No.F.4-6/2022-MD (M-50)
Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
Drug Regulatory Authority of Pakistan
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Islamabad the 21st October, 2022.

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

The applications of following applicants were placed before Medical Device Board (MDB) in its 50th meeting held on 22nd September, 2022 and Board deferred these applications being deficient of the information/documents as specified in last column (V) of the Table below:

S.#	Name of Firm (s)	Name of Manufacturer	Name of Medical Devices.	Decision
(I)	(II)	(III)	(IV)	(V)
1.	M/s Ferozsons Laboratories Limited, P.O Ferozsons, Amangarh, Nowshera (KPK), Pakistan ELI: 00120. Evaluator AD-VI -3090-	**Legal Manufacturer**: Boston Scientific Corporation 300, Boston Scientific Way, Malborough, MA 01752 USA **Manufacturing Site:** Boston Scientific Corporation, 780 BROOKSLDE DRIVE SPENCER, IN USA FSC: U.S.A Valid till:27/01/2022,	ACQUIRE ™ [Flexible Endoscopic Ultrasound Fine Needle Biopsy (FNB) Device-Single Use]. Codes & Sizes: As per FSC Class-B Shelf life: 3 years or 37 months.	**Deferred** for provision of following info. / documents: - Provide the Original and Valid LoA containing the address as per ELI, original fee submission challan slips (DRAP Copy) and clearly mention the shelf life on application form.
2.	-do- Evaluator AD-VI -3093-	**Legal Manufacturer:** Boston Scientific Corporation 300, Boston Scientific Way, Malborough, MA 01752 USA **Manufacturing Site:** Boston Scientific Corporation 780 Brookside Drive Spencer, in 47460 USA FSC: 27.01/2022	ACQUIRE ™ (Pulmonary Endobronchial Ultrasound Fine Needle Biopsy Device) (Body Aspiration Needle-Single Use) Codes & Sizes: As per FSC Class-B Shelf life: 3 years or 37 months.	**Deferred** for provision of following info. / documents: - Provide the Original and Valid LoA containing the address as per ELI, original fee submission challan slips (DRAP Copy) and clearly mention the shelf life on application form.

3.	-do- Evaluator AD-VI -3094-	**Legal Manufacturer:** Boston Scientific Corporation 300, Boston Scientific Way, Malborough, MA 01752 USA **Manufacturing Site:** Boston Scientific Corporation 150 Baytech Drive San Jose, CA 95134 USA FSC: Ireland Valid till: 20.04.2023	iLAB ™ POLARIS Multi-Modality Guidance System (Cardiovascular Ultrasound Imaging System). Codes & Sizes: As per FSC Class-B Shelf life: N/A. Mean Time Between Failures (MBFT) of machine is mentioned is 09-years.	**Deferred** for provision of following info. / documents: - Provide the Original and Valid LoA containing the address as per ELI, original fee submission challan slips (DRAP Copy) and clearly mention the shelf life on application form.
4.	-do- Evaluator AD-VI -3091-	**Legal Manufacturer:** Boston Scientific Corporation 300, Boston Scientific Way, Malborough, MA 01752 USA **Manufacturing Site:** Boston Scientific de Costa Rica, S.R.L, 2546 First Street, Propark EI Coyol, Alajuela COSTA RICA 20904 FSC: USA Valid till: 10/12/2021	RADIAL JAW-4 Pediatric (Flexible endoscopic biopsy forceps, single-use). Codes & Sizes: As per FSC Class-B Shelf life: 3 years or 37 months.	**Deferred** for provision of following info. / documents: - Provide the Original and Valid LoA containing the address as per ELI, original fee submission challan slips (DRAP Copy), clarify about the manufacturing sites written on technical documentation and shelf life on application form.
5.	-do- Evaluator AD-VI -3092-	**Legal Manufacturer:** Boston Scientific Corporation 300, Boston Scientific Way, Malborough, MA 01752 USA **Manufacturing Site:** Boston Scientific de Costa Rica , S.R.L, 2546 First Street, Propark EI Coyol, Alajuela COSTA RICA 20904 FSC: U.S.A Valid till: 10/12/2021	RADIAL JAW-4 Pulmonary (Flexible endoscopic biopsy forceps, single-use) Codes & Sizes: As per FSC Class-B Shelf life: 3 years or 37 months.	**Deferred** for provision of following info. / documents: - Provide the Original and Valid LoA containing the address as per ELI, original fee submission challan slips (DRAP Copy), clarify about the manufacturing sites written on technical documentation and shelf life on application form.
6.	-do- Evaluator AD-VI -3095-	**Legal Manufacturer:** Boston Scientific Corporation 300, Boston Scientific Way, Malborough, MA 01752 USA	RADIAL JAW-4 Jumbo (Flexible endoscopic biopsy forceps single use) Codes & Sizes: As per FSC	**Deferred** for provision of following info. / documents: - Provide the Original and Valid LoA containing the address as per ELI, original fee submission challan slips (DRAP Copy), clarify about the manufacturing sites written on

		Manufacturing Site: Boston Scientific de Costa Rica , S.R.L, 2546 First Street, Propark EI Coyol, Alajuela COSTA RICA 20904 FSC: U.S.A Valid till: 10/12/2021	Class-B Shelf life: 3 years or 37 months.	technical documentation and shelf life on application form.
7.	-do- Evaluator AD-VI -3037-	**Legal Manufacturer:** Xeridiem Medical Devices 4700 S Overland Dr. Tucson, AZ, USA, 85714 **Manufacturing Site:** Xeridiem Medical Devices 7700 S Overland Dr. Tucson, AZ, USA 85714 FSC: U.S.A Valid till: 04.01.2024	ENDOVIVE Gastrostomy Tube, Straight, with Enfit Connector (Gastrostomy Feeding Tubes) Class-C Shelf life: 03-years	**Deferred** for provision of following info. / documents: - Provide the Original and Valid LoA containing the address as per ELI, original fee submission challan slips (DRAP Copy), clarify about grouping with application form.
8.	-do- Evaluator AD-VI -3039-	**Legal Manufacturer:** Boston Scientific Corporation 300, Boston Scientific Way, Marlborough , MA 01752, USA **Manufacturing Site:** Boston Scientific Ltd Business and Technology Park, Model Farm Road, Cork Ireland Stellartech Research Corporation 560 Cottonwood Drive, Milpitas, CA 95035, USA Boston Scientific Corporation 500, Commander Shea Boulevard, Quincy, MA 02171, USA FSC: 05.12.2023 FSC: U.S.A Valid till: 03.12.2022	ALAIR Bronchial Thermoplasty System (Radio-frequencyablation system) Codes & Sizes: As per FSC Class-C Shelf Life: 02-years	**Deferred** for provision of following info. / documents: - Provide the Original and Valid LoA containing the address as per ELI, original fee submission challan slips (DRAP Copy), clarify about grouping with application form.
9.	-do- Evaluator AD-VI -3038-	**Legal Manufacturer:** Boston Scientific Corporation 300, Boston Scientific Way, Marlborough , MA 01752, USA	SENTINEL Cerebral Protection System (Embolic capture guidewires)	**Deferred** for provision of following info. / documents: - Provide the Original and Valid LoA containing the address as per ELI, original fee submission challan slips (DRAP Copy), clarify about grouping with application form.

		Manufacturing Site: Boston Scientific Corporation 2546 First Street, Propark EI Coyol, atajuela Costa RICA 20904 FSC: U.S.A Valid till: 03.12.2022	Class-D Shelf life: 02-years	
10.	-do- Evaluator AD-VI -3050-	**Legal Manufacturer:** Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 U.S.A **Manufacturing Site:** Boston Scientific Corporation 780 Brookside Drive Spencer, in USA FSC: U.S.A Valid till: 08.11.2023	NAVIFLEX RX Delivery System (Polymeric Biliary Stent, Non-bioabsorbable) Codes & Sizes: As per FSC Class-C Shelf Life: 02-years	**Deferred** for provision of following info/documents: - Provide the Original and Valid LoA containing the address as per ELI, original fee submission challan slips (DRAP Copy), clarify about grouping with application form.
11.	-do- Evaluator AD-III 35-P (Renewal)	**Legal Manufacturer:** M/s M&G Products Co., Ltd No. 968-970 Mingzhuwan Yangzhong 212200, Jiangsu, China. FSC China Date of Issue: 10.12.2020 Valid for 2 years FSC Germany issuance 29-10-2021	Trow Set Infusion set (infusion set) Class-B Shelf Life: 5 years Sizes: Classic type	**Deferred** for the provision of differential fee of 20,000/-
12.	Sure Bio-Diagnostics & Pharmaceuticals, EE-10, Defense View Phase-II, Near Iqra University Shaheed-e-Millat Express Way, Karachi. (ELI-00084) Evaluator AD-III 3574	**Legal Manufacturer:** Terumo BCT, Ltd, Old Belfast Road, Millbrook, Larne, Co., Antrim, BT40 2SH, UK **Manufacturing Site:** Terumo BCT Inc. 10811 West Collins Ave., Lakewood, Colorado, 80215, USA. Certificate of Exportability US FDA issuance 02-28-2022 valid for 24 months	Terumo BCT Inc. Anticoagulant Citrate Dextrose Solution Class-C Shelf life: 24 months Code: 750ml Cat# 40818	**Deferred** for the provision of FSC in the country of origin or any SRA country.
13.	-do- Evaluator AD-III	**Legal Manufacturer:** Acandis GmbH Theordor-Fahrner-Str.6 75177 Pforzheim, Germany	Acclino Flex Plus stent (Intraluminal Support Stent)	**Defferred** due to following resons submission of valid ISO 13485 and FQA certificates and labels of the applied codes.

	1160-P	FSC: Germany Date of issue: 26.06.2019	Class-D Shelf Life: 3 years Code: 01-001122 01-001132 01-001152 01-001123 01-001133 01-001143 01-001153 01-001124 01-001134 01-001144 01-001154 01-001125 01-001135 01-001145 01-001155 01-001126 01-001136 01-001146 01-001156 01-001173 01-001193 01-001174 01-001194 01-001175 01-001195 01-001176 01-001196	
14.	M/s S.Ejazuddin & Co., P.O Box 5629 Zia Plaza Altaf Hussain Road Karachi-Pakistan ELI: 00078 [1378-K] Evaluator AD-II	**Legal Manufacturer and Manufacturing Site:** Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-Straβe 76 35041 Marburg Germany FSC **(scanned copy):** Germany Date of issue: 29-04-2019	Dade ® Actin ® Activated Cephaloplastin Reagent Codes: B4218-1-B4218-2 Class: C Shelf Life: 24 Months	**Deferred** due to following reasons: - • Justify the grouping of the applied device in a kit also clarify whether the applied components of medical device would be imported as a single packing unit or the diluents will be imported separately? • The provided original LOA duly notarized and scanned copy of ISO 13485 certificate are expired now but valid upon submission. • Scanned copy of FSC is provided. • Provide FQA certificate duly notarized by the country of origin. • Provide label as approved in the country of origin for B4218-2. • Provide the DECLARATION (on stamp paper) as per Form-7A.
15.	-do-	**Legal Manufacturer and Manufacturing Site:**	Dade ® Actin® FS Activated PTT Reagent	**Deferred** due to following reasons: - • Justify the grouping of the applied device in a kit also clarify whether

	[1178-K] Evaluator AD-II	Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-Straβe 76 35041 Marburg Germany FSC **(scanned copy):** Germany Date of issue: 29-04-2019	Dade Actin FS Activated PTT Reagent Codes: B4218-20 B4218-100 Class: C Shelf Life: 24 Month	the applied components of medical device would be imported as a single packing unit or the diluents will be imported separately? • The provided original LOA duly notarized and scanned copy of ISO 13485 certificate are expired now but valid upon submission. • Scanned copy of FSC is provided. • Provide FQA certificate duly notarized by the country of origin. • Provide label as approved in the country of origin for B4218-100. Provide the DECLARATION (on stamp paper) as per Form-7A.
16.	-do- [269] **Duplicate dossier** Evaluator AD-II	**Legal Manufacturer:** M/s Cella Vision AB Mobilvagen 12 SE-223 62 Lund Sweden FSC: Sweden (photocopy) Valid Till (25-05-2022)	Sysmex Automated Digital Cell Morphology Analyzer D1-60 along with accessories Codes: CC286297 Class-A Shelf-life: N/A	**Deferred** due to following reasons: - • The fee can't be transferred as per the legal opinion of the legal devision. • Since multiple codes are mentioned on form 6A and only code for Automated Digital Cell Morphology Analyzer DI-60 is mentioned in FSC and DOC, only code for Automated Digital Cell Morphology Analyzer DI-60 shall be considered in this application; apply separately for the rest of the codes. • The submitted copy of embassy attested FSC of Sweden is expired now but valid upon submission; provide ORIGINAL valid FSC duly attested by embassy of Pakistan. • Copy of LOA is provided; provide original LOA duly notarized by country of origin • The submitted copy of notarized ISO 13485 certificate is expired now but valid upon submission; provide original valid ISO 13485 certificate duly notarized by country of origin • Copy of notarized DoC is provided. • Provide complete documentation related to the manufacturing and quality control processes. • Provide the declaration (on stamp paper) as per Form-6A.
17.	-do- [208] Evaluator AD-II	**Legal Manufacturer:** M/s CellaVision AB Mobilvagen 12 SE-223, 62 Lund Sweden	Cella Vision DC-1 and DC-1 PPA along with accessories Codes: XU-10301, XU-10302	**Deferred** due to following reasons: - • Since multiple codes are mentioned on form 6A and only codes for Cella Vision DC-1 and DC-1 PPA is mentioned in FSC and DOC, explain the similarities and

		FSC Sweden Valid Till (25-05-2022)	Class-A Shelf-life: N/A	difference between these codes and justify how they can be grouped on one application, provide brochure and labels of all codes required. • **Duplicate dossier was evaluated; and the firm has provided photocopy of fee challan.** • The submitted copy of embassy attested FSC of Sweden is expired now but valid upon submission; provide ORIGINAL valid FSC duly attested by embassy of Pakistan. • The provided copy of LOA is expired now but valid upon submission; provide original valid LOA duly notarized by country of origin • The submitted copy of ISO 13485 certificate is expired now but valid upon submission; provide original valid ISO 13485 certificate duly notarized by country of origin. • Provide the Full QA certificate or equivalent, duly notarized by the country of origin • Copy of Declaration of Conformity is provided. • Provide complete documentation related to the manufacturing and quality control processes. Provide the declaration (on stamp paper) as per Form-6A
18.	M/s Chemical House, 6-C Sikandar Malhi Road, Canal Park, Gulberg II, Lahore Pakistan. ELI: 00156 [2961-P] Evaluator AD-II	**Legal Manufacturer:** M/s Bio-Rad Laboratories, Inc, 9500 Jeronimo Road Irvine, CA 92618 USA FSC: France **(photocopy)** Original with letter No. Nil, dated 05-08-2022 submitted in DRAP on 10-08-2022 **could not be traced yet** Date of issuance: 11-04-2021	Amplichek I (HIV-1/ Hepatitis C Virus/Hepatitis B Virus Nucleic Acid IVD Control) Codes and sizes: 12000527 (10 x 1.2ml), 12000528 (10 x 1.2ml), 12000529 (10 x 1.2ml), 12000530 (10 x 1.2ml), 12000531 (4 x 1.2ml) Class-C	**Deferred** due to following reasons: - ▪ The Provided original FSC (USA) duly attested by embassy of Pakistan is expired now but valid upon submission. ▪ The provided FSC (France) is photocopy. ▪ Provided copy of ISO 13485 and FQA certificate valid till 27-11-2022; provide duly notarized copies of ISO 13485 and FQA certificates. ▪ Incomplete and un-notarized copy of credentials of the manufacturer abroad is provided. ▪ Provide original LOA duly notarized by the country of origin, the already submitted LOA is scanned copy.

			Shelf Life: 16 months	▪ Provided copy of Declaration of Conformity (DoC), provide original DoC duly signed by responsible person.
19.	M/s Trans-Continental Pharma (Pvt) Ltd, House # 1, Street # 4. Abshaar Colony, Warsak Road, Peshawar ELI: 000524 2989-P Evaluator AD-II	Legal Manufacturer: M/s Parcus Medical LLC, 6423 Parkland Dr. Sarasota, FL 34243 USA FSC: U.S.A Valid till: 04.03.2023	**Parcus Suspensory Ligament Devices** (Suspensory Fixation Devices) Codes & Sizes: to be confirmed Class-C Shelf Life: 5 years	**Deferred** due to following reasons: ▪ Codes required are not mentioned on form 7-A and multiple types are mentioned in FSC and DOC. Clearly state the codes required on this application, explain the similarities and difference between these codes and justify how they can be grouped together in one application, also provide brochure and labels of all codes required. ▪ Copies of Free Sale Certificate, Letter of Authorization, Full Quality Assurance and ISO 13485 certificates are provided, provide original and valid documents as per law. ▪ Provide credentials of manufacturer abroad duly notarized from the country of origin. ▪ Provide copy of valid establishment license ▪ Provide the details of manufacturing and quality control processes. ▪ Provide the shelf-life and storage conditions justified with stability studies. ▪ Provide the proposed MRP of medical device. ▪ Provide label (as approved in the country of origin) and its packaging, promotion material and brochure. ▪ Provide the declaration (on stamp paper) as per Form 7-A.
20.	Health Care Products 237/A, Block-2 P.E.C.H.S., Shahrah-e-Quaideen, Karachi, Pakistan (ELI-00613) 3639	Legal Manufacturer: Suretex Limited 31/1 Moo 4, Suratthani-Thakuapha Road, Tambon Khao Hua Kwai, Amphur Phunphin, Suratthani 84130, Thailand FSC: Thailand (scanned copy)	**1. Natural Rubber Latex Male Condoms** Contempo Bareback Contempo Rough Rider Contempo Wet N' Wild 2. **Natural Rubber**	**Deferred** due to following reasons: - ▪ Natural rubber latex and synthetic polyisoprene male condoms (both medicated and non-medicated) are mentioned on form 7A while fee for only synthetic polyisoprene condoms is submitted; clearly state the codes required on this application, justify how they can be grouped on one

	Evaluator AD-II	Validity: 13-07-2022	**Latex Male Condoms with Benzoceine** Contempo Endurance Class C Shelf-life: 5 years **Codes to be confirmed**	application, explain the similarities and difference between these codes and apply separately for the rest. ▪ Provide the credentials of manufacturer abroad duly notarized from the country of origin as per format approved by the MDB in its 3rd meeting. ▪ Provide the proposed MRP of medical device ▪ Provide original valid LOA / agency agreement duly notarized by the country of origin. ▪ The provided scanned copy of FSC of Thailand is expired now but valid upon submission; provide ORIGINAL Valid FSC duly attested by embassy of Pakistan. ▪ Provide the original valid free sale certificate of any RRA as per rule 67 duly attested by embassy of Pakistan ▪ The provided scanned copy of ISO 13485 certificate is expired now but valid upon submission; provide original valid ISO 13485 certificate duly notarized by country of origin. ▪ The provided scanned copy of FQA certificate is valid till 21-11-2022. ▪ Provide the Essential principle of safety and performance. ▪ Provide the Declaration of conformity (DoC) to be printed on manufacturer letterhead, filled and duly signed by responsible person. ▪ Provide label (as approved in the country of origin) and its packaging, promotion material and brochure
21.	Health Care Products 237-A, Block-2 PECHS 75400 Karachi, Pakistan (ELI-00613) 3640 Evaluator AD-II	Legal Manufacturer: Suretex Limited 31/1 Moo 4, Suratthani-Thakuapha Road, Tambon Khao Hua Kwai, Amphur Phunphin, Suratthani 84130, Thailand FSC: Thailand (scanned copy) Validity: 13-07-2022	**Natural Rubber Latex Male Condoms** Lifestyles Classic Lifestyles Sensation Lifestyles Sensitive Lifestyles Epic **Natural Rubber Latex Male** Lifestyles Love time Class C Shelf-life: 5 years	**Deferred** due to following reasons: ▪ Natural rubber latex and synthetic polyisoprene male condoms (both medicated and non-medicated) are mentioned on form while fee for only natural rubber latex male condoms is submitted; clearly state the codes required on this application, justify how they can be grouped on one application, explain the similarities and difference between these codes and apply separately for the rest. ▪ Provide the credentials of

			Codes to be confirmed	manufacturer abroad duly notarized from the country of origin as per format approved by the MDB in its 3rd meeting. ▪ Provide the proposed MRP of medical device ▪ Provide original LOA / agency agreement ▪ Provided scanned copy of FSC of Thailand is valid till 13-07-2022; provide ORIGINAL Valid FSC duly attested by embassy of Pakistan. ▪ Provide the original and valid free sale certificate of any RRA as per rule 67 duly attested by embassy of Pakistan ▪ The provided scanned copy of ISO 13485 certificate is expired now but valid upon submission; provide original valid ISO 13485 certificate duly notarized by country of origin. ▪ The provided scanned copy of FQA certificate is valid till 21-11-2022. ▪ Provide the Essential principle of safety and performance. ▪ Provide the Declaration of conformity (DoC) to be printed on manufacturer letterhead, filled and duly signed by responsible person. ▪ Provide label (as approved in the country of origin) and its packaging, promotion material and brochure
22.	M/s Safe Health Pakistan Bizcon, Office No.25, 2nd Floor, Dilkushan Chamber, Marston Road, Karachi (ELI-00275) 4117 Evaluator AD-II	Legal Manufacturer: L&Z US Inc., 49 Walnut street Unit #1 Norwood, NJ USA **FSC: USA** (original, embassy attested) Valid Till: 01-02-2023	CATHTONG Peripherally Inserted Central Catheter (PICC) Single & Dual Lumen Codes: to be confirmed All Sizes: 3f,4f, & 5f, Class: C Shelf Life: As Per Stability Study	**Defferred** due to following: The firm has applied CATHTONG Peripherally Inserted Central Catheter (PICC) Single & Dual Lumen in Class-C while the MDB has approved the subject devices in **Class-D**. ▪ The applied Medical Devices are grouped as set, justify how it qualifies subject grouping; also provide similarities and differences among them. ▪ Differential fee Rs. 25,000/- is required. ▪ Both single and Dual lumen PICC are applied on single application, and the required codes are not mentioned on Form 7A while

				multiple codes are mentioned in FSC (USA). Give priority for one of these types, explain the similarities and difference between these codes and apply separately for the other. Also, submit revised form 7A along with copy of FSC clearly mentioning/highlighting the required codes and sizes of the applied MD. ▪ Provide the shelf-life & storage conditions, justified with stability studies. ▪ Provide valid ISO 13485 certificate, FQA certificate and Declaration of Conformity duly notarized by the country of origin. ▪ Provide essential principles of safety and performance. ▪ Provide label (as approved in the country of origin) and its packaging, promotion material and brochure for each configuration to be registered. ▪ Provide the declaration (on stamp paper) as per Form-7A
23.	Altimi Biosciences Pvt Ltd. 201, 2nd Floor, 43-C, Bukhari Commercial Lane # 10, Phase-VI, DHA Karachi-75500, Pakistan (ELI-00575) 3140 Evaluator AD-II	**Legal manufacturer:** M/s A&D Company Limited, 1-243 Asahi, Kitamoto-shi, Saitama-ken, 364-8585, Japan And 3-23-14, Higashi Ikebukuro, Toshima-ku, Tokyo, 170-0013, Japan **Manufacturing Site:** M/s KENSEI KOGYO CO. Ltd. 4210-15 Takasai, Shimotsuma-shi, Ibaraki-ken, 304-0031, Japan FSC: Japan **(unattested scanned copy)** Date of issuance: 30-06-2020	Ambulatory Blood Pressure Monitor Model:TM-2441 Class-B Shelf life: **Not provided**	**Deferred** due to following ▪ Submit Free Sale Certificate (Japan) ▪ Present original Letter of Authorizatio ▪ Provide shelf life supported with stability studies data. ▪ Provide the proposed MRP of Medical Device.
24.	Altimi Biosciences Pvt Ltd. 201, 2nd Floor, 43-C, Bukhari Commercial Lane # 10, Phase-VI,	**Legal manufacturer:** M/s A&D Company Limited, 1-243 Asahi, Kitamoto-shi, Saitama-ken, 364-8585, Japan And	Ambulatory Blood Pressure Monitor Model: TM-2440 Class-B	Defferred due to following ▪ Submit Free Sale Certificate (Japan) ▪ Present original Letter of Authorizatio ▪ Provide shelf life supported with

	DHA Karachi-75500, Pakistan (ELI-00575) 3145 Evaluator AD-II	3-23-14, Higashi Ikebukuro, Toshima-ku, Tokyo, 170-0013, Japan **Manufacturing Site:** M/s KENSEI KOGYO CO. Ltd. 4210-15 Takasai, Shimotsuma-shi, Ibaraki-ken, 304-0031, Japan FSC: Japan **(unattested scanned copy)** Date of issuance: 30-06-2020	Shelf life: **Not provided**	stability studies data. ▪ Provide the proposed MRP of Medical Device.
25.	Altimi Biosciences Pvt Ltd. 201, 2nd Floor, 43-C, Bukhari Commercial Lane # 10, Phase-VI, DHA Karachi-75500, Pakistan (ELI-00575) 3143 Evaluator AD-II	**Legal manufacturer:** ScheBo Biotech AG Netanyastr.3 35394 Giessen Germany FSC: Germany **(scanned copy)** Date of issuance: 14-08-2020	ScheBo® Master Quick-Prep™ (Master Quick Prep) Class B Codes and sizes: As per DoC Shelf life: **Not provided**	**Deferred** due to following: ▪ Present the Original letter of authorization ▪ Provide the complete list of various configurations to be registered ▪ Provide that the MD contain any active ingredient, poison or drug ▪ Provide the details of manufacturing and quality control processes. ▪ Provide the shelf-life & storage conditions, i.e., justified with stability studies ▪ Provide the Proposed MRP of medical device ▪ Clarify the grouping ▪ Provide the Complete description ▪ Valid ISO 13485 certificate ▪ Provide the Full QA certificate or equivalent, ▪ Provide label (as approved in the country of origin) and its packaging, promotion material and brochure.
26.	Altimi Biosciences Pvt Ltd. 201, 2nd Floor, 43-C, Bukhari Commercial Lane # 10, Phase-VI, DHA Karachi-75500, Pakistan (ELI-00575) 3146 Evaluator	**Legal manufacturer:** ScheBo Biotech AG Netanyastr.3 35394 Giessen Germany FSC: Germany **(scanned copy originally attested)** Date of issuance: 14-08-2020	ScheBo® Tumor M2-PK™ (Tumor M2-PK™ EDTA Plasma test) Class B Codes and sizes: As per DoC Shelf life: **Not provided**	**Deferred** due to following: ▪ Present the Original letter of authorization ▪ Provide the complete list of various configurations to be registered ▪ Provide that the MD contain any active ingredient, poison or drug ▪ Provide the details of manufacturing and quality control processes. ▪ Provide the shelf-life & storage conditions, i.e., justified with stability studies

	AD-II			▪ Provide the Proposed MRP of medical device ▪ Clarify the grouping ▪ Provide the Complete description ▪ Valid ISO 13485 certificate ▪ Provide the Full QA certificate or equivalent, ▪ Provide label (as approved in the country of origin) and its packaging, promotion material and brochure.
27.	Altimi Biosciences Pvt Ltd. 201, 2nd Floor, 43-C, Bukhari Commercial Lane # 10, Phase-VI, DHA Karachi-75500, Pakistan (ELI-00575) 3147 Evaluator AD-II	**Legal manufacturer:** ScheBo Biotech AG Netanyastr.3 35394 Giessen Germany FSC: Germany **(scanned copy)** Date of issuance: 14-08-2020	ScheBo® Tumor M2-PK™ (Tumor M2-PK™ Stool Test) Class B Codes and sizes: As per DoC Shelf life: **Not provided**	**Deferred** due to following: ▪ Present the Original letter of authorization ▪ Provide the complete list of various configurations to be registered ▪ Provide that the MD contain any active ingredient, poison or drug ▪ Provide the details of manufacturing and quality control processes. ▪ Provide the shelf-life & storage conditions, i.e., justified with stability studies ▪ Provide the Proposed MRP of medical device ▪ Clarify the grouping ▪ Provide the Complete description ▪ Valid ISO 13485 certificate ▪ Provide the Full QA certificate or equivalent, . ▪ Provide label (as approved in the country of origin) and its packaging, promotion material and brochure.
28.	Altimi Biosciences Pvt Ltd. 201, 2nd Floor, 43-C, Bukhari Commercial Lane # 10, Phase-VI, DHA Karachi-75500, Pakistan (ELI-00575) 3141 Evaluator AD-II	**Legal manufacturer:** ScheBo Biotech AG Netanyastr.3 35394 Giessen Germany FSC: Germany **(scanned copy)** Date of issuance: 14-08-2020	ScheBo Pancreas Elastase 1 Quick ™ (Pancreas Elastase 1 Quick ™) Class B Codes and sizes: As per DoC Shelf life: **Not provided**	**Deferred** due to following: ▪ Present the Original letter of authorization ▪ Provide the complete list of various configurations to be registered ▪ Provide that the MD contain any active ingredient, poison or drug ▪ Provide the details of manufacturing and quality control processes. ▪ Provide the shelf-life & storage conditions, i.e., justified with stability studies ▪ Provide the Proposed MRP of medical device ▪ Clarify the grouping ▪ Provide the Complete description

				▪ Valid ISO 13485 certificate ▪ Provide the Full QA certificate or equivalent, . ▪ Provide label (as approved in the country of origin) and its packaging, promotion material and brochure. ▪
29.	Altimi Biosciences Pvt Ltd. 201, 2nd Floor, 43-C, Bukhari Commercial Lane # 10, Phase-VI, DHA Karachi-75500, Pakistan (ELI-00575) 3165 Evaluator AD-II	**Legal manufacturer:** ScheBo Biotech AG Netanyastr.3 35394 Giessen Germany FSC: Germany **(scanned copy)** Date of issuance: 14-08-2020	ScheBo® M2-PK Quick™ (M2-PK Quick™) Class B Codes and sizes: As per DoC Shelf life: **Not provided**	**Deferred** due to following: ▪ Present the Original letter of authorization ▪ Provide the complete list of various configurations to be registered ▪ Provide that the MD contain any active ingredient, poison or drug ▪ Provide the details of manufacturing and quality control processes. ▪ Provide the shelf-life & storage conditions, i.e., justified with stability studies ▪ Provide the Proposed MRP of medical device ▪ Clarify the grouping ▪ Provide the Complete description ▪ Valid ISO 13485 certificate ▪ Provide the Full QA certificate or equivalent, . ▪ Provide label (as approved in the country of origin) and its packaging, promotion material and brochure. ▪
30.	Altimi Biosciences Pvt Ltd. 201, 2nd Floor, 43-C, Bukhari Commercial Lane # 10, Phase-VI, DHA Karachi-75500, Pakistan (ELI-00575) 3148 Evaluator AD-II	**Legal manufacturer:** ScheBo Biotech AG Netanyastr.3 35394 Giessen Germany FSC: Germany **(scanned copy)** Date of issuance: 14-08-2020	ScheBo® 2 in 1 Quick™ (2 in 1 Quick™) Class B Codes and sizes: As per DoC Shelf life: **Not provided**	**Defferred** due to following: ▪ Present the Original letter of authorization ▪ Provide the complete list of various configurations to be registered ▪ Provide that the MD contain any active ingredient, poison or drug ▪ Provide the details of manufacturing and quality control processes. ▪ Provide the shelf-life & storage conditions, i.e., justified with stability studies ▪ Provide the Proposed MRP of medical device ▪ Clarify the grouping ▪ Provide the Complete description ▪ Valid ISO 13485 certificate ▪ Provide the Full QA certificate or equivalent, . ▪ Provide label (as approved in the

				country of origin) and its packaging, promotion material and brochure.
31.	Altimi Biosciences Pvt Ltd. 201, 2nd Floor, 43-C, Bukhari Commercial Lane # 10, Phase-VI, DHA Karachi-75500, Pakistan (ELI-00575) 3167 Evaluator AD-II	**Legal manufacturer:** Bittium Biosiganls Ltd. Pioneerinkatu 6, FI-70800 Kuopio Finland FSC: Finland **(photocopy)** Date of issuance: 24-02-2020	**Bittium Faros 180** (System for Offline and Online ECG) Class B Codes and sizes: **Not provided** Shelf life: **Not provided**	**Deferred** due to following: ▪ Present the Original letter of authorization ▪ Provide the complete list of various configurations to be registered ▪ Provide that the MD contain any active ingredient, poison or drug ▪ Provide the details of manufacturing and quality control processes. ▪ Provide the shelf-life & storage conditions, i.e., justified with stability studies ▪ Provide the Proposed MRP of medical device ▪ Clarify the grouping ▪ Provide the Complete description ▪ Valid ISO 13485 certificate ▪ Provide the Full QA certificate or equivalent, . ▪ Provide label (as approved in the country of origin) and its packaging, promotion material and brochure.
32.	Altimi Biosciences Pvt Ltd. 201, 2nd Floor, 43-C, Bukhari Commercial Lane # 10, Phase-VI, DHA Karachi-75500, Pakistan (ELI-00575) 3142 Evaluator AD-II	**Legal manufacturer:** Bittium Biosiganls Ltd. Pioneerinkatu 6, FI-70800 Kuopio Finland FSC: Finland **(photocopy)** Date of issuance: 24-02-2020	**Bittium Faros 360** (3-Channel Cardiac Monitoring ECG System) Class B Codes and sizes: **Not provided** Shelf life: **Not provided**	**Defferred** due to following: ▪ Present the Original letter of authorization ▪ Provide the complete list of various configurations to be registered ▪ Provide that the MD contain any active ingredient, poison or drug ▪ Provide the details of manufacturing and quality control processes. ▪ Provide the shelf-life & storage conditions, i.e., justified with stability studies ▪ Provide the Proposed MRP of medical device ▪ Clarify the grouping ▪ Provide the Complete description ▪ Valid ISO 13485 certificate ▪ Provide the Full QA certificate or equivalent, . ▪ Provide label (as approved in the country of origin) and its packaging, promotion material and brochure.

33.	M/s Ali Gohar & Company (Pvt) Ltd., State Life Building 1-B, I.I. Chundrigar Road, Karachi (ELI-00004) 4573 Evaluator AD-II	**Legal Manufacturer:** Zimmer Inc. 1800 West Center Street, Warsaw, IN 46580, USA FSC: (USFDA) Validity: 06-07-2023	Trabecular Metal Modular Acetabular Shells (Acetabular shells) Codes: 00-6202-046-20 00-6202-048-20 00-6202-050-20 00-6202-052-20 00-6202-054-20 00-6202-056-20 00-6202-058-20 00-6202-060-20 00-6202-062-20 Applied in Class-C **but as per DOC class III and the MDB has also registered the subject medical device in Class-D** Shelf Life: 10 years	**Defferred** due to the following shorcomings ▪ The firm has applied in Class-C but as per DOC classified as class III MD and the MDB has also registered the subject medical device in Class-D. ▪ The provided copy of credentials of manufacturer abroad is not as per format approved in 3rd meeting of the MDB, provide the same as per approved format duly notarized from the country of origin. ▪ As per the Medical Devices Rules, 2017 *"A medical device shall be grouped as a single medical device if its proprietary name is identified by the manufacturer with a specific intended use and it is sold as a distinct packaged entity and may be offered in a range of package sizes"*; clarify whether the applied configurations of medical device (MD) would be imported as a single packing unit or otherwise and provide accordingly the grouping of MD with relevant rules. ▪ Scanned copy of letter of Authorization (LOA) is provided; provide original valid LOA duly notarized by the country of origin. ▪ Copy of Free Sale Certificate (FSC) of country of origin (USA) is provided; provide original valid FSC duly attested by embassy of Pakistan. ▪ Scanned copy of notarized ISO 13485 certificate is provided; provide originally notarized ISO 13485 certificate or reference to the dossier containing the same. ▪ The provided Full Quality Assurance (FQA) and Design Examination (DE) certificates are expired even upon submission; provide original valid FQA and DE certificates duly notarized by the country of origin.
34.	M/s Ali Gohar & Company (Pvt) Ltd., State Life Building 1-B, I.I.	**Legal Manufacturer:** Zimmer Inc. 1800 West Center Street, Warsaw, IN 46580, USA	ZCA All Poly Acetabular Cup (Hip System)	**Defferred** due to the following shortcoimgs ▪ The firm has applied in Class-C but

	Chundrigar Road, Karachi (ELI-00004) 4575 Evaluator AD-II	FSC: (USFDA) Validity: 06-07-2023	Codes: 00-8005-644-28 00-8005-646-28 00-8005-648-28 00-8005-650-28 00-8005-652-28 00-8005-654-28 00-8005-656-28 00-8005-658-28 00-8065-644-28 00-8065-646-28 00-8065-648-28 00-8065-650-28 00-8065-652-28 00-8065-654-28 00-8065-656-28 00-8065-658-28 Applied in Class-**C but as per DOC class III and the MDB has also registered the subject medical device in Class-D** Shelf Life: 8 Years	as per DOC classified as class III MD and the MDB has also registered the subject medical device in Class-D. ▪ The provided credentials of manufacturer abroad is photocopy; provide original credentials of manufacturer abroad duly notarized from the country of origin. ▪ As per the Medical Devices Rules, 2017 *"A medical device shall be grouped as a single medical device if its proprietary name is identified by the manufacturer with a specific intended use and it is sold as a distinct packaged entity and may be offered in a range of package sizes"*; clarify whether the applied configurations of medical device (MD) would be imported as a single packing unit or otherwise and provide accordingly the grouping of MD with relevant rules. ▪ Scanned copy of letter of Authorization (LOA) is provided; provide original valid LOA duly notarized by the country of origin. ▪ Copy of Free Sale Certificate (FSC) of country of origin (USA) is provided; provide original valid FSC ▪ Scanned copy of notarized ISO 13485 and Design Examination (DE) certificates is provided; provide originally notarized ISO 13485 and DE certificates or reference to the dossier containing the same. ▪ The provided Full Quality Assurance (FQA) certificate is photocopy; provide original valid FQA certificate duly notarized by the country of origin or reference to the dossier containing the same.
35.	M/s Ali Gohar & Company (Pvt) Ltd., State Life Building 1-B, I.I. Chundrigar Road, Karachi (ELI-00004)	Zimmer Inc. 1800 West Center Street, Warsaw, IN 46580, USA FSC: (USFDA) Validity: 06-07-2023	Allen Medullary Cement Plug (Orthopedic Cement Plug) Codes: 00-8011-020-12 00-8011-020-16	**Defferred due to the following shortcoings** ▪ As per the Medical Devices Rules, 2017 *"A medical device shall be grouped as a single medical device if its proprietary name is identified by the manufacturer*

	4576 Evaluator AD-II		00-8011-020-20 00-8011-020-24 Class- C Shelf-life: 10 Years	*with a specific intended use and* ***it is sold as a distinct packaged entity*** *and may be offered in a range of package sizes";* clarify whether the applied configurations of medical device (MD) would be imported as a single packing unit or otherwise and provide accordingly the grouping of MD with relevant rules. ▪ The provided credentials of manufacturer abroad is photocopy; provide original credentials of manufacturer abroad duly notarized from the country of origin. ▪ Scanned copy of letter of Authorization (LOA) is provided; provide original valid LOA duly notarized by the country of origin. ▪ Copy of Free Sale Certificate (FSC) of country of origin (USA) is provided; provide original valid FSC ▪ Scanned copy of notarized ISO 13485 certificate is provided; provide originally notarized ISO 13485 certificate or reference to the dossier containing the same. ▪ The provided Full Quality Assurance (FQA) certificate is photocopy; provide original valid FQA certificate duly notarized by the country of origin or reference to the dossier containing the same.
36.	M/s Linkers Asia, H # 96, H-3, Johar Town, Lahore ELI: 00363 Evaluator AD-III 17-P (Renewal)	**<u>Legal Manufacturer:</u>** M/s Huaian Wanjia Medical Device Co. Ltd No. 3, Qingan Road Huaian City, Jiangsu Province, China FSC China	Unisilk (Silk Braided Surgical Sutures) Class-D Shelf Life: 5 years	**Deferred** for the provision of following:- • Submit properly filled form-7A with all relevant information including HS/GMDN codes, if applicable. • Submit differential fee of Rs. 25000/- as the application will be considered as new application for all the applied products. • Provide the evidence of 1st and 2nd renewal of the applied devices. • Provide Credentials of manufacturer's abroad as per format approved in 3rd meeting of MDB, duly notarized. • Provide manufacturing process and QC in detail. • Provide stability studies for the

				claimed shelf life. • Provided LOA is copy, submit original and notarized document. • Provide original and updated FSC in the country of origin, duly attested. • As the device is from Non-reference country, submit the original and valid FSC of any reference country, duly attested. • Provided ISO 13485 and FQA certificates are copies, submit originally notarized and updated documents. • Provide labels of required sizes as per FSC approved in the country of origin, required on this application along with product brochure. • Provide declaration of conformity to be printed on manufacturer's letter head duly filled and signed by responsible person, submit notarized document (both Production quality assurance and Product quality assurance certificates). • Provide product details including IFU, Warnings, Contraindications and validation process report. • Provide Essential Principle checklist. • Provide the grouping of the applied device as per form-7A checklist. • Provide design examination certificates for the products fall in class-D, duly notarized.
37.	-do- Evaluator AD-III 18-P (Renewal)	**Legal Manufacturer:** M/s Huaian Wanjia Medical Device Co. Ltd No. 3, Qingan Road Huaian City, Jiangsu Province, China FSC China	Unilon (Nylon Surgical Sutures) Class-D Shelf Life: 5 years	**Deferred** for the provision of following: - • Submit properly filled form-7A with all relevant information including HS/GMDN codes, if applicable. • Submit differential fee of Rs. 25000/- as the application will be considered as new application for all the applied products. • Provide the evidence of 1st and 2nd renewal of the applied devices. • Provide Credentials of manufacturer's abroad as per format approved in 3rd meeting of MDB, duly notarized. • Provide manufacturing process and QC in detail. • Provide stability studies for the

				claimed shelf life. • Provided LOA is copy, submit original and notarized document. • Provide original and updated FSC in the country of origin, duly attested. • As the device is from Non-reference country, submit the original and valid FSC of any reference country, duly attested. • Provided ISO 13485 and FQA certificates are copies, submit originally notarized and updated documents. • Provide labels of required sizes as per FSC approved in the country of origin, required on this application along with product brochure. • Provide declaration of conformity to be printed on manufacturer's letter head duly filled and signed by responsible person, submit notarized document (both Production quality assurance and Product quality assurance certificates). • Provide product details including IFU, Warnings, Contraindications and validation process report. • Provide Essential Principle checklist. • Provide the grouping of the applied device as per form-7A checklist. • Provide design examination certificates for the products fall in class-D, duly notarized.
38.	-do- Evaluator AD-III 19-P (Renewal)	**<u>Legal Manufacturer:</u>** M/s Huaian Wanjia Medical Device Co. Ltd No. 3, Qingan Road Huaian City, Jiangsu Province, China FSC China	Unicol Polyglycolic Acid (Surgical Sutures) Class-D Shelf Life: 5 years	**Deferred** for the provision of following:- • Submit properly filled form-7A with all relevant information including HS/GMDN codes, if applicable. • Submit differential fee of Rs. 25000/- as the application will be considered as new application for all the applied products. • Provide the evidence of 1st and 2nd renewal of the applied devices. • Provide Credentials of manufacturer's abroad as per format approved in 3rd meeting of MDB, duly notarized. • Provide manufacturing process and QC in detail.

				• Provide stability studies for the claimed shelf life. • Provided LOA is copy, submit original and notarized document. • Provide original and updated FSC in the country of origin, duly attested. • As the device is from Non-reference country, submit the original and valid FSC of any reference country, duly attested. • Provided ISO 13485 and FQA certificates are copies, submit originally notarized and updated documents. • Provide labels of required sizes as per FSC approved in the country of origin, required on this application along with product brochure. • Provide declaration of conformity to be printed on manufacturer's letter head duly filled and signed by responsible person, submit notarized document (both Production quality assurance and Product quality assurance certificates). • Provide product details including IFU, Warnings, Contraindications and validation process report. • Provide Essential Principle checklist. • Provide the grouping of the applied device as per form-7A checklist. • Provide design examination certificates for the products fall in class-D, duly notarized.
39.	-do- Evaluator AD-III 20-P (Renewal)	**Legal Manufacturer:** M/s Huaian Wanjia Medical Device Co. Ltd No. 3, Qingan Road Huaian City, Jiangsu Province, China FSC China	Unilene Polypropylene Monofilament (Surgical Sutures) Class-D Shelf Life: 5 years	**Deferred** for the provision of following:- • Submit properly • filled form-7A with all relevant information including HS/GMDN codes, if applicable. • Submit differential fee of Rs. 25000/- as the application will be considered as new application for all the applied products. • Provide the evidence of 1st and 2nd renewal of the applied devices. • Provide Credentials of manufacturer's abroad as per format approved in 3rd meeting of MDB, duly notarized.

				• Provide manufacturing process and QC in detail. • Provide stability studies for the claimed shelf life. • Provided LOA is copy, submit original and notarized document. • Provide original and updated FSC in the country of origin, duly attested. • As the device is from Non-reference country, submit the original and valid FSC of any reference country, duly attested. • Provided ISO 13485 and FQA certificates are copies, submit originally notarized and updated documents. • Provide labels of required sizes as per FSC approved in the country of origin, required on this application along with product brochure. • Provide declaration of conformity to be printed on manufacturer's letter head duly filled and signed by responsible person, submit notarized document (both Production quality assurance and Product quality assurance certificates). • Provide product details including IFU, Warnings, Contraindications and validation process report. • Provide Essential Principle checklist. • Provide the grouping of the applied device as per form-7A checklist. Provide design examination certificates for the products fall in class-D, duly notarized.
40.	-do- Evaluator AD-III 21-P (Renewal)	**<u>Legal Manufacturer:</u>** M/s Huaian Wanjia Medical Device Co. Ltd No. 3, Qingan Road Huaian City, Jiangsu Province, China FSC China	Unigut Chromic (Surgical Sutures) Class-D Shelf Life: 5 years	**Deferred** for the provision of following:- • Submit properly filled form-7A with all relevant information including HS/GMDN codes, if applicable. • Submit differential fee of Rs. 25000/- as the application will be considered as new application for all the applied products. • Provide the evidence of 1st and 2nd renewal of the applied devices. • Provide Credentials of manufacturer's abroad as per format approved in 3rd meeting of MDB, duly notarized.

				• Provide manufacturing process and QC in detail. • Provide stability studies for the claimed shelf life. • Provided LOA is copy, submit original and notarized document. • Provide original and updated FSC in the country of origin, duly attested. • As the device is from Non-reference country, submit the original and valid FSC of any reference country, duly attested. • Provided ISO 13485 and FQA certificates are copies, submit originally notarized and updated documents. • Provide labels of required sizes as per FSC approved in the country of origin, required on this application along with product brochure. • Provide declaration of conformity to be printed on manufacturer's letter head duly filled and signed by responsible person, submit notarized document (both Production quality assurance and Product quality assurance certificates). • Provide product details including IFU, Warnings, Contraindications and validation process report. • Provide Essential Principle checklist. • Provide the grouping of the applied device as per form-7A checklist. • Provide design examination certificates for the products fall in class-D, duly notarized.
41.	Allmed Solutions, A-21/3, KDA Scheme No.1 (ext) Stadium Road, Karachi. (ELI-00029) Evaluator AD-III 4109	**<u>Legal Manufacturer:</u>** IBA Dosimetry GmbH BahnhofstraBe 5, DE-60592 Schwarzenbruck, Germany FSC: Germany Issued: 23-2-2021	Dosimetry System (Dolphin & Compass) Class: C Shelf Life: 5 Years Model: COMPASS Software Version: 4.x Dolphin To be used with Compass	**Deferred** for the provision of following:- • Clearly state the brand name • Submit revised Form-7A with the required Article numbers of the applied device, the submitted FSC is missing the model/ article numbers. • Provide revised and updated LOA with the device category/ name mentioned on. • Provide updated ISO 13485 certificate. • The shelf life mentioned is 5 years whereas the studies are not provided,

				provide shelf life or Service life studies whatever applicable.
42.	M/s Uniplan Trade International Private Ltd 132/2 Quaid-e-Azam Industrial estate, Kot, Lakhpat Lahore. ELI: 00132 Evaluator AD-III 1759-P	**Legal Manufacturer:** M/s Chengdu OCI Medical Devices Co., Ltd No. 2401, west Port Avenue, Southwest Airport Economic Development Zone, Shuangliu District Chengdu, Sichuan Province, China FSC China Date of Issue: 28-10-2021 valid for 2 years	OCI Hollow Fiber Hemodialyzer (Polyethersulfone Hollow Fiber Hemodialyzer) Class-C Shelf Life: 3 years Code & Sizes as per FSC	**Deferred** for the provision of following:- Clarification is required as the DoC provided mentioning that CE marked document is issued by SGS, Belgium, N.B: No. 1639 whereas the document submitted is issued by SGS, UK N.B: No. 0120. FSC of reference country is required.
43.	M/s CSM Pakistan (Guarantee) Ltd, 23-C, Old Sunset Boulevard, Phase-2, DHA-Karachi ELI: 00418 Evaluator AD-III 3112	**Legal Manufacturer:** M/s Altas Link (Beijing) Technology co. Ltd Room 811, Zeyang Plaza No. 166 Fushi Road, Shijingshan Dist. Beining China FSC China Valid till: 19/08/2020	Xact (One Step Pregnancy Test Strip) Class-B Shelf life: 24 months Codes & Sizes as per FSC	**Deferred** for the provision of following:- • Provided LOA does not mention the device name, present the original agency agreement having device applied. • Provide FSC in the country of origin, • Provided FSC of reference country as the product is not from reference, duly attested. • Provide valid ISO 13485 and FQA certificate, duly notarized. • Provide Contraindications and warnings to inform on specific risk or hazard to the medical device. • Provide validation for medical device with sterile or with measuring function.
44.	M/s Mediland Office NO, B-09 2nd Floor, Masood Arcade IJP Road Near Saidpur Road Rawalpindi. ELI-00202 Evaluator AD-III 1814-P	**Legal manufacturer:** MAQUET Cardiopulmonary GmbH Kehler Street No. 31, 76437 Rastatt, Germany. **Manufacturing site:** Maquet Cardiopulmonary Medikal Teknik San. Tic. Ltd. Stl serbest Bolge R ada Yeni Liman 07070 Antalya, Turkey. FSC Germany Date of issue 26.03.2019	Quadrox-i Pediatric and Neonatal Oxygenator and Venous Hard shell Cardiotomy Combination of reservoir with (Oxygenator) Class-D Shelf life: 2 years Codes: VKMO 10000 VKMO 11000 VKMO 30000	**Deferred** for the provision of following: - • Provide credentials of manufacturer abroad. • Provide stability studies of claimed shelf life. • Present original and updated Agency agreement from the legal manufacturer • Provide original FSC of Germany as the provided FSC is copy. • Provide valid ISO 13485 and FQA certificate, duly notarized. • Provide valid Design Examination certificate as the provided certificate has been expired.

			VKMO 31000	• Provide Declaration of conformity to be printed on manufacturer's letter head duly filled and signed by responsible person.
45.	M/s. Mezan International 59 BR II, Opp. DCO, House Haji Meherban Road, Jhelum. ELI-00096 Evaluator AD-III 1779-P	**Legal Manufacturer:** M/s ACTO Pharma HIJYEN SANAYI TIC. A.S Akcaburgaz Mahallesi, 3038 SoK No 11, 34522 Esenyurt Istanbul Turkey. FSC Turkey Validity 16-03-2021	ACTOSED OPA Disinfectant 100g contains 0.55% Ortho-phthalaldehyde (OPA), corrosion inhibitor and auxiliary substances Class-C Shelf Life: 03 years Codes: 01.2323.5 (5L)	**Deferred** for the provision of following:- • Provide valid and FSC of reference country as the device is from non-reference country, • Submit credentials of manufacturer abroad as per format approved in 3rd meeting of MDB. • Provided FQA certificate is issued for Acto GmbH, Germany while the Certificate required for the legal manufacturer of Turkey. • Provide detailed QC tests of the applied devices and stability studies detail. The studies provided are of 18 months whereas the list attached showing 3 years' shelf life, justify. • submit the DoC of the applied device.
46.	-do- Evaluator AD-III 1782-P	**Legal Manufacturer:** M/s ACTO Pharma HIJYEN SANAYI TIC. A.S Akcaburgaz Mahallesi, 3038 SoK No 11, 34522 Esenyurt Istanbul Turkey. FSC Turkey Validity 16-03-2021	ACTOSED PA Powder 100g contains <50g Sodium percarbonate, <30g TAED, corrosion inhibitor and auxiliary substances Class-C Shelf Life: 03 years Codes: 01.9605.81 (81g)	**Deferred** for the provision of following:- • Provide valid and FSC of reference country as the device is from non-reference country, • Submit credentials of manufacturer abroad as per format approved in 3rd meeting of MDB. • Provided FQA certificate is issued for Acto GmbH, Germany while the Certificate required for the legal manufacturer of Turkey. • Provide detailed QC tests of the applied devices and stability studies detail. The studies provided are of 18 months whereas the list attached showing 3 years' shelf life, justify. • submit the DoC of the applied device.
47.	-do- Evaluator AD-III 2624-P	**Legal Manufacturer:** M/s ACTO Pharma HIJYEN SANAYI TIC. A.S Akcaburgaz Mahallesi, 3038 SoK No 11, 34522 Esenyurt Istanbul Turkey.	ACTOSED HP Ready Disinfectant (Activated product initially contains > 2000 ppm peracetic acid and > 5000ppm Hydrogen peroxide	**Deferred** for the provision of following:- • Provide valid and FSC of reference country as the device is from non-reference country, • Submit credentials of manufacturer

		FSC Turkey Validity 27-01-2023	Class-C Shelf Life: 18 Months Codes: 01.7303.5 (5L)	abroad as per format approved in 3rd meeting of MDB. • Provided FQA certificate is issued for Acto GmbH, Germany while the Certificate required for the legal manufacturer of Turkey. • Provide detailed QC tests of the applied devices and stability studies detail. The studies provided are of 18 months whereas the list attached showing 3 years' shelf life, justify. • submit the DoC of the applied device.
48.	Pharma Supply Corporation 49-J, Block-6, Pechs, Nursery Karachi Pakistan. (ELI-00092) Evaluator AD-III 4741	**Legal Manufacturer:** Shanghai Kinmed Import & Export Co., Ltd. Suit L, 12th Floor No. 588 Yingkou Road, 200433 Shanghai, Peoples Republic of China FSC: China Issued: 1-123-2021 Valid for 2 Years	Kinmed I.V Cannula Pen type Class-B Shelf life: 5 years Sizes as per FSC: I type (14G, 16G, 17G, 18G, 20G, 22G, 24G)	**Deferred** for the provision of following: - Shelf life studies for the claimed shelf life are not provided. Manufacturing and QC processes details are missing. ISO 13485 and Production quality assurance certificates are expired and without notarization. Apply separately for other three types.
49.	M/s. Medequips SMC Pvt Ltd, 30 Shahrah-e-Quaid-e-Azam Lahore. ELI-00362 Evaluator: AD-VIII 1577	Legal Manufacturer CANON MEDICAL SYSTEM CORPORATION, 1385 SHIMOISHIGAMI, OTWARA SHI TOCHIGI 324-8550, JAPAN. Canon Medical systems corporation is both the legal manufacturer and the physical manufacturing site of the Celesteion system. FSC: JAPAN Date of issue: 17.10.2019	**ZEXIRA** **RAFFINE-i** **PLESSART VIVO** **WINSCOPE** **PLESSART** (Remote control R/F system) Codes & Sizes: DREX-ZX80 DREX-RF80 DREX-W20PE8 DREX-PV50 Class-C Service life:	**Deferred** for the provision of following:- Clarify grouping of applied medical device under MDR 2017. Mentions the "proprietary name" of device to be registered. Accordingly submit revised Form-7A. Provided LOA is expired on 31 Dec 2020. Provide Original Valid LOA. Provide original valid FSC duly attested by Embassy of Pakistan for product as per revised Form-7A. The provided FQA is expired on 09 Sep 2021. Provide valid FQA. Clarify thats which of the following Notified body 2797 or 0123 has CE marked the product.

<table>
<tr><td></td><td></td><td></td><td></td><td>Provide label as approved in the country of origin.

The provided DoCs are expired on 10th April, 2018. Provide valid DoC.</td></tr>
<tr><td>50.</td><td>BAIN Medical SMC-Pvt) Ltd Ground Floor with Mazzanine, Plot 58-C, Street No. 24, Touheed Commercial Area, Phase 5 DHA Karachi (ELI-00614)

Evaluator:
AD-VIII

3727</td><td>Legal Manufacturer & Site:

M/s Giant Medical Equipment (Guangzhou) Co., Ltd., No.10 Juncheng Road, Eastern Area, Economic and Technological Devolpment District, Guangzhou 510760, PR. China

EC REP:
Medical Technology Promedit Consulting GmbH, Altenhofstrasse 80, 66386 St. Ingbert, Germany.

FSC:
Validity</td><td>GMKey® CENTERAL VENOUS CATHETER KITS

(single lumen, double lumen, triple lumen & quad lumen With straight puncture needle & With Y puncture needle)

Codes & Sizes:

As per FSC & DoC
174 variants 87 each

List of main components of Kit:
<table>
<tr><th>Part</th><th>Model & Specificatio</th></tr>
<tr><td>Vessel Dilator</td><td>Not mentioned</td></tr>
<tr><td>Guidewire</td><td>Not mentioned</td></tr>
<tr><td>Introducer Needle</td><td>Not mentioned</td></tr>
<tr><td>Disc Folder</td><td>Not mentioned</td></tr>
<tr><td>Blue Hollow Syringe</td><td>Not mentioned</td></tr>
<tr><td>Disposable Syringe</td><td>Not mentioned</td></tr>
<tr><td>Heparin Cap</td><td>Not mentioned</td></tr>
<tr><td>Plastic scalpel</td><td>Not mentioned</td></tr>
<tr><td>Injection Needle</td><td>Not mentioned</td></tr>
</table>
Class-C
Shelf Life: 3 Years</td><td>Deferred for the provision of following: -

Clarify that why the Free Sale Certificate (Germany) have been issued by the Ministry of Environment and consumer Protection. The provided FSC (Germany) is expired on 29 Dec 2021 and doesn't contain any of the applied 174 codes. Provide Original Valid FSC duly attested by embassy of Pakistan covering all codes of applied medical device.
Stability studies are not attached with application. Provide the shelf-life & storage conditions, i.e., justified with stability studies.
Provide the Free sale certificate in the country of origin duly attested by Embassy of Pakistan.
Provide label (as approved in the country of origin) of all the codes applied for registration and its packaging, promotion material and brochure.
Also provide complete list of components of KIT alongwith their specifications as part of label, promotional material etc.</td></tr>
<tr><td>51.</td><td>M/s. Future Scientific, FS House, Opposite</td><td>Legal Manufacturer:</td><td>Alegria® Test Strips (Anti-HSV-1/2 1gG)</td><td>Deferred for the provision of following:-</td></tr>
</table>

	Street No. 4, Main Road Shaheen Town, Gangal West, Post Office, Fazaia Colony, Rawalpindi. ELI-00209 Evaluator AD-VIII 1265-P	ORGENTEC Diagnostika GmbH Carl-Zeiss-Str, 49-51, 55129 Mainz, Germany FSC: Germany Date of issue. 19.07.2019	Code: ORG 905G (24 tests) Class: C Shelf Life: 15 months Storage temperature: 2-8°C	Verification of cold storage is required since the product require special storage condition. The provided LOA is photocopy and expired on 31st December, 2021. Provide Original and Valid Letter of Authorization. FSC is issued by "State Office of Social Affairs Youth and Supply". Justify this issuance by said department. Provide valid notarized ISO certificate. Provide label, IFU, Sales packages, brochures promotional material etc as approved in the country of origin. Provide European DoC mentioning the EC-Rep.
52.	M/s Global Clinial Cura 18, Mina Iqbal Road, Westridge-1 Rawalpindi, Pakistan ELI: 00196 Evaluator: AD-VIII 1237-P	Legal Manufacturer] Humasis Co., Ltd Rm 114, 502,504,604,604-1,B03-1, B03-2, 88 Jeonpa-ro, Dongan-gu, Anyang-si Gyeonggi-do, Republic of Korea FSC: Korea Date of issue: 20.05.2019	**HUBI-Troponin I Troponin I test** Catalog Number: Acti-8025 Class- C Shelf Life: 12 months	**Deferred** for the provision of following: - Provide Original Valid LOA. As per Korean FSC "HUBI Troponin I" is For Export Purpose. Clarify ication is required with documentary evidences. Clarify that why the scope of provided FQA certificate doesn't cover the applied medical device. Provide valid ISO & FQA. **The board decided to mention the category/type or temperature class of medical devices intended to be import on ELI of the firm to clarify the mandate of importer for storage of medical devices.**
53.	M/s Global Clinial Cura, 18, mian Iqbal Road, Westridge-1 Rawalpidni, Pakistan ELI: 00196 Evaluator:	Legal Manufacturer] Humasis Co., Ltd Rm 114, 502,504,604,604-1, B03-1, B03-2, 88 Jeonpa-ro, Dongan-gu, Anyang-si Gyeonggi-do, 431-836 Republic of Korea	**HUBI Cardiac 3 in-1** TnL, CK-MB, Myoglobin Test (ATCM-8025) Class C Shelf Life: 12 months	**Deferred** for the provision of following: - Provide Original Valid LOA. As per Korean FSC "HUBI Cardiac 3 In -1" is For Export Purpose. Clarify ication is required with documentary evidences.

	AD-VIII 1238-P	FSC: Korea Date of issue: 3.02.2017		Clarify that why the scope of provided FQA certificate doesn't cover the applied medical device. Provide valid ISO & FQA. **The board decided to mention the category/type or temperature class of medical devices intended to be import on ELI of the firm to clarify the mandate of importer for storage of medical devices.**
54.	M/s Easha Enterprises, 2B-04, Third Floor Adyala Towers Adyala Road, Rawalpindi ELI: 00203 Evaluator AD-VIII 2863(P)	Legal Manufacturer: M/s Beijing target Medical Technologies, Inc. No. 60 Shunren Road, Shunyi District, 101300 Beijing, P.R.China FSC: China Valid till: 17.09.2023	**Target Introducer Kit (Disposable Introducer Kit)** Codes & sizes: As per FSC Class - B Shelf Life: 3 years	**Deferred** for the provision of following:- Provide credential on specified format. Introducer Kit of M/s Lepu Medical Technology, China has already been registered in favor of M/s Intek Corporation Office No 30, First Floor Al Amin Plaza, The Mall Rawalpindi vide Registration Number MDIR-0001407. The firm attached Technical file, Stability studies, Checklist of Essential requirements, Declaration of Conformity, FSC photocopy of "Angiopower Inflation Device" instead of applied medical device i.e. "Target Introducer Kit". Provide all the documents as per checklist of Form-7A as per law.
55.	Muller & Phipps Pakistan (Pvt) Ltd., Uzma Court, Main Clifton Road, Karachi (ELI-00030) Evaluator AD-VIII 4346(K)	Legal Manufacturer: Lohmann & Rauscher International GmbH Co.KG, Westerwaldstraße 4, 56579 Rengsdorf, GERMANY FSC: Germany Date of Issue: 28 January 2021	**Lomatuell® Pro Contact forming contact Net** Codes & Sizes: as per FSC Class-C Shelf life: 3 Years	**Deferred** for the provision of following: What is the source of fat being used in Lomatuell® Pro Tulle. The stability studies summarized the Shelf Life that all characteristics meet the requirements "after a maximum of three months at the real time as well as accelerated", however the application form mentions 3 years shelf life, clarify or otherwise justify with documentary evidences. LOA N FQA The firm claimed that the notarized ISO and FQA certificates have been submitted with other Registration application i.e. Debrisoft pad.

<table>
<tr><td></td><td></td><td></td><td></td><td>Provide readable version of brochure of "Lomatuell® Pro Contact forming contact Net" the provided one is illegible copy with very small font size.

Provide label (as approved in the country of origin) for all the codes and sizes applied for registration. The firm has provided label of only two variants/codes/sizes i.e. 30870 & 30871.

provide complete DoC.</td></tr>
<tr><td>56.</td><td>Zedco,
203 Skymark tower, Plot A-13 Block 7/8, KCHSU Shahrah e faisal Karachi
ELI-00347

Evaluator
AD-VIII

3651 (K)</td><td>Legal Manufacturer:
Terumo BCT Inc.
10811 West Collins Ave., Lakewood, Colorado, 80215, USA

Manufacturing Sites:
Terumo BCT Inc.
10811 West Collins Ave., Lakewood, Colorado, 80215, USA

AND

Terumo BCT Vietnam Co., Ltd long Duc Industrial zone, Long Duc Commune, Long Thanh Distric, Dong nai Province, Vietnam.

FSC: USA
Validity: 10 Mar 2022</td><td>Terumo Trima Accel® Disposable Tubing Set

Codes & Sizes:
<table><tr><th>Device Name</th><th>Identifier</th></tr><tr><td>Trima Accel Platelet+ Sampler+ Auto PAS, MultiPlasma Sets</td><td>80310</td></tr><tr><td>Trima Accel LRS Platelet, Plasma RBC+ Auto PAS, Plasma, RBC Set</td><td>80410</td></tr><tr><td>Trima Accel MultiPlasma Sets</td><td>80700</td></tr></table>Class-C
Shelf life; 24 Months</td><td>Deferred for the provision of following:

That the product "Trima Accel Platelet+ Sampler+ Auto PAS, MultiPlasma Sets" with catalog ID#80310 is only for export purpose as per provided certificate no. CT0039-21 802, need clarification.

Provide original valid FSC duly attested by embassy of Pakistan covering all codes & manufacturing site of Vietnam.

Provide valid ISO certificate for both of manufacturing sites i.e. USA and Vietnam.

The firm is required to depute a technically well versed personal for explaining the working and differences among codes of applied medical device. The firm is required to explain the grouping of following codes 80310, 80410 & 80700 in a single registration application.
The firm provided material wise design verification Report.

Provide Stability Studies of finished product to justify the shelf life of applied medical device.</td></tr>
<tr><td>57.</td><td>M/s Zedco,
203 Skymark tower, Plot A-13 Block 7/8, KCHSU Shahrah e faisal</td><td>Terumo BCT Inc.
10811 West Collins Ave., Lakewood, Colorado, 80215, USA</td><td>Terumo Trima Accel® Disposable Tubing Set

Codes & Sizes:</td><td>Deferred for the provision of following:-

Explain the difference between 82310 & 80310; 82410 & 80410; 80700 &</td></tr>
</table>

	Karachi ELI-00347 Evaluator AD-VIII 3652 (K)	FSC: USA Validity: 10 Mar 2022	82330 82300 82310 82410 82700 Class-C Shelf life; 24 Months	82700 applied as separate medical device. That the product Catalog ID#82310 and Catalog ID#82330 are only for export purpose as per provided certificate no. CT0039-21 802, need clarification. Provide original valid FSC duly attested by Embassy of Pakistan covering all codes and manufacturing site of Vietnam. Provide valid ISO certificate for both of manufacturing sites i.e. USA and Vietnam. The firm is required to depute a technically well versed personal for explaining the working and differences among codes of applied medical device. The firm is required to explain the grouping of following codes 80310, 80410 & 80700 in a single registration application. The firm provided material wise design verification Report. Provide Stability Studies of finished product to justify the shelf life of applied medical device.
58.	Hospital Supply Corporation 42 Darul Aman Housing Society, Block 7 & 8, Karachi (ELI-00005) Evaluator AD-VIII 3215	**Legal Manufacturer:** Haemonetics Coorporation 400 Wood Road, Braintree, MA 02184, USA **Manufacturing Sites:** **Code:09000-220-E** Sanmina – SCI Systems (Malaysia) Sdn. Bhd. 202, Lorong Perusahaan Maju 9, Bukit Tengah Industrial Park, Perai Penang, 13600 Malaysia. **Code:0620E-00** PT. JMS BATAM, Lot 212, Jalan Berigin, Muka Kuning, Batamindo	**Haemonetics** Apheresis Unit with Apheresis System Tubing Set **Constituent-components:** MCS®+ 9000-220-E N/A PLS Bag 0690-00 3 Years PLS Bag 620E-00 5 Years BMB PLS Bowls 625B-00 5 Years PBSC Set (125mL Latham) 971E-00 3 Years TPE Set (225mL Latham) 980E-00 5 Years	**Deferred** for the provision of following:- Justify the grouping of applied multiple codes in a single registration application. The provided credentials of manufacturers are un-notarized and unsigned. As per MDR 2017, the medical device applied as system comprising of constituent-component shall be from the same manufacturer. It has been observed that the codes 09000-220-E & 0620E-00 are from different manufacturer located in Malaysia & Indonesia, respectively. These facilities belong to non-Reference Regulatory Authorities. Need clarification.

		Industrial Park, Batam 29433, Indonesia. **Other Codes:** Haemonetics Malaysia Sdn. Bhd. PMT 727, Persiaran Cassia Selatan 1, Taman Perindustrian Batu Kawan, 14100 Simpang Ampat, Penang, Malaysia. FSC: USA Validity: 31 July 2021	TPE Set (125mL Latham) 981E-00 5 Years Extended storage platelet (ESP) / Plasma Aphresis Set PLT & PLS Set single Dose 995E-00 3 Years PLT & PLS Set single Dose 996E-00 3 Years PLT & PLS Set double Dose 96E2-00 3 Years PLS Bundle Set W/Air Bag 0782-00 3 Years PLS 3-Bags Closed Set, BMB 623E-00 3 Years Codes and Sizes as per FSC Class-C	The firm attached two different "Sole Agency Certificate" one is issued from Haemonetics Corporation USA and the other is issued from Haemonetics S.A. Switzerland. Furthermore, the same was exclusively issued for Directorate General Defense Purchase. The said Agency agreements doesn't cover product code 0623E-00. Need clarification. The provided FSC photocopy expired on 31 July 2021 and the same doesn't cover all the applied codes. Provide valid original embassy attested FSC covering applied codes. As per provided label M/s Haemonetics Coorporation 400 Wood Road, Braintree, MA 02184, USA is the manufacturer of MD Code# 09000-220-E, However, as per provided credentials, the manufacturer is Sanmina – SCI Systems (Malaysia) Sdn. Bhd. 202, Lorong Perusahaan Maju 9, Bukit Tengah Industrial Park, Perai Penang, 13600 Malaysia. Similarly, the same discrepancy exists for other codes between provided label and credentials regarding manufacturing sites. The firm is required to clarify that who will be the manufacturer of applied Medical Device. Provide EU DoC. The product BMB PLS Bowls bearing code 00625B-00 has three different manufacturing sites, who will be the actual manufacturer exporting to Pakistan, need clarification. Provide valid ISO and FQA certificates covering all the manufacturing facilities including the sterilization facilities. Provide stability studies to justify the shelf life.
59.	S.Ejazuddin & Co., P.O Box 5629, Zia Plaza, Altaf Hussain Road, Karachi (ELI-00078)	**Legal Manufacturer:** Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-StraBe 76 35041 Marburg Germany	**Berichrom Antithrombin III (A)** Berichrom Antithrombin III (A) Code: OWWR15	**Deferred** for the provision of following:- Provided photocopy of LOA is expired on 10 April 2020. Provide valid original LOA.

	Evaluator AD-VIII 2607	FSC: Germany Validity:	Size: Shelf Life: 24 Months Berichrom Antithrombin III (A) Code: OWWR17 Size: 6x5ML Shelf Life: 30 Months Control Plasma N Code: ORKE41 Size: 10x15ML Shelf Life: 30 Months Standard Human Plasma Code: ORKL17 Size: 10X1ML Shelf Life: 24 Months Control Plasma P Code: OUPZ17 Size: 10X1ML Shelf Life: 24 Months Imidazol Buffer Solution Code: OQAA33 Size: 6x15ML Shelf Life: Class-C	Provided ISO certificate is expired on 15 Aug 2021. Provide valid ISO certificate. Provide FQA & DoC as per regulation 2017/746 on EU IVDR. Provided photocopy of FSC provide original FSC. It has been noticed that the same codes (ORKE41, ORKL17, OUPZ17, OQAA33) have been applied with other registration application. Clarification is required whether the these codes come with reagent(s) in a single package in a single import or otherwise justify. Composition sheet, Label, Stability report, Essential Requirement Checklist & product performance summary for code# OWWR15 & OWWR17 was not provided. Provide the same. Provide Brochure, promotional material, IFU, Manual etc. for the applied IVD- Medical Device(s).
60.	Johnson & Johnson Pakistan (Pvt) Ltd., Office No.806, 8th Floor, Horizon Tower, Block 3, Scheme 5, Clifton, Karachi (ELI-00154) Evaluator AD-VIII 2590	**Legal Manufacturer & manufacturing Site:** Depuy International Ltd. St. Anthony's Road, Leeds LS11 8DT, United Kingdom FSC: Not provided Validity: Not provided	**C Stem Void Centraliser** **Codes & Sizes** 961210500 – 10mm 961212500 – 12mm 961214500 – 14mm 961216500 – 16mm Class-C Shelf Life: 5 year	**Deferred** for the provision of following:- Provide notarized credentials of manufacturer. Provide latest credentials covering the manufacturing sites. List of codes not attached with application form as claimed. Provided ISO is expired on 12 Dec 2021. Provide valid ISO certificate. Provided FQA is expired on 29 Nov 2021. Provide valid FQA certificate. Provide label for code 961216500 as approved in the country of origin. FSC not provided with application for registration. Provide original valid FSC duly attested by Embassy of Pakistan.

61.	Johnson & Johnson Pakistan (Pvt) Ltd., Office No.806, 8th Floor, Horizon Tower, Block 3, Scheme 5, Clifton, Karachi (ELI-00154) Evaluator AD-VIII 2719	**Legal Manufacturer:** Depuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, IN 46582 USA Manufacturing Site(s): DePuy Orthopaedics Inc. 325 Paramount Drive Raynham, MA 02767 USA DePuy Orthopaedics Inc. 700 Orthopaedic Drive Warsaw, IN 46582 USA FSC: Not attached Validity: not attached	**Sigma HP Partial Knee System** Codes & Sizes as per FSC 132 codes as per list attached with form Class-C Shelf Life: 5-10 Years	**Deferred** for the provision of following:- The firm attached Challan No. 2027544 with registration application of Sigma HP Partial Knee System. However on said challan the fee was submitted for registration of Celsius Thermocool Catheter (thermo couple) Class-D product. Need clarification. The provided credentials doesn't cover DePuy Orthopaedics Inc. 325 Paramount Drive Raynham, MA 02767 USA. The Annexure-5 doesn't mentions any details of manufacturing process and quality control processes as claimed on application form. Therefore, provided requisite information as required. Sigma HP Partial Knee System is the name of applied medical device as family. However, no such name is given on Letter of Authorization. Furthermore, the device description of each component of family is different in different document like LOA & EC Design Examination etc., need clarification. The firm is required to depute a technically well versed personal for explaining the working and differences among codes of applied medical device. The firm is required to explain the grouping of applied codes in a single registration application. Provide valid FSC covering the applied medical device and its codes. ISO certificate and FQA not attached with the application. Therefore provide valid ISO certificate and FQA covering all manufacturing and sterilization sites. The DoC mentions 133 Codes while LOA and Design Examination mentions 132 codes, need clarification Provide label of all codes applied for registration mentioning the manufacturing site(s). The application form mentions two different manufacturing sites i.e. "DePuy Orthopaedics Inc. 325 Paramount Drive Raynham, MA 02767 USA" and "DePuy Orthopaedics Inc. 700 Orthopaedic Drive Warsaw, IN 46582 USA" however no such site-

				specific manufacturing is reflected in any attachment of application. Need clarification.
62.	Johnson & Johnson Pakistan (Pvt) Ltd., Office No.806, 8th Floor, Horizon Tower, Block 3, Scheme 5, Clifton, Karachi (ELI-00154) Evaluator AD-VIII 2595	**Legal Manufacturer:** M/s Ethicon Endo-Surgery, LLC, 475 Calle C Guaynabo, Puerto Rico, 00969 USA Manufacturing Site: Ethicon Endo-Surgery S.A. DE C.V. Avenida De La Torres No. 7125 Colonia salvarcar 118, Cludad Juarez Chibuahua, Mexico - 32580. FSC: US FDA Valid Till: 5-11-2020	**Echelon Circular Powered Staplers** Codes & Sizes as per FSC Class-C Shelf Life: 3 Years	**Deferred** for the provision of following:- FSC photocopy provided was expired on 5 Nov 2020. Provide valid FSC. The FSC mentions more than one manufacturing site for applied product. However, the application form mentions only one manufacturing site. Provide ISO certificate of Sterilization site of applied medical device. Provided FQA doesn't cover manufacturing site. Provide FQA covering the manufacturing site. Provided label doesn't mentions manufacturing site. Provide lable mentioning the manufacturing site of applied Medical Device.
63.	Johnson & Johnson Pakistan (Pvt) Ltd., Office No.806, 8th Floor, Horizon Tower, Block 3, Scheme 5, Clifton, Karachi (ELI-00154) Evaluator AD-VIII 2562	**Legal Manufacturer:** Synthes GmbH 3 Eimattstrasse, 4436 Oberdorf, CH Switzerland. Manufacturing Site Synthes Produktions GmbH Solothhurnstrasse 186, 2540 Grenchen, Switzerland (only for code 04.268.000S) Synthes USA LLC 35 Airport Rd., Horseheads, NY 14845, USA. FSC: Switzerland Valid Till: 31-01-2023	**Femoral Neck System (FNS) - Implants** Codes & Sizes as per FSC Class-C Shelf Life: 10 year	**Defferred** due the following shortcomings LOA and FSC and Provide credentials specific to applied medical device. Clarify the exact manufacturer whether it is Depuy Synthes Grenchen, Switzerland or Synthes USA LLC 35 Airport Rd., Horseheads, NY 14845, USA Provide valid ISO certificate covering all manufacturing site including sterilization site(s). FQA doesn't cover manufacturing site(s) of applied medical device. Provided Label doesn't mentions manufacturing site(s). application the product has two physical manufacturers. Justify the grouping of applied medical device as family.
64.	Johnson & Johnson Pakistan (Pvt) Ltd., Office No.806, 8th Floor, Horizon Tower, Block 3, Scheme 5, Clifton, Karachi (ELI-00154) Evaluator AD-VIII	**Legal Manufacturer:** Synthes GmbH 3 Eimattstrasse, 4436 Oberdorf, CH Switzerland **Manufacturing Sites:** Synthes Produktions GMBH Kanalstrasse west 30, 3942 Raron, Switzerland	**Midfoot Plates** Codes & Sizes: **Codes** / **Shelf life** 02.211.416 / N/A 02.211.416S / 10 02.211.417 / N/A 02.211.417S / 10 02.211.418 / N/A 02.211.418S / 10	**Deferred** for the provision of following:- Submit the copy of LoA & FSC and present original LOA to secretary MDB Provide credentials specific to applied medical device. Provide valid ISO certificate covering sterilization site(s) as the submitted

	2650	FSC: Switzerland Valid Till: 31-01-2023	02.211.419 N/A 02.211.419S 10 02.211.420 N/A 02.211.420S 10 02.211.421 N/A 02.211.421S 10 Class-C	certificate was expired on 10 October 2021. FQA doesn't cover manufacturing Provided Label doesn't mention manufacturing site(s). The technical file summary report TF10175FNS mentions two manufacturing sites however as per FSC and list of codes attached with registration application the product has one physical manufacturer. Clarify / justify.
65.	Johnson & Johnson Pakistan (Pvt) Ltd., Office No.806, 8th Floor, Horizon Tower, Block 3, Scheme 5, Clifton, Karachi (ELI-00154) Evaluator AD-VIII 2650	**Legal Manufacturer:** Synthes GmbH 3 Eimattstrasse, 4436 Oberdorf, CH Switzerland **Manufacturing Sites:** Synthes Produktions GmbH Solothhurnstrasse 186, 2540 Grenchen, Switzerland Synthes Produktions GMBH Kanalstrasse west 30, 3942 Raron, Switzerland (only for codes 440.831; 440.831S; 440.838 & 440.838S) Synthes USA, LLC 1051 Synthes Avenue, Monument, Co 80132, USA (only for code440.874) FSC: Switzerland Valid Till: 31-01-2023	**Tomofix Plate Implants** **Codes & Sizes as per FSC** **Codes / Shelf life** 04.120.550 N/A 04.120.550 S 10 04.120.551 N/A 04.120.551 S 10 440.831 N/A 440.831S 10 440.834 N/A 440.834S 10 440.837 N/A 440.837S 10 440.838 N/A 440.838S 10 440.843 N/A 440.843S 10 440.853 N/A 440.853S 10 440.864 N/A 440.864S 10 440.874 N/A 440.874S 10 Class-C	**Deferred** for the provision of following:- Submit LOA and FSC Provide credentials specific to applied medical device. The firm is required to depute a technically well versed personal for explaining the working and differences among codes of applied medical device and their grouping as family (tibial plates and femoral plates). Provide valid ISO certificate covering sterilization site(s) as the submitted ISO certificate was expired on 10 October 2021. FQA doesn't cover manufacturing site(s) of applied medical device Provided Label doesn't mention manufacturing site(s). Clarify /justify the manufacturing site discrepancies in documents submitted like manufacturing process information and FSC / list of codes attached with registration application.
66.	Johnson & Johnson Pakistan (Pvt) Ltd., Office No.806, 8th Floor, Horizon Tower, Block 3, Scheme 5, Clifton, Karachi (ELI-00154)	**Legal Manufacturer:** Synthes GmbH 3 Eimattstrasse, 4436 Oberdorf, CH Switzerland **Manufacturing Sites:** Synthes Produktions GMBH Kanalstrasse west	**Carpal Fusion Plates** Codes & Sizes as per FSC **Codes / Shelf life**	**Deferred** for the provision of following:- Submit LOA and FSC Provide credentials specific to applied medical device. Provide valid ISO certificate covering sterilization site(s). as the submitted

	Evaluator AD-VIII 2587	30, 3942 Raron, Switzerland FSC: Switzerland Valid Till: 31-01-2023	02.111.300 N/A 02.111.300S 10 02.111.301 N/A 02.111.301S 10 04.111.300 N/A 04.111.300S 10 04.111.301 N/A 04.111.301S 10 Class-C	ISO certificate was expired on 10 October 2021. FQA doesn't cover manufacturing site(s) of applied medical device. Provided Label doesn't mention manufacturing site(s). Clarify /justify the manufacturing site discrepancies in documents submitted like manufacturing process information and FSC / list of codes attached with registration application.
67.	Johnson & Johnson Pakistan (Pvt) Ltd., Office No.806, 8th Floor, Horizon Tower, Block 3, Scheme 5, Clifton, Karachi (ELI-00154) Evaluator AD-VIII 2556	**Legal Manufacturer:** Ethicon Endo surgery LLC 475, Calle C Guaynabo, Puerto Rico USA 00969 **Manufacturing Site:** Ethicon Endo-Surgery S.A. DE C.V. Avenida De La Torres No. 7125 Colonia salvarcar 118, Cludad Juarez Chibuahua, Mexico - 32580. FSC: USA Valid Till: 5-11-2020	**PROXIMATE® PPH Procedure for Prolapse and Hemorrhoids Set** (Hemorrhoidal circular stapler, Suture Threader, Circular Anal Dilator and Purse-string Suture Anoscope) Codes & Sizes (PPH03 SET) 33MM Class-C Shelf life: 5 years	**Deferred** for the provision of following:- Clarify whether the accessories will collectively be used to achieve intended purpose or otherwise. Provided photocopy of FSC is expired on 5 Nov, 2020. Provide Valid FSC as per law. Clarify the manufacturing site of applied medical device. Since the FSC mentions three manufacturing sites. Provided FQA doesn't cover the manufacturing site neither as per application form nor as per FSC. Provided label doesn't mentions name of physical manufacturer. Clarify /justify.
68.	M/s Mian Enterprises, Office No. UG-400 Deans Trade Center Islamia Road, Peshawar Cantt 25000, Pakistan ELI: 00507 Evaluator AD-VIII 3012	Legal Manufacturer: M/s Kowa Company Ltd 4.14, 3-Chome, Nihonbashi-Honcho, Chuo-ku, Tokyo 103-8433, Japan **Manufacturing Site:** Kowa Company, Ltd. IOL Research Dept. (Hamamatsu) 3-1, 1-Chome, Shin-Miyakoda, Kta-ku, Hamamatsu, Shizuoka, 431-2013, JAPAN. FSC original: Japan Date of issue: 25 Nov 2020	**Avansee Preload1P Clear** **(Preloaded Aspheric Hydrophobic Acrylic Clear UV Intraocular Lens (IOL))** **Model identifier:** CP2.2R Class-C Shelf Life: 5 years	**Deferred** for the provision of following:- The provided original ISO certificate of manufacturing site was expired even upon submission of application (Exp. Dt: 30 Mar 2022). Provide Valid ISO certificate. Provide stability studies to justify the claimed shelf life of 5 years. Model identifier of Avansee Preload1P Clear not mentioned on FSC. Provide the declaration (on stamp paper) as per Form-7A.

69.	M/s Iqbal & Company, Alfalah Manzil Opp. National Police Foundation, Street # 26, Sector, E-11/4, Islamabad, Pakistan. (ELI: 00117) Evaluator AD-VIII 2906	Legal Manufacturer and manufacturing site: M/s Gambro Dialysatoren GmbH Holger-Crafoord-Strasse 26 72379 Hechingen Germany Original FSC: Germany Date of issue: 6 Aug 2021	**POLYFLUX** **(Hemodialyzer)** Codes & Sizes: 102057 102058 104176 103579 115821 103580 103530 Class-C Shelf Life: 3 years	**Deferred** for the provision of following:- As per provided manufacturing process flowchart and FSC, the manufacturing of Polyflux 210H (115821) is sub-contracted to Gambro Industries S.A.S 7 avenue Lionel Terray BP 126, 69883 in Meyzieu Cedex France. However, neither ISO nor FQA certificate cover that facility of Gambro Industries located in France. Furthermore, what is the difference between code 115821 and 103580 having same local trade name i.e. Polyflux 210H as per Annexure-A of Letter of Authorization and FSC? The submitted Essential Requirements checklist is for Prismaflex M & ST sets, furthermore, the same mentions "Gambro Industries S.A.S 7 avenue Lionel Terray BP 126, 69883 in Meyzieu Cedex France" as legal manufacturer and manufacturing location. Need clarification. Stability studies /shelf life validation studies not attached for justification of 3year shelf life. Provide the Stability Studies.
70.	M/s Med Lab Services Office No. 1, First Floor, ABC Plaza, commercial center, Satellite town, Rawalpindi. (ELI-00056) Evaluator AD-VIII 1881 (P)	**Legal Manufacturer:** M/s VIRCELL, S.L, Parque Tecnologico de la Salud, Avicena 8, 18016 Granada (Spain) M/s VIRCELL Spain, S.L., Poligono Industrial Dos de Octubre, Plaza Dominguez Ortiz 1. 18320 Santa Fe, Granada, Spain **FSC:** Spain **Date of issue** 04.01.2018	**PNEUMOBACT ELISA 1gM** **Refrence:** M1040 **No. of Tests:** 96 **VIRCELL PNEUMOBACT PLATE** Size: 1x 96 wells plate **VIRCELL SERUM DILUENT** Size: 1x 25ml **VIRCELL LEGIONELLA IgM POSITIVE CONTROL** Size: 1x 500µL **VIRCELL MYCOPLASMA**	**Deferred** for the provision of following:- Credentials of manufacturer not attached with application. Therefore, provide notarized Credential of manufacturer covering the manufacturing site(s). The provided photocopy of Letter of Authorization (LOA) is expired on 31 Dec, 2021. Provide valid LOA. Provided ISO certificate is expired on 17 Dec 2021. Provide valid ISO certificate. Clarification is required that all the component-constituents applied as single registration will be imported as single unit/package or otherwise. Mention code of each component-constituent being packaged under reference M1040 as well as shelf life of each constituent-component.

			IgM POSITIVE CONTROL Size: 1x 500µL **VIRCELL COXIELLA IgM POSITIVE CONTROL** Size: 1x 500µL **VIRCELL CHLAMYDOPHILA IgM POSITIVE CONTROL** Size: 1x 500µL **VIRCELL LEGIONELLA IgM CUT OFF CONTROL** Size: 1x 500µL **VIRCELL MYCOPLASMA IgM CUT OFF CONTROL** Size: 1x 500µL **VIRCELL COXIELLA IgM CUT OFF CONTROL** Size: 1x 500µL **VIRCELL CHLAMYDOPHILA IgM CUT OFF CONTROL** Size: 1x 500µL **VIRCELL IgM NEGATIVE CONTROL** Size: 1x 500µL **VIRCELL IgM CONJUGATE I** Size: 1x 9ml **VIRCELL IgM CONJUGATE II** Size: 1x 9ml **VIRCELL TMB SUBSTRATE SOLUTION** Size: 1x 15ml **VIRCELL STOP REAGENT** Size: 1x 15ml **VIRCELL WASH BUFFER** Size: 1x50ml (20x)	It may be clarified that the "technological scope of Notified Body#0318 was extended on 16 Jun 2018 regarding inclusion of instruments and software for invitro diagnostic". However, the Spanish Free Sale Certificate was issued on 04 Jan 2018 than which notified body audited the firm having relevant scope and given compliance report of applied medical device. Provide that certificate of compliance with 98/79/EEC and report thereof.

			Class-C Shelf Life: 21 months	
71.	M/s Med Lab Services Office No. 1, First Floor, ABC Plaza, commercial center, Satellite town, Rawalpindi. (ELI-00056) Evaluator AD-VIII 1881 (P)	**Legal Manufacturer:** M/s VIRCELL, S.L, Parque Tecnologico de la Salud, Avicena 8, 18016 Granada (Spain) M/s VIRCELL Spain, S.L., Poligono Industrial Dos de Octubre, Plaza Dominguez Ortiz 1. 18320 Santa Fe, Granada, Spain **FSC:** Spain **Date of issue:** 04.01.2018	**TOXOPLASMA ELISA 1gsG** Refence: **G1027** No. of Tests: **96** **VIRCELL TOXOPLASMA PLATE** Size: 1x96 well plate **VIRCELL SERUM DILUENT** Size: 1x25ml **VIRCELL IgG POSITIVE** CONTROL Size: 1x 500µL **VIRCELL IgG CUT OFF CONTROL** Size: 1x 500µL **VIRCELL IgG NEGATIVE CONTROL** Size: 1x 500µL **VIRCELL IgG CONJUGATE** Size: 1x 15ml **VIRCELL TMB SUBSTRATE SOLUTION** Size: 1x 15ml **VIRCELL STOP REAGENT** Size: 1x 15ml **VIRCELL WASH BUFFER** Size: 1x 50ml (20x) **VIRCELL SEMIQUANTIFICATION SAMPLE CONTROL** Size: 1x 500µL Class-C Shelf Life: 21 months	**Deferred** for the provision of following: - Toxoplasma Elisa 1gG is considered under against this registration application. Firm is required to submit a separate application for registration of Toxoplasma Elisa 1gM Capture: Ref: M1027. Credentials of manufacturer not attached with application. Therefore, provide Credential of manufacturer covering the manufacturing site(s). The provided photocopy of Letter of Authorization (LOA) is expired on 31 Dec, 2021. Provide valid LOA. Provided ISO certificate is expired on 17 Dec 2021. Provide valid ISO certificate. Clarification is required that all the component-constituents applied as single registration will be imported as single unit/package or otherwise. Mention **code** of each component-constituent being packaged under reference M1040 as well as **shelf life** of each constituent-component. It may be clarified that the "technological scope of Notified Body#0318 was extended on 16 Jun 2018 regarding inclusion of instruments and software for invitro diagnostic". However, the Spanish Free Sale Certificate was issued on 04 Jan 2018 than which notified body audited the firm having relevant scope and given compliance report of applied medical device. Provide that certificate of compliance with 98/79/EEC and report thereof.
72.	M/s Fresenius Medical Care Pakistan Pvt. Ltd,: TAMC, First Floor, 27C III, M.M. Alam Road	Legal Manufacturer: M/s Fresenius Medical Care Deutschland GmbH, Oberelenbach Plant, Steinmuhlstrasse 24 61352	**multiFiltrate PRO-Kit Ci-CA HD 1000 (F00000463)** Class-C	**Deferred** for the provision of following:- Provide stability studies of components to justify shelf life of applied medical device.

	Gulberg III, Lahore 54660, Pakistan ELI-00315 Evaluator AD-VIII 2900	Bad Homburg Germany Manufacturing Site: Nova Med GmbH, Antalya Serbest bolgesi Merkez Subesi No: 16, Liman Serbest Bolgesi Mahallesi 07070, Antalya, Turkey FSC: Germany Date of issue: 20.05.2020	Shelf Life: 3 year	The manufacturing site "Fresenius medical Care Deutschland GmbH Obererlenbach Plant SteinmuhlstraBe 24 61352 Bad Homburg Germany" for "procedure pack" of applied MD doesn't cover under provided photocopy of FSC of procedure pack. The provided photocopy of ISO 13485 certificate is expired on 04 Apr 2022. Provide valid certificate.
73.	M/s Fresenius Medical Care Pakistan Pvt. Ltd,: TAMC, First Floor, 27C III, M.M. Alam Road Gulberg III, Lahore 54660, Pakistan ELI-00315 Evaluator AD-VIII 2901	**Legal Manufacturer:** M/s Fresenius Medical Care Deutschland GmbH, Oberererlenbach Plant, Steinmuhlstrasse 24 61352 Bad Homburg Germany **Manufacturing Site:** **Site for Procedure Pack:** Nova Med GmbH, Antalya Serbest bolgesi Merkez Subesi No: 16, Liman Serbest Bolgesi Mahallesi 07070, Antalya, Turkey FSC: Germany Date of issue: 20.05.2020	**multiFiltrate PRO-Kit Ci-CA HDF 1000 (F00005329)** Class-C Shelf Life: 3 year	**Deferred** for the provision of following:- Provide stability studies of components to justify shelf life of applied medical device. The manufacturing site "Fresenius medical Care Deutschland GmbH Obererlenbach Plant SteinmuhlstraBe 24 61352 Bad Homburg Germany" for "procedure pack" of applied MD doesn't cover under provided photocopy of FSC of procedure pack. The provided photocopy of ISO 13485 certificate is expired on 04 Apr 2022. Provide valid certificate. Provide EPSP checklist.
74.	M/s Aston-Medical Pakistan, 4-A, 4th Floor, 38 C Bukhari Commercial Lane. 8 Phase 6, D.H.A, Karachi (ELI-00797) **Evaluator:** AD-IV [4396]	Manufacturer: ARTHESYS 4 rue Rene Razel 91400 Saclay France FSC France issued on 14-6-2021	Pegase Hydro Aspiration Catheter Class D Codes: Pegase Hydro 6F S ---04030101 Pegase Hydro 7F S ---04030102 Shelf life: 3 years	**Defferred** as the following documents are deficient: 1. The same cover letter in your response is submitted for Citra-Lock Catheter Lock Solution and even in this application response, the name of the product mentioned is Citra-Lock Catheter Lock Solution and not Pegase Hydro Aspiration Catheter 2. CE technical file maintained by the manufacturer and submitted to EU notified CABs is required as per rule 15(2) for the applied product. It is still NOT provided. 3. ISO13485 is copy and NOT notarized. Provide ISO13485 with

				ORIGINAL notarization. 4. Full QA certificate is copy. Provide complete Full QA certificate with ORIGINAL notarization.
75.	M/s Cardiac Care, 848-C, Shadman-1, Lahore 54610, Pakistan ELI: 00070 Evaluator: [AD-VIII] 2869	**Legal Manufacturer:** KIMAL PLc Anrundel Road, Uxbridge, Middlesex, UBB 2SA United Kingdom **Manufacturing site:** KIMAL Plc, 34 Sherwood Rd, Bromsgrove Worcestershire B60 3DR United Kingdom FSC: UK Date of issue: 16.03.20200	Altius Classic Central Venous Catheter- 5 Lumen Set (Central Venous Catheter adult and paediatric) Codes & sizes: KCS115705 KCS115855 KCS120855 KCS130855 KCV115855 KCV120855 KCV130855 Class-D Shelf Life: 3 years	**Deferred** with final opportunity due to following deficiencies: i. Provide labels as approved in country of origin for all codes and sizes as per FSC. Since the provided one doesn't mention the name of manufacturer.
76.	M/s Medtronic Pakistan (Pvt) Ltd., Ocean Tower, 21st Floor, Plot No.G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi (ELI-00273) Evaluator: [AD-VIII] 4351	**Legal Manufacturer:** M/s Medtronic Inc. 710 Medtronic Parkway, Minneapolis, MN 55432, USA M/s Medtronic Mexico S.de R.L. de CV, Av. Paseo Cucapah, Baja California, Mexico **FSC: Ireland** **Date of issue: 11-08-2021**	**Solarice NC Rapid Exchange Balloon Dilatation Catheter** **Codes & Sizes: as per FSC** **Class-D** **Shelf life: 2**	**Deferred with final opportunity due to following deficiencies:** i. Provide embassy attested original FSC since the firm provided scanned copy in dossier and photocopy in the reply of shortcomings.
77.	Medtronic Pakistan (Pvt) Ltd., Ocean Tower, 21st Floor, Plot No.G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi (ELI-00273) Evaluator: [AD-VIII] 4308	**Legal Manufacturer:** M/s Medtronic Inc. 710 Medtronic Parkway, Minneapolis, MN 55432, USA M/s Medtronic Mexico S.de R.L. de CV, Av. Paseo Cucapah, Baja California, Mexico **FSC: Ireland** **Date of issue: 11-08-2021**	**Solarice Rapid Exchange Balloon Dilitation Catheter** **Codes & Sizes: as per FSC** **Class-D** **Shelf life: 2 Year**	**Deferred with final opportunity due to following deficiencies:** i. Provide embassy attested original FSC since the firm provided scanned copy in dossier and photocopy in the reply of shortcomings.
78.	M/s K.M Enterprises, K.M Mansion, 605 D,	Legal Manufacturer: Eurolatex Sdn. Bhd. Plot	KINGSTER (Male Latex	**Deferred with final opportunity due to following deficiencies:**

	Block MA, Johar Town, Lahore ELI: 00054 Evaluator: [AD-VIII] 2864	33 Kuala Ketil Industrial Estate, 09300 Kuala Ketil, Kedah, Malaysia **FSC:** Malaysia Valid till: 12.10.2023	Condom) Codes & sizes: As per FSC Class-C Shelf Life: 5 years	i. The firm once again submitted un-notarized credentials. Therefore, provide notarized credentials of manufacturer. ii. Provide the Original and valid free sale certificate of any RRA as per rule 67 duly attested by embassy of Pakistan. iii. Provide valid Full quality assurance or equivalent, duly notarized by the country of origin since the provided one is expired upon submission (18-02-2021). iv. The provided configurations of the medical devices to be registered are not mentioned on provided Free Sale Certificate, clarification is required.
79.	M/s Optisurg, 17/C-1, Valencia Town, Lahore ELI: 00305 Evaluator: [AD-VIII] 2151	Legal Manufacturer: Medicontur Medical Engineering Ltd, Herceghalmi Road 1, 2071 Zsambek, Hungary FSC: Hungary Date of issue: 24.09.20	Medicontur 677ADY Bi-Flex (Aspheric hydrophilic acrylic IOL with blue light filter for implantation into the capsular bag) odes & Sizes: As per FSC Class- C Shelf Life:5 years	**Deferred with final opportunity due to following deficiencies:** i.The firm submitted embassy attested photocopy of the Free Sale Certificate (FSC) issued by TGA, Australia regarding Medicontur (Model: 677ADY Bi-Flex). Therefore, provide original FSC duly attested by embassy of Pakistan.
80.	M/s Cardiac Care, 848-C, Shadman-1, Lahore 54610, Pakistan (ELI: 00070) **Evaluator** AD-VII	Legal Manufacturer: KIMAL Plc Arundel Road, Uxbridge, Middlesex, UB8 2SA United Kingdom Manufacturing site: KIMAL Plc, 34 Sherwood Rd, Bromsgrove Worcestershire B60 3DR United Kingdom	Altius Classic Central Venous Catheters-3 Lumen Codes & sizes: KCS105403 KCS105503 KCS108403 KCS108503 KCS113403 KCS113503 KCS115703 KCS115853 KCS120703 KCS120853 KCS130403 KCS130503 KCS130703 KCV111703 KCV115703	**Deferred with final opportunity due to following deficiencies:** i. Provide labels as approved in country of origin for all codes and sizes as per FSC. Since the provided one doesn't mention the name of manufacturer.

			KCV115853 KCV120703 KCV120853 KCV130703 Class-D Shelf Life: 3 years	
81.	M/s Medequips SMC Pvt. Ltd, 30-Shahrah e Quaid e azam, Lahore ELI: 00362 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: N/A	**Deferred with final opportunity due to following deficiencies:** i. The firm provided photocopy of valid FSC issued by USFDA. Therefore, provide original FSC. ii. 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. iii. Provide stability studies/validation studies/service life studies or otherwise justify.
82.	M/s Vertex Medical (Pvt) Ltd, 70-B-1, Gulberg-III, Lahore ELI-00150 Evaluator AD-VIII 2305-P	**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	SORIN XTRA Disposables (Collection Systems, Disposable Sets and Accessories for Autotransfusion, PPP, PRP, PLT GEL) Codes & Sizes: As per FSC Class-C Shelf Life: 3 Years	**Deferred with final opportunity due to following deficiencies:** i. Provide credentials of manufactuerer covering the manufacturing site i.e. Sorin Group Italia S.r.l Via Statale Nord 12, 86 41037 Mirandola MO, Italy ii. Provide original & valid LOA. iii. Provide original & valid FSC. iv. Provide Shlef life studies to justify 3 years shelf life. v. The firm is required to depute technical person for demonstration on applied codes of procedure packs.
83.	M/s Genus, 220, Block:3 DMCHS, S. Abdul Tawwab road,	M/s Shanghai Kindly Medical Instruments Co., Ltd., NO. 925, Jinyuan No. 1 Road, Shanghai China	Path Finder (Guiding Catheter) Codes & Sizes: As pe FSC	**Deferred with final opportunity due to following deficiencies:** i. Provide notarized credentials of manufacturer.

	Karachi Pakistan (ELI-00038) Evaluator: AD-VIII 4339 (K)	FSC: Germany Date of issue: 26 Aug 2019	Class D Shelf Life: 24 months	ii. Specify the models/codes to be registered of applied medical device and submit revised application form. iii. Therefore, provide Original, valid FSC in the country of origin duly attested by the embassy of Pakistan, covering Path Finder (Guiding Catheter) & its model/codes. iv. Explain the differences between various codes of GC & Sl models of guiding catheter as these models are not covered under Technical data sheet attached with application for registration. v. The DoC mentions 385 different codes of Guiding Catheter however the FSC of Germany mentions only 220 codes, explanation is required. Also provide EU Declaration of KDL Guiding Catheter for corroboration. vi. The firm applied the Guiding catheter with brand name "Path Finder", However the technical file and DoC states the brand name as "KDL", please clarify the situation and submit harmonized documents mentioning the applied name or otherwise. vii. Provide notarized copy of ISO 13485 (No. Q5 081681 0020 Rev. 03). viii. Provide design examination of applied medical device covering the models and codes of Path Finder (Guiding Catheter). ix. Explain why the submitted DoC mentions the class of applied product as IIa, while the product is of Class-D or Class-III? x. Provide Notarized and Embassy attested statement of Principle Manufactuerer on its letter head, that the product supplied to Pakistan with different brand name than Europe will be of same European specifications and quality.
84.	M/s Genus, 220, Block:3 DMCHS, S. Abdul Tawwab road,	M/s Shanghai Kindly Medical Instruments Co., Ltd., NO. 925, Jinyuan No. 1 Road, Shanghai China	G-Track (Diagnostic Angiographic Catheter)	**Deferred with final opportunity due to following deficiencies:**

	Karachi Pakistan (ELI-00038) Evaluator: AD-VIII 4340 (K)	FSC: Germany Date of issue: 26 Aug 2019	Codes & Sizes: As pe FSC Class D Shelf life 24 Months	i. Provide notarized credentials of manufacturer. ii. Specify the models/codes to be registered of applied medical device and submit revised application form. iii. Provide Original, valid FSC in the country of origin duly attested by the embassy of Pakistan, covering G-Track (Diagnostic Angiographic Catheter) & its model/codes. iv. The firm applied the Diagnostic Angiographic Catheter with brand name "G-Track", However the technical file and DoC states the brand name as "KDL – NT", please clarify the situation and submit harmonized documents mentioning the applied name or otherwise. v. Provide notarized copy of valid ISO 13485 (No. Q5 081681 0020 Rev. 03) vi. The DoC mentions 222 different codes of Guiding Catheter however the FSC of Germany mentions only 82 codes, explanation is required. Also provide EU Declaration of "KDL – NT" Diagnostic Angiographic Catheter for corroboration. vii. Explaint why the submitted DoC mentions the class of applied product as IIa, while the product is of Class-D or Class-III? viii. Provide Notarized and Embassy attested statement of Principle Manufactuerer on its letter head, that the product supplied to Pakistan with different brand name than Europe will be of same European specifications and quality.
85.	M/s Radiant Medical (Pvt) Ltd., 06 Sher Shah Block, New Garden Town, Lahore ELI: 00135 Evaluator AD-VIII	Legal Manufacturer: Carestream Health Inc. 150 Verona Street Rochester, New York 14608 (USA) Manufacturing site: Carestream Health Inc. (B-1049) West Ridge Road, Rochester, New York, 14615 (USA) FSC: USA	**DRX REVOLUTION MOBILE X-RAY SYSTEM** (Diagnostic Mobile X-Ray System) (Digital Radiography) Model: **DRXR-1**	**Deferred with final opportunity due to following deficiencies:** Provide stability studies. "The service life of product has been estimated to be 10 Years from the date of installation. However, studies were not provided. Therefore, provide studies to justify the proposed service life."

	2839	Valid till: 18.08.2022	Codes & Sizes: As per FSC Class-C Shelf Life: 10 years	
86.	M/s Radiant Medical (Pvt) Ltd., 06 Sher Shah Block, New Garden Town, Lahore ELI: 00135 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 with final opportunity due to following deficiencies:** Provide stability studies. "The service life of product has been estimated to be 10 Years from the date of installation. However, studies were not provided. Therefore, provide studies to justify the proposed service life."
87.	M/s A. S Enterprises, 03-Mozang Lahore, Pakistan ELI: 00190 Evaluator AD-VIII 1534-P	**Legal Manufacturer** Anhui Kangning Industrial (Group) Co., Ltd., South of Latitude three-way, west of longity 61 zone 239300 Tianchang, Anhui, People's Republic of China **EU Representative:** Shanghai International Holding Corp. (Europe) Eiffestrasse 80, D-20537, Hamburg, Germany FSC: China valid till: 01-03-2023	**Disposable Blood Transfusion Set with Needle** **Model:** KN/TS-01 KN/TS-02 KN/TS-03 KN/TS-04 Class-B Shelf Life: 3 years	**Deferred with final opportunity due to following deficiencies:** i. Submit revised properly filled application form containing relevant information against relevant field. ii. Provide Original FSC in the country of origin duly attested by Embassy of Pakistan. iii. Original and valid Free sale certificate (FSC) of any RRA as per rule 67, duly attested by embassy of Pakistan or CE certification or WHO pre-qualification in the light of Rule 15(2) of MDR 2017. iv. Complete list of various configurations to be registered supported with Free Sale Certificate or CE Marking Documents or WHO Prequalification Certifications etc. v. Clarify discrepancy in model numbers of applied **"Disposable Blood Transfusion Set with Needle"** as per DoC (KN/TS-01; KN/TS-02; KN/TS-03; & KN/TS-04) and FSC (KN-BT-01, KN-BT-02) or otherwise justify.

				vi. Provide label (as approved in the country of origin) and its packaging, promotion material and brochure for each applied model. vii. ISO 13485 is expired now. Provide valid copy. viii. Full Quality Assurance is expired now. Provide valid copy.
88.	M/s Verizon, 60-D, FCC, Zahoor Elahi Road, Gulgerg IV, Lahore ELI: 00087 Evaluator AD-VIII 2395-P	Legal Manufacturer: M/s Cook Ireland Limited O'Halloran Road National Technology Park, Limerick, Ireland FSC: Ireland Valid till: 13.08.2023	Cystotome™ Cystoenterostomy Needle Knife Codes & Sizes: CST-10 Class-C Shelf Life: 3 years	**Deferred with final opportunity due to following deficiencies:** i. The firm claimed that original LOA has been submitted in file No. 81 Billiary drainage catheter ultrathane. ii. The firm claimed that original FSC has been submitted in file No. 3 Cook HBS File, therefore attached copy with this file.
89.	M/s Verizon, 60-D, FCC, Zahoor Elahi Road, Gulgerg IV, Lahore ELI: 00087 Evaluator AD-VIII 2396-P	**Legal Manufacturer:** M/s Cook Ireland Limited O'Halloran Road National Technology Park, Limerick, Ireland FSC: Ireland Valid till: 13.08.2023	Geenen® Pancreatic Stent (Pancreatic Stents/Sets) Codes & Sizes: As per FSC Class-C Shelf Life: 3 years	**Deferred with final opportunity due to following deficiencies:** i. The firm claimed that original LOA has been submitted in file No. 81 Billiary drainage catheter ultrathane. ii. The firm claimed that original FSC has been submitted in file No. 3 Cook HBS File, therefore attached copy with this file.
90.	M/s. Sindh Medical Stores, 13-B, Block 6, PECHS, Karachi **Evaluator** AD-VII	InTec Products Inc. 332 Xinguang Road, Xinyang Ind. Area, Haicang, Xiamen, Fujian 361022, P.R.China.	Advanced Diagnostic Kit For Hepatitis B Virus Surface Antigen (ELISA) CAT. NO. ITP21001 96 Tests/Kit Class D Shelf life: 12 months FSC: China Valid Till: 25-10-2022	**Deferred** for provision of following:- i. In response to shortcoming regarding non availability of product in RRA / CE-certification / WHO pre-qualificiation, the company submitted declaration that they are marketing the same product since 2012 in 11 different non-reference regulatory authorities including Pakistan. The firm stated that their target market for this product is not EU hence not CE marked.
91.	M/s. Sindh Medical Stores, 13-B, Block 6, PECHS, Karachi. **Evaluator** AD-VII	InTec Products Inc. 332 Xinguang Road, Xinyang Ind. Area, Haicang, Xiamen, Fujian 361022, P.R.China.	Advance Quality One Step Malaria (p.f / p.v) Tri-Line Test CAT. NO. ITP11003, 25 Tests/Kit & 40 Tests/Kit" Class to be confirmed Shelf Life 24 months	**Deferred** for provision of following:- i. The firm attached photocopy of Belgium FSC (Cert. No.:100024; dt: 04-06-21). Provide Original valid embassy attested FSC. Contrary to that the firm submitted statement that their target market for this product is not EU hence not CE marked. ii. Provide Valid, original and embassy

			Class: D FSC: China Valid Till: 2-7-2021	attested Free Sale Certificate in the Country of Origin (China). No such FSC provided in reply as required vide shortcomming letter. iii. In response to shortcoming regarding non availability of product in RRA / CE-certification / WHO pre-qualificiation, the company submitted declaration that they are marketing the same product since 2016 in 12 different non-reference regulatory authorities including Pakistan and their target market for this product is not EU hence not CE marked.
92.	M/s. Sindh Medical Stores, 13-B, Block 6, PECHS, Karachi **Evaluator** AD-VII	Manufacturer InTec Products Inc. 332 Xinguang Road, Xinyang Ind. Area, Haicang, Xiamen, Fujian 361022, P.R. China.	Advanced Diagnostic Kit For Antibody to Hepatitis C Virus (ELISA) CAT. NO. ITP23001 96 Tests/Kit Shelf life 12 months FSC: China Valid Till: 25-10-2022 Class D	**Deferred** for provision of following:- i. The reply of firm found un-satisfactory. Therefore, clarify that why the brand name applied on Form-7A does not match the name on the FSC submitted. Need clarification or revision of Form-7A. ii.In response to shortcoming regarding non availability of product in RRA / CE-certification / WHO pre-qualificiation, the company submitted statement that EU is not target population for this product hence not CE marked.
93.	M/s. Sindh Medical Stores, 13-B, Block 6, PECHS, Karachi **Evaluator** AD-VII	InTec Products Inc. 332 Xinguang Road, Xinyang Ind. Area, Haicang, Xiamen, Fujian 361022, P.R. China.	Advanced Quality Rapid Anti HCV Test/ Diagnostic kit for antibody to hepatitis C Virus Collodial Gold CAT. NO. ITP01102, 40 Test/kit Shelf life 24 months Class D FSC: China Valid Till: 25-10-2022	**Deferred** for provision of following:- i. The firm submitted that the principle is manufacturing the exactly same product i.e. *Advanced Quality Rapid Anti HCV Test/ Diagnostic kit for antibody to hepatitis C Virus Collodial Gold* having same intended purpose but with two different codes i.e. ITP01102 and ITPW01152. ii. In response to shortcoming regarding non availability of product in RRA / CE- certification / WHO pre-qualificiation, the company submitted statement that EU is not target population for this product (ITP01102) hence not CE marked. The firm declared that this product is available in 37 countries since 2012 in different non-reference regulatory authorities including Pakistan. iii. Once again, the applied code (ITP01102) doesn't appear on provided photocopy of FSC in the country of origin china. The firm declares that FSC issued by NMPA does not reflect codes of product but the product names and specifications. iv. The stated that this product having code ITP01102 is not WHO pre-qualified.
94.	M/s. Sindh Medical Stores, 13-B, Block 6, PECHS, Karachi **Evaluator**	InTec Products Inc. 332 Xinguang Road, Xinyang Ind. Area, Haicang, Xiamen, Fujian 361022, P.R.China.	Advanced Quality Rapid Anti HCV Test/ Diagnostic kit for antibody to hepatitis C Virus	**Deferred** for provision of following:- i.The firm has submitted two applications with the same brand name but different codes i.e, ITP01102 and ITPW01152.

	AD-VII		Collodial Gold CAT. NO. ITPW01152,40 Test/kit FSC: China Valid Till: 25-10-2022 Class D Claimed Shelf Life 24months	**Code No.: ITPW01152 is WHO prequalified.** ii.The firm declares that FSC issued by NMPA does not reflect codes of product but the product names and specifications. Once againt the photocopy of FSC mentioned only name and don't have code with it. iii.Provide Embassy Attested FSC issued by China having codes on it. iv.Once again complete Stability studies were not provided. Therefore Provide complete stability studies to justify shelf life since the provided study is incomplete.
95.	M/s. Sindh Medical Stores, 13-B, Block 6, PECHS, Karachi **Evaluator** AD-VII	InTec Products Inc. 332 Xinguang Road, Xinyang Ind. Area, Haicang, Xiamen, Fujian 361022, P.R.China.	Advanced Quality ONE STEP HBsAg Test / Diagnostic Kit For Hepatitis B Virus Surface Antigen, Colloidal Gold (Whole Blood / Serum / Plasma) CAT. NO. ITP01003-Test Card 40 Shelf life 24 months Class D FSC: China Valid Till: 25-10-2022	**Deferred** for provision of following:- i. In response to shortcoming regarding non availability of product in RRA / CE-certification / WHO pre-qualificiation, the company submitted statement that EU is not target population for this product (ITP01003) hence not CE marked. The firm declared that this product is available in 34 countries since 2012 in different non-reference regulatory authorities including Pakistan.
96.	M/s. Sindh Medical Stores, 13-B, Block 6, PECHS, Karachi **Evaluator** AD-VII	InTec Products Inc. 332 Xinguang Road, Xinyang Ind. Area, Haicang, Xiamen, Fujian 361022, P.R.China.	Advanced Quality Rapid Anti HIV (1&2) Test / Diagnostic kit for Antibody to Human Immunodeficiency Virus (Collodial Gold) CAT. NO. ITP02002, 40Tests/Kit FSC: China Valid Till: 25-10-2022 Class D Shelf life 12 months	**Deferred** for provision of following:- i. The firm submitted that the principle is manufacturing the exactly same product i.e. *Advanced Quality Rapid Anti HIV (1&2) Test/ Diagnostic kit for antibody to Humanimmunodeficiency virus (Collodial Gold)* with two different codes i.e. ITP02002 and ITPW02152.. ii. As per document submitted by the firm the code No.: ITP02002 is not WHO pre-qualified. iii. Once again, the applied code (ITP02002) doesn't appear on provided photocopy of FSC in the country of origin china.
97.	M/s. Sindh Medical Stores, 13-B, Block 6, PECHS, Karachi **Evaluator** AD-VII	InTec Products Inc. 332 Xinguang Road, Xinyang Ind. Area, Haicang, Xiamen, Fujian 361022, P.R.China.	Advanced Quality One step Anti HIV (1&2) Test / Diagnostic kit for Antibody to Human Immunodeficiency Virus (Collodial Gold) CAT. NO. ITPW02152, 40Tests/Kit Class D Shelf Life 12 months FSC: China Valid Till: 25-10-2022 WHO PRE	**Deferred** for provision of following:- i. The firm has submitted two applications with the same brand name but different codes i.e, ITP02002 and ITPW02152. Code No.: ITPW02152 is WHO prequalified. ii.FSC doesn't have codes of product. The firm declared that FSC issued by NMPA doesnot reflect the product codes but only the product name and specifications.

98.	M/s Sindh Medical Stores, 13-B, Block 6, PECHS, Karachi **Evaluator** AD-VII	InTec Products Inc. 332 Xinguang Road, Xinyang Ind. Area, Haicang, Xiamen, Fujian 361022, P.R.China.	Advanced Quality One Step Anti TP (Treponema pallidum / Syphilis) Test / Diagnostic kit for Antibody to Treponema pallidum (Collodial Gold) CAT. NO. ITP03004, 40 Tests/Kit" Class C FSC: China Valid Till: 25-10-2022 Shelf life 24 months	**Deferred** for provision of following: i. In response to shortcoming regarding non availability of product in RRA / CE-certification / WHO pre-qualificiation, the company submitted statement that EU is not target population for this product (ITP03004) hence not CE marked. ii. However, the firm attached photocopy of Belgium FSC. Provide Original valid embassy attested FSC.

2. In the light of decision of MDB in its 37th meeting wherein Board in order to make quick disposal of cases decided for the firms who have submitted original, valid and Notarized/Embassy attested documents at the time of submission of application for registration/enlistment and is expired during the processing of applications, such firms shall only submit valid and original (where applicable) documents.

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

21/10/2022

(BABAR KHAN)
Additional Director (MDMC)/
Secretary MDB
Tele: 051-9262180