, DE, 19714, USA Manufacturing site:	Dimension Myoglobin Flex reagent cartridge (Kit) Class C	**Deferred** for provision of following documents:- • The legal manufacturer and manufacturing site as per FSC, DOC, IFU, label is different than that provided on Form 7A. Clarify the legal manufacturer and manufacturing site of the applied product.

		Siemens Healthcare Diagnostics Inc. 500 GBC Drive, Mailstop 514, P.O . Box 6101, Newark, DE, 19714, USA FSC UK MHRA valid till 03-05-2023	1. Dimension Myoglobin Flex reagent cartridge Code: RF422A / 10444907 Size: 120 Tests Shelf life: 12 Months 2. Dimension Myoglobin Calibrator Code: RC422 / 10445024 Size: 10x 1.0mL Shelf life: 18 Months	• Details of QC of the applied codes. • ISO13485 of legal manufacturer and manufacturing site as per FSC, DOC, • IFU, label not provided. Provide valid and notarized certificate
49.	-do- **Evaluator:** AD-IV [1264-K]	Legal Manufacturer: Siemens Healthcare Diagnostics Products Limited Glyn Rhonwy, Llanberis, Gwynedd, LL55 4EL, United Kingdom Manufacturing site: Siemens Healthcare Diagnostics Products Limited Glyn Rhonwy, Llanberis, Gwynedd, LL55 4EL, United Kingdom FSC UK MHRA valid till 16-10-2020	IMMULITE / IMMULITE 1000 CK-MB (Kit) Class C Code: LKMB1 / 10381016 Size: 100 Tests Shelf life: 12 Months	**Deferred** for provision of following documents:- • The legal manufacturer and manufacturing site as per FSC, DOC, label is different than that provided on Form 7A. Clarify the legal manufacturer and manufacturing site of the applied product. • Shelf life studies are not provided for this applied product. It is for some other product. • Details of manufacturing and QC of the applied product. • Valid FSC. • Valid ISO 13485
50.	-do- Evaluator: AD-IV [1257-K]	Legal Manufacturer: M/s Siemens Healthcare Diagnostics Inc. 511 Benedict Ave. Tarrytown, NY 10591, USA Manufacturing site: Randox Laboratories Limited 55 Diamond Road Crumlin County Antrim, BT29 4QY, United Kingdom FSC UK MHRA Valid Till 31-12-2020	ADVIA Chemistry Creatinine Kinase (CKNAC) Reagent (Kit) Class C 1. ADVIA Chemistry Creatinine Kinase Reagent Code: 10309494 Size: 980 Tests Shelf life: 36 Months 2. ADVIA Chemistry Creatinine Kinase Reagent Code: 10341111 Size: 1040 Tests Shelf life: 36 Months	**Deferred** for provision of following documents:- • Vaid and complete copy of Free Sale Certificate. • Details such as stability studies, EPSP, Label, IFU, DOC for the code 10729780. Also the difference of 10729780 is not clear from the other two codes applied. Clarification is required from manufacturer abroad as to what exactly is this difference and provide above mentioned documents • Details of QC of the applied codes not provided • Valid ISO13485 certificate

			3. ADVIA Chemistry Creatinine Kinase Reagent Code: 10729780 Size: 1100 Tests Shelf life: 36 Months	
51.	M/s Life-Tec, unit B, 1st floor, Block 20-D, G-8 Markaz, Islamabad. ELI: 00155 2540-P **Evaluator**: AD-IX	Legal Manufacturer: M/s Sichuan Nigale Biotechnology Co., Ltd., Office # 901-910, 9/FUnit 2, Bldg 1, No. 401 Shengan street, Hi-tech District, Chnegdu, Sichuan, China. Manufacturing Sire: M/s Sichuan Nigale Biotechnology Co., Ltd., No. 28 Kuixing road, 641400 Jianyang, Sichuan China. FSC: China (Certificate No. 20200017) valid till 23/03/2022.	Therapeutic Plasma Exchange (TPE) Machine with ACD (Acid Citrate Dextrose) solution Codes & Sizes: as per FSC Class-C Shelf Life: 5 years	**Deferred for:** • Submitted Free Sale Certificate (FSC) is expired and does not contain the name of applied product, please submit original, legalized and valid FSC mentioning the name of the applied product. Similarly, full quality assurance certificate does not have the name of the applied product. • ISO-13485 is issued for the manufacturing site while certificate issued for the legal manufacturer is required mentioning the name and address of manufacturing facility. • The submitted stability data for service life of the applied product is not provided while the said data of another product is submitted. Relevant data for the applied product is required. • Since FSC of non-reference country is submitted, therefore, FSC from a reference regulatory authority is required. • Provide instruction for use. • Provision of declaration of Conformity from the manufacturer is not submitted.
52.	-do- 2539-P **Evaluator**: AD-IX	Legal Manufacturer: M/s Sichuan Nigale Biotechnology Co., Ltd., Office # 901-910, 9/FUnit 2, Bldg 1, No. 401 Shengan street, Hi-tech District, Chnegdu, Sichuan, China. Manufacturing Sire: M/s Sichuan Nigale Biotechnology Co., Ltd., No. 28 Kuixing road, 641400 Jianyang, Sichuan China. FSC: China (Certificate No. 20200081) valid till 04/10/2022.	Nigale Platelet Apheresis Set / Kit (P-2000IE) with ACD (Acid Citrate Dextrose) (Disposable blood component apheresis set) Codes & Sizes: as per FSC Class- Shelf Life: 3 years	**Deferred for:** • Submitted Free Sale Certificate (FSC) is expired and does not contain the name of applied product, please submit original, legalized and valid FSC mentioning the name of the applied product. Similarly, full quality assurance certificate does not have the name of the applied product. • ISO-13485 is issued for the manufacturing site while certificate issued for the legal manufacturer is required mentioning the name and address of manufacturing facility. • The submitted stability data for service life of the applied product is not provided while the said data of another product is submitted. Relevant data for the applied product is required. • Since FSC of non-reference country is submitted, therefore, FSC from a reference regulatory authority is required. • Provide instruction for use. • Provision of declaration of Conformity from the manufacturer is not submitted.
53.	-do- 2538-P	**Legal Manufacturer:** M/s Sichuan Nigale	Nigale Platelet Apheresis Set/Kit (Disposable Blood	**Deferred** for provision of Free Sale Certificate of any SRA country or CE mark

	Evaluator: AD-III	Biotechnology Co, Ltd, No.28, Kuixing Road, Dongxi town, 641400, Jianyang, Sichuan, People's Republic of China. FSC China Valid till: 14.10.2022	Component Apheresis Set) Class-C Shelf Life: 3 Years Model: P-20001S	documents, Declaration of Conformity and labels.
54.	M/s Medequips SMC Pvt. Ltd. 30-Shahrah e Quaid e Azam Lahore. ELI: 00362 1570-P **Evaluator**: AD-IX	Legal Manufacturer: M/s Canon Medical Systens Corporation 1385 Shimoishigami, Otwara SHI tochigi 324-8550 Japan. FSC: Japan, Issued on 21/09/2018 (No. 218ACBZX00004000 for 8000C) (No. 220ACBZX00011000 for 8000H).	Alphenix System (Angiographic System) Codes & Sizes: Class-C Service Life:	
55.	-do- Evaluator AD-VIII 2651	**Legal Manufacturer:** M/s Bayer Medical Care Inc. 1 Bayer Drive, Indianola, PA 15051 USA **Manufacturing Site:** Bayer Medical Care Inc. 625 Alpha Drive Pittsburgh, PA 15238, USA FSC: U.S.A Valid Till: 09.07.2022	MEDRAD Mark 7 Arterion Injection System (Injector) Catalogue No.: ART 700 PEDL ART 700 TABL ART 700 OCS Class-C Shelf Life: As per stability study	**Deferred** for the provision of deficient document / clarification: i. Provide original LOA. The firm provided photocopy. ii. The firm provided photocopy of valid FSC issued by USFDA. Therefore, provide original FSC. iii. Provide the Full QA certificate or equivalent, duly notarized by the country of origin. Provided one is photocopy of incomplete certificate. iv. Provide valid ISO 13485 certificate the attached one is expired now but valid upon submission. v. It required clarification that the Catalogue No.: ART 700 PEDL; ART 700 TABL; and ART 700 OCS are individual Machine Units/ system as specified in LOA where these catalogue numbers are mentioned as "system packages" or otherwise these catalogues are sub-components of single machine unit/system being collectively used for common intended purpose. Support your reply with documentary evidences like brochures, catalogues etc. vi. Provide stability studies/validation studies/service life studies
56.	M/s Medicamp international, No.1 first floor, Raja Naseer, Mohalla Raja Yousaf, New Abadi Morgah, Rawalpindi. ELI: 00200 2426-P **Evaluator**:	Legal Manufacturer: M/s MDD SP.ZO.O Grudizaazka 159A, 87-100, Torun Poland. FSC:	Meditamp (Absorbable Hemostat Oxidized Cellulose) Codes & Sizes: Meditamp Fibrisoft Class-C	

	AD-IX		Service Life:	
57.	-do- -2425- **Evaluator**: AD-VI	Legal Manufacturer & mfg. site: MMD Sp. ZO. O Grudizaazka 159A, 87-100, Torun Poland FSC: Poland Date of Issue: 2020.06.05.	MEDITAMP DENSO KNIT (Absorbable Hemostat Oxidized Regenerated Cellulose) Class-C. Shelf life: 24-MONTHS.	**Deferred** for provision of following documents:- • Original FSC of RRA or in accordance of rule 15(2) & as per Sr. No. (4) of Form-7(A). • Original agency agreement and FSC of country of origin. • Product description and complete technical data sheet as the product is absorbable. • Notarized ISO-13485 certificate/ latest GMP report and QA certificate
58.	-do- **Evaluator**: AD-VII	Legal Manufacturer: Kollsut International Inc. 1763 NE 162nd Street, North Miami beach, FLS33162 FSC: U.S.A Date of Issue: 09.03.2022	SIETKA ™ Hernia Mesh (Sterile Srugical Mesh) Class-C Shelf Life: 4 years	**Deferred** for provision of the following documemts :- • Provide valid original and embassy attested FSC having name of the product, since the firm has provided copy. • Provide valid and notarised ISO 13485 certificate having scope of ISO certification. the firm has submitted copy and don't have scope of ISO 13485 certification for medical Devices. • Provide Notarised and valid Full Quality assurance certificate. • Provide the brand name • Provide valid, original and notarized letter of Authorization and credential of the company, since only copy is provided.
59.	M/s Mian Scientific Corporation (pvt) Ltd., 534-Jinnah Colony Faisalabad. ELI: 00442 2208-P **Evaluator**: AD-IX	Legal Manufacturer: M/s Yasee Biomedical Inc. No.9 Xiuyuan road, High-tech development zone, Chengyang District, Qingdao, 266000 China. Manufacturing facility: M/s. FSC: China, valid till 05/06/2021. (Certificate No. 20200017). It was valid at the time of submission of dossier FSC:	Blood Glucose Test Strips Codes & Sizes: As per FSC Class-C Shelf Life:	**Deferred** for provision of following documents:- • Valid and notarized Full quality assurance certificate. • Since the submitted Free Sale Certificate is from China which is not a reference regulatory authority, therefore, you are required to provide a free sale certificate from a reference regulatory authority. • Valid free sale certificate of country of origin. • Declaration of Conformity for the applied product from the manufacturer. • Stability studies of the applied product till claimed shelf life.
60.	-do- Evaluator: AD-IV [2209-P]	Manufacturer: M/s YASEE Biomedical Inc. No. 9, Xiuyuan Road, High-Tech Industrial	True Answer Blood Glucose Meter (Model: GLM-78) Blood Glucose Monitoring System	**Deferred** for provision of following documents:- • Sale in EU with which brand name? • Essential principles of safety and performance for the applied device

		Development Zone, Qingdao City, Shandong Province China FSC China valid till 20-10-2022	Class C Shelf Life: N/A	• China is not a reference country so provide original and valid free sale certificate duly attested by embassy of Pakistan from one of the reference countries provided in rule 67 of Medical Devices Rules, 2017. • Product Label is half. • Undertaking that same product with same specs.
61.	-do- Evaluator: AD-IV [2129-P]	Legal Manufacturer: Wuxi BioHermes Bio & Medical Technology Co, Ltd. 88 & 136 Mashan Meiliang Road, Binhu, Wuxi 214092, Jiangsu, China Manufacturing sites: 1) Wuxi BioHermes Bio & Medical Technology Co, Ltd. 88 & 136 Mashan Meiliang Road, Binhu, Wuxi 214092, Jiangsu, China 2) Wuxi BioHermes Bio & Medical Technology Co, Ltd. 11th Floor, 530 Mansion, No. 18 Qing Yuan Road, Xinwu District, Wuxi, 214135, Jiangsu, China EXPORT ONLY CERTIFICATE PROVIDED	Bio Hermes A1c Chek Pro Glycohemoglobin Analyzer Test Kit Codes & sizes: As per FSC Class C (to be confirmed) Shelf life: Not mentioned on Form	**Deferred** for provision of following documents:- • Justification from manufacturer for classifying the applied product in Class C by giving reference from the relevant provision in latest IMDRF document of IVD medical device classification. • The document provided as Free Sale Certificate (FSC) is EXPORT ONLY certificate from country of origin. Provide original, valid Embassy attested FSC from one of the reference countries mentioned in rule 67 of the MDR, 2017 containing the exact name and product code in it. • Clearly state that address of the legal manufacturer/product owner of this product and the address of the manufacturing site or if more than one site, then mention the exact address of those sites where this applied product is manufactured • The status of the product in European Union is not clear. Clarification is required from manufacturer abroad that if the applied product is SELF-DECLARED (general IVD or Others) in EU or classified as Annex-II list A, or Annex-II list B? • State the product code/cat no/part no of the applied product to be considered on this application. • The IFU of the product indicates that it is for PROFESSIONAL USE ONLY whereas the Full QA certificate is provided for SELF TESTING devices. Clarify and provide relevant certificate • QC details provided are for analyzer and not test kit. Provide relevant QC details • Shelf life not mentioned on form and IFU indicates stability to be 18 months, the provided studies show for 21 months. Clarification is required from manufacturer abroad as to what is the shelf life of this applied product • Letter of Authorization expiring soon. Arrange valid Letter of Authorization • Credentials of manufacturer abroad is a requirement of Form 7A. Provide credentials on format approved by Medical Device Board in its 3rd meeting duly notarized from country of origin. • Provided Essential principles of safety and performance is for analyzer and not

				applied test kit. Provide relevant EPSP
62.	M/s Noor International, Noor house, 39-D, Block-6, PECHS, Karachi ELI: 00061 1208-K **Evaluator**: AD-IX	Legal Manufacturer: M/s Bovie Medical Corporation 5115 Ulmerton road, clearwater, Florida, USA. Manufacturing facility: M/s Bovie-Bulgaria Limited, Blvd. Tsarigradsko Shose No. 133, building 3, Fl. 3 and Fl. 5, Sofia, Bulgaria. FSC: USA, (No. 14919-8-2018) valid till 05/09/2020.	Bovie High Frequency Electrosurgical Generator (Electrosurgical Generator) Codes/Models: IDS-210, IDS-310 Class-C Service life: 7 years	**Deferred** for provision of following documents:- • Notarized and valid ISO-13485 certificate. • Notarized and valid full quality assurance certificate. • Please justify the service life of 7 years for the applied device along with the supporting documents/data for all the applied models. • Essential Principles of Safety and Performance for the applied device. • Notarized and valid letter of authorization (LOA) since the submitted LOA is not notarized. • Details of the models/codes of the applied product along with the data of principles of safety and performance of all the models.
63.	M/s Optimus Entrepot, 194-F/1 Block Johar Town, Lahore. ELI: 00125 1712-P **Evaluator**: AD-IX	Legal Manufacturer: M/s SAV-Iol SA, Route De Falaises 74 2000, Neuchatel, Switzerland. FSC: Switzerland (copy), valid till 10/04/2022. (Certificate No. FSC-00001629). It was valid at the time of submission of dossier FSC:	Eden Posterior Chamber Intraocular Lens Codes & Sizes: As per FSC Class-C Shelf Life: 5 years	**Deferred** for provision of following documents:- • Notarized Credentials of manufacturer. • Notarized and Valid ISO-13485 certificate • Notarized and Valid full quality assurance certificate • Notarized and Valid letter of authorization. • Declaration of conformity for the applied product from the manufacturer • Original, valid and legalized Free Sale Certificate (FSC).
64.	-do- Evaluator AD-VIII 1713 (P)	**Legal Manufacturer:** M/s SAV-IOL SA route des Falaises 74 2000 Neuchatel, Switzerland FSC: Switzerland Validity: 10.04.2022	**Lucidis** (Posterior chamber intraocular lens) Codes & Sizes: Lucidis 108M Lucidis 124M Class-C Shelf Life: 5 years	**Deferred** for the provision of deficient document / clarification: i. Provided scanned copy of LOA. Provide original LOA. ii. Provided scanned copy of FSC issued by swissmedic which is expired now. Provide Original and valid FSC issued by swissmedic. iii. Provided ISO 13485 and FQA are expired. Provide valid ISO and FQA.
65.	M/s Optisurg, 17/C-1, Valencia town, Lahore ELI: 00305 1647-P **Evaluator**: AD-IX	Legal Manufacturer: M/s Oertli Instrument AG Hafnerwisenstrasse 4 9442 Berneck Switzerland. FSC:	U/S Phaco handpiece Hexadisq (reusable) Codes & Sizes: VG800011 Class-C Shelf Life: 200 cycles	**Deferred** for provision of following notarized and valid documents:- • ISO-13485 certificate. • Full quality assurance certificate. • Letter of authorization. • Declaration of conformity for the applied product from the manufacturer. • Original, valid and legalized Free Sale Certificate (FSC) mentioning the name of the applied product since the submitted copy of FSC is expired. • Instruction for use for the applied product.

66.	-do- 1648-P **Evaluator**: AD-IX	Legal Manufacturer: M/s Oertli Instrument AG Hafnerwisenstrasse 4 9442 Berneck Switzerland. FSC:	Oertli Cutting Instrument Reusable Codes & Sizes: VE103100 Class-C Shelf Life: 200 cycles	**Deferred** for provision of following notarized and valid documents:- • ISO-13485 certificate. • Full quality assurance certificate. • Letter of authorization. • Declaration of conformity for the applied product from the manufacturer. • Original, valid and legalized Free Sale Certificate (FSC) mentioning the name of the applied product since the submitted copy of FSC is expired.
67.	-do- Evaluator AD-II [1714-P]	**Legal Manufacturer:** Oertli Instrumente AG, Hafnerwisenstrasse 4 944 2 Berneck Switzerland FSC **(copy)**: Switzerland Valid till: 14.03.2020 **(expired even on submission)**	Oertli (Diathermy Tips Reusable) Class-C Codes: VE201721 VE201722 VE201723 VE201726 VE201730 VE201732 VE201734 VE201751 VE203902 Shelf-life: Max cycle no. 50; except VE203902: 20	**Deferred** for the provision of following documents document : • Multiple types are applied in single application; give priority for this application and submit separate applications for the rest. • Original and valid Free sale certificate in the country of origin duly attested by embassy of Pakistan. • Provide the details of quality control processes. • 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) for which sole authorization is given, validity of agreement, duly notarized by the country of origin; since the already submitted copy does not bear applied MD. • Credentials of manufacturer abroad, • Production Quality Management System Certificate (ISO 13485)/ GMP Certificate. • Full QA certificate or equivalent, duly notarized from the country of origin. • Valid copy of Declaration of conformity (DoC) to be printed on manufacturer letterhead, filled and duly signed by responsible person.
68.	M/s Physiomed Pvt Ltd 268/3, Kamal road, Saddar, Rawalpindi. ELI: 00315 2375-P **Evaluator**: AD-IX	Legal Manufacturer: M/s Avanos Medical, Inc. 5405 Windward Parkway Alpharetta, GA USA 30004. Manufacturing facility: M/s Avent S. de R.L. de C.V Carretera International Salida Norte No. 1053, Magdalena, Sonora, Mexico CP 84160.	Coolief Cooled Radiofrequency Kit Codes & Sizes: As mentioned in next column Class-C Shelf Life: 4 years	**Deferred for:** • Clarifictaion since the kit is composed of; 1 Coolief Cooled Radiofrequency Probe 3 Coolief Cooled Radio frequency fluid delivery introducers 1 Cooled Radio Frequency Sterile Tube Kit And all of the components are available in different sizes and codes comprising several kits' types. Therefore, you will be granted only one type of kit (of defined sizes/codes for all the 3 components) against one application unless justified. Please select one type of kit, describe the

		Sterilization site: M/s Isomedix Operations Inc. 1435 Isomdix Place, EI Paso, Texas 79936, USA. FSC: US FDA Valid till 25/03/2022. FSC is expired but it was valid at the time of submission of dossier. (Certificate No. 7327-3-2020)		codes/sizes for this application so that your case may be processed. • The submitted copy of Full Quality Assurance Certificate is expired, therefore, notarized and valid certificate is required. • Clarification since the sterilization site has not been described by Free Sale certificate. • Price has not been proposed in the submitted dossier, therefore, you are to provide MRP of the applied product.
69.	M/s Princess Scientific Services, plot No. 67/62, Adamjee road 1st floor, deen plaza Saddar, Cantonment, Rawalpindi. ELI: 00215 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 provision of following documents:- • Notarized and valid letter of authorization. • Original valid and legalized Free sale certificate (FSC) . • Stability studies along with the protocol.
70.	M/s Siemens Healthcare (pvt) Ltd., 4th floor, state life building, 15-A, Sir Agha Khan road, Lahore. ELI: 00146 2186-P **Evaluator**: AD-IX	Legal Manufacturer: M/s Siemens Shanghai Medical Equipment ltd. 278 Zhou Zhu road 201318 Shanghai, China. FSC: China expired	Mammomat (Mammographic X-ray System) Codes & Sizes: As per FSC Class- Service Life: 10 years	**Deferred** for provision of following notarized documents:- • Valid ISO 13485 certificate • Valid full quality assurance certificate. • Original, legalized and valid Free Sale Certificate (FSC) from reference regulatory authorities mentioning the codes/ models of the applied product since the product is manufactured in China which is not our reference regulatory authority. • Valid FSC from country of origin i.e. China mentioning the codes/models. • Price for the applied product has not been mentioned in the submitted dossier. • Credentials of manufacturer.
71.	-do- Evaluator: AD-IV [2844-P]	Manufacturer: Siemens Shenzhen Magnetic Resonance Ltd Siemens MRI Center Gaoxin, C Ave., 2nd Hi-Tech Industrial Park 518057 Shenzhen People's Republic of China FSC China valid till 21.04.2022 Copy of approval letter from ARTG	Artis One (X-Ray Angiography, Fluoroscopic, Radiographic System) Code: 10848600 Class C Shelf Life: N/A Service life: 10 years	**Deferred** for provision of following documents:- • Letter of Authorization/ Agency agreement which shall be original, notarized from the country of origin, signed & stamped, having validity, names and addresses of both manufacturer and importer and having name or category of medical devices for which sole/ exclusive authorization is given to importer. • Valid and notarized ISO 13485. • Notarized and valid Full Quality Assurance Certificate. • Valid Free Sale certificate of China. • MRP not provided

		Australia, Health Canada and US FDA 510 k provided		
72.	M/s Total technologies Pvt. Ltd, 696-J2 Johar Town Lahore. ELI: 00129 1456-P **Evaluator**: AD-IX	Legal Manufacturer: M/s Codan Argus AG, Oberneuhofstrasse 10 6340 Baar, Switzerland. FSC: Switzerland, (No. G-FSC-18-20099) valid till 30/01/2021.	A616S Syringe pump Codes/Models: A616S In Care/TCI Class- C Service life: years	**Deferred** for provision of following documents:- • Original, legalized and valid Free Sale Certificate (FSC). • Justify the claimed shelf life of the applied device with supporting document/ data. • Proposed MRP is required while it has not been provided in the submitted dossier.
73.	-do- 1463-P **Evaluator**: AD-IX	Legal Manufacturer: M/s Codan Argus AG, Oberneuhofstrasse 10 6340 Baar, Switzerland. FSC: Switzerland, (No. G-FSC-18-20099) valid till 30/01/2021.	Codan Volumetric Infusion Pump Codes/Models: A717V, A718V Class- C Shelf life: years	**Deferred** for provision of following documents:- • Original, legalized and valid Free Sale Certificate (FSC). • Justify the claimed shelf life of the applied device with supporting document/ data. • Proposed MRP is required while it has not been provided in the submitted dossier.
74.	-do- 1455-P **Evaluator**: AD-IX	Legal Manufacturer: M/s Steelco S.P.A., via Balegante, 27, 31039 Riese Pio X (TV), Italy. FSC:	Steelco Steam Sterilizer (VS Series) Codes/Models: as per FSC Class- Service life: 10 years	**Deferred** for provision of following documents:- • Original, legalized and valid Free Sale Certificate mentioning all the codes of the applied product. • Notarized letter of authorization. • Valid and notarized ISO-13485 and full quality assurance certificates. • Justification the claimed service life of 10 years the applied device with supporting document/data for every model/code along with valid declaration of conformity from the manufacturer. • Proposed MRP is required while it has not been provided in the submitted dossier.
75.	-do- 1461-P **Evaluator**: AD-IX	Legal Manufacturer: M/s Steelco S.P.A., via Balegante, 27, 31039 Riese Pio X (TV), Italy. FSC:	Steelco Chemical washer disinfector & Sterilizer for endoscope (EW1 series) Steelco endoscope washers for medical purpose (EW2 series) Codes/Models: EW1, EW1S, EW1 dual H. Class- Service life: 10 years	**Deferred for:** • Steelco Chemical washer disinfector & Sterilizer for endoscope (EW1 series) and Steelco endoscope washers for medical purpose (EW2 series) are two different medical devices (system), registration of which cannot be granted against one application, Moreover, separate applications are required for the registration of each model of a series whether it is EW1 or Ew1. Please select the series and model for registration against the submitted application and, submit separate applications for other models in EW1/EW2 Series, since different models of a series cannot be considered for registration against one application.

				• Provision of original, legalized and valid Free Sale Certificate mentioning the model/code of the applied product. • Provision of notarized letter of authorization. • Submission of valid and notarized ISO-13485 and full quality assurance certificates. • Justification regarding the claimed service life of 10 years the applied device with supporting document/data for the applied model/code along with valid declaration of conformity from the manufacturer. • Proposed MRP is required while it has not been provided in the submitted dossier.
76.	-do- 1460-P **Evaluator**: AD-IX	Legal Manufacturer: M/s Steelco S.P.A., via Balegante, 27, 31039 Riese Pio X (TV), Italy. FSC:	Steelco Washer Disinfectors Codes/Models: as per FSC Class-C Service life: 10 years	**Deferred** for provision of following documents:- • Original, legalized and valid Free Sale Certificate mentioning the models/codes of the applied product. • Notarized letter of authorization. • Valid and notarized ISO-13485 and full quality assurance certificates. • Please justify the claimed service life of 10 years of the applied device with supporting document/data for the applied model/code along with valid and notarized declaration of conformity from the manufacturer. • Proposed MRP is required while it has not been provided in the submitted dossier.
77.	-do- 1458-P **Evaluator**: AD-IX	Legal Manufacturer: M/s Steelco S.P.A., via Balegante, 27, 31039 Riese Pio X (TV), Italy. FSC:	Steelco Decontamination Cleaners for medical purpose with ultrasonic function Codes/Models: as per FSC Class-C Service life: 10 years	**Deferred for:** • Since the applied device is complete system which cannot be categorized as Family, therefore, submit separate applications for each model. Moreover, specify the model of the applied product for which should be considered against the existing application. • Provision of original, legalized and valid Free Sale Certificate mentioning the model/code of the applied product accordingly. • Provision of notarized letter of authorization. • Submission of valid and notarized ISO-13485 and full quality assurance certificates. • Justification regarding the claimed service life of 10 years of the applied device with supporting document/data for the applied model/code along with valid and notarized declaration of conformity from the manufacturer. • Proposed MRP is required while it has not been provided in the submitted dossier.
78.	-do- -2497- **Evaluator**:	Legal Manufacturer: M/s Edan Instruments, Inc. # 15 Jinhui Road, Jinsha Community,	Central Monitoring System (Fetal Cardiac Monitor)	**Deferred** for provision of following documents: - • Original and valid free sale certificate of

	AD-VI	Kengzi Sub-District, 518122 Shenzhen, P.R. China FSC: China Valid till. 01.03,2020	Codes & Sizes: As per FSC Class-C Shelf Life: Not applicable	country of origin and any RRA. • Valid ISO-13485 certificate/ latest GMP report. • Justify the quality of the products with quality control details and validation studies.
79.	-do- -2498- **Evaluator**: AD-VI	Legal Manufacturer: M/s Edan Instruments, Inc. # 15 Jinhui Road, Jinsha Community, Kengzi Sub-District, 518122 Shenzhen, P.R. China FSC: China Valid till. 01.03,2020	PC ECG (Interpretive Multichannel electrocardiograph) Codes & Sizes: As per FSC Class-C Shelf Life: Not applicable	**Deferred** for provision of following documents: - • Original and valid free sale certificate of country of origin and any RRA. • Valid ISO-13485 certificate/ latest GMP report. • Justify the quality of the products with quality control details and validation studies.
80.	M/s Varitron, 1st floor, 60-D, F.C.C. Zahoor Elahi road, Gulberg IV, Lahore. ELI: 00510 2612-P **Evaluator**: AD-IX	Legal Manufacturer: M/s Quanta Systen S.p.A Via Acquedotto 109, 21017 Samarate (VA) Italy. FSC: Italy, (certificate No.DGDMF/III/P/ 1.5.I.e.1/2021/471) issued on 21/04/2021.	Litho Surgical Laser Codes & Sizes: 30W, 35W (models are not mentioned in free sale certificate but DoC contains the detail of these two models) Class- Service Life: 10 years	**Deferred** for provision of Free Sale certificate (FSC) specifying the model of the applied product to be registered since the submitted FSC does not contain any information regarding the model of the Litho Surgical Laser.
81.	-do- **Evaluator**: AD-VII	Legal Manufacturer: M/s Quanta System S.p.A, Via Acquedotto 109, 21017 Samarate (VA) Italy FSC: Italy Date of issue: 24.03.2021	Cyber Ho 60 Cyber Ho 100 Cyber Ho 150 (Multicavity Holmium Laser System) Codes & Sizes: As per FSC: Class-C Shelf Life: 10 years	**Deferred** for provision of the following documemts:- • Provide valid original and embassy attested FSC, since the firm has provided copy. • Provide valid and notarised ISO 13485 and Full Quality assurance certificate. the firm has submitted copy . • Provide valid, original and notarized letter of Authorization and credential of the company, since only copy is provided • Provide Shelf life for Cyber 150.
82.	-do- **Evaluator**: AD-VII	Legal Manufacturer: M/s Quanta System S.p.A, Via Acquedotto 109, 21017 Samarate (VA) Italy FSC: Italy Date of issue: 24.03.2021	LITHO EVO (Surgical Laser) Codes & Sizes: As per FSC Class-C Shelf Life: 10 years	**Deferred** for provision of the following documemts:- • Provide valid original and embassy attested FSC, since the firm has provided copy. • Provide valid and notarised ISO 13485 and Full Quality assurance certificate. the firm has submitted copy • Provide valid, original and notarized letter of Authorization and credential of the company, since only copy is provided

83.	M/s Vertex Medical (pvt) Ltd., 70-B-1, Gulberg III, Lahore. ELI: 00150 1768-P **Evaluator**: AD-IX	Legal Manufacturer: Dragerwerk AG & Co. KGaA Moislinger Allee 53-55 23542 Lubeck Germany. FSC:	Drager Isolette C2000 (Infant Incubator) Codes & Sizes: As per FSC Class-C Shelf Life: N/A	**Deferred for:** • Clarification regarding the manufacturing facility and legal manufacturer of the applied product. Several certificates (ISO-13485, full quality assurance) wherein different legal manufacturers and manufacturing facilities are mentioned and provide following documents accordingly; Notarized Credentials of manufacturer Notarized and Valid ISO-13485 certificate Notarized and Valid full quality assurance certificate Notarized and Valid letter of authorization Declaration of conformity for the applied product from the manufacturer • Provision of original, valid and legalized Free Sale Certificate mentioning the name of the applied product, legal manufacturer and the manufacturing facility.
84.	-do- -1770- **Evaluator**: AD-VI	Legal Manufacturer: Drager Medical System Inc. 3135, Quarry Road Telford, PA 18969-1042 USA Head Office/Operating Office. mfg. site: Dragerwerk AG& Co. KGaA Moislinger Allee 53-55 23542 Lubeck Germany FSC: FDA U.S. FOOD & DRUG Valid till: 19.06.2021.	DRAGER ISOLETTE 8000 PLUS (Infant Incubator) Class-C. Shelf life: N/A	**Deferred** for provision of following documenrs:- • Original and valid FSC of RRA or in accordance of rule 15(2). • Original and valid agency agreement. • Clarify the principal manufacturer & actual manufacturer and their linkage in documented form. • Notarized ISO-13485 certificate/ latest GMP report. • QA certificate of manufacturer.
85.	-do- -1766- **Evaluator**: AD-VI	Legal Manufacturer: Drager Medical System Inc. 3135, Quarry Road Telford, PA 18969-1042 USA Head Office/Operating Office. mfg. site: Dragerwerk AG& Co. KGaA Moislinger Allee 53-55 23542 Lubeck Germany FSC: FDA U.S. FOOD & DRUG Valid till: 19.06.2021	DRAGER BABYLEO TN500. (Infant Incubator) Class-C. Shelf life: N/A	**Deferred** for provision of following documenrs:- • Original and valid FSC of RRA or in accordance of rule 15(2). • Original and valid agency agreement. • Clarify the principal manufacturer & actual manufacturer and their linkage in documented form. • Notarized ISO-13485 certificate/ latest GMP report. • QA certificate

<table>
<tr>
<td>86.</td>
<td>-do-

Evaluator
AD-VIII

2305-P</td>
<td>Legal Manufacturer:

Sorin Group Italia S.r.l Via Statale Nord 12, 86 41037 Mirandola MO, Italy

FSC: Italy

Date of Issue.15.07.2020</td>
<td>SORIN XTRA Disposables

(Collection Systems, Disposable Sets and Accessories for Autotransfusion, PPP, PRP, PLT GEL)

Codes & Sizes: As per FSC

Class-C

Shelf Life:</td>
<td>Deferred for the provision of deficient document / clarification:

i. Clarify the discrepancy in the addresses of manufacturer keeping in view the provided following documents:

<table>
<tr><th>Sr. no.</th><th>Document Type</th><th>Legal Manufacturer Address</th></tr>
<tr><td>1</td><td>Application form; ISO 13485; FQA; Label</td><td>Sorin Group Italia S.r.l Via Statale Nord 12, 86 41037 Mirandola MO, Italy</td></tr>
<tr><td>2</td><td>Credentials</td><td>Sorin Group Italia S.R.L Via Crescentino, sn 13040 Saluggia (VC), Italy</td></tr>
<tr><td>3</td><td>FSC, LOA</td><td>Sorin Group Italia S.R.L Via Benigno crespi 17, 20159 Milano, Italy</td></tr>
</table>
ii. Provide original & valid LOA. The provided one is expired now but valid upon submission.
iii. Provide Valid, Original and Embassy attested FSC. Clarify regarding date of issue since there two different dates mentioned on FSC i.e. 15 July 2020 & 16 Jan 2019. Therefore highlight & mention date of issue and expiration date.
iv. Provide valid ISO 13485 covering all the manufacturing sites of applied medical product including sterilization site. Provided one is expired now but valid upon submission.
v. Mention shelf life of each component of applied medical product as family and also provide stability studies of all applied codes to justify the shelf life.
vi. Clarification is required to the extent that whether all the codes, applied as a family, will be imported
vii. "at once" or otherwise different codes will be imported on, "as and when basis", against a single registration letter.</td>
</tr>
<tr>
<td>87.</td>
<td>-do-

Evaluator:
AD-IV
[1445-P]</td>
<td>Manufacturer:
Inomed Medizintechnik GmbH
Im Hausgrun 29
79312
Emmendingen
Germany

FSC Germany
Date of issue:
09.05.2019</td>
<td>ISIS IOM System

Codes: Not Clear

Class C

Shelf Life: Not clear</td>
<td>Deferred for provision of following documents:-

The grouping of the medical device is not clear. The product is applied as system and the FSC, DOC does not specify the components included in the system. Clarification is required from MANUFACTURER abroad on its letter head signed and stamped by responsible person and duly notarized in the country of origin containing the
name of the main system (Note: ISIS IOM System is applied on this application. ISIS IOM System Compact and ISIS Xpress will not be considered)
its components (including names, articles number/code, product description, whether it is sterile or not and shelf life and device class) (Note: Optional accessories or that are not included in the systems scope of supply will not be</td>
</tr>
</table>

				considered n this application) a justification of how these components are grouped as SYSTEM according to "System" definition as per schedule B of Medical Devices Rules, 2017 an explanation how the applied product is grouped in the country of origin along with evidence The components and codes provided by the manufacturer in the above-mentioned letter are to be highlighted on the FSC, Product manual and EU DOC and also to be provided in soft copy. (Note: The current DOC does not have any codes and two DOC are provided which is confusing. Provide the relevant DOC clearly stating the class of this applied product, codes etc) Provide CE technical file for the applied product from manufacturer abroad Keeping in view the marketing history of the product and its regulatory status internationally, provide copy of registration letter/ approvals or equivalent of the applied product and its grouping as system Credentials of manufacturer abroad not signed and stamped and not notarized. Invalid date of expiry is mentioned on Letter of Authorization and it is not notarized. Provide valid Letter of Authorization from manufacturer abroad, duly notarized in the country of origin. Letter of Authorization shall be original, signed & stamped, having validity, correct names and addresses of both manufacturer and importer and having name of medical devices for which sole/exclusive authorization is given to importer. Original Embassy attested FSC. ISO13485 Notarized Full QA Certificate. Production flow chart does not indicate that is of applied product.
88.	M/s Shams Scientific Traders, office no. 7, first floor, Sadiq Plaza, P-481 Jinnah Colony, Faisalabad. ELI: 00459 2669-P **Evaluator**: AD-IX	Legal manufacturer: M/s Healgen Scientific LLC, located at 3818 Fuqua street, Houston, TX 77047, USA. M/s Zhejiang Orient Gene Biotech Co., Ltd., 3787, east Yangguang Avenue, Dipu street Anji 313300 Huzhou, Zhejiang, China	Malaria P.f./Pan. Ag Rapid Test cassette (Whole Blood) Codes & Sizes: GCMAL(pf/pan)-402a Class-C Shelf Life: 2 years	**Deferred for** submission of Original, legalized and valid Free Sale Certificate is required.

		FSC:		
89.	-do- -2616- **Evaluator**: AD-VI	Legal Manufacturer & mfg. site: M/s Healgen Scientific LLC, 3818 Fuqua Street, Houston, TX 77047, USA FSC: USFDA Date of Issue: 14.04.2021	Troponin Rapid Test Cassette Class-C. Shelf Life:24-months.	**Deferred** for provision of following documents: - • Original FSC of SRA or in accordance of rule 15(2). • Original agency agreement, • Brand name and QC-details of the product.
90.	-do- Evaluator: AD-VIII 2659 (P)	**Legal Manufacturer:** M/s Healgen Scientific LLC, 3818 Fuqua Street, Houston, TX 77047, USA **Manufacturing site:** Zhejiang Orient Gene Biotech Co., Ltd., 3787#, East Yangguang Avenue, Dipu Street Anji 313300 Huzhou, Zhejiang, China. FSC: Belgium Date of Issue: 14.04.2021	Syphills Ab Rapid Test Cassette (Serum/Plasma) (Syphilis Ab Rapid Test) Codes & Sizes: GCSYP-302a Class-C Shelf Life: 24 months	**Deferred** for the provision of deficient document / clarification: i. Provided the stability studies is devoid of detailed procedure/protocols adopted to carry out stability studies in line with international practices, name of place/institute/site where stability study was performed also not mentioned, lack the signature of responsible persons performing the studies. Furthermore, the results are not discussed in detailed. ii. The firm submitted credentials of manufacturing site only, however no particulars are mentioned regarding legal manufacturer, required explanation. iii. The free sale certificate states that "This product actually **NOT** on the market in the exporting country (Belgium)", explanation is required. iv. The attached FSC doesn't cover the manufacturing site "Zhejiang Orient Gene Biotech Co., Ltd., 3787#, East Yangguang Avenue, Dipu Street Anji 313300 Huzhou, Zhejiang, China.", required explanation. v. Provided ISO 13485 certificate is expired now. Therefore, provide valid ISO certificate. vi. Provided label doesn't mention name of legal manufacturer, manufacturing site and EC\Rep in exporting country i.e. Belgium.
91.	-do- Evaluator: AD-VIII 2660 (P)	Legal Manufacturer: M/s Healgen Scientific LLC, 3818 Fuqua Street, Houston, TX 77047, USA Manufacturing Site: Zhejiang Orient Gene Biotech Co., Ltd., 3787#, East Yangguang Avenue, Dipu Street Anji	Typhoid 1gG/1gM Rapid Test Cassett (Serum/Plasma) Codes & Sizes: As per FSC Class-C Shelf Life: 24 months	**Deferred** for the provision of deficient document / clarification: i. Provided the stability studies is devoid of detailed procedure/protocols adopted to carry out stability studies in line with international practices, name of place/institute/site where stability study was performed also not mentioned, lack the signature of responsible persons performing the studies. Furthermore, the results are not discussed in detailed. ii. The firm submitted credentials of manufacturing site only, however no particulars are mentioned regarding

		313300 Huzhou, Zhejiang, China FSC: Belgium Date of Issue: 14.04.2021		legal manufacturer, required explanation. iii. Provide undertaking that whether the applied medical device will be manufactured by and imported from either legal manufacturer or Manufacturing site. iv. The provided FSC doesn't cover the applied IVD Kit i.e. "Syphills Ab Rapid Test Cassette (Serum/Plasma)". Furthermore, the free sale certificate states that "This product actually **NOT** on the market in the exporting country (Belgium)", The firm is required to explain the reason thereof and provide Original, Valid FSCs of applied Medical Device duly attested by the embassy of Pakistan in the country of origin as well as RRA. v. The attached FSC doesn't cover the manufacturing site "Zhejiang Orient Gene Biotech Co., Ltd., 3787#, East Yangguang Avenue, Dipu Street Anji 313300 Huzhou, Zhejiang, China.", required explanation. vi. Provided ISO 13485 certificate is expired now. Therefore, provide valid ISO certificate of all the manufacturing site (Manufacturing & QC). vii. Provided label doesn't mention name of legal manufacturer, manufacturing site and EC\Rep in exporting country i.e. Belgium.
92.	M/s Radiant Medical (pvt) ltd,. 06 Sher Shah Block, New Garden Town, Lahore. ELI: 00135 2838-P **Evaluator**: AD-IX	Legal Manufacturer: M/s Carestream Health, Inc. 150 Verona Street Rochester, New York 14608, USA. Manufacturing facility: M/s Rayco (Shanghai) Medical Product Company Limited, Building 7, No. 1510 Chuanqiao Road, China (Shanghai) Pilot Free Trade Zone 201206 Shanghai, China. FSC: USA, valid till 18/08/2022. (Certificate No. 13107-8-2020) (original is attached in 2841-P) FSC: China valid till 02/07/2022 (certificate No. 20200201)	DRX Ascend System (Diagnostic X-Ray System) Codes & Sizes: Not provided. Class-C Shelf Life: N/A	**Deferred for:** • Provision of detail of Codes/Sizes/Models for the applied product. • Provision of MRP for the applied medical device.

93.	-do- 2002-P **Evaluator**: AD-IX	Legal Manufacturer: M/s Brain lab AG Olof-Palme-Strasse 9, 81829 Munchen, German. Certificate of marketability: Germany, (Copy) the manufacturer is responsible for placing the product on the European economic area. (issue date 20/05/2019) No. AP-2697-22V3590-D22803/2019.	Cranial / ENT (Navigation system) Codes & Sizes: As per FSC Class-C Service life: 5 years	**Deferred for:** • Submission of valid and notarized letter of authorization since the notarization of submitted copy is expired. • Copy of Certificate of Marketability is submitted while original, legalized and valid certificate confirming the free sale of the applied product along with the detail of codes/models is required. • Notarized and valid ISO 13485 certificate is required.
94.	-do- 2005-P **Evaluator**: AD-IX	Legal Manufacturer: M/s Brain lab AG Olof-Palme-Strasse 9, 81829 Munchen, German.. Certificate of marketability: Germany, (Copy) the manufacturer is responsible for placing the product on the European economic area. (issue date 20/05/2019) No. AP-2697-22V3590-D22803/2019.	Spine & Trauma 2D Fluoro Express (Navigation system) Codes & Sizes: As per FSC Class-C Service life: 5 years	**Deferred for:** • Submission of valid and notarized letter of authorization since the notarization of submitted copy is expired. • Copy of Certificate of Marketability is submitted while original, legalized and valid certificate confirming the free sale of the applied product along with the detail of codes/models is required. • Notarized and valid ISO 13485 certificate is required. • Clarification since the complete brand name of the applied medical device is not mentioned in the label.
95.	-do- 2006-P **Evaluator**: AD-IX	Legal Manufacturer: M/s Brain lab AG Olof-Palme-Strasse 9, 81829 Munchen, German.. Certificate of marketability: Germany, (Copy) the manufacturer is responsible for placing the product on the European economic area. (issue date 20/05/2019) No. AP-2697-22V3590-D22803/2019.	Brainlab Elements (Treatment planning software) Codes & Sizes: As per FSC Class-C Service life: 5 years	**Deferred for:** • Submission of valid and notarized letter of authorization since the notarization of submitted copy is expired. • Notarized and valid ISO 13485 certificate is required. • Several devices such as Brainlab element (Object management), Brainlab element (image fusion) etc have bee applied for getting the registration against 01 application while separate applications are required for each device unless or otherwise the grouping is justified as family.
96.	-do- 2004-P **Evaluator**:	Legal Manufacturer: M/s Mobiud Imaging 2 Shaker road, Shirley, MA 01464 USA,	Airo Mobile CT System (Mobile CT Scanner)	**Deferred** for provision of following documents:-

	AD-IX	Certificate of marketability: Germany, (Copy)	Model: MobitCT-32 Class-C Service life: 5 years	• Submission of letter of authorization is required mentioning the name of the applied medical device. • Submission of original, legalized and valid certificate confirming the free sale of the applied product. • Submission of notarized and valid ISO-13485 certificate since the submitted certificate is expired.
97.	-do- 2009-P **Evaluator**: AD-IX	Legal Manufacturer: M/s Villa Sistemi Medicali S.P.A via delle Azalee 3 20090 Buccinasco (MI) Itely. FSC: Italy (No. DGDMF /III/P/I.5.I.e.1 /2019/988) issued on 12/07/2019.	Arcovis (Surgical C-Arms) Model/Code: Arcovis 3000R, Arcovis 3000S, Class-C Service life: 5 years	**Deferred** for provision of following documents:- • Notarized and valid letter of authorization. • Justification of the claimed service life for the applied device with supporting documents.
98.	-do-. -2841- **Evaluator**: AD-VI	Manufacturer By: Carestream Health Inc. (B-1049) West Ridge Road, Rochester, New York, 14615 (USA) Manufactured For: Carestream Health Inc. 150 Verona Street Rochester, New York 14608 Original FSC: USA Valid till: 18.08.2022	DRX Evolution Plus (Diagnostic X-Ray System) Codes & Sizes: As per FSC Class-C Shelf Life: 10-years	**Deferred** for provision of original & valid Agency Agreement and justifiable validation studies of the subject product.
99.	-do-. Evaluator: AD-VII	Legal Manufacturer: Brainlab AG Olof-Palme-Strasse 9, 81829 Munchen, Germany FSC: Germany Date of issue: 24.01.2020	Spin & Trauma Navigation System (Navigation System) Codes & Sizes: As per FSC Class-C Shelf Life: 5 years F.No 2003 (P) S 17.12.2020 Active surgical device	**Deferred** for provision of the following documents:- • Provide Valid embassy attested original FSC in the country of origin. • Provide codes/sizes of the component / accessories to be present in the navigation system. • 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. • Valid and notarized Authorization letter, the firm has provided photocopy which is expired • Provide Manufacturing method
100.	-do-. Evaluator: AD-VII	Legal Manufacturer: Brainlab AG Olof-Palme-Strasse 9, 81829 Munchen, Germany	Microscope Navigation (Medical Software) Codes & Sizes: As per FSC	**Deferred** for provision of the following documents:- • Provide Valid embassy attested original FSC in the country of origin having the product name/code..

		FSC: Germany Date of issue: 24.01.2020	Class-C Shelf Life: 5 years	• Provide codes/sizes of the component / accessories to be present in the navigation system. • 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. • Valid and notarized Authorization letter, the firm has provided photocopy which is expired • Provide Manufacturing method
101.	-do-. Evaluator: AD-VII	Legal Manufacturer: Brainlab AG Olof-Palme-Strasse 9, 81829 Munchen, Germany FSC: Germany Date of issue: 24.01.2020	Kick 2 (Navigation Station) Code & Sizes: As per FSC Class-C Shelf Life: 8 years 2007 (P)	**Deferred** for provision of the following documents:- • Provide Valid embassy attested original FSC in the country of origin. having the product and component accessories names/codes to be present in the navigation system. • 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. • Valid and notarized Authorization letter, the firm has provided photocopy which is expired • Provide Manufacturing method and quality control testing methods.
102.	-do-. Evaluator: AD-VII	Legal Manufacturer: Barkey GmbH & Co. KG Gewerbestrasse 8, 33818 Leopoldshoehe, Germany FSC: Germany Date of issue: 18.12.2019	Barkey autocontrol 3XPT Barkey autoline XPT 4R Class-C 2192-P	**Deferred** for provision of the following documents:- • Provide Valid embassy attested original FSC in the country of origin having the product and component accessories names/codes 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. • Valid and notarized Authorization letter, the firm has provided photocopy which is expired • Provide Manufacturing and quality control methods
103.	-do-. Evaluator: AD-VII	Legal Manufacturer: Villa Sistemi Medicali S.p.A Via delle Azalee 3 20090 Buccinasco (MI) Italy FSC: Italy	Appolo DRF, Apollo EZ DRF Code & Sizes: As per FSC Class-C	**Deferred** for provision of the following documents:- • Provide Valid embassy attested original FSC in the country of origin having the product and component accessories names/codes present (if any) with the product.

		Service life .? Date of issue: 12.07.2019		• Provide difference in between Appolo DRF and Apollo EZ DRF also provide their codes if any. • 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. • Valid and notarized Authorization letter, the firm has provided photocopy which is expired • Provide Manufacturing and quality control methods
104.	-do-. Evaluator: AD-VII	Legal Manufacturing: M/s Villa Sistemi Medicali S.p.A Via delle Azalee 3 20090 Buccinasco (MI) Itelay FSC: Italy Date of Issue: 12.07.2019 expirey not written	Visitor T Family (Visitor T4, Visitor T30 C,Visitor T30 C-DR, Visitor, T30 M,Visitor, T30 M-DR,Visitor T30 R,Visitor, T30 R-DR,Visitor T40 M,Visitor, T40 M-DR,Visitor, T40 M-DR (mobile xray) Class-C	**Deferred** for provision of the following documents:- • Provide Valid embassy attested original FSC in the country of origin having the product and component accessories names/codes present with the product. • Provide difference in between visitor T 30, T4 and T40 M etc. • 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. • Valid and notarized Authorization letter, the firm has provided photocopy which is expired
105.	-do-. Evaluator: AD-VII	Legal Manufacturing: M/s Villa Sistemi Medicali S.p.A Via delle Azalee 3 20090 Buccinasco (MI) Itelay FSC: Italy Date of Issue: 12.07.2019 expirey not written	Moviplan IC (Moviplan iC table, Column iC Tele IC G100C) Class-C Shelf life not applicable written	**Deferred** for provision of the following documents:- • Provide Valid embassy attested original FSC in the country of origin having the product and component accessories names/codes 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. • Valid and notarized Authorization letter, the firm has provided photocopy which is expired
106.	-do- Evaluator AD-II [1995-P]	Legal Manufacturer: Brainlab AG Olof-Palme-Strasse 9, 81829 Munich, Germany FSC (original embassy attested in dossier # 2006-P): Germany	Cranial Navigation System (Navigation System) Codes & Sizes: As per DoC Class-C Shelf Life: 5 years	**Deferred** for provision of following documents: - ▪ Valid and 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) for which sole authorization is given, validity of agreement, duly notarized by

		Date of issue: 20.05.2019		the country of origin.. ▪ Valid Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized by the country of origin.
107.	-do- Evaluator AD-II [2000-P]	Legal Manufacturer: Brainlab AG Olof-Palme-Strasse 9, 81829 Munich, Germany FSC (original embassy attested in dossier # 2006-P): Germany Date of issue: 20.05.2019	Curve (Navigation System) Codes &Sizes: As per DoC Class-C Shelf Life: 8 years and 5 years	**Deferred** for provision of following documents: - ▪ Valid and 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) for which sole authorization is given, validity of agreement, duly notarized by the country of origin.. ▪ Valid Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized by the country of origin.
108.	-do- 1996-P Evaluator AD-III	**Legal Manufacturer:** Brainlab AG Olof-Palme-Strasse 9, 81829 Munchen, Germany FSC Germany Date of issue: 24.01.2020	**Spin & Trauma 3D** (Navigation System) Class-C Service life: 7-8 years Codes as per FSC & DoC	**Deferred** for provision of valid Letter of Authorization, Manufacturing &QC process and labels.
109.	-do- Evaluator AD-VIII 2257	Legal Manufacturer: M/s BK Medical ApS, Mileparken 34, 2730 Herlev, Denmark FSC: Denmark Valid till: 26.01.2023	**BKSPECTO** **Diagnostic ultrasound scanner System type 1300** 1300-21 (with Battery) 1300-25 (Without Battery) Class-C Shelf Life: N/A	**Deferred** for the provision of deficient document / clarification: i. The firm has applied **BKSPECTO Diagnostic ultrasound scanner System type** 1300 and 2300 in a single application, the 1300 type is being considered here with following sub-types 1300-21 (with Battery) & 1300-25 (Without Battery), as applied by the firm. Furthermore, the firm may apply separately for other types. ii. The firm may be asked to provide Original valid LOA. iii. The case may be placed before MDB for its consideration and discussion on grant of **BKSPECTO Diagnostic ultrasound scanner System type** 1300 sub-types 1300-21 (with Battery) & 1300-25 (Without Battery) as a system in single application.
110.	-do- Evaluator AD-VIII 2839	Legal Manufacturer: Carestream Health Inc. 150 Verona Street Rochester, New York 14608 (USA) Manufacturing site:	**DRX REVOLUTION MOBILE X-RAY SYSTEM** (Diagnostic Mobile X-Ray System) (Digital Radiography)	**Deferred** for the provision of deficient document / clarification: i. Provided photocopy of LOA is expired now. Provide original and valid LOA. ii. Provided Photocopy of FSC. Provide Original FSC. iii. The application form states 10 Year shelf life. However, stability studies

		Carestream Health Inc. (B-1049) West Ridge Road, Rochester, New York, 14615 (USA) FSC: USA Valid till: 18.08.2022	Model: **DRXR-1** Codes & Sizes: As per FSC Class-C Shelf Life: 10 years	were not provided. Therefore, provide stability studies to justify the proposed shelf life, or otherwise clarify.
111.	-do- Evaluator AD-VIII 2839	**Legal Manufacturer:** M/s Carestream Health , Inc. 150 Verona Street, Rochester, New York 14608, USA **Manufacturing Site:** Rayco (Shanghai) Medical Product Company Limited Building 7, No. 1510 Chuanqiao Road, China (Shanghai) Pilot Free Trade Zone 201206 Shanghai, People republic of China FSC: China Valid till: 02.07.2022	**DRX Compass X-Ray System** (Diagnostic X-Ray System) Model: **DRX – compass X** Class-C Shelf Life: 10 years	**Deferred** for the provision of deficient document / clarification: i. Provided photocopy of LOA is expired now. Provide original and valid LOA. ii. Provided Photocopy of FSC issued by USFDA. Provide Original FSC issued by USFDA. iii. The application form states 10 Year shelf life. However, stability studies were not provided. Therefore, provide stability studies to justify the proposed shelf life, or otherwise clarify.
112.	M/s Global Marketing Services, 111, Hali Road Westridge-1, Rawalpindi ELI: 00109. -2363- **Evaluator**: AD-VI	Legal Manufacturer: M/s Steris Corporate, 5660 Heisley Road, Mentor Ohio 44060 USA Physical Manufacturer: Steris Mexico, S. De R.L De . C.V Avenida Avante 790 Parque Industrial guadalupe, Nuevo Leon Mexico 67190. Copy of FSC: U.S.A Valid till; 31-03-2023.	V-PRO S2 Low Temperature Sterilization System and Accessories. (Hydrogen Peroxide Gas Sterilizer) Codes & Sizes: As per FSC Class-C Shelf life: Not pfovided.	**Deferred** for provision of the original and valid agency agreement, FSC, QC- details of the product and justifiable validation studies of the subject product.
113.	M/s Medtronic Pakistan (Pvt) Ltd., Office No.1301, 13th Floor Dilkusha Forum Tariq Road, Karachi (ELI-00273) -1934- **Evaluator**: AD-VI	Legal Manufacturer: M/s Medtronic Inc., 8200 Coral Sea Street NE Mounds View, MN 55112, USA Manufacturing Faciltiy:	Sphera DR MRI Surescan (Model: SPDR01) Class C Shelf life: 08 Months	**Deferred** for provision of the original and valid agency agreement, FSC, QC- details of the product and justifiable validation studies of the subject product.

		M/s Medtronic Singapore Operations Pte Ltd., 49 Changi South Avenue 2 Nasaco Tech Centre Singapore 486056, Singapore FSC USFDA Valid Till (15-08-2021)	Codes & Sizes as per FSC	
114.	-do- **Evaluator**: AD-VII	Spectrum Medical Ltd. Harrier 4, Meteor Business Park, Cheltenham Road East, Gloucestershire GL2 9QL England	Quantum Pump Console Codes and Sizes as per FSC Class C Shelf life N/A written FSC UK issued on 1/2/2019	**Deferred** for provision of the following documents: - • Provide shelf life/ service life validation protocols /studies, the firm has not provided claimed service life/ shelf life. • Provide valid and notarized ISO 13485 certificate, the firm has provided expired certificate. • Provide components and codes of the product duly reflected from the documents.
115.	-do- **Evaluator**: AD-VII	Spectrum Medical Ltd. Harrier 4, Meteor Business Park, Cheltenham Road East, Gloucestershire GL2 9QL England	Quantum Workstation Codes and Sizes as per FSC Class C Shelf life N/A written FSC UK issued on 1/2/2019	**Deferred** for provision of the following documents:- • Provide shelf life/ service life validation protocols /studies, the firm has not provided claimed service life/ shelf life. • Provide valid and notarized ISO 13485 certificate, the firm has provided expired certificate. • Provide components and codes of the product duly reflected from the documents
116.	-do- **Evaluator**: AD-VII	Spectrum Medical Ltd. Harrier 4, Meteor Business Park, Cheltenham Road East, Gloucestershire GL2 9QL England	Quantum Ventilation Module Codes and Sizes as per FSC Class C Shelf life N/A written FSC UK issued on 1/2/2019	**Deferred** for provision of the following documents:- • Provide shelf life/ service life validation protocols /studies, the firm has not provided claimed service life/ shelf life. • Provide valid and notarized ISO 13485 certificate, the firm has provided expired certificate. • Provide components and codes of the product duly reflected from the documents
117.	-do- **Evaluator**: AD-VII	Spectrum Medical Ltd. Harrier 4, Meteor Business Park, Cheltenham Road East, Gloucestershire GL2 9QL England	Quantum Diagnostic Module Codes and Sizes as per FSC Class C Shelf life N/A written FSC UK issued on 1/2/2019	**Deferred** for provision of the following documents:- • Provide shelf life/ service life validation protocols /studies, the firm has not provided claimed service life/ shelf life. • Provide valid and notarized ISO 13485 certificate, the firm has provided expired certificate. • Provide components and codes of the product duly reflected from the documents
118.	-do-	Unomedical a/s Aaholmvej 1-3,	i-Port Advance	**Deferred** for provision of the following documents:-

	Evaluator: AD-VII	Osted 4320 Lejre Denmark	Codes and Sizes as per FSC Shelf life 3 years Class C	• provide valid and embassy attested original FSC in the country of origin. • Provide relation/ Authorization letter from Unomedical a/s Aaholmvej 1-3, Osted 4320 Lejre Denmark, authorizing Medtronic Pakistan. Unomedical a/s Aaholmvej 1-3, Osted 4320 Lejre Denmark is not present in the letter provided having list of Medtronic manufacturing facilities. • Provide valid ISO 13485 certificate for all the manufacturing sites , the submitted has been expired and does not mention all manufacturing sites. • Provide valid and notarized Full quality assurance certificate, the firm has submitted expired Full Quality assurance certificate. • Provide Notarized Credential of the manufacturer
119.	-do- **Evaluator**: AD-VII	Unomedical a/s Aaholmvej 1-3, Osted 4320 Lejre Denmark	Quick-set® Paradigm® (with P-cap) Codes and Sizes as per FSC Shelf life 3 years Class C	**Deferred** for provision of the following documents:- • provide valid and embassy attested original FSC in the country of origin. • Provide relation/ Authorization letter from Unomedical a/s Aaholmvej 1-3, Osted 4320 Lejre Denmark, authorizing Medtronic Pakistan. Unomedical a/s Aaholmvej 1-3, Osted 4320 Lejre Denmark is not present in the letter provided having list of Medtronic manufacturing facilities. • Provide valid ISO 13485 certificate for all the manufacturing sites , the submitted has been expired and does not mention all manufacturing sites. • Provide valid and notarized Full quality assurance certificate, the firm has submitted expired Full Quality assurance certificate. • Provide Notarized Credential of the manufacturer
120.	-do- **Evaluator:** AD-IV [1748]	Legal Manufacturer: Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA 55432 Manufacturing site: 1) Medtronic Singapore Operations Pte Ltd. 49 Changi South Avenue 2, Nasaco Tech Centre, Singapore, 486056 2) Medtronic Inc. 8200 Coral Sea St., Mounds View, MN 55112, USA	Attesta™ DR MRI Surescan™ (Model: ATDR01) (Dual Chamber pacemaker, rate responsive, MR-conditional) Class D Shelf Life: 18 Months	**Deferred** for provision of following documents:- • Original, valid, Embassy attested FSC for the applied product and submit revised Form 7A with new address of importer. Also the manufacturing sites shall be same as on FSC • Letter of Authorization/ Agency agreement. • Copy of Establishment License to import medical devices . • Valid ISO 13485 . • Declaration of conformity (DOC) . • QC details/ tests/ specs not provided specifically for the applied device

		(FSC US FDA Valid till 15-08-2021)		
121.	M/s. IBL HealthCare Limited; 9th Floor, NICL Building, Abbasi Shaheed Road, Karachi. (ELI-00119) 1390-K **Evaluator**: AD-VI	Legal Manufacturer:M/s. Ultra for Medical Products Co. (Ultramed) Manufacturing Site: Industrial Area, Arab El-Awamer, Abnoub, Assiut, Egypt. FSC: Egypt. Date of issue – 12-Dec-2019 Valid till – 28-Jul-2022	ULTRAMED Suction Catheter with & without Thumb Control. Codes and Sizes as per FSC Shelf life: 3-years Class B	**Deferred** for provision of following documents: - • Original and valid free sale certificate (FSC) of any RRA as per Rule 15(2). • Original & valid letter of authorization. • Valid ISO-13485 certificate/ latest GMP report. • Clarify about the product grouping and list of constituents-components or accessories that are grouped together for single intended purpose.
122.	-do- 1391-K **Evaluator**: AD-VI	Legal Manufacturers. Ultra for Medical Products Co. (Ultramed) Manufacturing Site: Industrial Area, Arab El-Awamer, Abnoub, Assiut, Egypt. FSC: Egypt. Date of issue – 12-Dec-2019 Valid till – 28-Jul-2022	KARIFUSION I.V. Infusion Set (I.V. Infusion Set).	**Deferred** for provision of following documents: - • Original and valid free sale certificate (FSC) of any RRA as per Rule 15(2). • Original & valid letter of authorization. • Valid ISO-13485 certificate/ latest GMP report. • Clarify about the product grouping and list of constituents-components or accessories that are grouped together for single intended purpose.
123.	-do- 1392-K **Evaluator**: AD-VI	Legal Manufacturer/s. Ultra for Medical Products Co. (Ultramed) Manufacturing Site: Industrial Area, Arab El-Awamer, Abnoub, Assiut, Egypt. FSC: Egypt. Date of issue – 12-Dec-2019 Valid till – 28-Jul-2022	ULTRAMED Twin Bore Nasal Oxygen Cannula.	**Deferred** for provision of following documents: - • Original and valid free sale certificate (FSC) of any RRA as per Rule 15(2). • Original & valid letter of authorization. • Valid ISO-13485 certificate/ latest GMP report. • Clarify about the product grouping and list of constituents-components or accessories that are grouped together for single intended purpose.
124.	-do- 1395-K **Evaluator**: AD-VI	Legal Manufacturer/s. Ultra for Medical Products Co. (Ultramed) Manufacturing Site: Industrial Area, Arab El-Awamer, Abnoub, Assiut, Egypt. FSC: Egypt. Date of issue – 12-Dec-2019	KARIFLEX Blood Transfusion Set	**Deferred** for provision of following documents: - • Original and valid free sale certificate (FSC) of any RRA as per Rule 15(2). • Original & valid letter of authorization. • Valid ISO-13485 certificate/ latest GMP report. • Clarify about the product grouping and list of constituents-components or accessories that are grouped together for single intended purpose.

		Valid till – 28-Jul-2022		
125.	-do- 1393-K **Evaluator**: AD-VI	Legal Manufacturer:M/s. Ultra for Medical Products Co. (Ultramed) Manufacturing Site: Industrial Area, Arab El-Awamer, Abnoub, Assiut, Egypt. FSC: Egypt. Date of issue – 12-Dec-2019 Valid till – 28-Jul-2022	ULTRAMED Infant Feeding Tube	**Deferred** for provision of following documents: - • Original and valid free sale certificate (FSC) of any RRA as per Rule 15(2). • Original & valid letter of authorization. • Valid ISO-13485 certificate/ latest GMP report. • Clarify about the product grouping and list of constituents-components or accessories that are grouped together for single intended purpose.
126.	-do- 1396-K **Evaluator**: AD-VI	Legal Manufacturer:M/s. Ultra for Medical Products Co. (Ultramed) Manufacturing Site: Industrial Area, Arab El-Awamer, Abnoub, Assiut, Egypt. FSC: Egypt. Date of issue – 12-Dec-2019 Valid till – 28-Jul-2022.	ULTRAMED Ryle's Tube	**Deferred** for provision of following documents: - • Original and valid free sale certificate (FSC) of any RRA as per Rule 15(2). • Original & valid letter of authorization. • Valid ISO-13485 certificate/ latest GMP report. • Clarify about the product grouping and list of constituents-components or accessories that are grouped together for single intended purpose.
127.	M/s Progressive Corporation; 147-D, Commercial Broadway, Phase-8 DHA; Lahore. ELI: 000114. -1602- **Evaluator**: AD-VI	Legal Manufacturer: Suzhou ZOEY Medical Devices Co., Ltd, the 2nd Floor, Building 18, No. 333 Guanpu Road, Guoxiang Street, Wuzhong Economic Development Zone, Suzhou, Jiangsu, China mfg. site: Suzhou CNNC Huadong Radiation Co., Ltd 4756 Jiao-tong Road songling Town, 215200 Wujiang City, Jiangsu Province, People's Republic of China FSC: China.	ZOEY (Hollow Fiber Hemodialyzer) Class: C. Shelf Life: 3 years. Codes & Sizes: As per FSC.	**Deferred** for provision of following documents: - • Original FSC of RRA or in accordance of rule 15(2) & as per Sr. No. (4) of Form-7(A). • Original and valid agency agreement. • Notarized and valid ISO-13485 certificate/ latest GMP report and QA certificate of all manufacturing sites involved.
128.	M/s. Biosorin (Private) Limited; 19- Usman Block, Boulevard New garden Town; Lahore. ELI:00186.	Legal Manufacturer & mfg. site: M/s. altona Diagnostics GmbH, Morkenstr. 1222767 Hamburg, Germany	Sydney IVF (Sydney IVF Media, made up of the following solutions;	**Deferred** for provision of following documents: - • Original FSC of RRA or in accordance of rule 15(2) & as per Sr. No. (4) of Form-7(A).

	-2798- **Evaluator**: AD-VI	Originan FSC: Germany Date of Issue: 19.08.2020.	-Sydney IVF Follicle Flush Buffer - Sydney IVF Gamete Buffer Sydney IVF speriment -Sydney IVF Culture Oil Sydney IVF Blastocyst Vitrification Kit _ Sydney IVF Blastocyst Warming Kit _ Sydney IVF sperm Medium -Sydney IVF Sperm Gradient Kit -Sydney IVF PVP -Sydney IVF Fertilization Medium -Sydney IVF Cleavage Medium -Sydney IVF Blastocyst Medium Codes & Sizes: As per FSC Class-D Shelf Life: 20-weeks.	• Original and valid agency agreement. • Notarized and valid ISO-13485 certificate/ latest GMP report and QA certificate of all manufacturing sites involved.
129.	M/s Anwar & Sons Apartment-10, Safari Villas-2 Commercial Complex, Bahria Town, Phase-7, Rawalpindi. ELI: 00017 {2122} **Evaluator**: AD-VI	Legal Manufacturer & mfg. site: M/s Wuhan BBT Mini-Invasive Medical Tech Co., Ltd, 4F, 2nd Building and Room 407, R&D Building 12nd Caifu Road Donghu New Technology Development Zone 430074, China. FSC:China Date of issue: 21.06.	Transducer (Ultrasonic Surgical System-Component) Codes&Sizes: As per FSC Class-C Shelf Life: 2 years	**Deferred** for provision of following documents: - • Original letter of authorization, • Original and valid FSC, • Valid certificate of ISO-13485, • QC details & CoA • justifiable shelf life studies/ protocols/ validation • Brand name of the product
130.	-do- -2123- **Evaluator**: AD-VI	Legal Manufacturer & mfg. site: M/s Wuhan BBT Mini-Invasive Medical Tech Co., Ltd, 4F, 2nd Building and Room 407, R&D Building 12nd Caifu Road Donghu New Technology Development Zone 430074, China FSC:China	U&R (Radio Frequency Ultrasonic Scalpel (Shear) Instrument Code s& Sizes: As per FSC Class-C Shelf Life: 2 years	**Deferred** for provision of following documents: - • Original letter of authorization, • Original and valid FSC, • Valid certificate of ISO-13485, • QC details & CoA • justifiable shelf life studies/ protocols/ validation • Brand name of the product

131.	-do- Evaluator AD-II [1932-P]	Legal Manufacturer: M/s SMI AG, Steinerberg 8. 4780-St. Vith Belgium **FSC** (original embassy attested): **Belgium** Date of issue: 22.05.19	BONE WAX 2.5g (Surgical Haemostatic) Class-C Shelf Life: 5 years	**Deferred** for provision of following documents:- ▪ Credentials of manufacturer abroad duly notarized from the country of origin since scanned copy is provided. ▪ 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) for which sole authorization is given, validity of agreement, duly notarized by the country of origin since already provided is copy. ▪ Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized by the country of origin since already submitted is expired now but valid upon submission. ▪ Full QA certificate or equivalent, duly notarized by the country of origin.
132.	M/s Ferozsons Laboratories Limited P.O Ferozsons, Amangarh, Nowshera (KPK) ELI-00120. -2628- **Evaluator**: AD-VI	Legal Manufacturer: Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA Manufacturing Sites: Boston Scientific Limited Ballybrit Business Park, Galway, Ireland FSC: U.S.A Valid till: 09.10.2021	WALLSTENT RX Biliary Endoprosthesis (Bare-metal Biliary Stent) Codes & Sizes: As per FSC Class-C Shelf Life: 19 months	**Deferred** for provision of following documents:- • Original and valid Free Sale Certificate duly attested by embassy of Pakistan. • Original & valid letter of authorization with updated address of importer as per ELI. • Valid ISO-13485 certificate/ latest GMP report.
133.	-do- 2682. **Evaluator**: AD-VI	Legal Manufacturer: Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA Manufacturing Site:Boston Scientific Limited Ballybrit Business Park Galway Ireland FSC: U.S Valid till: 27.01.2022	WALLFLEX Biliary Stent System (RX Fully Covered0 (Polymer-metal Biliary Stent) Codes & Sizes: As per FSC Class-C Shelf Life: 2 years	**Deferred** for provision of following documents:- • Original and valid Free Sale Certificate duly attested by embassy of Pakistan. • Original & valid letter of authorization with updated address of importer as per ELI. • Valid ISO-13485 certificate/ latest GMP report.
134.	-do- 2687. **Evaluator**: AD-VI	Legal Manufacturer Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA Manufacturing Site: Boston Scientific Limited Ballybrit Business Park Galway, Ireland	WALLFLEX Esophageal Fully covered Stent System (Polymer-metal esophageal stent, non-sterile) Codes & Sizes: As per FSC	**Deferred** for provision of following documents:- • Original and valid Free Sale Certificate duly attested by embassy of Pakistan. • Original & valid letter of authorization with updated address of importer as per ELI. • Valid ISO-13485 certificate/ latest GMP report.

		FSC: U. S Valid till: 27.01.2022	Class-C Shelf Life: 19 months	
135.	-do- **Evaluator**: AD-VII	Legal Manufacturer: Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA. Manufactuing Site: Boston Scientific Corporation 780 Brookside Drive Spencer, IN USA FSC: FDA U.S FOOD &DRUG Valid till: 27.01.2022	Advanix Pancreatic Stent Kit-Straight Stent No. Leading Barb (Polymeric Biliary Stent, non-bioabsorbable) Class-C Shelf Life: 1.5 years	**Deferred** for provision of the following documents:- • Provide valid original and embassy attested FSC, since the firm has provided copy. • Most of the technical documents provided are for Advanix ™ Biliary stent with NaviFlex ™ RX Delivery System and not for Advanix Pancreatic Stent Kit-Straight Stent No. Leading Barb. Since both of these products are separately given in the FSC and have separate sub codes, clarify.? • Provide valid ISO 13485 certificate for all the manufacturing sites, the firm has submitted expired copy. • Provide Notarised and valid Full Quality assurance certificate, the submitted is copy. • Provide Stability studies of the products to be registered, stability studies of Advanix ™ Biliary stent with NaviFlex ™ RX Delivery System provided , clarify. • Provide valid, original and notarized letter of Authorization, since the only copy is provided.
136.	-do- **Evaluator**: AD-VII	Legal Manufacturer: Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA. Manufactuing Site: Boston Scientific Corporation 780 Brookside Drive Spencer, IN USA FSC: FDA U.S FOOD &DRUG Valid till: 27.01.2022	Advanix Pancreatic Stent Kit-Straight Stent with leading Barb (Polymeric Biliary Stent, non-bioabsorbable) Class-C Shelf Life: 1.5 years	**Deferred** for provision of the following documents:- • Provide valid original and embassy attested FSC, since the firm has provided copy. • Most of the technical documents provided are for Advanix ™ Biliary stent with NaviFlex ™ RX Delivery System and not for Advanix Pancreatic Stent Kit-Straight Stent No. Leading Barb. Since both of these products are separately given in the FSC and have separate sub codes, clarify.? • Provide valid ISO 13485 certificate for all the manufacturing sites, the firm has submitted expired copy. • Provide Notarised and valid Full Quality assurance certificate, the submitted is copy. • Provide Stability studies of the products to be registered, stability studies of Advanix ™ Biliary stent with NaviFlex ™ RX Delivery System provided , clarify. • Provide valid, original and notarized letter of Authorization, since the only copy is provided
137.	M/s Chemical House, 6-C Sikander Malhi Road, Canal Park, Gulberg II, Lahore Pakistan. ELI: 00156. -2553- **Evaluator**:	Legal Manufacturer & Mfg. site: M/s BIO-RAD, 3 Boulevard Raymond Poincare, 92430, Marnes-la-Conquette, France. Scanned Copy of FSC: France provided.	GENSCREEN ULTRA HIV Ag-Ab assay (EIA Microplate Format) Codes & Sizes: As per FSC	**Deferred** for clarification from the firm regarding letter of authorization issued by the Bio-Rad, Switzerland, while all the legal documents including application form doesn't describe the subject site

	AD-VI		Class-D Shelf Life: 18 months	
138.	-do- -2554- **Evaluator**: AD-VI	Legal Manufacturer & Mfg. site: M/s BIO-RAD, 3 Boulevard Raymond Poincare, 92430, Marnes-la-Conquette, France Scanned Copy of FSC: France provided.	GEENIUS HIV (EIA Microplate Format) Codes & Sizes: As per FSC Class-D Shelf Life: 24 months	**Deferred** for clarification from the firm regarding letter of authorization issued by the Bio-Rad, Switzerland, while all the legal documents including application form doesn't describe the subject site Provide valid ISO 13485 Certificate.
139.	-do- -2550- **Evaluator**: AD-VI	Legal Manufacturer & Mfg. site: M/s BIO-RAD, 3 Boulevard Raymond Poincare, 92430, Marnes-la-Conquette, France Scanned Copy of FSC: France provided.	GEENIUS HCV Supplement Assay & Control Kit (Immunochromatographic test) Codes & Sizes: As per FSC Class-D Shelf Life: 12 months	**Deferred** for clarification from the firm regarding letter of authorization issued by the Bio-Rad, Switzerland, while all the legal documents including application form doesn't describe the subject site Provide valid ISO 13485 Certificate.
140.	M/s Optic Class Distribution Network, Office No 2, 1st Floor, Shan Arcade, Barkat Market, New Garden Town Lahore.. ELI-00304. 210-P **Evaluator**: AD-VI	Legal Manufacturer & MFG. SITE: M/s. Lapis Lazuli International N.V, Bolderweg 2, 1332 at Almere, The Netherlands. FSC Netherland Issued on 20.08.2018	Ultima All in One Soft Solution (Multipurpose Contact Lens Solution-120ml) Class C Shelf Life :03 years	**Deferred** for provision of following documents: - • Original FSC as per Rule 15(2) of MDR-2017. • ISO-13485 certificate of the subject manufacturer. • Label duly approved in the country of origin.
141.	-do- 211-P **Evaluator**: AD-VI	Legal Manufacturer & MFG. SITE M/s. Lapis Lazuli International N.V, Bolderweg 2, 1332 at Almere, The Netherlands. FSC Netherland Issued on 20.08.2018	Ultimate Plus(R) (Multipurpose Contact Lens Solution – 360ml) Class C Shelf Life :03 years	**Deferred** for provision of following documents: - • Original FSC as per Rule 15(2) of MDR-2017. • ISO-13485 certificate of the subject manufacturer. • Label duly approved in the country of origin.
142.	M/s Zedco, Office No. 203, Sky Mark Tower, Plot A-13, Block 7/8, K.C.H.S.U, Shahrah-e-Faisal, Karachi. -1691- (ELI-00347) **Evaluator**: AD-VI	Legal Manufacturer: Lorne Laboratories Ltd, Unit 1, Cutbush Park Industrial Estate, Danehill, Lower Earley, Reading, Bershire, RG6 4UT, United Kingdom. (FSC Valid 07-03-2023)	LORNE Reagents for Crossmatching of Blood Transfusion. Class-C. Shelf Life: Anti-human IgG (clear) 24 Months Anti-Human IgG (Green) 24 months A.H.G Elite (Clear) 24 months A.H.G Elite Green 24 months ANTI-C3D Monoclonal -24 Months	**Deferred** for provision of following documents: - • Original and valid FSC of SRA • Valid ISO-13485 certificate. • Original & valid agency agreement

			Serological Albumin 22% 24 Months Serological Albumin 30% 24 Months Control Precise Weak Anti-D 24 Months Buffer & Potentiators LISS Ready for use 12 Months LISS-ADD 24 Months PEG-ADD 24 Months. Sizes & Codes as Per FSC	
143.	B.Braun Pakistan (Pvt) Ltd., The Forum, Suite 216, Khayaban-e-Jami, Block No.9, Clifton, Karachi (ELI-00006) **Evaluator**: AD-VII	Aesculap AG. Am Aesculap-Platz, 78532, Tuttlingen, Germany	Caiman 12 Articulating Jaw PL730SU PL731SU Codes and sizes as per FSC Class C Shelf Life 3 Years 3413	**Deferred** for provision of the following documents: - •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. •Provide valid and notarized ISO 13485 certificate, full quality assurance certificate the firm has provided copies. •Provide Valid and notarized Authorization letter, the firm has provided photocopy which is expired
144.	-do- **Evaluator**: AD-VII	Aesculap AG. Am Aesculap-Platz, 78532, Tuttlingen, Germany Fsc issued on 26th June 2019	Caiman 5 Non Articulating Jaw Codes and sizes as per FSC Class C Shelf Life 2 Years 3414	**Deferred** for provision of the following documents:- •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. •Provide valid and notarized ISO 13485 certificate, full quality assurance certificate the firm has provided copies. Provide Valid and notarized Authorization letter, the firm has provided photocopy which is expired
145.	-do- **Evaluator**: AD-VII	Aesculap AG. Am Aesculap-Platz, 78532, Tuttlingen, Germany	Caiman 5 Articulating Jaw Codes and sizes as per FSC Class C Shelf Life 2 Years 3415	**Deferred** for provision of the following documents:- •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. •Provide valid and notarized ISO 13485 certificate, full quality assurance certificate the firm has provided copies. Provide Valid and notarized Authorization letter, the firm has provided photocopy which is expired

146.	-do- **Evaluator**: AD-VII	Aesculap AG. Am Aesculap-Platz, 78532, Tuttlingen, Germany	Caiman Vessel Sealer Lektrafuse HF Generator Bipolar GN200 Foot Switch GN201 Codes and sizes as per FSC Class C 3416 Shelf life not applicable as per their company letter	**Deferred** for provision of the following documents •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. •Provide valid and notarized ISO 13485 certificate, full quality assurance certificate the firm has provided copies. Provide Valid and notarized Authorization letter, the firm has provided photocopy which is expired
147.	-do- **Evaluator**: AD-VII	Aesculap AG. Am Aesculap-Platz, 78532, Tuttlingen, Germany	Caiman 5 Maryland Articulating Jaw Codes and sizes as per FSC Class C Shelf Life 2 Years 3510	**Deferred** for provision of the following documents:- •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. •Provide valid and notarized ISO 13485 certificate, full quality assurance certificate the firm has provided copies. Provide Valid and notarized Authorization letter, the firm has provided photocopy which is expired
148.	-do- **Evaluator**: AD-VII	Aesculap AG. Am Aesculap-Platz, 78532, Tuttlingen, Germany	Caiman 5 Maryland Non Articulating Jaw Codes and sizes as per FSC Class C Shelf Life 2 Years 3511	**Deferred** for provision of the following documents •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. •Provide valid and notarized ISO 13485 certificate, full quality assurance certificate the firm has provided copies. •Provide Valid and notarized Authorization letter, the firm has provided photocopy which is expired
149.	M/s Pharma Life, Office No. CB-94/1 Coblin, Near Askari-11 Sajid Bukhari Road, Afshan Colony, Rawalpindi ELI:00606 **Evaluator**: AD-VII	Legal Manufacturer: Saudi Mais Co for Medical Product, 3rd Industria Area, Alkharj Road, Street No, 256 Riyahd-Saudi, Arabia FSC: Saudi Arabia Date of issue: 17.02.2020	MaiCath I/V Catheter (All type/ model of series) Codes &Sizez: As per FSC Class-B Shelf Life: 5 year	**Deferred** for provision of the following documents:- •Provide valid, original and notarised Termination of authorization from the principle and NOC from M/s Pak Mais Co for medical products , Lahore. Since as per documents submitted the product was previously registered as drug in the name of Pak Mais Co for medical products, Lahore. •Provide stability Studies •Provide Valid and original Authorization letter the submitted has been expired after submission. •Provide Valid and embassy attested FSC in the country of origin for Pakistan. The submitted FSC is not embassy attested and

				is issued for Arab Authorities and not Pakistan. •Provide notarised and valid ISO 13485 certificate, Production Quality assurance certificate and Full quality assurance certificate. The submitted are not notarised and are expired. Furthermore, Full Quality Assurance certificate issued mentioned only haemodialysis and urethral stent catheter, and does not mention IV canula clarify? •Simce the product is from nonreference cuntry therefore Provide notarised and valid product CE certificates. or FSC of any reference regulatory authority. •Serial No 1 and 2 of Form-7A not filled therefore, fill Form-7A properly.
150.	Johnson & Johnson Pakistan (Pvt) Ltd., Office No.806, 8th Floor, Horizon Tower, Block 3, Scheme 5, Clifton, Karachi (ELI-00154) **Evaluator**: AD-VII	**Legal Manufacturer:** Synthes GmbH 3 Eimattstrasse, 4436 Oberdorf, CH Switzerland	Hand Plates Codes & Sizes as per FSC Class C FSC : Switzerland valid till 31.01.2023 Shelf Life: N/A for few components written and for few 10 Y (as per declaration documents)	**Deferred** for provision of the following documents:- •The firm has provided a list of 276 product codes to be registered under hand plate, of different manufacturing sites. The firm need to clarify the grouping/ family system of the components/ products to be registered under hand plate. Furthermore, name of all components not found in copy of FSC. Therefore, Provide valid original and embassy attested FSC having names and codes of all components/ products to be registered. •Provide valid ISO 13485 certificate for all the manufacturing sites, the submitted has been expired. •Provide Notarised and valid Full Quality assurance certificate, the submitted is copy. •Provide Stability studies of the products to be registered , since a letter has been provided mentioning the time period and no studies has been provided. •Provide valid, original and notarized letter of Authorization, since the provided is a copy.
151.	-do- **Evaluator**: AD-VII	**Legal Manufacturer:** Synthes GmbH 3 Eimattstrasse, 4436 Oberdorf, CH Switzerland	Wire Implants Codes & Sizes as per FSC FSC : Switzerland valid till 20.04.2023 Shelf Life: N/A for few components written and for few 10 Y (as per declaration documents)	**Deferred** for provision of the following documents:- • The firm has provided a list of 202 product codes to be registered under Wire Implants, of different manufacturing sites. The firm need to clarify the grouping/ family system of the components/ products to be registered under Wire Implants. Furthermore, name of all components not found in copy of FSC neither all sites mentioned on FSC. Therefore, Provide valid original and embassy attested FSC having names and codes of all components/ products to be registered. • Provide valid ISO 13485 certificate for all the manufacturing sites, the submitted has been expired.

				• Provide Notarised and valid Full Quality assurance certificate, the submitted is copy. • Provide Stability studies of the products to be registered, since a letter has been provided mentioning the time period and no studies has been provided. • Provide valid, original and notarized letter of Authorization, since the provided is a copy
152.	-do- **Evaluator**: AD-VII	**Legal Manufacturer:** Synthes GmbH 3 Eimattstrasse, 4436 Oberdorf, CH Switzerland	Proximal Humerus Plates Codes & Sizes as per FSC Class C FSC : Switzerland valid till 31.01.2023 Shelf Life: N/A for few components written and for few 10 Y (as per declaration documents)	**Deferred** for provision of the following documents:- • The firm has provided a list of 112 product codes to be registered under hand plate, of different manufacturing sites. The firm need to clarify the grouping/ family system of the components/ products to be registered under Proximal Humerus plate. Furthermore, name of all components not found in copy of FSC. Therefore, Provide valid original and embassy attested FSC having names and codes of all components/ products to be registered. • Provide valid ISO 13485 certificate for all the manufacturing sites, the submitted has been expired. • Provide Notarised and valid Full Quality assurance certificate, the submitted is copy. • Provide Stability studies of the products to be registered, since a letter has been provided mentioning the time period and no studies has been provided. • Provide valid, original and notarized letter of Authorization, since the provided is a copy
153.	-do- **Evaluator**: AD-VII	**Legal Manufacturer:** Synthes GmbH 3 Eimattstrasse, 4436 Oberdorf, CH Switzerland	Ulna Osteotomy Plates Codes & Sizes as per FSC FSC : Switzerland valid till 20.04.2023 Shelf Life: N/A for few components written and for few 10 Y (as per declaration documents)	**Deferred** for provision of the following documents:- • Provide valid original and embassy attested FSC, since the firm has provided copy. • The firm has provided a list of 08 product codes to be registered under Ulna Osteotomy Plates. The firm need to clarify the grouping/ family system of the components/ products to be registered under Ulna Osteotomy Plates. • Provide valid ISO 13485 certificate for all the manufacturing sites, the submitted has been expired. • Provide Notarised and valid Full Quality assurance certificate, the submitted is copy. • Provide Stability studies of the products to be registered, since a letter has been

				provided mentioning the time period only for few and no studies has been provided. • Provide valid, original and notarized letter of Authorization, since the provided is a copy.
154.	-do- **Evaluator**: AD-VII	**Legal Manufacturer:** Synthes GmbH 3 Eimattstrasse, 4436 Oberdorf, CH Switzerland	Pediatric Plates Codes & Sizes as per FSC FSC : Switzerland valid till 31.01.2023 Shelf Life: N/A. for few components written and for few 10 Y (as per declaration documents) File no 2526	**Deferred** for provision of the following documents:- • The firm has provided a list of 71 product codes to be registered under hand plate, of different manufacturing sites. The firm need to clarify the grouping/ family system of the components/ products to be registered under Pediatric Plates. Furthermore, name of all components not found in copy FSC. Therefore, Provide valid original and embassy attested FSC having names and codes of all components/ products to be registered. • Provide valid ISO 13485 certificate for all the manufacturing sites, 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 provided is a copy.
155.	-do- **Evaluator**: AD-VII	**Legal Manufacturer:** Synthes GmbH 3 Eimattstrasse, 4436 Oberdorf, CH Switzerland	Radius Plates Codes & Sizes as per FSC FSC : Switzerland valid till 31.01.2023 Shelf Life: N/A. for few components written and for few 10 Y (as per declaration documents) File no 2716	**Deferred** for provision of the following dicuments:- • The firm has provided a list of 08 product codes to be registered under Radius Plates. The firm need to clarify the grouping/ family system of the components/ products to be registered under Radius Plates. • Provide valid original and embassy attested FSC, since the firm has provided copy. • Furthermore, name of all components not found in FSC neither all sites mentioned on FSC. Therefore, Provide FSC having names and codes of all components/ products to be registered. • Provide valid ISO 13485 certificate for all the manufacturing sites, the submitted has been expired. • Provide Notarised and valid Full Quality assurance certificate, the submitted is copy. • Provide Stability studies of the products to be registered, since a letter has been

				provided mentioning the time period only for few and no studies has been provided. • 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.
156.	M/s Reaction Scientific Private (Ltd), 337, Street No. 17, Block-B, Sector B- 17, Islamabad. ELI: 00228 **Evaluator**: AD-VII	Legal Manufacturer: M/s Spinreact, S.A.U. Carretera Santa Coloma, 7. 17176. Sant Esteve de Bas. Girona, Spain FSC: Spain	ASO Latex (Slide Agglutination Serology Test Kit) Coes & sizes: As per FSC FSC issued on 3 September 2018 Class-C Shelf Life: 30 months	**Deferred** for provision of the following dicuments:- • Provide valid original and embassy attested FSC having name of the product, since the firm has provided copy. • Provide valid ISO 13485 certificate. the firm has submitted expired copy. • Provide Notarised and valid Full Quality assurance certificate. • Provide Stability studies of the products to be registered. • Provide valid, original and notarized letter of Authorization and credential of the company, since only copy is provided
157.	-do- **Evaluator**: AD-VII	Legal Manufacturer: M/s Spinreact, S.A.U. Carretera Santa Coloma, 7. 17176. Sant Esteve de Bas. Girona, Spain FSC: Spain	Salmonella Parayphi BO (Bacterial Antigen Serology Test Kit (100 tests)-Art # 1205041) Coes & sizes: As per FSC FSC issued on 3 September 2018 Class-C Shelf Life: 30 months	**Deferred** for provision of the following dicuments:- • Provide valid original and embassy attested FSC having name of the product, since the firm has provided copy. • Provide valid ISO 13485 certificate. the firm has submitted expired copy. • Provide Notarised and valid Full Quality assurance certificate. • Provide Stability studies of the products to be registered. • Provide valid, original and notarized letter of Authorization and credential of the company, since only copy is provided.
158.	-do- **Evaluator:** AD-IV [2881-P]	Manufacturer: M/s SPINREACT, S.A.U. Carretera Santa Coloma, 7. 17176. San Esteve De Bas. Girona, Spain FSC Spain issued on 3-9-2018	Spinreact Salmonella Typhi H (kit) [Bacterial antigen serology test kit] Code: 1205071 (100 test) Class C Shelf Life: 30 months	**Deferred** for provision of following documents:- • Brand name of the applied product? • Original documents such as Free Sale Certificate, Letter of Authorization, ISO13485, credentials of manufacturer not found in any dossier and in each Form it is written "original already submitted" Clarify in which dossier have the original documents been submitted along with documentary evidence. Otherwise you are required to submit the original documents • Instructions for use (IFU) of applied product. • Valid and notarized ISO13485. • Full QA certificate issued by CAB

				notified in NANDO Database is not provided for the applied product. • Design Examination certificate issued by CAB notified in NANDO Database is not provided for the applied product • Essential Principles of safety and performance (EPSP)/Essential Requirements checklist is not provided. The document provided is safety data sheet not EPSP • Declaration of Conformity (DOC) provided for the product does not have product Class mentioned on it. Provide complete EU DOC having Classification drawn by the manufacturer to claim CE marking of the applied product
159.	-do- ELI-00228 **Evaluator:** AD-IV [2884P-B]	Manufacturer: M/s SPINREACT, S.A.U. Carretera Santa Coloma, 7. 17176. San Esteve De Bas. Girona, Spain FSC Spain issued on 3-9-2018	Spinreact Salmonella Paratyphi AH (kit) [Bacterial antigen serology test kit] Code: 1205011 (100 test) Class C Shelf Life: 30 months	**Deferred** for provision of following documents:- • Brand name of the applied product? • Original documents such as Free Sale Certificate, Letter of Authorization, ISO13485, credentials of manufacturer not found in any dossier and in each Form it is written "original already submitted" Clarify in which dossier have the original documents been submitted along with documentary evidence. Otherwise you are required to submit the original documents • Instructions for use (IFU) of applied product. • Valid and notarized ISO13485. • Full QA certificate issued by CAB notified in NANDO Database is not provided for the applied product. • Design Examination certificate issued by CAB notified in NANDO Database is not provided for the applied product • Essential Principles of safety and performance (EPSP)/Essential Requirements checklist is not provided. The document provided is safety data sheet not EPSP • Declaration of Conformity (DOC) provided for the product does not have product Class mentioned on it. Provide complete EU DOC having Classification drawn by the manufacturer to claim CE marking of the applied product
160.	-do- **Evaluator:** AD-IV [2884-P]	Manufacturer: M/s SPINREACT, S.A.U. Carretera Santa Coloma, 7. 17176. San Esteve De Bas. Girona, Spain FSC Spain issued on 3-9-2018	Spinreact RF Latex (kit) [Slide Agglutination Serology Test Kit] Codes: 1200201 (50 test) 1200202 (100 test) 1200205 (200 test) Class B (applied as C) Shelf Life: 30 months	**Deferred** for provision of following documents:- • Brand name of the applied product? • Justification from manufacturer for classifying the applied product in Class C by giving reference from the relevant provision in latest IMDRF document of IVD medical device classification. • Original documents such as Free Sale Certificate, Letter of Authorization, ISO13485, credentials of manufacturer not found in any dossier and in each Form

				it is written "original already submitted" Clarify in which dossier have the original documents been submitted along with documentary evidence. Otherwise you are required to submit the original documents • Valid and notarized ISO13485. • Full QA certificate issued by CAB notified in NANDO Database for the applied product • Design Examination certificate issued by CAB notified in NANDO Database for the applied product. • Essential Principles of safety and performance (EPSP)/Essential Requirements checklist is not provided. The document provided is safety data sheet not EPSP. • Declaration of Conformity (DOC) provided for the product does not have product Class mentioned on it. Provide complete EU DOC having Classification drawn by the manufacturer to claim CE marking of the applied product
161.	-do- **Evaluator:** AD-IV [2883-P]	Manufacturer: M/s SPINREACT, S.A.U. Carretera Santa Coloma, 7. 17176. San Esteve De Bas. Girona, Spain FSC Spain issued on 3-9-2018	Spinreact RPR Carbon (kit) Code: 1200402 (500 tests) Class C Shelf Life: 30 months	**Deferred** for provision of following documents:- • Brand name of the applied product? • Original documents such as Free Sale Certificate, Letter of Authorization, ISO13485, credentials of manufacturer not found in any dossier and in each Form it is written "original already submitted" Clarify in which dossier have the original documents been submitted along with documentary evidence. Otherwise you are required to submit the original documents. • Valid and notarized ISO13485. • Full QA certificate issued by CAB notified in NANDO Database for the applied product. • Design Examination certificate issued by CAB notified in NANDO Database for the applied product. • Essential Principles of safety and performance (EPSP)/Essential Requirements checklist is not provided. The document provided is safety data sheet not EPSP. • Declaration of Conformity (DOC) provided for the product does not have product Class mentioned on it. Provide complete EU DOC having Classification drawn by the manufacturer to claim CE marking of the applied product • Instructions for use (IFU) of applied product not provided
162.	-do- **Evaluator:** AD-IV [2882-P]	Manufacturer: M/s SPINREACT, S.A.U. Carretera Santa Coloma, 7. 17176. San Esteve De Bas. Girona, Spain	Spinreact CRP Latex (kit) [Slide Agglutination Serology Test Kit] Code: 1200301 (50 tests) 1200302 (100 tests)	**Deferred** for provision of following documents:- • Brand name of the applied product? • Original documents such as Free Sale Certificate, Letter of Authorization, ISO13485, credentials of manufacturer