Government of Pakistan Ministry of National Health Services, Regulation & Coordination Drug Regulatory Authority of Pakistan

<u>DECISIONS OF 112th MEETING OF THE MEDICAL DEVICE BOARD (MDB)</u> HELD ON 11-12-2025 (MANUAL APPLICATION PART-II)

112th meeting of the Medical Device Board (MDB) was held in the committee room of Drug Regulatory Authority of Pakistan (DRAP), Prime Minister Health Complex, Chak Shahzad, Islamabad on 11th December, 2025. The meeting was chaired by Dr. Babar Khan, Chairman Medical Device Board, DRAP, Islamabad and attended by the following:

	Name and Designation/Department	Position in the MDB
S.No.	, 0	40° 00'
1.	Dr. Babar Khan, Director, Medical Devices	
	& Medicated Cosmetics, Drug Regulatory	Chairman
	Authority of Pakistan, Islamabad.	400
2.	Mr M Salik Zahid, Chief Drugs Inspector,	Member
	Nominee of DGHS Baluchistan	(attended meeting through videolink)
3.	Prof Dr Saqib Shafi Sheikh, Interventional	Member
	Cardiologist, 98 Babar block, New Garden	(attended meeting through videolink)
	Town, Lahore	
4.	Prof. Dr. Mehmood Ahmad, Former Dean,	Member
	Islamia University, Bahawalpur, House	(attended meeting through videolink)
	No. 144-D, St. No.14, OPF Housing	
	Scheme, Phase-1, Khayaban Jinnah, Near	
	Raiwind Road, Lahore.	
5.	Abdul Aleem Awan, Assistant Prof.	Member
	Pharmacy Department, Abbottabad	(attended meeting through videolink)
	University of Science & Technology,	
	Havelian.	711 (14. 3.
6.	Dr. Farid Khan, Senior Consultant Neuro	Member
	Surgery/Director Trauma &	(attended meeting through videolink)
	Emergency/Focal Person MSDS, Primary	
	& Secondary Healthcare Department,	eil's
	Punjab.	
7.	Dr. Ayesha Ali, Department of Pharmacy,	Member
	Pakistan Institute of Medical Sciences,	
0	Islamabad (Hospital Pharmacist).	N 1
8.	Mr. Luqman Ali, System Analyst, Pakistan	Member
0	Institute of Medical Sciences, Islamabad.	Mandan
9.	Mr. Wajahat Ali, Biomedical Engineer,	Member
	Liaquat College of Medicine and Dististry	(attended meeting through videolink)
	& Darul Sehat Hospitaol, Karachi.	
10.	Ms. Tazeen Saeed Bukhari, Biomedical	Co-Opted Expert
10.		• •
11.	C	
	1	meen cam becoming
11.	Engineer Mr. Ayyaz Ahmed, Additional Director (MD&MC), DRAP, Islamabad.	(attended meeting through videolink) Member-cum-Secretary

SR.NO.	NAME OF EVALUATOR	DESIGNATION
1.	Mr. Saadat Ali Khan	Deputy Director
2.	Mr. Waqar Ahmad	Deputy Director
3.	Mst. Sadaf Ahmad	Deputy Director
4.	Mr. Dr. Ghayoor Ahmad	Deputy Director
5.	Mr. Muhammad Ashfaq	Deputy Director
6.	Mr. Hafiz Muhammad Asif Iqbal	Deputy Director
7.	Mr. Rana Ahsan-ul-Haq Athar	Deputy Director
8.	Mr. Muhammad Amin	Deputy Director
9.	Mr. Ammar Ashraf Awan	Deputy Director
10.	Mr. Hanif Ullah	Deputy Director

The meeting commenced with the recitation of the Holy Quran. The Chairman, MDB welcomed all the participants. The Evaluators assisted the secretary in presenting the agenda of the meeting

Monday, 29 December, 2025, 9:9:1 AM

Assistant Director, 2025, 9:9:1 AM

Monday, 29 December, 2025, 9:9:1 AM

(Evaluator: Mr. Muhammad Amin, Deputy Director-IX)

Item No. I(A): APPLICATIONS FOR GRANT OF ESTABLISHMENT LICENSE TO

MANUFACTURE MEDICAL DEVICES UNDER MEDICAL DEVICES RULES,

2017

FRESH CASES-ELM:

S.#	Name and Address of Establishment	Name of Production Incharge	Name of QC Incharge	Decision of MDB
	Surgicare Cotton	Sabir Hussain	Nasira	The board considered the inspection report and
	Industries,	B-Pharm	Muhammad	recommendations of panel and approved
		Drug Testinf	BS (Hons.)	establishment licence to manufacture medical
	Office/godwon:	Laboratory	Biochemistry	devices for following sections:
	Chak No. 38-G.D,	Balochistan	QC Analyst	Absorbent cotton wool section.
	Faisalabad Road	Deputy Director	Experience 6	Crepe Bandage section
	Okara	Experience: 5	Years	Gauze Section (Sterile / Non Sterile).
1		Years	n' m	Cotton Bandage section."
		16	or Go,	N.B: The firm shall not perform sterilization
		65		procedure of Sterile Gauze Bandages from M/s Paras
		P 00		Radiation Services (PARAS), Lahore unless get
				approval of outsourcing for the same in light of Rule
				67 of Medical Devices Rules, 2017.
			•	

Item No. 1B: APPLICATION FOR GRANT OF ESTABLISHMENT LICENCE TO IMOPRT MEDICAL DEVICES UNDER MEDICAL DEVICES RULES, 2017.

FRESH CASES ELI

S.#	Name of Establishment	Name of Qualified Technical Person	Name of Management	Decision
1.	M/s Biomedics Pharmaceutica (Pvt.)	Syeda Nazia	Nasir Ali	Approved
	Ltd,	Hassan Naqvi	Niala Aziz	
	Office: 368-DD Phase IV, DI-IA Lahore, Cantonment, Lahore	Pharm D	Partner	
	Godown: Office No. 3, Rehmat Ullah building Green Homes street 308, Multan road, Lahore.			
2.	M/s Vertex International, first floor,	Muhammad	James Iqbal	Approved
	51/C-I, Park Avenue, university town,	Usama		
	Peshawar.		CEO	
		Medical Lab		
		Technologist		

3.	M/s RAAB Scientific Solutions,	Khubaib Shakeel	Uzair Zahid	Approved
	Office /Codesum 4/2 Constant	Dan Diames Heat	CEO	
	Office/Godown: 4/2 Canal park,	Bsc Biomedical	CEO	
	Gulberg-II, Lahore Lahore.	Engineering		
4.	M/s AR Enterprises,	Muhammd Shan	Muhammad Rashid	Approved
	•			
	Office/godown: P-8/1, Muslim town-	Pharm D	CEO	
	B, Sargodha road, Faisalabad.			
5.	M/s Baihe Medical Group (SMC-	Muhammad	Muhammad Asghar	Approved
	Pvt.) Ltd,	Asghar	3,0,.	
			CEO	
	Office/godown: Apartment No. 102,	Pharm D	S	
	1 st Floor, Florets Luxury Apartment, Ahmad Block, New Garden Town,	G, *0, ~U,		
	Lahore.	Con Vo		
6.	M/s Hcare International	Naima Safdar	Azhan ul Hassan	Approved
0.	W/S Heare international	Tuma Saraa	Syeda Hiba Ali	ripproved
	Office/godwon: Plot No A-54 ground	Pharm D	27000 11100 1111	
	floor RECHS society bock 13-A	C	Partner	
	Gulshan e Iqbal karachi Karachi			
7.	M/s MEDI CRAFT DEVICES		MR. SHAHID	Approved
	(PRIVATE) LIMITED	MRS. SUMRA	AKHTAR	
	1073	ASHFAQ	Sufian Shahid	
	Office/godown: 547-F, Canal View		Hasan Naeem	
	Society, 12-KM, Multan Road Lahore	Pharm D	Abdul Rehman	
0	M/- CLUZEM INTERNIATIONIAL.	M-11	Mrs. Zunera Muneeb	A 7
8.	M/s SUZEM INTERNATIONAL;	Muhammad ahmed	Muhammad Umer Khan	Approved
	Office/godown: House No.16 block	anneu	IXIIali	
	A-5 bismillah city unit no.10	B.Sc Biomedical	CEO	
	104: Color of Handanolo of	Engine	79.	
9.	M/s Alexiz Solution (private) laimited, Karachi.		Syed Afaq Ahmad	Deferred. The
	laimited, Karachi.	A 40, 00		board
	AUI	160	CEO	deferred the
	700			case and
				approved
	Laine	-611		request of the
	1510-0	0		firm to delay
	651-06	V		inspection for
				one month.

ITEM NO. I(C): INCOMPLETE APPLICATIONS FOR GRANT OF ESTABLISHMENT LICENSE TO IMPORT

1.	M/s Ibne-Seena Health and	Hira Quddos	Muhammd Irfan	The firm was asked to submit below mentioned
	Care Society,			documents for further processing their
			CEO	application for grant of ELI:
		Pharm D		

Office: Street No. 22, Block 6, Main University road, gulshan e Iqbal, Karachi.	 Registration of firm as commercial entity with FBR or any other competent authority. NOC from Ministry of Interior.
Godown: Ibne Seena Hospital, 3 rd Floor, Street 22/B, Main University road, block 6, Gulshan e Iqbal, Karachi.	However, the firm failed to provide the requisite information. Submitted for consideration of board please

Decision:

The board deliberated on the application of the firm for grant of establishment license to import medical devices and response submitted by the firm subsequent to the communication of shortcomings.

The board also took opinion of Legal Affairs Division and observed that the firm is an NGO which is primarily a non-commercial activity and rule 24 of Medical Devices Rules 2017 to which applicant is referring to for grant of license is for personal and hospital use of medical devices. Therefore, applicant need to register their organization as commercial entity with FBR/ SECP and/or Registrar of firms.

In view of above, the board decided to reject application of M/s Ibn-e-Seena Health and Care Society Karachi for establishment license to import medical devices under Medical Devices Rules 2017.

Item No. I(D):

APPLICATIONS FOR GRANT OF ESTABLISHMENT LICENSE TO IMPORT MEDICAL DEVICES UNDER MEDICAL DEVICES RULES, 2017.

DEFERRED CASES OF ELI:

S. #	Name of	Name of Qualified	Decision
	Establishment	Technical Person	
1.	M/s Precimmo (Pvt)	Dr. Shoaib Rao	he board considered request of the applicant in the light
	Ltd., F-748/N, Old		of Rule 6(4) of Medical Devices Rules 2017 regarding
	Star Labour Colony,	Dr. rer. nat (Cancer	qualifications of technical staff/ qualified person for
	S.I.T.E, Karachi	Biology)	establishment license to import medical devices and
			accepted degree in Molecular Genetics (BS) and Cancer
		G _o	Biology (Ph.D) as a degree in broader field of
			Biotechnology which is primary requirement of law.
			Therefore, board approved establishment license to
		V0, U11	import medical devices in favor of M/s Precimmo (Pvt)
			Ltd., F-748/N, Old Star Labor Colony, S.I.T.E, Karachi
		"OI -OI	and approved Dr. Shoaib Rao (Ph.D) as qualified
		iche co	person.
		es O	<u></u>
		5 - O	

Item No. I(E): <u>APPLICATIONS FOR RENEWAL OF LICENSE TO IMPORT MEDICAL DEVICES UNDER MEDICAL DEVICES RULES, 2017.</u>

FRESH CASES FOR RENEWAL OF ELI:

S.#	Name of Establishment	Name of Qualified Technical Person	Name of Management	Decision
1.	M/s Sorabjee Patel & Co,	Asif Wazir	Romina Mansoor,	Approved
	Office/Godown: 45 Badri Building 1.1, Chundrigar road, Karachi.	Pharm D	CEO	
	ELI-00067			
2.	M/s ACP System, Office/godown: 13 & 23	Samara Ahmed Pharm D	Jawad Akhtar Tahir Mahmood Shaikh Asadullah tahir	Approved
	Naval Fleet Club, Iqbal (SJ) Shaheed road, Karachi.	O Soil	Partner	
3.	ELI-00001 M/s K.S Agencies,	M Shafi Fahad	M Idress Memon	Approved
3.	Office: Office No. 210, Business arcade, Main University Road, Karachi. Godown: 33 & 34 Business arcade, Main University	Pharm D	CEO	Арргочец
	Road, Karachi. ELI-00382	3,		
4.	M/s Save on Healthcare Office/godown: House number 06, Street no. 2, Ibraheem colony, Link road, aziz bhatti town, Lahore	Muhammad RAzi Butt Pharm D	M Jamil Hassan Shahbaz idress khan Muhammad Amir	Approved
	ELI-00027	AUI CCL	79	
5.	M/s Shams Scientific traders, Office: Office NO. 7, First Floor, Sadiq plaza, Faisalabaf.	Aqsa Sheikh Pharm D	Irfan Ayaz CEO	Approved
	Godown: 22-Y-J, Madina Town, Lahore ELI-00459	3,		
6.	M/s Ahmad Medix (Pvt) Ltd,	Rabia Itaiz Pharm D	Dr Sohail Mukhtar Ahmad Adeel Ahmad Kashif Sohail	Approved

7.	Offic/godown: 129/6, Quaid- e-azam Industrial estate, Lahore. ELI-00380 M/s Ali Noor Industries,	Ms Tabinda	Partner Ahsun Ali Noor	Approved
	Office/Godown: office no. 1, 2 nd floor, central point plaza, Gulberg III, Lahore. ELI-00816		Rao Ali Athar khan Partner	
8.	M/s Advance Cardiology system., Office/Godown: 316,317, Building -11, 3 rd Floor, Panorama centre, Raja Ghanzafar Ali Khan road, Near Hotel Avari tower, Karachi.	Hina Pharm D	Mohammad Sadiq CEO	Approved
9.	M/s DIA SCIENT INTERNATIONAL Office: 11,12,13,14, EMAAN ARCADE, IQBAL STADIUM ROAD, NEW CIVIL LINE, Faisalabad Godown: 35-G, DIA, Scient Medical Complex, Building Raja road, Gulistan Colony No. 01 Near Aziz Fatima Hospital Raja Road Faisalabad ELI-00439	Rhuram Shehzad Post Diploma of Associate Engineer in biomedical Technology	Muhammad Ehsan CEO	Approved
10.		Ms Sadaf Naz Pharm D	Sarfraz Ali Shah CEO	Approved

11.	M/s Sindh Medical Stores,	Usman Ghani	M Younas Billoo Kishwar Billoo	Approved
	Office/godown: 13-B, Block	B-Pharm	Tasmia Abeer	
	6, PECHS, Shahrah E faisal			
	Karachi.			
	ELI-00010			
12.	M/s Uniferoz (Pvt) Limited,	Nazeen Ayub	Tariq Mehtab Feroz	Approved
	0.000 - 71 - 32 - 02 - 0		M Sadiq Mehtab Feroz	
	Office: Plot No. 32/8 and	Pharm D	Muneer Mehtab feroz	
	33/2, Sector-15, Korangi Industrial Area, Karachi.		Mehtab Udidn feroz	
	ilidustifat Afea, Karaciii.	4.6	1112.00	
	Godown: Plot No. 108 &		16, 0.	
	109 Sector-23, Korangi		(4) (1)	
	Industrial Area, Karachi		00	
	EL 1 0000 4	120011180		
13	ELI-00284 M/s MIRAJ	Qindeel Mushtaq Ahmed	Mushtaq Ahmad	Deferred for
	CORPORATION,	Qinacci washaq i minca	Trustitud Tittilud	approval of
	,	M.Phil Biotechnology	CEO	technical staff
	Office/Godwon: Office no	·SIS 0		and fee.
	13-14, second floor, Jinnah	200		
	Business center, Chandni			
	Chowk, Rawalpindi	3,		
	ELI-00326			
14.	M/s Nimrall Farma	Ms Tanya Waseem	Shahzad Saeed	Deferred for
			Muhammad Kashif	approval of
	Office: 15E 2nd Floor	Pharm D	Kalsoom Mubbshir	technical staff
	Sheikh Building Bata Chowk, Aziz Bhatti Road		112,01.	and fee
	Lalkurti Rawalpindi		(1), 0,	
	Lancara Rawaipinai	200	1001	
	Godown:	, Gr 40	1 201/2	
	Nimrall Farma Flat No. E-	AUI LOCK		
	15, Aziz Bhatti Road, 2nd	100 cill		
	Floor, LalKurti, District	h The Vol		
	Rawalpindi	Alodul Gadificació		
	ELI-00251	cist of		
15.	M/s Surgi vision,	Ayza Nawaz	Babar Abbas	Deferred for
	0.65. (0.1. 100.33	N D	CTC.	approval of
	Office/Godown: 108-H, Model town, Lahore.	Pharm D	CEO	technical staff
	wiouei towii, Lanore.			and change of godown with
	ELI-00384			complete fee and
	Mi			relevant
				documents.

16.	M/s Cabbot Surgicals, Office: Ho No CB 6060 Rose Lane 3-A New Lalazar Rawalpindi. Godown: 09 Rose Lane 01, Gulberg Avenue, New Lalazar Rawalpindi. ELI-00415	Firdous Rasheed Pharm D	Muhammad Attique Shahid CEO	The firm shall also submit an undertaking that the facility shall not be used for residential purposes and this can be inspected any time without hindrance. Deferred for approval of technical staff and change of godown with fee and relevant documents
17.	M/s Biomax international, Office/godown: P-150, Street No. 8, Opposite allied hospital near Daewoo terminal Akbarabad, Chowk ,Faisalabad. ELI-00950	Rubab asghar Bs Hons Medical Laboratory technology	Kashif Javed CEO	Deferred for approval of management change with fee and relevant documents
18.		Muhammad Luqam BS Biotechnology	Zeeshan Haider CEO	Deferred for approval of change of godown with fee and relevant documents
19.		Wajiha Ghalib Pharm D	Mohammad Yousaf CEO	Deferred for approval of technical staff and change of godown with complete fee and

			MIS).9:1 A	relevant documents. The firm shall also submit an undertaking that the facility shall not be used for residential purposes and this can be inspected any time without hindrance
20.	M/s Medi Bridge, Office: Plot No. 500, Block-D, 2 nd Floor, M.A Jinnah Road, Lahore. Godown: Plot No. 500, Block-D, Ground Floor, M.A Jinnah Road, Lahore. ELI-00058	Haroon Ahmad Bio Medical Engineer	Iftikhar Ahmad CEO	Deferred for approval of technical staff and fee
21.	M/s Accu Sight, Office /Godown: 131 - Nasheman-e-Iqbal, Housing Society, Lahore ELI-00049	Maryam Ishaq Pharm D	Zaigham Mansoor Khan CEO	Deferred for change of premises to a non-residential area within 02 months failing which show cause notice to be issued for cancellation of license.
22.	M/s IRTEQA BIOTEK, Office/Godown: H 159, St 8 Chaklala Scheme 3 ELI-00218	Mahwish Dar M.phil biochemistry	Muhammad Azm Saeed Dar CEO	Show cause notice. The board considered the inspection findings and observed grave violations of conditions of license under Medical Devices Rules 2017. Therefore, it was decided to issue show cause notice to the firm for cancellation of

23.	M/s Servier Research and Pharmaceuticals Pakistan (Pvt) Ltd,	Mrs. Anila Zareen	Nicolas C.Marie Joseph Bouts Pierre Albert Paul	license and to provide opportunity of personal hearing to the firm. The board considered the written statement
	Office: 65 Main Boulevard Gulberg Lahore Godown: Kot Abdul Malik Ferozwala, District Sheikhupura. ELI-00179	dul Gedir	Dussaud	of the firm and decided to issue notice of personal hearing before cancellation of license to comply with conditions of law.
24.	M/s Don Valley Pharmaceuticals (Pvt) Ltd, Office/Godown: 15-C/2, Vogue Tower, Gulberg III, MM Alam Road, Lahore ELI-00561	Mr. Mukhtar Ahmed	Dr. Shahla Javed Akram Mr. Saad Javed Akram Mr. Abdul Shabbir Khokhar	The board considered the written statement of the firm and decided to issue notice of personal hearing before cancellation of license to comply with conditions of law.

Item No. I(E): <u>APPLICATIONS FOR GRANT OF RENEWAL OF LICENSE TO IMPORT MEDICAL DEVICES UNDER MEDICAL DEVICES RULES, 2017.</u>

DEFERRED CASES FOR RENEWAL OF ELI:

S. #	Name of Establishment	Name of Qualified	Name of Management	Decision
		Technical Person		
1.	M/s Meximp Technologies,	Muhammad Samiulahaq	Faiyaz Ahmad	Approved
	B-62, Block-5, Gulshan-e-	*31, 68,		
	Iqbal, Karachi (ELI- 00052)	B-Pharmacy	Mudassir Ahmad	
		55,0	Inamdar	
2.	M/s AA Enterprizes,	Abu Bakar Siddique	Muhammad Waqas	Approved
	·	Bs Bio medical		
	Offce: 57, 15-16 First Floor	Engineering		
	Mobi Plaza, Haider Road,			
	Saddar, Rawalpindi			
	Miles			
	Godown:			
	Plot No. 4, House No. 286/4			
	, Main Peshawar Road,			
	Rawalpindi Westridge,			

	Adjacent to Am-Anglo School, Near Polo Ground, Rawalpindi.			
3.	M/s Optical Palace, Hemani Mension, M.A Jinnah Road Opposite KMC , G.P.O, Box No. 1249, Karachi(ELI-00527)	Muhammand Ovais Siddiqui Pharm D	Atif Jamil Ur Rehman Aamir Rahman Akif Rehman	Approved
4.	M/s Surebio Diagnostic, EE- 10, Defense View Phase II, Near Iqra University, Shaheed-e-Millat, Express Way, Karachi ELI: 00084	Romana Adil B-Pharm	Shaikh Shakeel Ahmed CEO	Approved

${\bf Agenda\ Item\ No.\ II\ \underline{ENLISTMENT/REGISTRATION\ OF\ \underline{MEDICAL\ DEVICES\ FOR\ \underline{IMPORT.}}}$

Dr. Hanif Ullah (Deputy Director-XI)

Agenda Item II (a) <u>APPLICATIONS SUBMITTED ON CASE MANAGEMENT SYSTEM:</u>

	TOP TRADER, 2 nd Floor, Usman Plaza, Commercial Area, Chaklala Scheme-3, Rawalpindi ELI -01045 R&I Date: NIL Fee: 31000/-	Legal Manufacturer: Xuzhou Kaixin Electronic Instrument Co., Ltd. Kaixin Mansion	Brand Name: AB SCAN ODU5 Generic Name: Ophthalmological A/B	Deferred for: Submit the R&I record the application. Submit the scanned copy of Form-7A.
1	Slip # 70191730288 This evaluation is based on the on-line data submitted through E-App. Tracking ID: 55J-Z6B-Q45J	C -01, Economic Development Zone, Xuzhou, Jiangsu, China LOA Type: scanned copy Notarization: Yes, CCPIT Validity: NIL FSC Type: scanned copy Issued by: Jiangsu Medical Products Administration Legalization: Apostilled the notarization of CCPIT Validity: 12.11.2026 ISO – Certificate: Type: scanned copy Notarization: yes, CCPIT Validity: 31.03.2026 CE certificate: Type: scanned copy Notarization: CCPIT notarized the declaration of the firm, not CE certificate. Validity: 26.05.2024 Extended till 31.12.2028	Mode Ultrasound Scanner ODU5 Applied as: Kit Class: B Models/Code/sizes (as per FSC & application: ODU5 Shelf Life: NIL	Submit notarized copy of LOA with validity. Submit legalized copy of valid FSC in the country of origin. The device Ophthalmologic al AB mode ultrasound scanner ODU5 has been written as "Ophthalmologic al AB mode ultrasound scanner ODU3/5. Clarification is required. Submit notarized copy of valid ISO 13485 certificate. Shelf life verification / stability studies report is required. Submit DOC on the letterhead of the firm. Clarification is required about the applied grouping. You have mentioned the Probe covers or gel. footswitch (as optional) ultrasound gel, thermal printer, and disposable probe sleeves as part of the kit along with correction of the grouping. Clarification is required. Notarized copy of CE certificate is required.
	TOP TRADER, 2nd Floor, Usman Plaza, Commercial Area,	Legal Manufacturer: Xuzhou Kaixin Electronic	Brand Name: ASCAN OD1-A	Deferred for: Submit the R&I record the application.

Chaklala Scheme-3,	Instrument Co.,	Generic Name: Bio &	Submit the scanned copy
Rawalpindi	Ltd.	Pachy	of Form-7A.
ELI -01045	Kaixin Mansion	Meter	Submit notarized copy of
R&I Date: NIL	C -01, Economic	Applied as: Kit	LOA with validity.
Fee: 31000/-	Development	Class: B	Submit legalized copy of
Slip # 7069649429	Zone, Xuzhou,	Models/Code/sizes (as	valid FSC in the country
This evaluation is based on the on-line	Jiangsu, China	per FSC & application:	of origin.
data submitted through	LOA	ODU5	The device "Bio &
E-App.	Type: scanned copy	Shelf Life: NIL	Pachy
Tracking ID: T8Z-	Notarization: Yes, CCPIT		Meter" has been written
8ZY-HTL9	Validity: NIL	- A	as "Ophthalmological
021 11129	FSC	15) O''	ultrasonic measuring
	Type: scanned copy		instruments OD1-
	Issued by: Jiangsu Medical		A/P/AP". Clarification is
	Products Administration	(4) (0)	required.
	Legalization:), ² 0 _h	Submit notarized copy of
	Apostilled the notarization of		valid ISO 13485
	CCPIT		certificate.
	Validity: 12.11.2026		Shelf life verification /
	ISO – Certificate:		stability studies report is
	Type: scanned copy		required.
	Notarization: yes, CCPIT		Submit DOC on the
	Validity: 31.03.2026		letterhead of the firm.
	CE certificate:		Clarification is required
	Type: scanned copy		about the applied
	Notarization: CCPIT		grouping.
20	notarized the declaration of		You have mentioned the
10,	the firm, not CE certificate.		gel, probe covers,
B.	Validity: 26.05.2024		footswitch (as optional),
	Extended till 31.12.2028		printer, and system
		.C)^	calibrator as part of the
		1/19, 0.	kit. Clarification is
		(1/4, 0)	required along with
	2011	1, 52,	correction of the
	, Q		grouping.
	"" " "C"	133	Notarized copy of CE
	100 -i100	X 1	certificate is required.

Agenda Item II (b) <u>APPLICATIONS SUBMITTED (HARD DOSSIERS):</u>

S. #	Name of Firm	Manufacturer Name	Name of Medical	Decision
		00	Device	
1.	Martin Dow	Legal Manufacturer:	Brand Name: iFlash-	Deferred for:
	Specialties Private	Shenzhen Yhlo Biotech Co.,	NT-proBNP	The application form has
	Limited, Nice Trade	Ltd., Building 1, Yhlo	Generic Name:	been signed by Director
	Orbit Building 7th	Biopark, Baolong 2nd Road,	Chemiluminescent	Regulatory Affairs.
	Floor, 44-A, Block-6,	Baolong Subdistrict,	Immunoassay (2 x 50	Authorization letter for
	PECHS, Shahrah-e-	Longgang District, Shenzhen,	test/kit)	the signatory is required.
	Faisal, Karachi	Guangdong, China	Applied as: Kit	Declaration on stamp
	Godown: Plot No. 130, Sector-15,	Mfg site:	Class: C	paper to be issued in the

	Korangi Industrial Area, Karachi ELI-00160 R&I Date: 17.07.2025 Fee: 62000/- Slip # 7229139749 The firm has referred to RRA FSC submitted in the dossier of HSV 1 & 2 IgG control.	Building 2, Yhlo Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong, China LOA Type: photocopy of notarized document Notarization: Yes, CCPIT Validity: 31.12.2025 FSC Type: original Issued by: NIL Legalization: Apostilled the notarization of CCPIT Validity: 12.01.2026 FSC in RRA Type: photocopy Issued by: TGA, Australia Legalization: Embassy attested	Code/sizes (as per FSC & application): C89244-S C89244 Shelf Life: 18 month	name of the firm / signatory is required. English translation of the issuing authority in FSC is required. Notarized copy of LOA and legalized copy of FSC (origin) is required.
	Mo	Issue date: 21.01.2025 ISO – Certificate: Type: scanned copy Notarization: CCPIT notarized the declaration of the firm, not certificate. Validity: 09.06.2028		
2.	Martin Dow Specialties Private Limited, Nice Trade Orbit Building 7th Floor, 44-A, Block-6, PECHS, Shahrah-e- Faisal, Karachi Godown: Plot No. 130, Sector-15, Korangi Industrial Area, Karachi ELI-00160 R&I Date: 17.07.2025 3241-C-Sindh Fee: 62000/- Slip # 18631516 The firm has referred to RRA FSC submitted in the dossier of HSV 1 & 2 IgG control, and and FSC (origin) ISO certificate in iFlash- NT-proBNP dossier.	Legal Manufacturer: Shenzhen Yhlo Biotech Co., Ltd., Building 1, Yhlo Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong, China Mfg site: Building 2, Yhlo Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Longgang District, Shenzhen, Guangdong, China LOA Type: photocopy of notarized document Notarization: Yes, CCPIT Validity: 31.12.2025 FSC Type: photocopy Issued by: NIL Legalization:	Brand Name: iFlash-CA242 Generic Name: Chemiluminescent Immunoassay (2 x 50 test/kit) Applied as: Kit Class: C Code/sizes (as per FSC & application): C86069-S C86069 Shelf Life: 18 month	Deferred for: The application form has been signed by Director Regulatory Affairs. Authorization letter for the signatory is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required. English translation of the issuing authority in FSC is required. Notarized copy of LOA and legalized copy of FSC (origin) is required.

3.	Martin Dow Specialties Private Limited, Nice Trade Orbit Building 7th Floor, 44-A, Block-6, PECHS, Shahrah-e- Faisal, Karachi Godown: Plot No. 130, Sector-15, Korangi Industrial Area, Karachi ELI-00160 R&I Date: 17.07.2025 3249-C-Sindh Fee: 62000/- Slip # 18631516 The firm has referred to RRA FSC submitted in the	No Validity: 12.01.2026 FSC in RRA Type: photocopy Issued by: TGA, Australia Legalization: Embassy attested Issue date: 21.01.2025 ISO – Certificate: Type: photocopy Notarization: No Validity: 09.06.2028 Legal Manufacturer: Shenzhen Yhlo Biotech Co., Ltd., Building 1, Yhlo Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong, China Mfg site: Building 2, Yhlo Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Longgang District, Shenzhen, Guangdong, China LOA Type: photocopy of notarized document Notarization: Yes, CCPIT Validity: 31.12.2025	Brand Name: iFlash-Gastrin-17 Generic Name: Chemiluminescent Immunoassay (2 x 50 test/kit) Applied as: Kit Class: C Code/sizes (as per FSC & application): C86055-S C86055 C86055-L Shelf Life: 18 month	Deferred for: The application form has been signed by Director Regulatory Affairs. Authorization letter for the signatory is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required. English translation of the issuing authority in FSC is required. Notarized copy of LOA and legalized copy of FSC (origin) is required.
	IgG control, and FSC (origin) ISO certificate in iFlash-NT-proBNP dossier.	FSC Type: photocopy Issued by: NIL Legalization: No Validity: 12.01.2026 FSC in RRA Type: photocopy Issued by: TGA, Australia Legalization: Embassy attested Issue date: 21.01.2025 ISO – Certificate: Type: photocopy Notarization: No Validity: 09.06.2028	81,5052,9:9.	
4.	Martin Dow Specialties Private Limited, Nice Trade Orbit Building 7th Floor, 44-A, Block-6,	Legal Manufacturer: Shenzhen Yhlo Biotech Co., Ltd., Building 1, Yhlo Biopark, Baolong 2nd Road, Baolong Subdistrict,	Brand Name: iFlash- SCC Generic Name: Chemiluminescent	Deferred for: The application form has been signed by Director Regulatory Affairs. Authorization letter for

	DECHE Chahaal a	Longgong District Classeller	Immunosassy (2 50	the signatory is required
	PECHS, Shahrah-e- Faisal, Karachi	Longgang District, Shenzhen,	Immunoassay (2 x 50	the signatory is required.
	Godown: Plot No.	Guangdong, China	test/kit)	Declaration on stamp
	130, Sector-15,	Mfg site:	Applied as: Kit	paper to be issued in the
	Korangi Industrial	Building 2, Yhlo Biopark,	Class: C	name of the firm /
	Area, Karachi	Baolong 2nd Road, Baolong	Code/sizes (as per FSC	signatory is required.
	ELI-00160	Subdistrict, Longgang	& application):	English translation of the
	R&I Date: 17.07.2025	District, Shenzhen,	C86067-S	issuing authority in FSC
	3242-C-Sindh	Guangdong, China	C86067	is required.
	Fee: 62000/-	LOA	Shelf Life: 18 month	Notarized copy of LOA
	Slip # 114602501	Type: photocopy of notarized		and legalized copy of
	The firm has referred	document		FSC (origin) is required.
	to RRA FSC	Notarization: Yes, CCPIT	.(5) (1))
	submitted in the	Validity: 31.12.2025		
	dossier of HSV 1 & 2	FSC	' (1/2, 20,	
	IgG control, and FSC	Type: photocopy	44 001	
	(origin) ISO	Issued by: NIL		
	certificate in iFlash-	-	75.	
	NT-proBNP dossier.	Legalization:	4.	
	TVI probivi dossier.	No		
		Validity: 12.01.2026		
		FSC in RRA		
		Type: photocopy		
		Issued by: TGA, Australia		
		Legalization:		
		Embassy attested		
		Issue date: 21.01.2025		
		ISO – Certificate:		
		Type: photocopy		
	, 10	Notarization: No		
		Validity: 09.06.2028		
5.	Martin Dow	Legal Manufacturer:	Brand Name: EB VCA	Deferred for:
	Specialties Private	Shenzhen Ever-Blue Biotech	IgG, IgM & IgA	The application form has
	Limited, Nice Trade	CO., Ltd, Building 1, YHLO	Control	been signed by Director
	Orbit Building 7th	Biopark, Baolong 2nd Road,	Generic Name:	Regulatory Affairs.
	Floor, 44-A, Block-6,	Baolong Subdistrict,		Authorization letter for
	PECHS, Shahrah-e-		Immunoassay Controls	
	Faisal, Karachi	Longgang District, Shenzhen,	EB VCA IgG	the signatory is required.
	Godown: Plot No.	Guangdong 518116, China	(Negative control	Declaration on stamp
	130, Sector-15,	Mfg site:	2x2ml) (positive	paper to be issued in the
	Korangi Industrial	Shenzhen Yhlo Biotech Co.,	control 2x2ml)	name of the firm /
	Area, Karachi	Ltd. Building 2, Yhlo	EB VCA IgM	signatory is required.
	ELI-00160	Biopark, Baolong 2nd Road,	(Negative control	English translation of the
	R&I Date: 10.07.2025	Baolong Subdistrict,	2x2ml) (positive	issuing authority in FSC
	3061-C-Sindh	Longgang District, Shenzhen,	control 2x2ml)	is required.
	Fee: 62000/-	Guangdong, China	EB VCA IgA	The address of legal
	Slip # 88042480876	LOA	(Negative control	manufacturer shall be the
	The firm has referred	Type: photocopy of notarized	2x2ml) (positive	same in Form 7A, LOA,
	to RRA FSC	document	control 2x2ml)	FSC (origin), FSC
	submitted in the	Notarization: Yes, CCPIT	Applied as: Kit	(RRA), and ISO
	dossier of HSV 1 & 2	Validity: 31.12.2025	Class: C	certificate.
	IgG control.	FSC		The address of
		Type: photocopy	Code/sizes (as per FSC	manufacturing site shall
		Issued by: NIL	& application):	be the same in Form 7A,
		155ucu by. INIL	CC853	be the same in Politi /A,

		Legalization:	CC854	LOA ESC (origin) ESC
		-		LOA, FSC (origin), FSC
		No Validity, 20, 12, 2026	CC855	(RRA), and ISO certificate.
		Validity: 20.12.2026	Shelf Life: 48 month	
		FSC in RRA		The applied group is
		Type: photocopy of Embassy		separate devices in the
		attested document		FSC. Clarification is
		Issued by: TGA, Australia		required about the
		Legalization:		applied grouping.
		Issue date: 21.01.2025		DIA.
		ISO – Certificate:		V
		Type: photocopy	112101	
		Notarization: No	(M), O.	
		Validity: 14.11.2025	16.6	
6.	Martin Dow	Legal Manufacturer:	Brand Name: Toxo IgG	Deferred for:
	Specialties Private	Shenzhen Ever-Blue Biotech	and IgM Control	The application form has
	Limited, Nice Trade	CO., Ltd, Building 1, YHLO	Generic Name:	been signed by Director
	Orbit Building 7th	Biopark, Baolong 2nd Road,	Immunoassay Controls	Regulatory Affairs.
	Floor, 44-A, Block-6,	Baolong Subdistrict,	Toxo IgG	Authorization letter for
	PECHS, Shahrah-e-	Longgang District, Shenzhen,	(Negative control	the signatory is required.
	Faisal, Karachi	Guangdong 518116, China	2x2ml) (positive	Declaration on stamp
	Godown: Plot No.	Mfg site:	control 2x2ml)	paper to be issued in the
	130, Sector-15,	Shenzhen Yhlo Biotech Co.,	Toxo IgM	name of the firm /
	Korangi Industrial	Ltd. Building 2, Yhlo	(Negative control	signatory is required.
	Area, Karachi	Biopark, Baolong 2nd Road,	` •	English translation of the
	ELI-00160	Baolong Subdistrict,	2x2ml) (positive	issuing authority in FSC
	R&I Date: 10.07.2025	Longgang District, Shenzhen,	control 2x2ml)	is required.
	3072-C-Sindh Fee: 62000/-		Applied as: Kit	-
	Slip # 98155929	Guangdong, China LOA	Class: C	The address of legal manufacturer shall be the
	The firm has referred		Code/sizes (as per FSC	
	to RRA FSC	Type: photocopy of notarized	& application):	same in Form 7A, LOA,
	submitted in the	document	CC841	FSC (origin), FSC
	dossier of HSV 1 & 2	Notarization: Yes, CCPIT	CC842	(RRA), and ISO
	IgG control.	Validity: 31.12.2025	Shelf Life: 48 month	certificate.
	0	FSC	 U.S. 	The address of
		Type: photocopy	5. ⁰ 0 h	manufacturing site shall
		Issued by: NIL		be the same in Form 7A,
		Legalization:		LOA, FSC (origin), FSC
		No		(RRA), and ISO
		Validity: 20.12.2026		certificate.
		FSC in RRA		The applied group is
		Type: photocopy of Embassy		separate device in the
		attested document		FSC. Clarification is
		Issued by: TGA, Australia		required about the
		Legalization:		applied grouping.
		-23		
		Issue date: 21.01.2025		
	40	ISO – Certificate:		
		Type: photocopy		
		Notarization: No		
		Validity: 14.11.2025		
		validity. 17.11.2023		

7. Martin Dow Legal Manufacturer: Brand Name: Tumor Deferred for: Specialties Private Shenzhen Ever-Blue Biotech Marker Multi Control The application form has Limited, Nice Trade CO., Ltd, Building 1, YHLO Generic Name: been signed by Director Orbit Building 7th Biopark, Baolong 2nd Road, Immunoassay Controls Regulatory Affairs. Floor, 44-A, Block-6, Baolong Subdistrict, Authorization letter for Level 1 (2x3ml) PECHS, Shahrah-e-Longgang District, Shenzhen, the signatory is required. Level 2 (2x3ml) Faisal, Karachi Guangdong 518116, China Applied as: Kit Declaration on stamp Godown: Plot No. Mfg site: paper to be issued in the Class: C 130, Sector-15, Shenzhen Yhlo Biotech Co., name of the firm / Code/sizes (as per FSC Korangi Industrial Ltd. Building 2, Yhlo signatory is required. & application): Area, Karachi Biopark, Baolong 2nd Road, English translation of the CC816 ELI-00160 Baolong Subdistrict, issuing authority in FSC R&I Date: 10.07.2025 Shelf Life: 36 month Longgang District, Shenzhen, is required. 3066-C-Sindh Fee: 62000/-Guangdong, China The address of legal Slip # 67063477621 LOA manufacturer shall be the The firm has referred Type: photocopy of notarized same in Form 7A. LOA. to RRA FSC FSC (origin), FSC document submitted in the Notarization: Yes, CCPIT (RRA), and ISO dossier of HSV 1 & 2 Validity: 31.12.2025 certificate. IgG control. **FSC** The address of Type: photocopy manufacturing site shall Issued by: NIL be the same in Form 7A, Legalization: LOA, FSC (origin), FSC Apostilled the notarization of (RRA), and ISO CCPIT certificate. Validity: 15.03.2027 FSC in RRA MIS) 9:9:1 AM Type: photocopy of embassy legalized document Issued by: TGA, Australia Legalization: No Issue date: 21.01.2025 ISO – Certificate: Type: photocopy Notarization: No Validity: 14.11.2025 8. Martin Dow Legal Manufacturer: Brand Name: M. Deferred for: Specialties Private Shenzhen Ever-Blue Biotech Pneumoniae IgG and The application form has Limited, Nice Trade CO., Ltd, Building 1, YHLO IgM Control been signed by Director Orbit Building 7th Biopark, Baolong 2nd Road, Generic Name: Regulatory Affairs. Floor, 44-A, Block-6, Baolong Subdistrict, Immunoassay Controls Authorization letter for PECHS, Shahrah-e-Longgang District, Shenzhen, the signatory is required. M. Pneumoniae Faisal, Karachi Guangdong 518116, China Declaration on stamp IgG (Negative Godown: Plot No. Mfg site: paper to be issued in the control 2x2ml) 130, Sector-15, Shenzhen Yhlo Biotech Co., (positive control name of the firm / Korangi Industrial Ltd. Building 2, Yhlo signatory is required. 2x2mlArea, Karachi Biopark, Baolong 2nd Road, English translation of the M. Pneumoniae ELI-00160 Baolong Subdistrict, issuing authority in FSC R&I Date: 10.07.2025 IgM (Negative Longgang District, Shenzhen, is required. 3066-C-Sindh control 2x2ml) Fee: 62000/-Guangdong, China Slip # 017472652090

The firm has referred	IOA	(nacitiva control	The address of legal
The firm has referred to RRA FSC submitted in the dossier of HSV 1 & 2 IgG control.	LOA Type: photocopy of notarized document Notarization: Yes, CCPIT Validity: 31.12.2025 FSC Type: photocopy Issued by: NIL Legalization: No Validity: 20.12.2026 FSC in RRA Type: photocopy of embassy legalized document Issued by: TGA, Australia Legalization: No Issue date: 21.01.2025 ISO – Certificate: Type: photocopy Notarization: No Validity: 14.11.2025	(positive control 2x2ml) Applied as: Kit Class: C Code/sizes (as per FSC & application): CC847 CC848 Shelf Life: 48 month	The address of legal manufacturer shall be the same in Form 7A, LOA, FSC (origin), FSC (RRA), and ISO certificate. The address of manufacturing site shall be the same in Form 7A, LOA, FSC (origin), FSC (RRA), and ISO certificate. The applied group is separate device in the FSC. Clarification is required about the applied grouping.
9. Martin Dow Specialties Private Limited, Nice Trade Orbit Building 7th Floor, 44-A, Block-6, PECHS, Shahrah-e- Faisal, Karachi Godown: Plot No. 130, Sector-15, Korangi Industrial Area, Karachi ELI-00160 R&I Date: 10.07.2025 3071-C-Sindh Fee: 62000/- Slip # 54847950240 The firm has referred to RRA FSC submitted in the dossier of HSV 1 & 2 IgG control.	Legal Manufacturer: Shenzhen Ever-Blue Biotech CO., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116, China Mfg site: Shenzhen Yhlo Biotech Co., Ltd. Building 2, Yhlo Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong, China LOA Type: photocopy of notarized document Notarization: Yes, CCPIT Validity: 31.12.2025 FSC Type: photocopy Issued by: NIL Legalization: No Validity: 20.12.2026 FSC in RRA Type: photocopy of embassy legalized document Issued by: TGA, Australia	Brand Name: CMV IgG and IgM Control Generic Name: Immunoassay Controls CMV IgG (Negative control 2x2ml) (positive control 2x2ml) CMV IgM (Negative control 2x2ml) (positive control 2x2ml) Applied as: Kit Class: C Code/sizes (as per FSC application): CC843 CC844 Shelf Life: 48 month	Deferred for: The application form has been signed by Director Regulatory Affairs. Authorization letter for the signatory is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required. English translation of the issuing authority in FSC is required. The address of legal manufacturer shall be the same in Form 7A, LOA, FSC (origin), FSC (RRA), and ISO certificate. The address of manufacturing site shall be the same in Form 7A, LOA, FSC (origin), FSC (RRA), and ISO certificate. The applied group is separate device in the FSC. Clarification is

		Legalization:		required shout the
10.	Martin Dow	Legalization: No Issue date: 21.01.2025 ISO – Certificate: Type: photocopy Notarization: No Validity: 14.11.2025 Legal Manufacturer:	Brand Name: Rubella	required about the applied grouping. Deferred for:
	Specialties Private Limited, Nice Trade Orbit Building 7th Floor, 44-A, Block-6, PECHS, Shahrah-e- Faisal, Karachi Godown: Plot No. 130, Sector-15, Korangi Industrial Area, Karachi ELI-00160 R&I Date: 10.07.2025 3059-C-Sindh Fee: 62000/- Slip # 7694497778 The firm has referred to RRA FSC submitted in the dossier of HSV 1 & 2 IgG control.	Shenzhen Ever-Blue Biotech CO., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116, China Mfg site: Shenzhen Yhlo Biotech Co., Ltd. Building 2, Yhlo Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong, China LOA Type: photocopy of notarized document Notarization: Yes, CCPIT Validity: 31.12.2025 FSC Type: photocopy Issued by: NIL Legalization: No Validity: 20.12.2026 FSC in RRA Type: photocopy of embassy legalized document Issued by: TGA, Australia Legalization: No Issue date: 21.01.2025 ISO – Certificate: Type: photocopy Notarization: No Validity: 14.11.2025	IgG and IgM Control Generic Name: Immunoassay Controls Rubella IgG (Negative control 2x2ml) (positive control 2x2ml) Rubella IgM (Negative control 2x2ml) (positive control 2x2ml) Applied as: Kit Class: C Code/sizes (as per FSC & application): CC845 CC846 Shelf Life: 48 month	The application form has been signed by Director Regulatory Affairs. Authorization letter for the signatory is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required. English translation of the issuing authority in FSC is required. The address of legal manufacturer shall be the same in Form 7A, LOA, FSC (origin), FSC (RRA), and ISO certificate. The address of manufacturing site shall be the same in Form 7A, LOA, FSC (origin), FSC (RRA), and ISO certificate. The applied group is separate devices in the FSC. Clarification is required about the applied grouping.
11.	Martin Dow Specialties Private Limited, Nice Trade Orbit Building 7th Floor, 44-A, Block-6, PECHS, Shahrah-e- Faisal, Karachi Godown: Plot No. 130, Sector-15,	Legal Manufacturer: Shenzhen Ever-Blue Biotech CO., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116, China Mfg site:	Brand Name: EB EA IgM Control Generic Name: Immunoassay Controls • EB EA IgM (Negative control 2x2ml) (positive control 2x2ml)	Deferred for: The application form has been signed by Director Regulatory Affairs. Authorization letter for the signatory is required. Declaration on stamp paper to be issued in the

	W : I - I : - 1	C11	A1: - 1 1Z:4	
	Korangi Industrial	Shenzhen Yhlo Biotech Co.,	Applied as: Kit	name of the firm /
	Area, Karachi ELI-00160	Ltd. Building 2, Yhlo	Class: C	signatory is required.
		Biopark, Baolong 2nd Road,	Code/sizes (as per FSC	English translation of the
	R&I Date: 10.07.2025	Baolong Subdistrict,	& application):	issuing authority in FSC
	3068-C-Sindh	Longgang District, Shenzhen,	CC856	is required.
	Fee: 62000/-	Guangdong, China	Shelf Life: 48 month	The address of legal
	Slip # 50730774 The firm has referred	LOA		manufacturer shall be the
	to RRA FSC	Type: photocopy of notarized		same in Form 7A, LOA,
	submitted in the	document		FSC (origin), FSC
	dossier of HSV 1 & 2	Notarization: Yes, CCPIT		(RRA), and ISO
	IgG control.	Validity: 31.12.2025		certificate.
	igo controi.	FSC	.(6) (1)	The address of
		Type: photocopy	1/11/200	manufacturing site shall
		Issued by: NIL	' (1/2, 20,	be the same in Form 7A,
		Legalization:	1.1052,	LOA, FSC (origin), FSC
		No		. 0
			73	(RRA), and ISO
		Validity: 20.12.2026		certificate.
		FSC in RRA	3° '	
		Type: photocopy of embassy		
		legalized document		
		Issued by: TGA, Australia		
		Legalization:		
		No		
		Issue date: 21.01.2025		
		ISO – Certificate:		
		Type: photocopy		
		Notarization: No		
		Validity: 14.11.2025		
12.	Martin Dow	Legal Manufacturer:	Brand Name: Anti-	Deferred for:
	Specialties Private	Shenzhen Ever-Blue Biotech	HBc Control	The application form has
	Limited, Nice Trade	CO., Ltd, Building 1, YHLO	Generic Name:	been signed by Director
	Orbit Building 7th	Biopark, Baolong 2 nd Road,	Immunoassay Controls	Regulatory Affairs.
	Floor, 44-A, Block-6,	Baolong Subdistrict,	• (Negative control	Authorization letter for
	PECHS, Shahrah-e-	Longgang District, Shenzhen,	2x2ml, positive	the signatory is required.
	Faisal, Karachi	Guangdong 518116, China	control 2x2ml)	Declaration on stamp
	Godown: Plot No.	Mfg site:	Applied as: Kit	paper to be issued in the
	130, Sector-15,	Shenzhen Yhlo Biotech Co.,	Class: D	name of the firm /
	Korangi Industrial	Ltd. Building 2, Yhlo	Code/sizes (as per FSC	signatory is required.
	Area, Karachi ELI-00160	Biopark, Baolong 2nd Road,	& application):	English translation of the
	R&I Date: 10.07.2025	Baolong Subdistrict,	CC867	issuing authority in FSC
	3062-C-Sindh	Longgang District, Shenzhen,	Shelf Life: 18 month	is required.
	Fee: 62000/-	Guangdong, China	SHOIL LITE, TO HIGHIN	The address of legal
	Slip # 206375176	LOA		manufacturer shall be the
	The firm has referred			
	to RRA FSC	Type: photocopy of notarized		same in Form 7A, LOA,
	submitted in the	document		FSC (origin), FSC
	dossier of HSV 1 & 2	Notarization: Yes, CCPIT		(RRA), and ISO
	IgG control.	Validity: 31.12.2025		certificate.
		FSC		The address of
		Type: photocopy		manufacturing site shall
		Issued by: NIL		be the same in Form 7A,
		Legalization:		LOA, FSC (origin), FSC

		No		(RRA), and ISO
		Validity: 20.12.2026		certificate.
		FSC in RRA		Submit Ce design
		Type: photocopy of embassy		examination certificate
		legalized document		and applicable
		Issued by: TGA, Australia		requirements for class D
		Legalization:		device.
		No		
		Issue date: 21.01.2025		
		ISO – Certificate:		
		Type: photocopy	~ A	
		Notarization: No	1/2/01/	•
		Validity: 14.11.2025	18/11 0:3	
13.	Martin Dow	Legal Manufacturer:	Brand Name: HBeAg	Deferred for:
	Specialties Private	Shenzhen Ever-Blue Biotech	Control	The application form has
	Limited, Nice Trade	CO., Ltd, Building 1, YHLO	Generic Name:	been signed by Director
	Orbit Building 7th	Biopark, Baolong 2nd Road,	Immunoassay Controls	Regulatory Affairs.
	Floor, 44-A, Block-6,	Baolong Subdistrict,	(Negative control	Authorization letter for
	PECHS, Shahrah-e-	Longgang District, Shenzhen,	2x2ml, positive	the signatory is required.
	Faisal, Karachi Godown: Plot No.	Guangdong 518116, China	control 2x2ml)	Declaration on stamp
	130, Sector-15,	Mfg site:	Applied as: Kit	paper to be issued in the
	Korangi Industrial	Shenzhen Yhlo Biotech Co.,	Class: D	name of the firm /
	Area, Karachi	Ltd. Building 2, Yhlo	Code/sizes (as per FSC	signatory is required.
	ELI-00160	Biopark, Baolong 2nd Road,	& application):	English translation of the
	R&I Date: 10.07.2025	Baolong Subdistrict,	CC865	issuing authority in FSC
	3069-C-Sindh	Longgang District, Shenzhen,	Shelf Life: 18 month	is required.
	Fee: 62000/-	Guangdong, China		The address of legal
	Slip # 37271390485	LOA		manufacturer shall be the
	The firm has referred	Type: photocopy of notarized		same in Form 7A, LOA,
	to RRA FSC	document		FSC (origin), FSC
	submitted in the	Notarization: Yes, CCPIT	.(6) 0.7	(RRA), and ISO
	dossier of HSV 1 & 2 IgG control.	Validity: 31.12.2025		certificate.
	igo controi.	FSC	(11, 9,	The address of
		Type: photocopy	(4) (1)	manufacturing site shall
		Issued by: NIL), ² O ₁ h	be the same in Form 7A,
		Legalization:		LOA, FSC (origin), FSC
		No		(RRA), and ISO
		Validity: 20.12.2026		certificate.
		FSC in RRA		Submit Ce design
		Type: photocopy of embassy		examination certificate
		legalized document		and applicable
		Issued by: TGA, Australia		requirements for class D
		Legalization:		device.
		No		
		Issue date: 21.01.2025		
		ISO – Certificate:		
	, 10	Type: photocopy		
	Mill	Notarization: No		
	<u> </u>	Validity: 14.11.2025		
14.	Martin Dow	Legal Manufacturer:	Brand Name: HSV 1 &	Deferred for:
	Specialties Private		2 IgG Control	
	Limited, Nice Trade			

Orbit Building 7th Shenzhen Ever-Blue Biotech Generic Name: The application form has Floor, 44-A, Block-6, CO., Ltd, Building 1, YHLO Immunoassay Controls been signed by Director PECHS, Shahrah-e-Biopark, Baolong 2nd Road, HSV - 1 IgGRegulatory Affairs. Faisal, Karachi Baolong Subdistrict, (Negative control Authorization letter for Godown: Plot No. Longgang District, Shenzhen, the signatory is required. 2x2ml, positive 130, Sector-15, Guangdong 518116, China Declaration on stamp control 2x2ml) Korangi Industrial Mfg site: paper to be issued in the HSV - 2 IgGArea, Karachi Shenzhen Yhlo Biotech Co., name of the firm / (Negative control ELI-00160 Ltd. Building 2, Yhlo signatory is required. 2x2ml, positive R&I Date: 10.07.2025 Biopark, Baolong 2nd Road, English translation of the control 2x2ml) 3063-C-Sindh Baolong Subdistrict, issuing authority in FSC Fee: 62000/-Applied as: Kit Longgang District, Shenzhen, is required. Slip # 96072293 Class: D Guangdong, China The address of legal Code/sizes (as per FSC manufacturer shall be the LOA & application): Type: photocopy of notarized same in Form 7A, LOA, CC837 document FSC (origin), FSC CC839 Notarization: Yes, CCPIT Shelf Life: 48 month (RRA), and ISO Validity: 31.12.2025 certificate. **FSC** The address of Type: photocopy manufacturing site shall Issued by: NIL be the same in Form 7A, Legalization: LOA, FSC (origin), FSC No (RRA), and ISO Validity: 20.12.2026 certificate. FSC in RRA Submit Ce design Type: photocopy examination certificate Issued by: TGA, Australia and applicable Legalization: requirements for class D Embassy legalized device. Issue date: 21.01.2025 The applied group is ISO – Certificate: separate devices in the Type: photocopy FSC. Clarification is Notarization: No required about the Validity: 14.11.2025 applied grouping. 15. Legal Manufacturer: Brand Name: iFlash-Martin Dow Deferred for: Specialties Private Shenzhen Yhlo Biotech Co., hs-cTnI The application form has Limited, Nice Trade Ltd. Building 1, YHLO Generic Name: been signed by Director Orbit Building 7th Biopark, Baolong 2nd Road, Chemiluminescene Regulatory Affairs. Floor, 44-A, Block-6, Baolong Subdistrict, Immunoassay (2x50 Authorization letter for PECHS, Shahrah-e-Longgang District, Shenzhen, tests /kit) the signatory is required. Faisal, Karachi Guangdong 518116, China Applied as: Kit Declaration on stamp Godown: Plot No. Mfg site: Class: C paper to be issued in the 130, Sector-15, Code/sizes (as per FSC Shenzhen Yhlo Biotech Co., name of the firm / Korangi Industrial Ltd. Building 2, Yhlo & application): signatory is required. Area, Karachi Biopark, Baolong 2nd Road, C86304 English translation of the ELI-00160 Baolong Subdistrict, Shelf Life: 18 month issuing authority in FSC R&I Date: 17.07.2025 Longgang District, Shenzhen, is required. 3237-C-Sindh Fee: 62000/-Guangdong, China Notarized copy of LOA Slip # 342994579819 LOA and legalized copy of The firm has referred FSC (origin) is required. to RRA FSC

submitted in the dossier of HSV 1 & 2 IgG control.	Type: photocopy of notarized document Notarization: Yes, CCPIT Validity: 31.12.2025 FSC Type: photocopy Issued by: NIL Legalization: No Validity: 12.01.2026 FSC in RRA Type: photocopy Issued by: TGA, Australia Legalization: Embassy legalized Issue date: 21.01.2025 ISO – Certificate: Type: photocopy Notarization: No Validity: 09.06.2028	31-12025,9:9:1 31-12025	
16. Martin Dow Specialties Private Limited, Nice Trade Orbit Building 7th Floor, 44-A, Block-6, PECHS, Shahrah-e- Faisal, Karachi Godown: Plot No. 130, Sector-15, Korangi Industrial Area, Karachi ELI-00160 R&I Date: 17.07.2025 3231-C-Sindh Fee: 62000/- Slip # 0788391427 The firm has referred to RRA FSC submitted in the dossier of HSV 1 & 2 IgG control.	Legal Manufacturer: Shenzhen Yhlo Biotech Co., Ltd. Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116, China Mfg site: Shenzhen Yhlo Biotech Co., Ltd. Building 2, Yhlo Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong, China LOA Type: photocopy of notarized document Notarization: Yes, CCPIT Validity: 31.12.2025 FSC Type: photocopy Issued by: NIL Legalization: No Validity: 12.01.2026 FSC in RRA Type: photocopy Issued by: TGA, Australia Legalization: Embassy legalized Issue date: 21.01.2025	Brand Name: iFlash-D-dimer Generic Name: Chemiluminescene Immunoassay (2x50 tests /kit) Applied as: Kit Class: C Code/sizes (as per FSC & application): C86238 Shelf Life: 18 month	Deferred for: The application form has been signed by Director Regulatory Affairs. Authorization letter for the signatory is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required. English translation of the issuing authority in FSC is required. Notarized copy of LOA and legalized copy of FSC (origin) is required.

		ISO – Certificate: Type: photocopy Notarization: No Validity: 09.06.2028		
17.	Global EngiTech, Office Suite 8, First Floor, AL-Sehat Centre, Rafiq Shaheed Road, Off Shahrah-e- Faisal, Karachi ELI-01262 R&I Date: 29.05.2025 2354-B-Sindh Fee: 31000/- Slip # 43526358934	Legal Manufacturer: OptiBio Co., Ltd., No. 301, 401, 404, 405, 406, 409, 414, Chungbuk TP Bonbukwan, 76, Yeongudaniro, Ochang-eup, Cheongwongu, Cheongju-si, Chungcheongbuk-do, Republic of Korea LOA Type: photocopy of notarized document Notarization: No Validity: 31.12.2024 FSC Type: photocopy Issued by: National Institute of Medical Device Safety Information, Seoul, Korea Legalization: Apostilled Issue date: 02.10.2024 ISO – Certificate: Type: photocopy Notarization: No Validity: 28.04.2026	Brand Name: Optical Q, CRP, Detection Buffer CRP Generic Name: CRP (C-Reactive Protein), Buffer Applied as: Kit Class: B Code/sizes (as per FSC & application): NIL Shelf Life: 24 month	Deferred for: The firm has applied CRP (C-Reactive Protein) and Buffer. The submitted FSC of Korea contains Optical Q, CRP only. Clarification is required. Code is not mentioned in the FSC. Clarification is required. The firm has submitted fee challan meant for various products. Original fee challan in respect of the applied product is required. The address of importer in LOA and Application Form shall be the same as in ELI. Declaration on stamp paper to be issued in the name of the firm / signatory is required. Legalized FSC in reference country or notarized CE certificate is required. Submit notarized copy of valid LOA and ISO-
18.	Global EngiTech, Office Suite 8, First Floor, AL-Sehat Centre, Rafiq Shaheed Road, Off Shahrah-e- Faisal, Karachi ELI-01262 R&I Date: 29.05.2025 2360-B-Sindh Fee: 31000/- Slip # 43526358934	Legal Manufacturer: OptiBio Co., Ltd., No. 301, 401, 404, 405, 406, 409, 414, Chungbuk TP Bonbukwan, 76, Yeongudaniro, Ochang-eup, Cheongwongu, Cheongju-si, Chungcheongbuk-do, Republic of Korea LOA Type: photocopy of notarized document Notarization: No Validity: 31.12.2024 FSC	Brand Name: Optical Q, PCT, Detection Buffer PCT Generic Name: PCT (Prolactonin), Buffer Applied as: Kit Class: B Code/sizes (as per FSC & application): NIL Shelf Life: 24 month	Deferred for: The firm has applied PCT and Buffer. The submitted FSC of Korea contains Optical Q, PCT only. Clarification is required. Code is not mentioned in the FSC. Clarification is required. The firm has submitted copy of fee challan meant for various products. Original fee challan in respect of the

		T 1		1. 1
		Type: photocopy (original attached in Optical Q, CRP)		applied product is required.
		Issued by: National Institute		The address of importer
		of Medical Device Safety		in LOA and Application
		1		Form shall be the same
		Information, Seoul, Korea		
		Legalization:		as in ELI.
		Original apostilled		Declaration on stamp
		Issue date: 02.10.2024		paper to be issued in the
		ISO – Certificate:		name of the firm /
		Type: photocopy		signatory is required.
		Notarization: No	۸. ۱۵	Legalized FSC in
		Validity: 28.04.2026	112,00	reference country or
		274	181, 0:	notarized CE certificate
		Olli		is required.
		C.o.	((, ⁽);),	Submit notarized copy of
), U(),	valid LOA and ISO-
		70, 200		13485 certificate.
19.	Global EngiTech,	Legal Manufacturer:	Brand Name: Optical	Deferred for:
	Office Suite 8, First	OptiBio Co., Ltd.,	Q, Reagent	Specifying the brand
	Floor, AL-Sehat	No. 301, 401, 404, 405, 406,	Generic Name: TSH	names.
	Centre, Rafiq Shaheed	409, 414, Chungbuk TP	(Thyroid stimulating	The firm has applied
	Road, Off Shahrah-e-	Bonbukwan, 76, Yeongudani-	hormone), Buffer	Reagent (TSH) and
	Faisal, Karachi	ro, Ochang-eup, Cheongwon-	Applied as: Kit	Buffer. The submitted
	ELI-01262	gu, Cheongju-si,	Class: B	FSC of Korea contains
	R&I Date: 29.05.2025	Chungcheongbuk-do,	Code/sizes (as per FSC	Optical Q, TSH only.
	2356-B-Sindh	Republic of Korea	& application):	Clarification is required.
	Fee: 31000/- Slip # 96729712469	LOA	NIL	Code is not mentioned in
	Silp # 90729712409	Type: photocopy of notarized	Shelf Life: 24 month	the FSC. Clarification is
		document		required.
		Notarization: No		The firm has submitted
		Validity: 31.12.2024	.6	copy of fee challan
		FSC	1/19, '0.	meant for various
		Type: photocopy (original	1.1052, 0:3	products. Original fee
		attached in Optical Q, CRP)	11/201	challan in respect of the
		Issued by: National Institute		applied product is
		of Medical Device Safety	, 05,	required.
		Information, Seoul, Korea		The address of importer
		Legalization:		in LOA and Application
		Original apostilled		Form shall be the same
		Issue date: 02.10.2024		as in ELI.
		ISO – Certificate:		
				Declaration on stamp
		Type: photocopy		paper to be issued in the name of the firm /
		Notarization: No		
		Validity: 28.04.2026		signatory is required.
		70,		Legalized FSC in
				reference country or
	7/0			notarized CE certificate
				is required.
				Submit notarized copy of
				valid LOA and ISO-
				13485 certificate.

20.	Global EngiTech,	Legal Manufacturer:	Brand Name: Optical	Deferred for:
20.	Office Suite 8, First	OptiBio Co., Ltd.,	Q HbA1c Reagents	Code is not mentioned in
	Floor, AL-Sehat	No. 301, 401, 404, 405, 406,	Generic Name:	
	Centre, Rafiq Shaheed			the FSC.
	Road, Off Shahrah-e-	409, 414, Chungbuk TP	Hemoglobin A1c	Clarification is required.
	Faisal, Karachi	Bonbukwan, 76, Yeongudani-	(glycatedhaemoglobin)	The address of importer
	ELI-01262	ro, Ochang-eup, Cheongwon-	Applied as: Kit	in LOA and Application
	R&I Date: 29.05.2025	gu, Cheongju-si,	Class: B	Form shall be the same
	2368-B-Sindh	Chungcheongbuk-do,	Code/sizes (as per FSC	as in ELI.
	Fee: 31000/-	Republic of Korea	& application):	Declaration on stamp
	Slip # 96436550	LOA	NIL	paper to be issued in the
	•	Type: photocopy of notarized	Shelf Life: 24 month	name of the firm /
		document	112101	signatory is required.
		Notarization: No	(M) 0:3	Legalized FSC in
		Validity: 31.12.2024	111.	reference country or
		FSC	(4, 50,5)	notarized CE certificate
		Type: photocopy (original	D. 00h	is required.
		attached in Optical Q, CRP)		Submit notarized copy of
		Issued by: National Institute		valid LOA and ISO-
		of Medical Device Safety		13485 certificate.
		Information, Seoul, Korea		
		Legalization:		
		Original apostilled		
		Issue date: 02.10.2024		
		ISO – Certificate:		
		Type: photocopy		
		Notarization: No		
		Validity: 28.04.2026		
21.	Global EngiTech,	Legal Manufacturer:	Brand Name: Optical	Deferred for:
	Office Suite 8, First	OptiBio Co., Ltd.,	Q Ferritin, Detection	The firm has applied
	Floor, AL-Sehat	No. 301, 401, 404, 405, 406,	Buffer	Reagent (Ferritin) and
	Centre, Rafiq Shaheed	409, 414, Chungbuk TP	Generic Name:	Buffer. The submitted
	Road, Off Shahrah-e-	Bonbukwan, 76, Yeongudani-	Ferritin, Buffer	FSC of Korea contains
	Faisal, Karachi	ro, Ochang-eup, Cheongwon-	Applied as: Kit	Optical Q, Ferritin only.
	ELI-01262	gu, Cheongju-si,	Class: B	Clarification is required.
	R&I Date: 29.05.2025	Chungcheongbuk-do,	Code/sizes (as per FSC	Code is not mentioned in
	2370-B-Sindh	Republic of Korea	& application):	the FSC.
	Fee: 31000/- Slip # 8254046051	LOA	NIL	Clarification is required.
	Silp # 6234040031	Type: photocopy of notarized	Shelf Life: 24 month	The address of importer
		document		in LOA and Application
		Notarization: No		Form shall be the same
		Validity: 31.12.2024		as in ELI.
		FSC		Declaration on stamp
		Type: photocopy (original		paper to be issued in the
		attached in Optical Q, CRP)		name of the firm /
		Issued by: National Institute		signatory is required.
		of Medical Device Safety		Legalized FSC in
	40	Information, Seoul, Korea		reference country or
		Legalization:		notarized CE certificate
		Original apostilled		is required.
		Issue date: 02.10.2024		- 1. · · · · · · · · · · · · · · · · · ·
		ISO – Certificate:		

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		Type: photocopy		Submit notarized copy of
		Notarization: No		valid LOA and ISO-
		Validity: 28.04.2026		13485 certificate.
22.	Global EngiTech,	Legal Manufacturer:	Brand Name: Optical	The firm has applied
	Office Suite 8, First	OptiBio Co., Ltd.,	Q, Prolactin, Detection	Reagent (Prolactin) and
	Floor, AL-Sehat	No. 301, 401, 404, 405, 406,	Buffer Prolactin	Buffer. The submitted
	Centre, Rafiq Shaheed	409, 414, Chungbuk TP	Generic Name:	FSC of Korea contains
	Road, Off Shahrah-e-	Bonbukwan, 76, Yeongudani-	Prolactin,	Optical Q, PRL only.
	Faisal, Karachi	ro, Ochang-eup, Cheongwon-	Buffer	Clarification is required.
	ELI-01262	gu, Cheongju-si,	Applied as: Kit	Code is not mentioned in
	R&I Date: 29.05.2025	Chungcheongbuk-do,	Class: B	the FSC. Clarification is
	2363-B-Sindh			
	Fee: 31000/-	Republic of Korea	Code/sizes (as per FSC	required.
	Slip # 416934793	LOA	& application):	The applied product is a
		Type: photocopy of notarized	NIL	strip in the FSC. The
		document	Shelf Life: 24 month	firm has applied as kit.
		Notarization: No	, U.S.	Clarification is required.
		Validity: 31.12.2024	4.	The firm has submitted
		FSC	7	copy of fee challan
		Type: Original		meant for various
		Issued by: National Institute		hormones. Original fee
		of Medical Device Safety		challan in respect of the
		Information, Seoul, Korea		applied product is
		Legalization:		required.
		No		The address of importer
		Issue date: 02.10.2024		in LOA and Application
		ISO – Certificate:		Form shall be the same
		Type: photocopy		as in ELI.
	. 10	Notarization: No		Declaration on stamp
		Validity: 28.04.2026		paper to be issued in the
	· ·	varianty. 28.04.2020		name of the firm /
			A. (2)	
			(12) 0:	signatory is required.
		2.44	(M), O;	Legalized FSC in
				reference country or
			(4) "0,0,0	notarized CE certificate
		1 6 1), ^O O _N	is required.
		4011 600		Submit notarized copy of
		, ho oile		valid LOA and ISO-
		Pp. " N. 70		13485 certificate.
23.	Global EngiTech,	Legal Manufacturer:	Brand Name: Optical	Deferred for:
	Office Suite 8, First	OptiBio Co., Ltd.,	Q, FSH, Detection	The firm has applied
	Floor, AL-Sehat	No. 301, 401, 404, 405, 406,	Buffer FSH	Reagent (FSH) and
	Centre, Rafiq Shaheed	409, 414, Chungbuk TP	Generic Name: Follicle	Buffer. The submitted
	Road, Off Shahrah-e-	Bonbukwan, 76, Yeongudani-	stimulating hormone,	FSC of Korea contains
	Faisal, Karachi	ro, Ochang-eup, Cheongwon-	Buffer	Optical Q, FSH only.
	ELI-01262	gu, Cheongju-si,	Applied as: Kit	Clarification is required.
	R&I Date: 29.05.2025	Chungcheongbuk-do,	Class: B	Code is not mentioned in
	2355-b-Sindh			
	Fee: 31000/-	Republic of Korea	Code/sizes (as per FSC	the FSC. Clarification is
	Slip # 416934793	LOA	& application):	required.
		Type: photocopy of notarized	NIL	The applied product is a
		document	Shelf Life: 24 month	strip in the FSC. The
		Notarization: No		
_				

		Validity: 31.12.2024		firm has applied as kit.
		FSC		Clarification is required.
				The firm has submitted
		Type: photocopy of apostilled		
		certificate (original in		fee challan meant for
		Prolactin dossier.		various hormones.
		Issued by: National Institute		Original fee challan in
		of Medical Device Safety		respect of the applied
		Information, Seoul, Korea		product is required.
		Legalization:		The address of importer
		No		in LOA and Application
		Issue date: 02.10.2024	- A	Form shall be the same
		ISO – Certificate:	15) o''	as in ELI.
		Type: photocopy		Declaration on stamp
		Notarization: No	(11, 9,	paper to be issued in the
		Validity: 28.04.2026	(4) (1)	name of the firm /
		varialty: 20.04.2020		signatory is required.
		" III " C"	75	Legalized FSC in
		1000-1100	K 4	
		Ph 0, 2		reference country or
				notarized CE certificate
		101, col,		is required.
		islocio		Submit notarized copy of
		c515 00		valid LOA and ISO-
		020		13485 certificate.
24.	Global EngiTech,	Legal Manufacturer:	Brand Name: Optical	Deferred for:
	Office Suite 8, First	OptiBio Co., Ltd.,	Q, LH, Detection	The firm has applied
	Floor, AL-Sehat	No. 301, 401, 404, 405, 406,	Buffer LH	Reagent (LH) and
	Centre, Rafiq Shaheed	409, 414, Chungbuk TP	Generic Name:	Buffer. The submitted
	Road, Off Shahrah-e-	Bonbukwan, 76, Yeongudani-	Luteinizing hormone,	FSC of Korea contains
	Faisal, Karachi	ro, Ochang-eup, Cheongwon-	Buffer	Optical Q, LH only.
	ELI-01262	gu, Cheongju-si,	Applied as: Kit	Clarification is required.
	R&I Date: 29.05.2025	Chungcheongbuk-do,	Class: B	Code is not mentioned in
	2362-B-Sindh Fee: 31000/-	Republic of Korea	Code/sizes (as per FSC	the FSC. Clarification is
	Slip # 416934793	LOA	& application):	required.
	Sup # 410934793	Type: photocopy of notarized	NIL	The applied product is a
		document	Shelf Life: 24 month	strip in the FSC. The
		Notarization: No	Ziron Ziron Zir montin	firm has applied as kit.
		Validity: 31.12.2024		Clarification is required.
		FSC	3	The firm has submitted
		Type: photocopy of apostilled		fee challan meant for
				various hormones.
		certificate (original in		
		Prolactin dossier.		Original fee challan in
		Issued by: National Institute		respect of the applied
		of Medical Device Safety		product is required.
		Information, Seoul, Korea		The address of importer
		Legalization:		in LOA and Application
		No		Form shall be the same
	10	Issue date: 02.10.2024		as in ELI.
	Miles	ISO – Certificate:		Declaration on stamp
	_	Type: photocopy		paper to be issued in the
		Notarization: No		name of the firm /
		Validity: 28.04.2026		signatory is required.
	l .	j: =5.0 = 0=0	l	o justoquirou.

	Т		Т	·
				Legalized FSC in
				reference country or
				notarized CE certificate
				is required.
				Submit notarized copy of
				valid LOA and ISO-
				13485 certificate.
25.	Global EngiTech,	Legal Manufacturer:	Brand Name: Optical	Deferred for:
	Office Suite 8, First	OptiBio Co., Ltd.,	Q, beta-hCG,	The firm has applied
	Floor, AL-Sehat	No. 301, 401, 404, 405, 406,	Detection Buffer LH	Reagent (LH) and
	Centre, Rafiq Shaheed	409, 414, Chungbuk TP	Generic Name: beta	Buffer. The submitted
	Road, Off Shahrah-e-	Bonbukwan, 76, Yeongudani-	human chorionic	FSC of Korea contains
	Faisal, Karachi	ro, Ochang-eup, Cheongwon-	gonadotropin hormone,	Optical Q, LH only.
	ELI-01262	gu, Cheongju-si,	Buffer	Clarification is required.
	R&I Date: 29.05.2025	Chungcheongbuk-do,	Applied as: Kit	Code is not mentioned in
	2365-B-Sindh	Republic of Korea	Class: B	the FSC. Clarification is
	Fee: 31000/-	LOA	Code/sizes (as per FSC	required.
	Slip # 416934793	Type: photocopy of notarized	& application):	The applied product is a
		document	NIL	strip in the FSC. The
		Notarization: No	Shelf Life: 24 month	firm has applied as kit.
		Validity: 31.12.2024	Shell Elic. 2 i month	Clarification is required.
		FSC FSC		The firm has submitted
		Type: photocopy of apostilled		fee challan meant for
		certificate (original in		various hormones.
	40	Prolactin dossier.		Original fee challan in
		Issued by: National Institute		
				respect of the applied
		of Medical Device Safety		product is required.
		Information, Seoul, Korea	1/2/01	The address of importer
		Legalization:	(M), O!?	in LOA and Application
		No	16.6	Form shall be the same
		Issue date: 02.10.2024		as in ELI.
		ISO – Certificate:), ⁰ 0,	Declaration on stamp
		Type: photocopy	1,5052	paper to be issued in the
		Notarization: No		name of the firm /
		Validity: 28.04.2026		signatory is required.
				Legalized FSC in
		· Char Co		reference country or
		CIS OB		notarized CE certificate
		15°-0'		is required.
		K. 12		Submit notarized copy of
				valid LOA and ISO-
		203		13485 certificate.

ENLISTMENT/REGISTRATION OF MEDICAL DEVICES FOR IMPORT.

Evaluator: Muhammad Ashfaq, Deputy Director (DD-VI)

S. No.	Name of Applicant(s)	Name of Manufacturer	Medical Device	Decision
1.	M/s Mediserve, 4 Canal Park Fountain Corner Near Edhi Homes	Name of Manufacturer: Leboo Healthcare Product Limited, No. 18 Tiaxian Street, Tianmen Hubei, P.R.	Brand name: Leboo	Approved
	Gulberg II Lahore.	China.	Generic Name: Surgical Gown	
	(ELI- 00705)	• LOA	-113.9.	
	D 0 I J.4-9	Type: Copy of apostilled	Applied as: Family	
	R&I detail 03-02-2025	Attested By: Apostilled Validity: 31-12-2026	Class: A	
	Fee: 6,000/-	Validity: 31-12-2020	Class. A	
	Slip: 68902593015	• FSC (China)	Model/Codes/Sizes as Per	
	•	Type: Copy of apostilled	FSC and application:	
	Fee: 20,100/-	Issued By: NMPA	Standard Surgical Gown:	
	Slip: 57771484608	Legalization: Apostilled	• XS (105cm x 130cm)	
		Validity: 23-06-2026	• S (115cm x 135cm)	
		615 06	• M (120cm x 140cm)	
		• ISO Certificate	• L (125cm x 145cm)	
		Type: Copy Notarization: by CCPIT	• XL (130cm x 150cm)	
		Validity: 20-10-2026	• XXL (135cm x 155cm)	
		validity: 20 10 2020	Shelf life:	
			3 Years	
2.	M/s Mediserve, 4 Canal	Name of Manufacturer:	Brand name:	Approved
	Park Fountain Corner	Leboo Healthcare Product Limited, No.	Leboo	11
	Near Edhi Homes	18 Tiaxian Street, Tianmen Hubei, P.R.		
	Gulberg II Lahore.	China.	Generic Name: Mob Cap	
	(ELI- 00705)	• LOA	(14. 3.	
		Type: Copy of apostilled	Applied as: Single	
	R&I detail	Attested By: Apostilled		
	03-02-2025 Fee: 6,000/-	Validity: 31-12-2026	Class: A	
	Slip: 656798948497	• FSC (China)	Model/Codes/Sizes as Per	
	Shp. 030770740477	Type: Copy of apostilled	FSC and application:	
		Issued By: NMPA	N62D01	
		Legalization: Apostilled		
		Validity: 23-06-2026	Shelf life:	
		65°-0'	3 Years	
		• ISO Certificate		
		Type: Copy Notarization: by CCPIT		
		Validity: 20-10-2026		
3.	M/s Mediserve 4 Canal	Name of Manufacturer:	Brand name:	Approved
	Park Fountain Corner	Leboo Healthcare Product Limited, No.	Leboo	
	Near Edhi Homes	18 Tiaxian Street, Tianmen Hubei, P.R.		
	Gulberg II Lahore.	China.	Generic Name:	
	(EL 1 00505)	104	Surgical Face Mask	
	(ELI- 00705)	• LOA		

	Town on Communification and illed	T	<u> </u>
D 0 I 1-4-21	Type: Copy of apostilled	Annilla I and David	
R&I detail	Attested By: Apostilled	Applied as: Family	
03-02-2025	Validity: 31-12-2026	CT.	
Fee: 6,000/-		Class: A	
Slip: 62923152	• FSC (China)		
	Type: Copy of apostilled	Model/Codes/Sizes as Per	
Fee: 20,100/-	Issued By: NMPA	FSC and application:	
Slip: 6160865637	Legalization: Apostilled	Surgical Face mask with Ear	
	Validity: 23-06-2026	Loop A (Non-sterile) (17.5cm x	
		9.5cm, 14.5cm x 9.5cm)	
	ISO Certificate		
	Type: Copy	Shelf life:	
	Notarization: by CCPIT	3 Years	
	Validity: 20-10-2026		
4. M/s Mediserve 4 Canal	Name of Manufacturer:	Brand name:	Deferred since
Park Fountain Corner	Leboo Healthcare Product Limited, No.	Leboo	the applied
Near Edhi Homes	18 Tiaxian Street, Tianmen Hubei, P.R.	CIL	device has not
Gulberg II Lahore.	China.	Generic Name:	been mentioned
	12000:10001	CPE Shoe cover	in FSC.
(ELI- 00705)	• LOA		Moreover, sizes
	Type: Copy of apostilled		required have
R&I detail	Attested By: Apostilled	Applied as: Family	not been
03-02-2025	Validity: 31-12-2026		mentioned in
Fee: 6,000/-	els Os	Class: A	application.
Slip: 18533277567	• FSC (China)		
	Type: Copy of apostilled	Model/Codes/Sizes as Per	
Fee: 20,100/-	Issued By: NMPA	FSC and application:	
Slip: 64951309371	Legalization: Apostilled	CPE Shoe Cover	
	Validity: 23-06-2026		
40	,	Shelf life:	
	ISO Certificate	3 Years	
Bur	• ISO Certificate Type: Copy	3 Years	
Bu	• ISO Certificate Type: Copy Notarization: by CCPIT	3 Years	

AGENDA ITEM II (D): ENLISTMENT/REGISTRATION OF MEDICAL DEVICES FOR LOCAL MANUFACTURING.

S. No.	Name of Applicant(s)	Name of Manufacturer	Medical Device	Decision
1.	Sayyed Healthcare	Sayyed Healthcare Limited, 37	Healthcare + Disposable	Approved
	Limited, 37 Allama Iqbal	Allama Iqbal Industrial City,	Syringe 10cc	
	Industrial City, Faisalabad	Faisalabad		
	[ELM-0079]	[ELM-0079]	Class B	
	Fee: 25000 Fee Slip No. 66689967	29	Model/Size: 10ml (21G x 1.5" TW)	
	Š	3 3,	Shelf Life: 5 Years	
2.	Sayyed Healthcare	Sayyed Healthcare Limited, 37	Healthcare + Disposable	Approved
	Limited, 37 Allama Iqbal	Allama Iqbal Industrial City,	Syringe 1cc	
	Industrial City, Faisalabad	Faisalabad		
	[ELM-0079]	[ELM-0079]	Class B	
	Fee: 25000		Model/Size: 1ml (26G x ½" TW)	

Fee Slip No. 620916212567	Shelf Life: 5 Years	
Fee: 6000 Fee Slip No. 30637431329		
R& I: 16-05-2025		

Evaluator: Mr. Ammar Ashraf

Agenda Item II (e) Hard Copy Cases

Sr.	Name of Applicant(s)	Name of Manufacturer	Medical Device	
No. 1.	M/s. MEDICO INTERNATIONAL, 235-B, B-BLOCK SATELLITE TOWN, RAWALPINDI (ELI-01038) R&I Date: 24-06-2025 Fee: PKR 31,030.00 Slip # 3554830191	Name of Manufacturer: Shenzhen Fitconn Technology Co., Ltd Address: Tth Floor, No. 116 Xiangshan Road, Luotian community, Songgang Street, Bao'an Shenzhen, Guangdong, P.R.C LOA Type: Original Notarization: Notarized Validity: 20-03-2030 FSC	Brand Name: MEDICO MESH NEBULIZER (MY-135) Generic Name: NEBULIZER Applied as: Single	Approved
2.	M/s. MEDICO INTERNATIONAL, 235-B, B-BLOCK SATELLITE TOWN, RAWALPINDI (ELI-01038) R&I Date: 24-06-2025 Fee:	Name of Manufacturer: Shenzhen Fitconn Technology Co., Ltd Address:	Brand Name: MEDICO MESH NEBULIZER (MY-135) Generic Name: NEBULIZER Applied as: Single Class: B Models/Code/sizes (as per FSC & application 1 PCS	Approved
	PKR 31,030.00	Notarization: Notarized	Shelf Life: 3 YEARS	

	Slip # 02295281778	 Validity: 20-03-2030 FSC Type: Original Issued By: NMPA Legalization: Apostille Validity: 11-05-2027 ISO – Certificate: Type: Original Notarization: Notarized Validity: 02-11-2027 CE Certificate Type: Original Notarization: Notarized Validity: 15-01-2027 	(MIS) 9:9:1 AM	
3.	Sohail Corporation Address: Plot no 7, SR-5 Serai Quarters, Techno City, Warehouse No 42, Karachi-Pakistan. (ELI-00676) R&I Date: 04-07-2025 Fee: 6030/- Slip # 4087594889 Differential Fee: 330/- Slip # 983046178	M/s: Wuxi Exanovo Medical Instrument Co., Ltd Manufacturing Site Address: C2-LianDong U Gu, Xibei Town, Xishan District, Wuxi 214194 Jiangsu P.R. China. LOA Type: Copy Notarization: Yes Validity: 05-04-2030 • FSC Type: Original Legalization: Apostille Issued by: Jiangsu Medical Product Admiistration Validity: 26-03-2027 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 21-10-2026	Brand Name: Metro Aneroid Sphygmomanometer Generic Name: Aneroid Sphygmomanometer Applied as: Single Class: A Models/Code/sizes: MC-20-(50) Shelf Life: 5 Years	Approved
4.	Sohail Corporation Address: Plot no 7, SR-5 Serai Quarters, Techno City, Warehouse No 42, Karachi-Pakistan. (ELI-00676) R&I Date: 04-07-2025 Fee Rs. 6,000/- Slip # 30172546461	CE certificate: M/s: Wuxi Exanovo Medical Instrument Co., Ltd Manufacturing Site Address: C2-LianDong U Gu, Xibei Town, Xishan District, Wuxi 214194 Jiangsu P.R. China. LOA Type: Original Notarization: Yes Validity: 05-04-2030 • FSC Type: Original Legalization: Apostille	Brand Name: Metro Stethoscope Generic Name: Stethoscope Applied as: Single Class: A Models/Code/sizes: MC-230 MC-220 Shelf Life: 5 Years	Approved. Firm is advised to select one model before issuance of enlistment certificate

		Issued by: Jiangsu Medical Product Admiistration Validity: 31-03-2027 • ISO – Certificate: Type: Original Notarization: Yes		
		Validity: 21-10-2026 CE certificate: N/A		
5.	Sohail Corporation Address: Plot no 7, SR-5 Serai Quarters, Techno City, Warehouse No 42, Karachi-Pakistan. (ELI-00676) R&I Date: 17-07-2025 Fee: 31030/- Slip # 5018230514	M/s: Huaian Angel Medical Instrument Co Ltd. Manufacturing Site Address: No. 19 East Zhuhai Road Huaian Jiangsu P.R. China. LOA Type: Copy Notarization: Yes Validity: 23-12-2029 • FSC Type: Copy Legalization: Apostille Issued by: CCMHPIE Validity: 18-12-2026 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 26-04-2025 CE certificate: N/A	Brand Name: Metro Umbilical Cord Clamp Generic Name: Umbilical Cord Clamp Applied as: Single Class: B Models/Code/sizes: Shelf Life: 5 years	Deferred for following: Valid notarized copy of ISO certificate shall be submitted. Original legalized FSC issued by the relevant regulatory authority of country of origin shall be submitted.
6.	Sohail Corporation Address: Plot no 7, SR-5 Serai Quarters, Techno City, Warehouse No 42, Karachi-Pakistan. (ELI-00676) R&I Date: 17-07-2025 Fee: 31030/- Slip # 47255990434	M/s: Huaian Angel Medical Instrument Co Ltd. Manufacturing Site Address: No. 19 East Zhuhai Road Huaian Jiangsu P.R. China. LOA Type: Original Notarization: Yes Validity: 23-12-2029 • FSC Type: Original Legalization: Apostille Issued by: CCMHPIE Validity: 18-12-2026 • ISO – Certificate: Type: Original Notarization: Yes Validity: 26-04-2025 CE certificate: Notarized Quality Assurance certificate submitted	Brand Name: Metro Sterile Surgical Blade Generic Name: Sterile Surgical Blade Applied as: Single Class: B Models/Code/sizes: 9, 10, 11, 12, 13,14,15,16,18,19,20,21,22,2 3,24,25,26,27,34,36 Shelf Life: 5 years	Deferred for following: Valid notarized copy of ISO certificate shall be submitted. Original legalized FSC issued by the relevant regulatory authority of country of origin shall be submitted along with differential fee for applying family of different sizes

7.	Sohail Corporation Address: Plot no 7, SR-5 Serai Quarters, Techno City, Warehouse No 42, Karachi-Pakistan. (ELI-00676) R&I Date: 17-07-2025 Fee: 31030/- Slip # 19544972	M/s: Huaian Angel Medical Instrument Co Ltd. Manufacturing Site Address: No. 19 East Zhuhai Road Huaian Jiangsu P.R. China. LOA Type: Original Notarization: Yes Validity: 23-12-2029 • FSC Type: Copy Legalization: Apostille Issued by: CCMHPIE Validity: 18-12-2026 • ISO – Certificate:	Brand Name: Metro Sterile Blood Lancet Generic Name: Sterile Blood Lancet Applied as: Single Class: B Models/Code/sizes: (as per FSC & Product Brochures) Shelf Life: 5 years	Deferred for following: Valid notarized copy of ISO certificate shall be submitted. Original legalized FSC issued by the relevant regulatory authority of country of origin shall be submitted along with details of intended model/size
		Type: Original Notarization: Yes Validity: 26-04-2025 CE certificate: Notarized Quality Assurance certificate submitted		
8.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44- A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi (ELI-00160) R&I Date: 10-07-2025 Fee: 62,000/- Slip #017472652090	Name of Manufacturer: Legal Manufacturer: ShenzhenEver-Blue Biotech Co., Ltd, Address: Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong Manufacturing Site: SHENZHEN YHLO BIOTECH CO., LTD. Address: Building 2, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang	Brand Name: M. Pneumoniae IgG & IgM Control Generic Name: Immunoassay Controls • M. Pneumoniae IgG Control (Negative: 2×2.0ml) • M. Pneumoniae IgM Control (Negative: 2×2.0ml) • M. Pneumoniae IgM Control (Negative: 2×2.0ml) (Positive: 2×2.0ml)	Approved
	Mol	District, Shenzhen, Guangdong 518116 China LOA Type: Copy Notarization: No Validity: 31-12-2025 • FSC Type: Copy Issued By: China Chamber of International Commerce (Country of Origin) FSC issued by Australian Government (TGA)	Applied as: Kit Class: C Models/Code/sizes (as per FSC & application: M. Pneumoniae IgG Control: CC847 M. Pneumoniae IgM Control: CC848 Shelf Life: M. Pneumoniae IgG Control: 48 Months	

		Legalization: No Validity: 20-12-2026 (Country of Origin FSC) Date of Issue: 21-01-2025 (RRA FSC) • ISO – Certificate: Type: Copy Notarization: No Validity: 14-11-2025	M. Pneumoniae IgM Control: 48 Months	
9.	M/s Intra Health, 56A,	CE certificate: N/A Name of Manufacturer:	Brand Name:	Approved
J.	Unit No. 1, Justice	Prime Medical Inc.	Prime Splint	Approved
	Inamullah Road,	Address: 335 Namyang-ro,	Generic Name:	
	Block 7/8, KCHS -	Namyang-eup, Hwaseong-si,	Splint General purpose	
	Karachi	Gyeonggi-do, South Korea	Applied as: Single	
	ELI-00049	LOA	Applied as: Single	
	R&I Date: 30-05-2025	Type: Copy Notarization: Notarized	Class: A	
	Fee: 6,000/-	Validity: 23-01-2030	Models/Code/sizes (as per	
		els Oe	FSC & application:	
		• FSC	PrimeSplint F21 0 (5cm x	
		Type: Original	25cm)	
		Legalized: Apostille	PrimeSplintF335 (7.5cm x	
		Issued by: National Institute of	90cm)	
		Medical Device Safety	PrimeSplint F430 (10.0cm x	
	"VO"	Information, Korea	76cm)	
		Issue date: 25-07-2025	PrimeSplint F545 (12.5cm x	
		• ISO – Certificate:	115cm)	
		Type: Copy	,. PrimeSplint P312 (7.5cm x	
		Notarization: Yes	30cm)	
		Valid till: 11-09-2027	PrimeSplint P415 (1 0cm x	
			40cm)	
		EU MDR Certificate		
		Issued dated 01-03-2024	PrimeSplint P530 (12.5cm x	
		no olife of	76cm)	
		DD " D. "DO.	PrimeSplint R002 (5.0cm •	
			4.Sm)	
		19. CO.	PrimeSplint R004 (1 0.2cm •	
			4.Sm)	
		165 OV	PrimeSplint R006 (15.2cm •	
		12 J.	4.Sm)	
		313	PrimeSplint F312 (7.5cm x	
		707	30cm)	
	_0	O S	PrimeSplint F415 (10.0cm x	
	~ VO,	Vezier Den	40cm)	
	B.		PrimeSplint F530 (12.5cm x	
			76cm)	
			PrimeSplint P21 0 (5cm x 2	
			5cm)	

	PrimeSplint P335 (7.5cm x
	90cm)
	PrimeSplint P430 (1 0cm x
	76cm)
	PrimeSplint P545 (1 2.5cm x
	115cm)
	PrimeSplint R003 (7.6cm •
	4.Srn)
	PrimeSplint ROOS (12.7cm •
	4.Sm)
	Shelf Life:
	3 Years

CMS Cases Agenda Item II (f)

			3 Years	
A	agenda Item II (f) <u>CMS</u>	<u>Cases</u>	2025.	
10.	M/s Bright Vision Suit No 103, 1st Floor, Fine Centre Commercial Block V Gulshan-e-Iqbal Karachi (ELI-00474) R&I Date: 03-09-2021 CMS tracking ID: 5D7- 2J2-3WRU Fee: 25,000/-	Name of Manufacturer: Shenzhen GLD Biotechnology Ltd Address: 25 Bldg., MeiBao Industrial Zone, Lian Tang Industrial City, ShangCun Village, GongMing Town, Gunagming District Shenzhen PR China LOA Type: Copy Notarization: Yes Validity date: 07-03-2024 • FSC Type: Copy Issued By: Provincial Drug Administration Legalization: Legalized Validity: 14-04-2022 • ISO – Certificate: Type: Not submitted Notarization: Validity: CE certificate: Not submitted	Brand Name: 1 Answer Ovulation Test Generic Name: Ovulation LH Test Applied as: Single Class: B Models/Code/sizes (as per FSC & application: 1pcs/pouch, 1pcs/box,2pcs/box,3pcs/bo x.5pcs/box,6pcs/box,7pcs/box, 10pcs/box,12pcs/box,15ps/box,2 0pcs/box,25pcs/box,30pcs/box,5 0pcs/box,100 pcs / box. Shelf Life: 2 years	Deferred for following: Valid FSC, LOA shall be submitted. Valid ISO & CE certificates shall be submitted
11.	M/s Bright Vision Suit No 103, 1st Floor, Fine Centre Commercial Block V Gulshan-e-Iqbal Karachi (ELI-00474) R&I Date: 03-09-2021	Name of Manufacturer: Shenzhen GLD Biotechnology Ltd Address: 25 Bldg., MeiBao Industrial Zone, Lian Tang Industrial City, ShangCun Village, GongMing Town, Gunagming District Shenzhen PR China LOA	Brand Name: 1 Answer Midstream Pregnancy Test Generic Name: Pregnancy HCG Test Applied as: Single Class: B	Deferred for following: Valid FSC, LOA shall be submitted. Valid ISO & CE certificates shall be submitted

	CMS tracking ID: XZH- JUM-ZDVW Fee: 25,000/-	Type: Copy Notarization: Yes Validity date: 07-03-2024 • FSC Type: Copy Issued By: Provincial Drug Administration Legalization: Legalized Validity: 14-04-2022 • ISO – Certificate: Type: Not submitted Notarization: Validity:	Models/Code/sizes (as per FSC & application: 25 pcs/plastic drum,50 pic/plastic drum, 1 pcs/pouch, 1pcs/box,2pcs/box,3pcs/bo, 5pcs/box, 6pcs/box, 7pcs/box, 10p cs/box, 12pcs/box,15pcs/box,20pcs/box, 25pcs/box, 30pcs/box, 50pcs/box, 100pcs/box Shelf Life: 2 years	
12.	M/s Bright Vision Suit No 103, 1st Floor, Fine Centre Commercial Block V Gulshan-e-Iqbal Karachi (ELI-00474) R&I Date: 03-09-2021 CMS tracking ID: GPP- S4Q-5EQE Fee: 25,000/-	Type: Copy Notarization: Yes Validity date: 07-03-2024 • FSC Type: Copy Issued By: Provincial Drug	Brand Name: 1 Answer Pregnancy Rapid Test Strip Generic Name: Pregnancy HCG Test Applied as: Family Class: B Models/Code/sizes (as per FSC & application: 1 pc/pack 25pc/pack Shelf Life: 2 years	Deferred for following: Valid FSC, LOA shall be submitted. Valid ISO & CE certificates shall be submitted
13.	M/s Hoora Pharma (Pvt.) Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi. (ELI-00037) R&I Date: 10-12-2020 CMS tracking ID: M85- Z8M-BT7U Fee: 5,000/-	Name of Manufacturer: Legal Manufacturer: Siemens Healthcare Diagnostics Inc. Address: 511 Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site: Name: Diatron MI Plc Address: Tablas Str. 39 Budapest, Hungary H1097 LOA Type: No	Brand Name: ADVIA 360 Hematology System Generic Name: N/A Applied as: System Class: A Models/Code/sizes (as per FSC & application: 11170841	Deferred for following: Clarification shall be submitted for applying the intended product as Class A. CE certificate shall be submitted.

		Validity date: 16-01-2026	Shelf Life: N/A	Valid legalized FSC shall be
		• FSC Type: Original Issued By: HPRA of Ireland Legalization: Apostille Issued: 04-06-2024		submitted
		• ISO – Certificate: Type: Copy Notarization: Notarized Validity: 31-12-2027	119) o:1 AM	
		CE certificate: N/A		
14.	M/s Hoora Pharma (Pvt.) Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi.	Name of Manufacturer: Legal Manufacturer: Siemens Healthcare Diagnostics Inc. Address: 511 Benedict Ave.	Brand Name: ADVIA 560 Hematology System Generic Name: N/A	Deferred for following: Clarification shall be submitted for
	(ELI-00037) R&I Date:	Tarrytown, NY 10591, USA Manufacturing Site: Name: Diatron MI Plc Address:	Applied as: System Class: A	applying the intended product as
	14-06-2021 CMS tracking ID: QZ8-	Tablas Str. 39 Budapest, Hungary H1097	Models/Code/sizes (as per FSC	Class A.
	Z9Y-JGDM Fee: 5,000/-	LOA Type: Original Notarization: No	& application: 11170842 Shelf Life:	CE certificate shall be submitted. Valid legalized
	Moug	 Validity date: 16-01-2026 ► FSC Type: Original Issued By: HPRA of Ireland Legalization: Apostille Issued: 04-06-2024 	N/A	FSC shall be submitted
		• ISO – Certificate: Type: Copy Notarization: Notarized Validity: 31-12-2027	5052,	
		CE certificate: N/A		
15.	M/s Hoora Pharma (Pvt.) Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi. (ELI-00037)	Name of Manufacturer: Legal Manufacturer: Siemens Healthcare Diagnostics Inc. Address: 511 Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site:	Brand Name: Advia 2120i Hematology System with its accessories Generic Name: N/A	Deferred for following: Clarification shall be submitted for applying the intended
	R&I Date: 14-01-2021	Name: Siemens Healthcare Diagnostics Manufacturing Ltd.	Applied as: System	product as Class A.
	CMS tracking ID: T93- Y42-HUWY Fee: 5,000/-	Address: Chapel Lane Swords, Co. Dublin, Ireland LOA	Class: A Models/Code/sizes (as per FSC	CE certificate shall be
	100. 5,000/-	Type: Original Notarization: No	& application: 11219531: ADVIA 2120i	submitted.
		Validity date: 16-01-2026	without Autosampler	

		 FSC Type: Original Issued By: HPRA of Ireland Legalization: Apostille Issued: 20-11-2024 ISO – Certificate: Type: Copy Notarization: Notarized Validity: 31-12-2027 CE certificate: N/A 	10488923: ADVIA 2120i with SAA Autosampler Instrument 11219529: ADVIA 2120i with DAA Autosampler 11170843: ADVIA Autoloader Shelf Life: N/A	
16.	M/s Hoora Pharma (Pvt.) Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi. (ELI-00037) R&I Date: 10-12-2020 CMS tracking ID: V7H- HLB-7LDE Fee: 5,000/-	Name of Manufacturer: Legal Manufacturer: Siemens Healthcare Diagnostics Inc. Address: 511 Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site: Name: INPECO SA Address: Inpeco S.p.aProduction Plant in Via Givoletto 15-10040 -Val Della Torre (TO)-Itlay LOA Type: No Validity date: 16-01-2026 FSC Type: Original Issued By: US FDA Legalization: Apostille Valid: 12-01-2027 ISO – Certificate: Type: Copy Notarization: Notarized Validity: 31-12-2027	Brand Name: Aptio® Automation System with its Accessories Generic Name: N/A Applied as: System Class: A Models/Code/sizes (as per FSC & application: 1701360 Shelf Life: N/A	Deferred for following: Clarification shall be submitted for applying the intended product as Class A. CE certificate shall be submitted along with details of the function of each constituent part
17.	M/s Hoora Pharma (Pvt.) Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi. (ELI-00037) R&I Date: 28-04-2021 CMS tracking ID: NV7- 72A-4V3D Fee: 5,000/-	CE certificate: N/A Name of Manufacturer: Legal Manufacturer: Siemens Healthcare Diagnostics Inc. Address: 511 Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site: Name: Siemens Healthcare Diagnostics Manufacturing Ltd. Address: 62 Flanders-Bartley Road Flanders, NJ, 07836, USA LOA Type: Original Notarization: No Validity date: 16-01-2026	Brand Name: Atellica CH 930 Analyzer Generic Name: N/A Applied as: System Class: A Models/Code/sizes (as per FSC & application: 11067000 Shelf Life: N/A	Deferred for following: The submitted FSC declares that the applied product can be marketed in Ireland till May, hence afresh valid FSC shall be submitted Clarification, hence shall be submitted for

		 FSC Type: Original Issued By: HPRA of Ireland Legalization: Apostille Issued: 22-05-2023 ISO – Certificate: Type: Copy Notarization: Notarized Validity: 31-12-2027 CE certificate: N/A 	S) o. A AM	applying the intended product as Class A. CE certificate shall be submitted.
18.	M/s Hoora Pharma (Pvt.) Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi. (ELI-00037) R&I Date: 14-01-2021 CMS tracking ID: D1D- NHJ-MVNY Fee: 5,000/-	Name of Manufacturer: Legal Manufacturer: Siemens Healthcare Diagnostics Inc. Address: 511 Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site: Name: Siemens Healthcare Diagnostics Manufacturing Ltd. Address: 62 Flanders-Bartley Road Flanders, NJ, 07836, USA LOA Type: Original Notarization: No Validity date: 12-05-2025 • FSC Type: Original Issued By: HPRA of Ireland Legalization: Apostille Issued: 22-05-2023 • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 31-12-2027 CE certificate: N/A	Brand Name: Atellica IM 1600 & Atellica IM 1300 Analyzer with its Accessories Generic Name: N/A Applied as: System Class: A Models/Code/sizes (as per FSC & application: 11066000 11066001 Accessories: 11069001 SH Prime 11069004 SH Additional 11068008 Atellica DL Shelf Life: N/A	Deferred for following: The submitted FSC declares that the applied product can be marketed in Ireland till May, hence afresh valid FSC shall be submitted Clarification, hence shall be submitted for applying the intended product as Class A. Valid Notarized LOA shall be submitted Justification shall be submitted for applying two different analyzers in same application. CE certificate shall be
19.	M/s Hoora Pharma (Pvt.) Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi. (ELI-00037) R&I Date: 14-01-2021	Name of Manufacturer: Legal Manufacturer: Siemens Healthcare Diagnostics Inc. Address: 511 Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site: Name: Eurotrol B.V,	Brand Name: EPOC Reader & Power Supply & EPOC Host, RX, INT'L Generic Name: N/A Applied as: System	submitted. Deferred for following: The scope of submitted ISO certificate does not include the manufacturing site.

CMS tracking ID: LU2-9J7-GZG7 Fee: 5,000/-	Address: Keplerlaan 20 6716BS Ede Netherlands LOA Type: Original Notarization: No Validity date: 16-01-2026 • FSC Type: Original Issued By: HPRA of Ireland	Class: A Models/Code/sizes (as per FSC & application: 10736398 10736420 Shelf Life: N/A	Clarification shall be submitted for applying the intended product as Class A. The submitted FSC identifies the applied
	Legalization: Apostille Issued: 03-04-2024 • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 31-12-2027 CE certificate: N/A	2025, 9:9:1 All	product with different names and product code while the applicant has applied several products in single application. Clarification
Mond	ssistante central		shall be submitted for applying different The description of each device applied shall be submitted with intended use and role for the accessories.
	Qadir.	WI20:0:1,	CE certificate shall be submitted.
20. M/s Hoora Pharma (Pvt.) Ltd. WH-01-20-A7-A8, Korangi	Name of Manufacturer: Legal Manufacturer: Siemens Healthcare Diagnostics	Brand Name: Hematek 3000	Deferred for following:
Creek Industrial Park, Karachi. (ELI-00037) R&I Date:	Inc. Address: 511 Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site: Name: Siemens Healthcare	Generic Name: N/A Applied as: System	description and role of the each accessory item shall be submitted.
CMS tracking ID: XEV-5BD-ZJ5V Fee: 5,000/-	Diagnostics Manufacturing Ltd Address: Emil-Von -Behring - Str.76 35041 Marburg, Germany LOA Type: Original Notarization: No Validity date: 16-01-2026	Class: A Models/Code/sizes (as per FSC & application: 10805311	clarification shall be submitted whether the applied accessories are exclusive for
	• FSC Type: Original	System Accessories 10316256 Hematek Cannula Set 10323320 Hematek Under Platen Tubing	the applied product or not.

		Issued By: German Authority Legalization: legalized Issued: 27-12-2024 • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 31-12-2027 CE certificate: N/A	10285244 Hematek PCB AS 10312656 Hematek Pump T 10323320 Hematek Under 10327149 Fan Assy Shelf Life: N/A	CE certificate shall be submitted. Clarification shall be submitted for applying the intended product as Class A.
Ltd WH Cre Ka (EI R& 14- CM PU	H-01-20-A7-A8, Korangi eek Industrial Park, arachi. LI-00037) &I Date: -01-2021 MS tracking ID: JQ-JSY-ABPE ee: 5,000/-	Name of Manufacturer: Legal Manufacturer: Siemens Healthcare Diagnostics Inc. Address: 511 Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site: Name: Siemens Healthcare Diagnostics Manufacturing Ltd Address: 62 Flanders-Bartley Road Flanders, NJ, 07836, USA LOA Type: Original Notarization: No Validity date: 16-01-2026 FSC Type: Original Issued By: HPRA of Ireland Legalization: legalized Issued: 22-05-2023 ISO – Certificate: Type: Copy Notarization: Notarized Validity: 31-12-2027 CE certificate: N/A	Brand Name: Immulite 2000 Xpi Immunoassay System & Immulite 2000 Immunoassay System Along with accessories Generic Name: N/A Applied as: System Class: A Models/Code/sizes (as per FSC & application: 10373214 10380062 System Accessories 10374179 Immulite 2000 Nesting Cups 2mL 10374178 Immulite 2000 Nesting Cups 1mL for 12-mm and 13-mm sample tubes Shelf Life: N/A	Deferred for following: The submitted FSC declares that the applied product can be marketed in Ireland till May, hence afresh valid FSC shall be submitted The submitted FSC identifies each product separately while the applicant has applied two systems in one application. The description and role of the each accessory item shall be submitted. Clarification shall be submitted whether the applied accessories are exclusive for the applied product or not. CE certificate shall be submitted.

				Clarification shall be submitted for applying the intended product as Class A.
22.	M/s Hoora Pharma (Pvt.) Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi. (ELI-00037) R&I Date: 10-12-2020 CMS tracking ID: REX-36U-GZAD Fee: 5,000/-	Name of Manufacturer: Legal Manufacturer: Siemens Healthcare Diagnostics Inc. Address: 511 Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site: Name: Siemens Healthcare Diagnostics Manufacturing Ltd Address: Northern Road, Chilton Industrial Sudbury, Suffolk CO10 2XQ, UK LOA Type: Original Notarization: No Validity date: 16-01-2026 FSC Type: Original Issued By: HPRA of Ireland Legalization: legalized Issued: 17-05-2023 ISO – Certificate: Type: Copy Notarization: Notarized Validity: 31-12-2027 CE certificate: N/A	Brand Name: RAPID Point® 500e Blood Gas System, RP500 BLOOD GAS ANALYSER, & RAPID Point 500 System & Immulite 2000 Immunoassay System Along with accessories Generic Name: N/A Applied as: System Class: A Models/Code/sizes (as per FSC & application: 11416751 11416752 11416754 11416755 10492730 10696855 10697306 System Accessories 11416778 2D Barcode scanner kit 11317626 Holder, barcode scanner 10629576 RAPID Point 500 USB flash drive 10320798 Fuse Pack 10329097 Wash/Waste Cartridge (4) 10341179 Wash/Waste Cartridge (1) 10323407 Sample port/capillary kit 10322638 Air Filter 10702063 CO-ox Lamp	Deferred for following: The submitted FSC identifies each product separately while the applicant has applied two systems in one application. The description and role of the each accessory item shall be submitted. Clarification shall be submitted whether the applied accessories are exclusive for the applied product or not. CE certificate shall be submitted. Clarification shall be submitted. Clarification shall be submitted. Clarification shall be submitted for applying the intended product as Class A.
			Shelf Life:	

			N/A	
23. `	M/s Hoora Pharma (Pvt.)	Name of Manufacturer:	Brand Name:	Deferred for
	Ltd.	Legal Manufacturer:	Rapid lab 348EX Blood Gas	following:
	WH-01-20-A7-A8, Korangi	Siemens Healthcare Diagnostics	Analyzer with its consumables.	The submitted
	Creek Industrial Park,	Inc.	Generic Name:	FSC identifies
	Karachi.	Address: 511 Benedict Ave.	N/A	each product
	(ELI-00037)	Tarrytown, NY 10591, USA		separately
	DOID (Manufacturing Site:	Applied as: System	while the
	R&I Date:	Name: Siemens Healthcare		applicant has
	28-04-2021	Diagnostics Manufacturing Ltd	Class: A	applied two
	CMS tracking ID:	Address: Northern Road, Chilton	Models/Code/sizes (og ner ESC	systems in one
	61Q-V89-5T8X Fee: 5,000/-	Industrial Estate Sudbury, Suffolk CO10 2XQ U.K	Models/Code/sizes (as per FSC & application:	application.
	Fee: 3,000/-	LOA	10844678	The
		Type: Original	10697818	
		Notarization: No	System Accessories	description and
		Validity date: 16-01-2026	10309775 Deproteinizer	role of the each accessory item
		Valuity date. 10-01-2020	10311078 Conditioner 10844682	shall be
		- FCC	RAPIDLab 348EX Ca++ Starter	submitted.
		• FSC	Kit	Clarification
		Type: Original	10844683 RAPIDLab 348EX Cl-	shall be
		Issued By: HPRA of Ireland	Starter Kit 10844684 RAPIDLab	submitted
		Legalization: legalized	348EX Starter Kit Blood Gas	whether the
		Issued: 17-05-2023	Only	applied
		750 6 40	11046804 RAPID R Lab 348EX	accessories are
		• ISO – Certificate:	Software Upgrade Kit	exclusive for
		Type: Copy	10311662 Sample & Reagent	the applied
		Notarization: Notarized	Pump Tubing Kit	product or not.
	2	Validity: 31-12-2027	Shelf Life:	product or not.
		GT 188 1 N/A	N/A	CE certificate
	Mo.	CE certificate: N/A	IVA	shall be submitted.
		Abdul Oadil	2025,9:9:1	Clarification shall be submitted for applying the intended product as Class A.
24.	M/s Hoora Pharma (Pvt.)	Name of Manufacturer:	Brand Name:	Approved
	Ltd.	Legal Manufacturer:	Anticoagulant Citrate Dextrose	
	WH-01-20-A7-A8, Korangi	Terumo BCT, Inc	Ph Eur (ACD) Solution A (ACD-	
	Creek Industrial Park,	Address: 10811 West Collins	A) Generic Name:	
	Karachi.	Avenue, Lakewood,	Anticoagulant Citrate Dextrose	
	(ELI-00037)	Colorado,80215 USA	Applied as: System	
		Manufacturing Site:		
	R&I Date:	Name: Terumo BCT Ltd. Address:	Class: A	
	12-09-2022	Old Belfast Road Millbrook Larne		
	CMS tracking ID:	BT40 2SH, United Kingdom	Models/Code/sizes (as per FSC	
	1ET-38B-DQN3	LOA	& application:	
	Fee: 50,000/-	Type: Copy	Codes: 40814 40801	
		Notarization: Yes	Sizes:	
i	1	Issue date: 02-09-2022	12x750ml units/pack	1

		T	10 - 500 - 1 1 - 500 - 1/- 1	
			18x 500ml unis/pack 500ml/pack	
		• FSC	750ml/pack	
		Type: Original	Shelf Life:	
		Issued By: MHRA of UK	2 years	
		Legalization: Apostille		
		Validity: 01-03-2027		
		valuity: 01-05-2027		
		• ISO – Certificate:		
		Type: Copy	_	
		Notarization: Notarized		
		Validity: 04-03-2026		
		Validity. 04-03-2020		
		CT	.61 -1	
		CE certificate:	112.01	
		Date of Issue: 04-09 2023 Date OF	(B), O'.	
		Expiry 01-03- 2026		
25.	M/s Hoora Pharma (Pvt.)	Name of Manufacturer:	Brand Name:	Approved
	Ltd.	Legal Manufacturer:	Trima Accel ® Automated Blood	
	WH-01-20-A7-A8, Korangi	Terumo BCT, Inc	collection System	
	Creek Industrial Park,	Address: 10811 West Collins	Generic Name:	
	, and the second			
	Karachi.	Avenue, Lakewood,	utomated Blood collection	
	(ELI-00037)	Colorado,80215 USA	System	
		Manufacturing Site:	Applied as: Single	
	R&I Date:	Terumo BCT, Inc		
	12-09-2022	Address: 10811 West Collins	Class: C	
	CMS tracking ID:	Avenue, Lakewood,		
	AUE-S1E-TYT1		Models/Code/signs (as non ESC	
		Colorado,80215 USA	Models/Code/sizes (as per FSC	
	Fee: 50,000/-	LOA	& application:	
	>	Type: Copy	81000	
	-01	Notarization: Yes	Shelf Life:	
	10	Issue date: 02-09-2022	N/A	
	M			
		• FSC	$V_{M_{i}}$	
		Type: Original		
			.61 ~'	
		Issued By: US FDA	112.0	
		Legalization: Apostille	(Mr. O).	
		Validity: 19-05-2026	100	
			יפים	
		• ISO – Certificate:	LOV	
		Type: Copy		
		Notarization: Notarized		
			1	
		Valid till 21.04.28		
		CE certificate:		
		Date of Issue: 04-09 2023 Date OF		
		Expiry 01-03- 2026.		
26.	M/s Hoora Pharma (Pvt.)	Name of Manufacturer:	Brand Name:	Approved
	Ltd.	Legal Manufacturer:	Spectra Optia® Collection Set	-FF-0.53
	WH-01-20-A7-A8, Korangi	Terumo BCT, Inc	(10120, 12120)	
	_			
	Creek Industrial Park,	Address: 10811 West Collins	Generic Name:	
	Karachi.	Avenue, Lakewood,	Collection Set	
	(ELI-00037)	Colorado,80215 USA	Applied as: Single	
	10	Manufacturing Site:		
	R&I Date:	FB Manufacturing SRL	Class: C	
	19-08-2024	Address: Calle 58, Zona Franca la		
	CMS tracking ID:	lima, Planta de Terumo BCT Calle	Models/Code/sizes (as per FSC	
	_	,	· -	
	SPX-D45-NDPB	Duan y Avendia Turrialba La	& application:	
	Fee: 50,000/-		10120, 12120	
-	•		•	•

		Lima, Guadalupe 3106, Cartago,		
		Costa Ric	Shelf Life:	
1		Costa Nic	N/A	
		104	N/A	
1		LOA		
		Type: Copy		
		Notarization: Yes		
		Issue date: 02-09-2022		
		• FSC		
		FSC (APOSTILE)		
		(Australia)		
		Certificate Number:		
		22/093	MIS) 9:9:1 AM	
		Date of issue: 4th- April 2022	-1112	
		Valid for: not provided	(14. 0).	
		Country of origin:	601	
		FSC (APOSTILE) (Costa		
		Rica)		
		Kica)		
		Certificate Number: N/a		
		Date of issue: N/a		
		Valid for: 17-02-2027		
		• ISO – Certificate:		
		Type: Copy		
		Notarization: Notarized		
		Valid till 06-12-2027 Issuance date		
	,	07-12-2024 CE certificate:		
		Date of Issue: 04-09- 2023 Date of		
		Expiry: 01-03- 2026		
	1	1 - · ·		
27.	M/s Hoora Pharma (Pvt.)	Name of Manufacturer:	Brand Name:	Approved
27.	M/s Hoora Pharma (Pvt.) Ltd.			Approved
27.	Ltd.	Legal Manufacturer:	Platelet Pooling Set (41910) and	Approved
27.	Ltd. WH-01-20-A7-A8, Korangi	Legal Manufacturer: Terumo BCT, Inc	Platelet Pooling Set (41910) and Reveos Platelet Pooling Set	Approved
27.	Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park,	Legal Manufacturer: Terumo BCT, Inc Address: 10811 West Collins	Platelet Pooling Set (41910) and Reveos Platelet Pooling Set (41940))	Approved
27.	Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi.	Legal Manufacturer: Terumo BCT, Inc Address: 10811 West Collins Avenue, Lakewood,	Platelet Pooling Set (41910) and Reveos Platelet Pooling Set (41940)) Generic Name:	Approved
27.	Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park,	Legal Manufacturer: Terumo BCT, Inc Address: 10811 West Collins Avenue, Lakewood, Colorado,80215 USA	Platelet Pooling Set (41910) and Reveos Platelet Pooling Set (41940)) Generic Name: Blood Transfer Set	Approved
27.	Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi. (ELI-00037)	Legal Manufacturer: Terumo BCT, Inc Address: 10811 West Collins Avenue, Lakewood, Colorado,80215 USA Manufacturing Site:	Platelet Pooling Set (41910) and Reveos Platelet Pooling Set (41940)) Generic Name:	Approved
27.	Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi. (ELI-00037) R&I Date:	Legal Manufacturer: Terumo BCT, Inc Address: 10811 West Collins Avenue, Lakewood, Colorado,80215 USA Manufacturing Site: Terumo BCT Vietnam Co., Ltd,	Platelet Pooling Set (41910) and Reveos Platelet Pooling Set (41940)) Generic Name: Blood Transfer Set Applied as: Family	Approved
27.	Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi. (ELI-00037) R&I Date: 11-07-2023	Legal Manufacturer: Terumo BCT, Inc Address: 10811 West Collins Avenue, Lakewood, Colorado,80215 USA Manufacturing Site: Terumo BCT Vietnam Co., Ltd, Address: Long Duc Industrial	Platelet Pooling Set (41910) and Reveos Platelet Pooling Set (41940)) Generic Name: Blood Transfer Set	Approved
27.	Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi. (ELI-00037) R&I Date: 11-07-2023 CMS tracking ID:	Legal Manufacturer: Terumo BCT, Inc Address: 10811 West Collins Avenue, Lakewood, Colorado,80215 USA Manufacturing Site: Terumo BCT Vietnam Co., Ltd, Address: Long Duc Industrial Park, Long Duc Commune, Long	Platelet Pooling Set (41910) and Reveos Platelet Pooling Set (41940)) Generic Name: Blood Transfer Set Applied as: Family Class: C	Approved
27.	Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi. (ELI-00037) R&I Date: 11-07-2023 CMS tracking ID: 5AN-41U-T2QH	Legal Manufacturer: Terumo BCT, Inc Address: 10811 West Collins Avenue, Lakewood, Colorado,80215 USA Manufacturing Site: Terumo BCT Vietnam Co., Ltd, Address: Long Duc Industrial Park, Long Duc Commune, Long Thanh District, Dong Nai Province,	Platelet Pooling Set (41910) and Reveos Platelet Pooling Set (41940)) Generic Name: Blood Transfer Set Applied as: Family Class: C Models/Code/sizes (as per FSC	Approved
27.	Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi. (ELI-00037) R&I Date: 11-07-2023 CMS tracking ID:	Legal Manufacturer: Terumo BCT, Inc Address: 10811 West Collins Avenue, Lakewood, Colorado,80215 USA Manufacturing Site: Terumo BCT Vietnam Co., Ltd, Address: Long Duc Industrial Park, Long Duc Commune, Long Thanh District, Dong Nai Province, Vietnam	Platelet Pooling Set (41910) and Reveos Platelet Pooling Set (41940)) Generic Name: Blood Transfer Set Applied as: Family Class: C Models/Code/sizes (as per FSC & application:	Approved
27.	Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi. (ELI-00037) R&I Date: 11-07-2023 CMS tracking ID: 5AN-41U-T2QH	Legal Manufacturer: Terumo BCT, Inc Address: 10811 West Collins Avenue, Lakewood, Colorado,80215 USA Manufacturing Site: Terumo BCT Vietnam Co., Ltd, Address: Long Duc Industrial Park, Long Duc Commune, Long Thanh District, Dong Nai Province, Vietnam LOA	Platelet Pooling Set (41910) and Reveos Platelet Pooling Set (41940)) Generic Name: Blood Transfer Set Applied as: Family Class: C Models/Code/sizes (as per FSC & application: 41910 41940	Approved
27.	Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi. (ELI-00037) R&I Date: 11-07-2023 CMS tracking ID: 5AN-41U-T2QH	Legal Manufacturer: Terumo BCT, Inc Address: 10811 West Collins Avenue, Lakewood, Colorado,80215 USA Manufacturing Site: Terumo BCT Vietnam Co., Ltd, Address: Long Duc Industrial Park, Long Duc Commune, Long Thanh District, Dong Nai Province, Vietnam LOA Type: Copy	Platelet Pooling Set (41910) and Reveos Platelet Pooling Set (41940)) Generic Name: Blood Transfer Set Applied as: Family Class: C Models/Code/sizes (as per FSC & application: 41910 41940 Shelf Life:	Approved
27.	Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi. (ELI-00037) R&I Date: 11-07-2023 CMS tracking ID: 5AN-41U-T2QH	Legal Manufacturer: Terumo BCT, Inc Address: 10811 West Collins Avenue, Lakewood, Colorado,80215 USA Manufacturing Site: Terumo BCT Vietnam Co., Ltd, Address: Long Duc Industrial Park, Long Duc Commune, Long Thanh District, Dong Nai Province, Vietnam LOA Type: Copy Notarization: Yes	Platelet Pooling Set (41910) and Reveos Platelet Pooling Set (41940)) Generic Name: Blood Transfer Set Applied as: Family Class: C Models/Code/sizes (as per FSC & application: 41910 41940	Approved
27.	Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi. (ELI-00037) R&I Date: 11-07-2023 CMS tracking ID: 5AN-41U-T2QH	Legal Manufacturer: Terumo BCT, Inc Address: 10811 West Collins Avenue, Lakewood, Colorado,80215 USA Manufacturing Site: Terumo BCT Vietnam Co., Ltd, Address: Long Duc Industrial Park, Long Duc Commune, Long Thanh District, Dong Nai Province, Vietnam LOA Type: Copy	Platelet Pooling Set (41910) and Reveos Platelet Pooling Set (41940)) Generic Name: Blood Transfer Set Applied as: Family Class: C Models/Code/sizes (as per FSC & application: 41910 41940 Shelf Life:	Approved
27.	Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi. (ELI-00037) R&I Date: 11-07-2023 CMS tracking ID: 5AN-41U-T2QH	Legal Manufacturer: Terumo BCT, Inc Address: 10811 West Collins Avenue, Lakewood, Colorado,80215 USA Manufacturing Site: Terumo BCT Vietnam Co., Ltd, Address: Long Duc Industrial Park, Long Duc Commune, Long Thanh District, Dong Nai Province, Vietnam LOA Type: Copy Notarization: Yes Issue date: 02-09-2022	Platelet Pooling Set (41910) and Reveos Platelet Pooling Set (41940)) Generic Name: Blood Transfer Set Applied as: Family Class: C Models/Code/sizes (as per FSC & application: 41910 41940 Shelf Life:	Approved
27.	Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi. (ELI-00037) R&I Date: 11-07-2023 CMS tracking ID: 5AN-41U-T2QH	Legal Manufacturer: Terumo BCT, Inc Address: 10811 West Collins Avenue, Lakewood, Colorado,80215 USA Manufacturing Site: Terumo BCT Vietnam Co., Ltd, Address: Long Duc Industrial Park, Long Duc Commune, Long Thanh District, Dong Nai Province, Vietnam LOA Type: Copy Notarization: Yes Issue date: 02-09-2022	Platelet Pooling Set (41910) and Reveos Platelet Pooling Set (41940)) Generic Name: Blood Transfer Set Applied as: Family Class: C Models/Code/sizes (as per FSC & application: 41910 41940 Shelf Life:	Approved
27.	Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi. (ELI-00037) R&I Date: 11-07-2023 CMS tracking ID: 5AN-41U-T2QH	Legal Manufacturer: Terumo BCT, Inc Address: 10811 West Collins Avenue, Lakewood, Colorado,80215 USA Manufacturing Site: Terumo BCT Vietnam Co., Ltd, Address: Long Duc Industrial Park, Long Duc Commune, Long Thanh District, Dong Nai Province, Vietnam LOA Type: Copy Notarization: Yes Issue date: 02-09-2022 • FSC Issued by: FAMHP of Belgium	Platelet Pooling Set (41910) and Reveos Platelet Pooling Set (41940)) Generic Name: Blood Transfer Set Applied as: Family Class: C Models/Code/sizes (as per FSC & application: 41910 41940 Shelf Life:	Approved
27.	Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi. (ELI-00037) R&I Date: 11-07-2023 CMS tracking ID: 5AN-41U-T2QH	Legal Manufacturer: Terumo BCT, Inc Address: 10811 West Collins Avenue, Lakewood, Colorado,80215 USA Manufacturing Site: Terumo BCT Vietnam Co., Ltd, Address: Long Duc Industrial Park, Long Duc Commune, Long Thanh District, Dong Nai Province, Vietnam LOA Type: Copy Notarization: Yes Issue date: 02-09-2022	Platelet Pooling Set (41910) and Reveos Platelet Pooling Set (41940)) Generic Name: Blood Transfer Set Applied as: Family Class: C Models/Code/sizes (as per FSC & application: 41910 41940 Shelf Life:	Approved
27.	Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi. (ELI-00037) R&I Date: 11-07-2023 CMS tracking ID: 5AN-41U-T2QH	Legal Manufacturer: Terumo BCT, Inc Address: 10811 West Collins Avenue, Lakewood, Colorado,80215 USA Manufacturing Site: Terumo BCT Vietnam Co., Ltd, Address: Long Duc Industrial Park, Long Duc Commune, Long Thanh District, Dong Nai Province, Vietnam LOA Type: Copy Notarization: Yes Issue date: 02-09-2022 • FSC Issued by: FAMHP of Belgium	Platelet Pooling Set (41910) and Reveos Platelet Pooling Set (41940)) Generic Name: Blood Transfer Set Applied as: Family Class: C Models/Code/sizes (as per FSC & application: 41910 41940 Shelf Life:	Approved
27.	Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi. (ELI-00037) R&I Date: 11-07-2023 CMS tracking ID: 5AN-41U-T2QH	Legal Manufacturer: Terumo BCT, Inc Address: 10811 West Collins Avenue, Lakewood, Colorado,80215 USA Manufacturing Site: Terumo BCT Vietnam Co., Ltd, Address: Long Duc Industrial Park, Long Duc Commune, Long Thanh District, Dong Nai Province, Vietnam LOA Type: Copy Notarization: Yes Issue date: 02-09-2022 • FSC Issued by: FAMHP of Belgium Date of issue: 22-06-2022	Platelet Pooling Set (41910) and Reveos Platelet Pooling Set (41940)) Generic Name: Blood Transfer Set Applied as: Family Class: C Models/Code/sizes (as per FSC & application: 41910 41940 Shelf Life:	Approved
27.	Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi. (ELI-00037) R&I Date: 11-07-2023 CMS tracking ID: 5AN-41U-T2QH	Legal Manufacturer: Terumo BCT, Inc Address: 10811 West Collins Avenue, Lakewood, Colorado,80215 USA Manufacturing Site: Terumo BCT Vietnam Co., Ltd, Address: Long Duc Industrial Park, Long Duc Commune, Long Thanh District, Dong Nai Province, Vietnam LOA Type: Copy Notarization: Yes Issue date: 02-09-2022 • FSC Issued by: FAMHP of Belgium Date of issue: 22-06-2022 Valid for: not provided	Platelet Pooling Set (41910) and Reveos Platelet Pooling Set (41940)) Generic Name: Blood Transfer Set Applied as: Family Class: C Models/Code/sizes (as per FSC & application: 41910 41940 Shelf Life:	Approved
27.	Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi. (ELI-00037) R&I Date: 11-07-2023 CMS tracking ID: 5AN-41U-T2QH	Legal Manufacturer: Terumo BCT, Inc Address: 10811 West Collins Avenue, Lakewood, Colorado,80215 USA Manufacturing Site: Terumo BCT Vietnam Co., Ltd, Address: Long Duc Industrial Park, Long Duc Commune, Long Thanh District, Dong Nai Province, Vietnam LOA Type: Copy Notarization: Yes Issue date: 02-09-2022 • FSC Issued by: FAMHP of Belgium Date of issue: 22-06-2022 Valid for: not provided Country of origin:	Platelet Pooling Set (41910) and Reveos Platelet Pooling Set (41940)) Generic Name: Blood Transfer Set Applied as: Family Class: C Models/Code/sizes (as per FSC & application: 41910 41940 Shelf Life:	Approved
27.	Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi. (ELI-00037) R&I Date: 11-07-2023 CMS tracking ID: 5AN-41U-T2QH	Legal Manufacturer: Terumo BCT, Inc Address: 10811 West Collins Avenue, Lakewood, Colorado,80215 USA Manufacturing Site: Terumo BCT Vietnam Co., Ltd, Address: Long Duc Industrial Park, Long Duc Commune, Long Thanh District, Dong Nai Province, Vietnam LOA Type: Copy Notarization: Yes Issue date: 02-09-2022 • FSC Issued by: FAMHP of Belgium Date of issue: 22-06-2022 Valid for: not provided Country of origin: FSC (APOSTILE) (Costa	Platelet Pooling Set (41910) and Reveos Platelet Pooling Set (41940)) Generic Name: Blood Transfer Set Applied as: Family Class: C Models/Code/sizes (as per FSC & application: 41910 41940 Shelf Life:	Approved
27.	Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi. (ELI-00037) R&I Date: 11-07-2023 CMS tracking ID: 5AN-41U-T2QH	Legal Manufacturer: Terumo BCT, Inc Address: 10811 West Collins Avenue, Lakewood, Colorado,80215 USA Manufacturing Site: Terumo BCT Vietnam Co., Ltd, Address: Long Duc Industrial Park, Long Duc Commune, Long Thanh District, Dong Nai Province, Vietnam LOA Type: Copy Notarization: Yes Issue date: 02-09-2022 • FSC Issued by: FAMHP of Belgium Date of issue: 22-06-2022 Valid for: not provided Country of origin: FSC (APOSTILE) (Costa Rica)	Platelet Pooling Set (41910) and Reveos Platelet Pooling Set (41940)) Generic Name: Blood Transfer Set Applied as: Family Class: C Models/Code/sizes (as per FSC & application: 41910 41940 Shelf Life:	Approved
27.	Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi. (ELI-00037) R&I Date: 11-07-2023 CMS tracking ID: 5AN-41U-T2QH	Legal Manufacturer: Terumo BCT, Inc Address: 10811 West Collins Avenue, Lakewood, Colorado,80215 USA Manufacturing Site: Terumo BCT Vietnam Co., Ltd, Address: Long Duc Industrial Park, Long Duc Commune, Long Thanh District, Dong Nai Province, Vietnam LOA Type: Copy Notarization: Yes Issue date: 02-09-2022 • FSC Issued by: FAMHP of Belgium Date of issue: 22-06-2022 Valid for: not provided Country of origin: FSC (APOSTILE) (Costa Rica) Certificate Number: N/a	Platelet Pooling Set (41910) and Reveos Platelet Pooling Set (41940)) Generic Name: Blood Transfer Set Applied as: Family Class: C Models/Code/sizes (as per FSC & application: 41910 41940 Shelf Life:	Approved
27.	Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi. (ELI-00037) R&I Date: 11-07-2023 CMS tracking ID: 5AN-41U-T2QH	Legal Manufacturer: Terumo BCT, Inc Address: 10811 West Collins Avenue, Lakewood, Colorado,80215 USA Manufacturing Site: Terumo BCT Vietnam Co., Ltd, Address: Long Duc Industrial Park, Long Duc Commune, Long Thanh District, Dong Nai Province, Vietnam LOA Type: Copy Notarization: Yes Issue date: 02-09-2022 • FSC Issued by: FAMHP of Belgium Date of issue: 22-06-2022 Valid for: not provided Country of origin: FSC (APOSTILE) (Costa Rica) Certificate Number: N/a Date of issue: N/a	Platelet Pooling Set (41910) and Reveos Platelet Pooling Set (41940)) Generic Name: Blood Transfer Set Applied as: Family Class: C Models/Code/sizes (as per FSC & application: 41910 41940 Shelf Life:	Approved

28.	M/S Medi Health Services Address: 1 st Floor, 16/E, Mehta Street, Temple Road, Lahore (ELI-00180) R&I Date: 26th July, 2022 CMS tracking ID: 52T-J5A-SAZ2 Fee: 25,000/-	Type: Copy Notarization: Notarized Valid till 04-03-2026 CE certificate: N/A Name of Manufacturer: Name: Bioland Technology Ltd. Address: No. A6B7, Block G, Shang Rong Industrial Park, Boalong 5th Road, Long Gang, 518116, Shenzhen, China LOA Type: Copy Notarization: Apostille Issue date: 11-10-2029 • FSC Type: Copy Legalized: Yes Issued by: Provincial Supervision Body Valid for: 02-09-2026 • ISO – Certificate: Type: Copy Notarization: No Valid till: 31-01-2027 CE certificate: Valid till 31-12-2028	Brand Name: Fast Lab (Model: 2008) Generic Name: Blood Pressure Monitor Applied as: Set Class: B Models/Code/sizes (as per FSC & application: 41910 41940 Shelf Life: 6 years	Approved
29.	M/S Talha Enterprises Address: 67/E, Jami Commercial Street#7, DHA phase VII (ELI-00925) R&I Date: 21-01-2025 CMS tracking ID: E8B-GVU-WP5L Fee: 50,000/-	Name of Manufacturer: Name: Beijing ZKSK Technology Co., Ltd Address: Building 9,6&No.6 yuan Hengye North 7th Street, Yongle Economic Development Zone, Tongzhou District, Beijing 101105, China LOA Type: Copy Notarization: Yes Issue date: 02-09-2022 • FSC Type: Copy Legalized: Apostille Issued by: Provincial Supervision Body Valid for: 31-03-2028 • ISO – Certificate: Type: Copy Notarization: Yes Valid till: 05-01-2028 CE certificate: Valid till 31-12-2028	Brand Name: ZKSK Generic Name: Disposable Pulse Lavag Applied as: Family Class: B Models/Code/sizes (as per FSC & application: • EP18-01 • EP 18-02 • EP 18-03 Shelf Life: 6 years	Approved
30.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS,	Name of Manufacturer: Legal Manufacturer: Diagnostic Stago S.A.S. Address:	Brand Name: PTT LA Generic Name: IVD Test Kit (6 x 2ml) Applied as: Kit	Approved

	Razi Road, Shahrah-e-	3 Allée Thérés - 92600 Asnières sur			
	Faisal, Karachi	Seine	Class: B		
	ELI-00160	France	14 11 /G 1 / 1 / 1 FGG		
	R&I Date:	Manufacturing Site:	Models/Code/sizes (as per FSC		
	04-04-2025	DIAGNOSTICA STAGO S.A.S. Address:	& application: 00599		
	CMS tracking ID: 3HN-QJY-LJGR	23-29 Rue Constantin Pecqueur	Shelf Life:		
	Fee: 31,000/-	ZAC "Les Châtaigners" 95150	2 years (2 - 8°C)		
	ree. 31,000/-	Taverny, France	2 years (2 ° c)		
		LOA Type: Copy Notarization: Yes	2025,9:9:1 AM		
		Notarization: No			
		Valid till: 23-05-2028			
		CE certificate: Endorsed in FSC			
31.	M/s Martin Dow Specialties	Name of Manufacturer:	Brand Name:	Approved	
	(Pvt) Limited 7th Floor,		CK Prest 2		
	Nice Trade Orbit Building, 44-A&B, Block-6, PECHS,	Diagnostic Stago S.A.S. Address:	Generic Name: 6 x 2-ml Vials of Reagent 1		
	Razi Road, Shahrah-e-	3 Allée Thérés - 92600 Asnières sur	(C.K. Prest® 2) 6 x 2-ml Vials of		
	Faisal, Karachi	Seine	Reagent 2 (Activator)		
	ELI-00160	France	Applied as: Kit		
	R&I Date:	Manufacturing Site:			
	14-04-2025	DIAGNOSTICA STAGO S.A.S.	Class: C		
	CMS tracking ID:	Address:	(A), O:2		
	JPS-B7D-9E82	125, 131 Avenue Louis Roche	Models/Code/sizes (as per FSC		
	Fee: 62,000/-	92230 Gennevilliers FRANCE	& application:		
		LOA Type: Copy	00598 Shelf Life:		
		Notarization: Yes	2 years (2 - 8°C)		
		Issue date: 31-12-2025	2 years (2 % %)		
		• FSC			
		Type: Copy			
		Legalized: Legalized			
		Issued by: France			
		Valid for: 24-05-2024			
		• ISO – Certificate: Type: Copy			
1			1		
	~6	1 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7			
	1000	Notarization: No			
	Moug	1 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7			
32.	M/s Royal Medical	Notarization: No Valid till: 23-05-2028 CE certificate: Valid till 25-04-	Brand Name:	Approved.	
32.	M/s Royal Medical Office No. 26th, 3rd Floor United Trade Center Plot #	Notarization: No Valid till: 23-05-2028 CE certificate: Valid till 25-04- 2027 Name of Manufacturer:	Brand Name: ANTMED Generic Name:	Approved. Firm advised	is

5, Block-6, Gulshan-eIqba Karachi ELI-00691 R&I Date: 22-04-2025 CMS tracking ID: 3M5-GJA-UEAS Fee: 62,000/-	18 Jinhui Ave., Pingshan New District, Shenzhen 518122, China Manufacturing Site: Shenzhen Antmed Co., Ltd Address: No.3 Hualian Ave, Songshanhu District 523800 Dongguan LOA Type: Copy Notarization: Yes Issue date: 16-02-2030 • FSC Type: Copy Legalized: Apostille Issued by: Provincial Supervision Body Valid for: 26-10-2025 • ISO – Certificate: Type: Copy Notarization: Yes Valid till: 30-10-2026 CE certificate: Valid till 05-02-2029	Disposable Pressure Trasnducer Applied as: Single Class: C Models/Code/sizes (as per FSC & application: PT-01, PT-012, PT013, PT-02, PT-022, PT-023, PT-03, PT032, PT-033 Shelf Life: 5 years	select one model for issuance of enlistment letter.
33. M/s Royal Medical Office No. 26th, 3rd Floo United Trade Center Plot is 5, Block-6, Gulshan-eIqba Karachi ELI-00691 R&I Date: 22-04-2025 CMS tracking ID: TH7-7PG-DVXV Fee: 31,000/-	Name of Manufacturer: Legal Manufacturer: Shenzhen Antmed Co., Ltd.	Brand Name: ANTMED Generic Name: Manifold Applied as: Single Class: B Models/Code/sizes (as per FSC & application: MD-M-1, MD-M-2, MD-M-3, MD-M4,MD-L-1, MD-L-2, MD-L-3, MD-L-4 Shelf Life: 3 years	Approved. Firm is advised to select one model for issuance of enlistment letter.
34. M/S POPULAR INTERNATIONAL PVT		Brand Name: HUMASCOPE Generic Name:	Deferred for following:

	ELI-00091 R&I Date: 30-06-2025 CMS tracking ID: 522-W3L-5MZ7 Fee: 6,000/-	Address: Max-PlanckRing 21, 65205 Wiesbaden, Germany LOA Type: Copy Notarization: Yes Issue date: 16-02-2030 FSC Type: Copy Legalized: Legalized Issued by: German Authority Valid for: N/A ISO – Certificate: Type: Copy Notarization: Notarized Valid till: 11-03-2028 CE certificate: Valid till 26-05-2025	Microscopic System Applied as: Kit Class: B Models/Code/sizes (as per FSC & application: 14400, 14500, 14600, 14601, 14700, 14701, 14800, 14801, 14802, 14803, 14804, 14900, 14901, 14000/210, 14000/866, 14000/867, 14000/877, 14000/878, 14804 Shelf Life: N/A	The submitted FSC does not include the name of the applied product Clarification shall be submitted for applying different models within same application as a kit.
35.	M/S POPULAR INTERNATIONAL PVT LTD ELI-00091 R&I Date: 30-06-2025 CMS tracking ID: UH2-698-7HW5 Fee: 6,000/-		Brand Name: HUMANEX A1C VARIANT Generic Name: Glycated Haemoglobin Monitoring System Applied as: Kit Class: A Models/Code/sizes (as per FSC & application: 16199, 16180, 16185, 16187, 16189, 16195, 16197, 16190, 16190/10 Shelf Life: N/A	Deferred for following: Justification shall be submitted for applying the intended product as Class A Product. Clarification shall be submitted for the list of constituents along with the applied product and their role. Declaration regarding the exclusivity of the constituents with the intended product is required.
36.	M/S POPULAR INTERNATIONAL PVT LTD ELI-00091 R&I Date: 13-06-2025 CMS tracking ID:		Brand Name: HUMAMETER A1C Generic Name: Glycated Haemoglobin Monitoring System Applied as: Kit	Deferred for following: Justification shall be submitted for applying the intended

	MEX-TRV-U8SL	Type: Copy	Class: A	product as
	Fee: 6,000/-	Notarization: Yes		Class A
		Issue date: 31-12-2029	Models/Code/sizes (as per FSC & application:	Product.
		• FSC	16086, 16085/50, 16080, 16081,	Clarification
		Type: Copy	16082	shall be
		Legalized: Legalized	Shelf Life:	submitted for
		Issued by: German Authority	N/A	the different
		Valid for: N/A		codes for
		• ISO – Certificate:		applied
		Type: Copy		product and
		Notonization, Notonizad		their role.
		Valid till: 11-03-2028	1/2/0:	Declaration
		CE certificate: Valid till 26-05-	WIII OF	regarding the
		2025		exclusivity of
			0,0,	the .
		10,	70 h	constituents
		AUI GO		with the
		Modifie al		intended
		VP " D. " 100.		product is
				required.
		Valid till: 11-03-2028 CE certificate: Valid till 26-05-2025		The submitted
				brand name
		65,00		does not clarify
	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	7 9		whether the
				applied
		03'		product is a
				system or
	10/1			reagent.
				The generic
			Dly.	term of
				"Glycenated
			113,00.	Haemoglobin Monitoring
			M, 0:3	system" shall
		2011, 1		be clarified.
		000	(1) (1) (1) (1) (1) (1) (1) (1) (1) (1)	oc ciai gica.
37.	M/S CONCEPT Pharma		Brand Name:	Deferred for
	(Pvt) Ltd	VITROMED GmbH Address:	IVF LABWARE	following:
	Address: 825-E, Johan	Hans-Knoell Strasse. 6 07745 Jena,	Generic Name:	Justification
	Town Lahore, Pakistan.	Germany	Labware pipette	shall be
	ELI-00112	TO 400 -011	Applied as: Family	submitted for
	R&I Date:	LOA		applying the
	11-09-2023	Type: Copy	Class: A	intended
	CMS tracking ID:	Notarization: Yes	M. J.J./C. J. / FCC	product as
	1NL-9QB-3N63	Issue date: 31-03-2025	Models/Code/sizes (as per FSC	Class A Product.
	Fee: 5,000/-	FCC	& application:	Valid LOA,
	>	• FSC	Models Ref. no	FSC & ISO
	-01	Type: Copy		certificate shall
	, VO),	Legalized: Legalized	V- V-CWD-	be submitted.
	B.	Issued by: German Authority Issued: 13-01-2023	CENTERWE 60	
			LL-60 V- V-CTD-90	
		• ISO – Certificate:	CULTURED V-C1D-90	
1		Type: Copy		1
		Notarization: Notarized	ISH-90	

38.	M/S CONCEPT Pharma (Pvt) Ltd Address: 825-E, Johar Town Lahore, Pakistan. ELI-00112 R&I Date: 11-09-2023 CMS tracking ID: 1NL-9QB-3N63 Fee: 5,000/-	VITROMED GmbH Address:	V- V-CTD-60 CULTURED ISH-60 V- V-CTD-35 CULTURED ISH-35 V- V-ICD-50 ICSIDISH— 50 V- 4WELLDIS H	Deferred for following: Valid LOA, FSC & ISO certificate shall be submitted.
		Act Dinber	Shelf Life: 3 years	
39.	M/S CONCEPT Pharma (Pvt) Ltd Address: 825-E, Johar Town Lahore, Pakistan. ELI-00112 R&I Date: 11-09-2023 CMS tracking ID: LET-XA3-MVMN Fee: 5,000/-	Name of Manufacturer: VITROMED GmbH Address: Hans-Knoell Strasse. 6 07745 Jena, Germany LOA Type: Copy Notarization: Yes Issue date: 31-03-2025 • FSC Type: Copy Legalized: Legalized	Brand Name: IVF LABWARE Generic Name: Labware tubes Applied as: Family Class: A Models/Code/sizes (as per FSC & application: Models Ref. no	Deferred for following: Valid LOA, FSC & ISO certificate shall be submitted.

			[**	1
		Issued by: German Authority	V- V-RTU-14 ROUNDTU	
		Issued: 13-01-2023	BE-14	
		• ISO – Certificate:	V- V-RTU-5	
		Type: Copy	ROUNDTU	
		Notarization: Notarized	BE-5	
		Valid till: 01-05-2025	V-Conical V-CTU-15	
		CE certificate: Not submitted	tube-15	
		CE certificate: 1 (of Submitted		
			Shelf Life:	
			3 years	
40.	M/S CONCEPT Pharma	Name of Manufacturer:	Brand Name:	Deferred for
10.	(Pvt) Ltd	VITROMED GmbH Address:	IVF LABWARE	following:
	Address: 825-E, Johan	Hans-Knoell Strasse. 6 07745 Jena,	Generic Name:	Valid LOA,
	Town Lahore, Pakistan.	Germany	V CRYOVIAL	
	-	Germany		
	ELI-00112	7.01	Applied as: Single	certificate shall
	R&I Date:	LOA	-000	be submitted.
	11-09-2023	Type: Copy	Class: A	
	CMS tracking ID:	Notarization: Yes		
	EVJ-B73-PGBR	Issue date: 31-03-2025	Models/Code/sizes (as per FSC	
	Fee: 5,000/-	70° OII '81'	& application:	
		• FSC		
		Type: Copy	V-CRV-2	
			Shelf Life:	
		Legalized: Legalized	3 years	
		Issued by: German Authority	3 years	
		Issued: 13-01-2023		
		• ISO – Certificate:		
		Type: Copy		
		Notarization: Notarized		
		Valid till: 01-05-2025		
	1011	CE certificate: Not submitted		
41.	M/S CONCEPT Pharma	Name of Manufacturer:	Brand Name:	Deferred for
11.	(Pvt) Ltd	VITROMED GmbH Address:	V-DENUPET	following:
	Address: 825-E, Johan		Generic Name:	Valid LOA,
	Town Lahore, Pakistan.	1		FSC & ISO
		Germany	Denudation pipette	
	ELI-00112	101	Applied as: Family	certificate shall
	R&I Date:	LOA		be submitted.
	11-09-2023	Type: Copy	Class: B	
	CMS tracking ID:	Notarization: Yes	00	
	P9A-G8B-8NA1	Issue date: 31-03-2025	Models/Code/sizes (as per FSC	
	Fee: 25,000/-	100-110	& application:	
		• FSC		
		Type: Copy	Models Ref. no	
		Legalized: Legalized		
			V-DEN	
		Issued by: German Authority	V 125	
		Issued: 13-01-2023	DENUPET	
	\	• ISO – Certificate:	125	
		Type: Copy	VDENUPET V-DEN	
		Notarization: Notarized	135 135 VDENUPET V-DEN	
	2	Valid till: 01-05-2025	VDENOPE1 V-DEN	
	-0	CE certificate: Not submitted	VDENUPET V-DEN	
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	10		150 150	
	Mo.		VDENUPET V-DEN	
	Mor		VDENUPET V-DEN 175 175	
	Mor		VDENUPET V-DEN 175 175 VDENUPET V-DEN	
	Mor		VDENUPET V-DEN 175 175 VDENUPET V-DEN 200 200	
	Mor		VDENUPET V-DEN 175 175 VDENUPET V-DEN	

42.	M/S CONCEPT Pharma (Pvt) Ltd Address: 825-E, Johar Town Lahore, Pakistan. ELI-00112 R&I Date: 27-10-2021 CMS tracking ID: 7GJ-QL1-GX39 Fee: 5,000/-	GYNETICS	VDENUPET V-DEN 300 300 VDENUPET V-DEN 600 600 Shelf Life: 5 years Brand Name: Gynetics Generic Name: Sterile Endometrial Curette (Sampling) Applied as: Family Class: A Models/Code/sizes (as per FSC & application: #4164 Probet #4164 In/Out #5164 Echosampler Shelf Life: 4 years	Deferred for following: Valid FSC & ISO certificate shall be submitted. The submitted FSC declares that the applied product is not authorized to be placed on the market for use in the exporting country while it also claims that the applied product actually on the market in the exporting country. Clarification shall be submitted for this disparity.
43.	M/S CONCEPT Pharma (Pvt) Ltd Address: 825-E, Johar Town Lahore, Pakistan. ELI-00112 R&I Date: 11-09-2023 CMS tracking ID: 2PM-9RT-172J Fee: 5,000/-	VITROMED GmbH	Brand Name: IVF LABWARE Generic Name: V SAMPLE CONTAINER Applied as: Single Class: A Models/Code/sizes (as per FSC & application: Models Ref. no V-SAC- V- Sample Container- 100 Shelf Life: 3 years	Deferred for following: Valid LOA, FSC & ISO certificate shall be submitted.

44.	M/S CONCEPT Pharma (Pvt) Ltd Address: 825-E, Johar Town Lahore, Pakistan. ELI-00112 R&I Date: 11-09-2023 CMS tracking ID: 2PM-9RT-172J Fee: 5,000/-	Name of Manufacturer: VITROMED GmbH Address: Hans-Knoell Strasse. 6 07745 Jena, Germany LOA Type: Copy Notarization: No Issue date: 31-3-2025 • FSC Type: Copy Legalized: Yes Issued by: German Authority Issued: 08-05-2023 • ISO – Certificate: Type: Copy Notarization: Notarized Valid till: 01-05-2025 CE certificate: Not submitted	Brand Name: V-SPERM MORPHO SLIDE Generic Name: Sperm assessment slide Applied as: Single Class: A Models/Code/sizes (as per FSC & application: V-SMS-01 Shelf Life: 1 year	Deferred for following: Valid LOA, FSC & ISO certificate shall be submitted.
45.	M/S CONCEPT Pharma (Pvt) Ltd Address: 825-E, Johar Town Lahore, Pakistan. ELI-00112 R&I Date: 27-12-2021 CMS tracking ID: Q2J-923-Y1US Fee: 5,000/-	Name of Manufacturer: GYNETICS MEDICAL PRODUCTS NV Address: Rembert Dodoensstraat 51, 3920 Lommel, Belgium LOA Type: Copy Notarization: Yes Issue date: 31-12-2025 FSC Type: Copy Legalized: Yes Issued by: FAMHP of Belgium Issued: 28-04-2021 ISO – Certificate: Type: Copy Notarization: Notarized Valid till: 30-01-2023 CE certificate: Not submitted	Brand Name: Gynetics Generic Name: Sterile intra-Uterine Insemination Catheter/Canuula Applied as: Family Class: A Models/Code/sizes (as per FSC & application: Single Lumen Flush Smooze #4225 Smooze Medium #4225 Smooze Long #4220 IUI #4220 IUI Memo #4220 Plus Shelf Life: 4 year	Deferred for following: Valid FSC & ISO certificate shall be submitted. The submitted FSC declares that the applied product is not authorized to be placed on the market for use in the exporting country while it qlso claims that the applied product actually on the market in the exporting country. Clarification shall be submitted for this disparity. Justification for applying the product as Class A
46.	M/S CONCEPT Pharma (Pvt) Ltd	Name of Manufacturer: GYNETICS MEDICAL PRODUCTS NV	Brand Name: Gynetics Generic Name:	Deferred for following:

Address: Address: Rembert Valid FSC & 825-E, Johar Sterile Embryo transfer catheters Town Lahore, Pakistan. Dodoensstraat 51, 3920 ISO certificate ELI-00112 Lommel, Belgium **Applied as:** Family shall **R&I Date:** LOA submitted. 27-12-2021 Type: Copy Class: A CMS tracking ID: **Notarization:** Yes The submitted V35-J9J-XX7S **Issue date:** 31-12-2025 Models/Code/sizes (as per FSC FSC declares Fee: 5,000/-& application: that the applied #2000 Semtrac C product is not • FSC #2000 C TIS authorized Type: Copy #2000 Semtrac Set 4.2 be placed on Legalized: No #2000 Semtrac Set 4.2 SP the market for **Issued by:** FAMHP of Belgium #2000 Set 4.2 TIS in use **Issued:** 28-04-2021 #2000 Set 4.2 TIS SP exporting • ISO - Certificate: #2000 Semtrac Set 5 country while it Type: Copy #2000 Semtrac Set 5 A qlso claims that Notarization: Notarized #2000 Semtrac Set 5 AB the applied Valid till: 30-01-2023 #2000 Semtrac Set CS product CE certificate: Not submitted #2000 Semtrac Set 5 SP actually on the #2000 Semtrac Set Short market in the #2000 Semtrac Set 5 Trial exporting #2000 Set 5 TIS country. #2000 Set 5 TIS SP Clarification shall be submitted for this disparity. Monday, Salah Cember, 2025, 9:9:1 Justification for applying the product as

Class A

		Abdul Ozdifi i Abdul Ozdifi i Abdul Ozdifi Directori	#2000 Semtrac W-180 SP #2000 Semtrac W-180 SP #2000 Semtrac W-180 Tria #2000 W-180 TIS SP #2000 Semtrac W-240 #2000 Semtrac W-240 SP #2000 Semtrac W-240 Tria #2000 W-240 TIS #2000 W-240 TIS SP #4000 The Tulip Memo #4000 The Tulip Memo A #4000 The Tulip S TIS #4000 Tulip S TIS #4000 Tulip S TIS #4000 Tulip S TIS #4000 Tulip L TIS #4000 Tulip L TIS #4000 Tulip LS TIS #4000	
Add 2nd	vices dress: Office No. 14, Floor, Mujahid Plaza,		Brand Name: Getein Generic Name: Activator	Approved.
EL R&	e area, Islamabad I-00112 I Date: 09-2024	LOA Type: Copy Notarization: Yes Issue date: 31-12-2025	Applied as: Kit Class: A	
AZ	S tracking ID: H-7S8-GYZYFee:	• FSC	Models/Code/sizes (as per FSC	
5,00	00/-	Type: Copy Legalized: Apostille	& application: 220uL×25, 220uL×50, 220uL×100, 1000mL×2,	

		• ISO – Certificate: Type: Copy Notarization: Notarized Valid till: 25-07-2026 CE certificate: Copy of Legalized FSC form Spanish Authority has been submitted which endorses the CE status dated 10-11-2022	500mL×2, 250mL×2, 1000mL×4, 500mL×4, 250mLx4 Shelf Life: 1 year	
48.	M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore ELI-00150 R&I Date: 17-06-2021 CMS tracking ID: 3AH-A2B-AUHV Fee: 5,000/-	Name of Manufacturer: ARJOHUNTLEIGH AB ADDRESS: Hans Michelsensgatan	Brand Name: Arjo Sara Combilizer and Sara Stedy, Sara Stedy Compact Generic Name: Standing and Raising Aid Applied as: Single Class: A Models/Code/sizes (as per FSC & application: Sara Stedy NTB2000 Sara Stedy Compact NTB 3000 Shelf Life: 10 years	Approved.
49.	M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore ELI-00150 R&I Date: 17-06-2021 CMS tracking ID: 9G4-BM6-RTG1 Fee: 5,000/-	valid till 10-01-2026 has been submitted Name of Manufacturer: ARJOHUNTLEIGH AB ADDRESS: Hans Michelsensgatan	Brand Name: Arjo Concerto Shower Trolley Generic Name: Shower Trolley Applied as: Single Class: A Models/Code/sizes (as per FSC & application: BABxxxx-xx, BAB5000-xx Shelf Life: 10 years	Approved. The firm is advised to select one model for issuance of enlistment certificate.

50.	M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore ELI-00150 R&I Date: 17-06-2021 CMS tracking ID: L35-GTZ-6D3S Fee: 5,000/-	ARJOHUNTLEIGH AB ADDRESS: Hans Michelsensgatan 10 211 20 Malmo Sweden LOA Type: Copy Notarization: Yes Issue date: 31-12-2025 • FSC Type: Copy Legalized: Legalized Issue date: 12-07-2023 • ISO – Certificate: Type: Copy Notarization: Notarized	Brand Name: Arjo Carevo Shower Trolley Generic Name: Shower Trolley Applied as: Single Class: A Models/Code/sizes (as per FSC & application: BAC11xx-xx Shelf Life: 10 years	Approved.
		Notarized copy of EU Quality Management System Certificate valid till 10-01-2026 has been submitted		
51.	M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore ELI-00150 R&I Date: 17-06-2021 CMS tracking ID: EUX-A22-A431 Fee: 5,000/-	Name of Manufacturer: ARJOHUNTLEIGH AB ADDRESS: Hans Michelsensgatan 10 211 20 Malmo Sweden LOA Type: Copy Notarization: Yes Issue date: 31-12-2025 • FSC Type: Copy Legalized: Legalized Issued by: SMPA of Sweden Issue date: 12-07-2023 • ISO – Certificate: Type: Copy Notarization: Notarized Valid till: 05-01-2027 Notarized copy of EU Quality Management System Certificate valid till 10-01-2026 has been submitted	Brand Name: Arjo Sara Combilizer Generic Name: Standing and Raising Aid Applied as: Single Class: A Models/Code/sizes (as per FSC & application: APA1000xx Shelf Life: 10 years	Approved.
52.	M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore ELI-00150 R&I Date: 22-03-2021 CMS tracking ID: 7AS-N24-6AQL Fee: 5,000/-	ARJOHUNTLEIGH AB ADDRESS: Hans Michelsensgatan	Brand Name: Arjo Generic Name: Hygiene Lifters Miranti Applied as: Single Class: A Models/Code/sizes (as per FSC & application:	Approved. The firm is advised to select one model for issuance of enlistment certificate.

		1	Lanna Series	T
		• FSC	CEB8xxx-xx, CEB8xxx-xx	
		Type: Copy		
		Legalized: Legalized	Shelf Life:	
		Issued by: SMPA of Sweden	10 years	
		Issue date: 12-07-2023		
		• ISO – Certificate:		
		Type: Copy		
		Notarization: Notarized		
		Valid till: 05-01-2027		
		Notarized copy of EU Quality		
		Management System Certificate		
		valid till 10-01-2026 has been	72) 0.,	
			1	
		submitted		
53.	M/s Vertex Medical Pvt.		Brand Name: Arjo	Approved.
	Ltd.	ARJOHUNTLEIGH AB	Generic Name:	The firm is
	Address : 401-402, Block –	ADDRESS: Hans Michelsensgatan	Hygiene Lifters Bolero	advised to
	F, Johar Town, Lahore	10		select one
	ELI-00150	211 20 Malmo Sweden LOA	Applied as: Single	model for
	R&I Date:	Type: Copy		issuance of
	22-03-2021	Notarization: Yes	Class: A	enlistment
	CMS tracking ID:	Issue date: 31-12-2025	Caussia	certificate.
	BN6-NP1-3JR4	135de date: 31 12 2023	Models/Code/sizes (as per FSC	certificate.
			· -	
	Fee: 5,000/-	• FSC	& application:	
		Type: Copy	CEB6xxx-xx, CEB6x2x-xx	
		Legalized: Legalized		
		Issued by: SMPA of Sweden	Shelf Life:	
		Issue date: 12-07-2023	10 years	
		• ISO – Certificate:		
	, NO),			
		Type: Copy		
	~	Notarization: Notarized	DIA.	
		Valid till: 05-01-2027		
			(2) (3)	
		Notarized copy of EU Quality	~ We will a second	
		Management System Certificate	(14. 0).	
		valid till 10-01-2026 has been	-61	
		submitted	23.5	
54.	M/s Vertex Medical Pvt.		Brand Name: Prioma Medical	Deferred for
5 1.	Ltd.	CARETEK MEDICAL LIMITED	Bed	submission of
	Address : 401-402, Block –	Address: UNIT A 10/F,AMTEL	Generic Name:	
				valid legalized
	F, Johar Town, Lahore		Prioma Medical Bed	FSC, issued by
	ELI-00150	ROAD CENTRAL,HK		the relevant
	R&I Date:	· Glo GO	Applied as: Set	regulatory
	03-01-2023	Name of Manufacturer:		authority of
	CMS tracking ID:	Caretek (China) Medical PLC.	Class: A	country of
	123-HEV-9VY7	Address: Xiguakeng, Guanqiao		origin.
	Fee: 5,000/-	Village, Shilou Town, Panyu	Models/Code/sizes (as per FSC	
		District, Guangzhou City,	& application:	
	>	Guangdong Province, P.R. China.	P400, P500, P600	
	-01	LOA	Shelf Life:	
	NO)			
		Type: Copy	10 years	
		Notarization: Yes		
		Issue date: 06-02-2026		
1		• FSC		
		150		

55.	M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore ELI-00150 R&I Date: 03-01-2023 CMS tracking ID: 8L9-NJD-NNZB Fee: 5,000/-	CARETEK MEDICAL LIMITED Address: UNIT A 10/F,AMTEL BUILDING 144-148 DES VOEUX ROAD CENTRAL,HK Name of Manufacturer: Caretek (China) Medical PLC.	Brand Name: Prioma Medical Couches Generic Name: Prioma Medical Couches Applied as: Family Class: A Models/Code/sizes (as per FSC & application: Prioma Semi Electric Couches: HC1, HC2, HC3 Prioma Electric Couches EC1, EC2, EC Shelf Life: 10 years	Deferred for submission of valid legalized FSC, issued by the relevant regulatory authority of country of origin.
56.	M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore ELI-00150 R&I Date: 03-01-2023 CMS tracking ID: Z9Z-4LS-VBZ7 Fee: 5,000/-	Legal manufacturer: CARETEK MEDICAL LIMITED Address: UNIT A 10/F,AMTEL	Brand Name: Prioma Birthing Beds (PBB2) Generic Name: Prioma Birthing Beds (PBB2) Applied as: Single Class: A Models/Code/sizes (as per FSC & application: PBB2 Shelf Life: 10 years	Deferred for submission of valid legalized FSC, issued by the relevant regulatory authority of country of origin.

		• FSC		
		Type: Copy Legalized: Legalized Issued by: China Chamber of Commerce Valid date: 12-03-2025 • ISO – Certificate:		
		Type: Copy Notarization: Notarized Valid till: 03-03-2026 CE Certificate: N/A	115) o: 1 AM	
57.	M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore ELI-00150 R&I Date: 22-03-2021 CMS tracking ID: HRE-XS6-RTVD Fee: 25,000/-	ARJOHUNTLEIGH AB ADDRESS: Hans Michelsensgatan 10 211 20 Malmo Sweden LOA Type: Copy Notarization: Yes Issue date: 31-12-2025	Brand Name: Arjo Skin IQ Generic Name: Skin IQ 365 Applied as: Single Class: B Models/Code/sizes (as per FSC & application: Skin IQ TM 365 Shelf Life: 1 Year or 35 Laundry Cycles	Approved.
58.	M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore ELI-00150 R&I Date: 05-10-2021 CMS tracking ID: U1V-SLE-4QZZ Fee: 25,000/-	ARJOHUNTLEIGH AB ADDRESS: Hans Michelsensgatan 10 211 20 Malmo Sweden LOA Type: Copy Notarization: Yes Issue date: 31-12-2025	Brand Name: Arjo Flowtron ACS 900 Generic Name: Flowtron ACS900 Applied as: Single Class: B Models/Code/sizes (as per FSC & application: Flowtron ACS900 Pump (526000-xx) Shelf Life: 7 Years	Approved.

59.	M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore ELI-00150 R&I Date: 05-10-2020 CMS tracking ID: GP2-8L1-Z59Q Fee: 25,000/-	ARJOHUNTLEIGH AB ADDRESS: Hans Michelsensgatan	Brand Name: Arjo NINJO Generic Name: Flusher Disinfectors Applied as: Single Class: B Models/Code/sizes (as per FSC & application: FD16xx Shelf Life: 10 Years	Approved.
60.	M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore ELI-00150 R&I Date: 21-02-2021 CMS tracking ID: T7B-NJA-8523 Fee: 25,000/-	Name of Manufacturer: Sorin Group Italia S.r.l., ADDRESS:	Brand Name: LILLIPUT Generic Name: Infant and neonatal oxygenators Applied as: Family Class: B Models/Code/sizes (as per FSC & application: 597, 050596, 050578, 050598, 050579, 050580 Shelf Life: 3 Years	Approved. Firm is advised to select one model before issuance of enlistment certificate.
61.	M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore ELI-00150 R&I Date: 21-02-2021	Name of Manufacturer: Sorin Group Italia S.r.l., ADDRESS:	Brand Name: CARDIO ACCESSORIES Generic Name: Auxiliary devices for cardiac surgery Applied as: Set	Deferred for submission of role of each accessory in the applied MD.

CMS tracking ID: 36M-AWD-84NS	Notarization: Yes Issue date: 31-12-2025	Class: B	
Fee: 25,000/-	• FSC Type: Copy Legalized: yes Issued by: Ministry of Health Italy Issue date: 26-04-2024 • ISO – Certificate: Type: Copy Notarization: Apostille Valid till: 14-05-2027 EU MDR Certificate Valid till: 06-04-2026	Models/Code/sizes (as per FSC & application: 05004, 05005, 05006, 05052, 05053, 05055, 05057, 05119, 05200, 05201, 05202, 05203, 05204, 05205, 05206, 05207, 05208, 05209, 05212, 05213, 05214, 05215, 05216, 05217, 05218, 05219, 05220, 05221, 05222, 05223, 05224, 05225, 05226, 05227, 05228, 05229, 05230, 05231, 05234, 05236, 05237, 05238, 05239, 05240, 05241, 05242, 05246, 05247, 05248, 05249, 05250, 05275, 05277, 05278, 05300, 05301, 05303, 05480, 05481, 05483, 05490, 05494, 05495, 05496, 05497, 05498, 050547, 050575, 050660, 050661, BS351-70, BS352-80, BS353- 50, BS354-25, BS361-50, BS900-17, S351-70, S352-80, S353-50, S354-25, S361-50, S900-17, 050662. Shelf Life:	
62. M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore ELI-00150 R&I Date: 22-12-2020 CMS tracking ID: EPV-195-BZPY Fee: 25,000/-	Sorin Group Italia S.r.l., ADDRESS:	Brand Name: SORIN Generic Name: Dideco Data Master Applied as: Family Class: B Models/Code/sizes (as per FSC & application: 05170, 05171, 05172, 05173 Shelf Life: 4 Years	Approved.
63. M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore ELI-00150	Name of Manufacturer: Sorin Group Italia S.r.l., ADDRESS: Via Statale Nord 12, 86 41037 Mir andola MO, Italy	Brand Name: SORIN Generic Name: Dideco Data Master	Approved.

	R&I Date:	LOA		
	22-12-2020	Type: Copy	Class: B	
	CMS tracking ID:	Notarization: Yes	Ciuss. D	
	2B3-YSJ-D34P	Issue date: 31-12-2025	Models/Code/sizes (as per FSC	
	Fee: 25,000/-	135te date: 31 12 2023	& application:	
	Fee: 23,000/-	- FSC	05170, 05171, 05172, 05173	
		• FSC	Shelf Life:	
		Type: Copy	4 Years	
		Legalized: yes	4 Tears	
		Issued by: Ministry of Health Italy		
		Issue date: 26-04-2024		
		• ISO – Certificate:		
		Type: Copy		
		Notarization: Apostille	1/3, 0/.	
		Valid till: 14-05-2027	(M), O'.	
		EU MDR Certificate	-0,5,	
		Valid till: 06-04-2026	60°	
64.	M/s Vertex Medical Pvt.		Brand Name:	Deferred for
	Ltd.	Sorin Group Italia S.r.l.,	LIVANOVA	submission of
	Address : 401-402, Block –	ADDRESS:	Generic Name:	valid legalized
	F, Johar Town, Lahore		Coronary Artery Perfusion	FSC for the
	ELI-00150	andola MO, Italy	Cannula	applied
	R&I Date:	LOA	Applied as: Family	product.
	20-11-2020	Type: Copy	Applied as: I amily	product.
	CMS tracking ID:	Notarization: Yes	Class: B	
	B3X-GYG-GURL Fee:		Class. D	
	25,000/-	18sue date: 51-12-2025	Models/Code/sizes (as per FSC	
	25,000/-	Fig.	Models/Code/sizes (as per FSC	
		• FSC	& application:	
		Type: Copy	CP-11010, CP-11012, CP-11014,	
		Legalized: yes	CP12010, CP-12012, CP-12014	
		Issued by: Ministry of Health Italy	Shelf Life:	
		Issue date: 26-04-2024	4 Years	
		• ISO – Certificate:	.6)1	
		Type: Copy	10.0	
		Notarization: Apostille	(61, 0).	
		Valid till: 14-05-2027	-61	
		Co. Al	73.	
		EU MDR Certificate		
		Valid till: 06-04-2026		
65.	M/s Vertex Medical Pvt.		Brand Name:	Deferred for
05.	Ltd.	Sorin Group Italia S.r.l.,	SORIN	submission of
	Address : 401-402, Block –	ADDRESS:	Generic Name:	valid legalized
	F, Johar Town, Lahore		Dideco Micro	FSC for the
	ELI-00150	andola MO, Italy	Applied as: Family	applied
	R&I Date:	LOA	rippiicu as. raimry	product.
	22-12-2020	Type: Copy	Class: B	թւսանն.
	CMS tracking ID:	Notarization: Yes	Cidos. D	
	B3X-GYG-GURL Fee:		Models/Code/sizes (as per FSC	
	25,000/-	1550C uate. 51-12-2025	& application:	
1	25,000/-	- FCC		
	NO1.	• FSC	05340, 05341, 05342, 05343,	
		Type: Copy	05344,	
		Legalized: yes	05345, 05367, 05368, 05369	
		Issued by: Ministry of Health Italy	Shelf Life:	
		Issue date: 26-04-2024	4 Years	
1		• ISO – Certificate:		
	_1		<u> </u>	<u> </u>

66.	M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore ELI-00150 R&I Date: 19-05-2020 CMS tracking ID: QYV-VMG-SE9V Fee: 25,000/-	Inomed Medizintechnik GmbH ADDRESS: Im Hausgruen 29 79312 Emmendingen Germany LOA Type: Copy Notarization: Yes	Brand Name: Inomed Generic Name: Microdrive Applied as: Family Class: A Models/Code/sizes (as per FSC & application: Inomed Micro Drive Shelf Life: 10 Years	Deferred for clarification for applying the intended product as Class A Medical Device.
67.	M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore ELI-00150 R&I Date: 19-05-2020 CMS tracking ID: 9DS-6AD-H53A Fee: 25,000/-	Name of Manufacturer: Inomed Medizintechnik GmbH ADDRESS: Im Hausgruen 29	Brand Name: Inomed Generic Name: Stereotactic System Applied as: System Class: A Models/Code/sizes (as per FSC & application: ZD, RM and OSS Shelf Life: 5 Years	Deferrred fro submission of role of each accessory in MD.
68.	M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore ELI-00150 R&I Date:	Name of Manufacturer: Inomed Medizintechnik GmbH ADDRESS: Im Hausgruen 29	Brand Name: Inomed Generic Name: ISIS MER System Applied as: System	Deferred for submission of constituents of the system along with their codes.

	19-05-2020	Type: Copy	Class: B	
	CMS tracking ID: V2V-XG6-V9YT Fee:	Notarization: Yes Issue date: 31-12-2024	Models/Code/sizes (as per FSC	
	25,000/-	-a.c	& application:	
		• FSC	ISIS MER System Shelf Life:	
		Type: Copy	10 Years	
		Legalized: Yes	10 Tears	
		Issued by: German Authority		
		Issue date: 04-07-2022		
		• ISO – Certificate:		
		Type: Copy Notarization: Notarized		
		Valid till: 16-01-2026	12,00	
		V MINU VIIIV 10 01 2020	M, O.S	
		EC Certificate		
		Extension Valid till: 31-12-2028	(1) (1) (1) (1) (1) (1) (1) (1) (1) (1)	
69.	M/s Vertex Medical Pvt.		Brand Name:	Deferred for
	Ltd.	TECHNOLOGIE MEDICALE	Venturi TM2	submission of
	Address: 401-402, Block –	ADDRESS: 101, RUE VAILLANT	Generic Name:	valid, legalized
	F, Johar Town, Lahore		Venturi Ejector	FSC
	ELI-00150 R&I Date:	NOISY LE SEC, France LOA Type: Copy	Applied as: Single	
	08-02-2021	Notarization: No	Class: B	
	CMS tracking ID:	Validity: 30-09-2027	Class. B	
	9DS-5W1-MWJU Fee:		Models/Code/sizes (as per FSC	
	25,000/-	• FSC	& application:	
		Type: Copy	Venturi TM2 - 20239	
		Legalized: No	Shelf Life:	
		Issued by: Trade Facilitation	10 Years	
		Department, France		
		Issue date: 23-03-2020	" Eli	
		• ISO – Certificate:	- A Y	
		Type: Copy	"(2) O.;)	
		Notarization: No	Will Ois	
		Valid till: 11-03-2028		
		EC Certificate	-0,5,	
		Extension Valid till: 31-12-2028	0	
70.	M/s Vertex Medical Pvt.		Brand Name:	Deferred for
	Ltd.	TECHNOLOGIE MEDICALE	RTM3	submission of
	Address : 401-402, Block –	ADDRESS: 101, RUE VAILLANT	Generic Name:	valid, legalized
	F, Johar Town, Lahore	COUTURIER, 93130	Flow meter with floating ball	FSC
	ELI-00150	NOISY LE SEC, France LOA	Applied as: Single	
	R&I Date:	Type: Copy		
	08-02-2021	Notarization: No	Class: B	
	CMS tracking ID: SS2-UPA-QH2Q Fee:	Validity: 30-09-2027	Models/Code/sizes (as per FSC	
	25,000/-	• FSC	Models/Code/sizes (as per FSC & application:	
	23,000/	Type: Copy	Venturi TM2 - 20239	
		Legalized: No	Shelf Life:	
	"VO.	Issued by: Trade Facilitation	10 Years	
		Department, France		
		Issue date: 23-03-2020		
		• ISO – Certificate:		
		Type: Copy		
<u> </u>	1	V # 1 V	l .	1

		Notarization: No Valid till: 11-03-2028		
		EC Certificate Extension Valid till: 31-12-2028		
71.	M/s ASTO Life Science Pvt. Ltd. Address: Plaza No. 1 Block Orchard 1, Paragon City Barki Road, Lahore Cantt. ELI-00103 R&I Date: 21-03-2025 CMS tracking ID: 8VH-5T3-831V Fee: 6,000/-	Name of Manufacturer: Becton, Dickinson and Company	Brand Name: BD BACTECTM Platelet Aerobic culture media BD BACTECTMM Platelet Anaerobic culture media Generic Name: Platelet Aerobic culture media & Platelet Anaerobic culture media Applied as: Not mentioned Class: A Models/Code/sizes (as per FSC & application: Venturi TM2 - 20239 Shelf Life: 1 Year	Deferred for following: Valid, legalized FSC shall be submitted. Valid notarized ISO certificate cand LOA shall be submitted Description of the product along with DOC shall be submitted Clarification for applying Anaerobic & Aerobic Culture media in same application, shall be submitted.
72.	M/s ASTO Life Science Pvt. Ltd. Address: Plaza No. 1 Block Orchard 1, Paragon City Barki Road, Lahore Cantt. ELI-00103 R&I Date: 09-04-2025 CMS tracking ID: R6Z-19Q-ENV4 Fee: 25,000/-	Becton, Dickinson and Company ADDRESS: 7 Loveton Circle	M120:0	Deferred for following: Valid, legalized FSC shall be submitted. Valid notarized ISO certificate shall be submitted Description of the product along with DOC shall be submitted Clarification for applying different reagents and solutions in one application shall be submitted.

			349202 BD FACS™ Lysing Solution 334224 BD FACS™ Shutdown Solution 336911 BD FACS™ Sheath Solution 340345 BD FACS™ Cleaning Solution 342003 BD FACSFlow™ Sheath Fluid	
			340542 BD CD3 (SK7) FITC 349201 BD CD3 (SK7) FITC 349209 BD CD19 (4G7) PE 340298 BD Tritest™ CD4/CD8/CD3 340334 BD Trucount™ Tubes 335775 BD FAGS™ 7-Color Setup	
		Abdul Oadill Assistant Director 1	Beads 344563 Stem Cell Enumeration Kit 50 Tests 340911 Multi-check CD4 control (BL) 340912 BD Multi-Check Control	
		Moduli Director	2X2.5mL IVD 340913 BD Multi-Check Control 5X2.5mL IVD	
		sistant centre	340914 Multi-check CD4 control (BL) 2.5ml 340915 BD multi-check CD4 Low Ctrl	
	1	2529	2X2.5mL IVD	
	Mond	(a),	Generic Name: Biosciences reagents & IVD Kits Applied as: Not mentioned	
		Ogdif r.l	Class: B Models/Code/sizes (as per FSC & application: Shelf Life: 24Year	
73.	M/s EXCEL CORPORATION 435 BYJ Society, Bahadurabad,	Name of Manufacturer: Suzhou Suning Underpad Co Ltd ADDRESS: No. 70 Yong An Road Xuguan New district	Brand Name: Star Adult Diapers Generic Name: Adult Diapers	Deferred for submission of Legalized FSC. Notarized ISO
	Karachi. ELI-00110 R&I Date:	215151 Suzhou PR China LOA Type: Copy Notarization: No	Applied as: Not mentioned Class: A	certificate and valid LOA. Details of the
	13-01-2021 CMS tracking ID: AY5-MGE-BWQ2	Validity: 14-07-2030 • FSC	Models/Code/sizes (as per FSC & application: Sizes:	models or sizes shall be submitted
	Fee: 5,000/-	Not submitted • ISO – Certificate: Type: Copy Notarization: No Valid till: 31-08-2028	N/A Shelf Life: N/A	along with product description Details of shelf life required
		EC Certificate: N/A		

74.	M/s EXCEL CORPORATION 435 BYJ Society, Bahadurabad, Karachi. ELI-00110 R&I Date: 13-01-2021 CMS tracking ID: AY5-MGE-BWQ2 Fee: 5,000/-	Name of Manufacturer: Suzhou Suning Underpad Co Ltd ADDRESS: No. 70 Yong An Road Xuguan New district 215151 Suzhou PR China LOA Type: Copy Notarization: No Validity: 14-07-2030 • FSC Type: Copy Legalized: No Issued by: JSMPA Valid date: 14-03-2027 • ISO – Certificate: Type: Copy Notarization: No Valid till: 31-08-2028 EC Certificate: N/A	Brand Name: Star Disposable Underpad (Dignity Sheet) Generic Name: Disposable Underpad (Dignity Sheet) Applied as: Not mentioned Class: A Models/Code/sizes (as per FSC & application: Sizes: 24×19, 50×40, 55×40, 55× 45, 60×40, 60×50, 60×60, 65×30, 70×70, 85×65, 90×60, 90×75, 120×80, 120×90, 130×70, 140×70, 150×60, 115×105, 150×110 , 160×80, 190×70, 200×80	Deferred for following: Legalized FSC shall be submitted. Notarized ISO certificate and LOA shall be submitted. Details of shelf life required
7.		esisto Deco	, 200×100, 200×120, 200×150, 210×150, 215×75 , 220×70, 220×80, 220×90, 220×120, 230×75, 350×190 Shelf Life: N/A	
75.	M/s MOODY Global Services, Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad		Brand Name: Getein Generic Name: Cleaning Solution Applied as: Kit	Deferred for following: Legalized valid FSC shall be submitted
	ELI-00926 R&I Date: 02-09-2024 CMS tracking ID: TB1-77T-X1X6 Fee: 5,000/-	LOA Type: Copy Notarization: yes Validity: 09-05-2029 • FSC Type: Copy Legalized: yes Issued by: JSMPA Valid date: 11-07-2025 • ISO – Certificate: Type: Copy Notarization: No	Class: A Models/Code/sizes (as per FSC & application: Sizes: 1lx1, 11x2, 21x1, 51x1 7lx1, 10Lx1, 20L×1, 1 5mlx25, 1.5ml×50, 1.5ml×100, 500ml×1, 500ml×2,500mL×4, 10 00mL×1, 1000mL×2, 1000mlx4, 5000mL×1, 5000mL×2, 5000m Lx4, 7000mlx1, 7000mL×2, 7000mlx4, 10000mL×1,	
	,ond	Valid till: 25-07-2026 EC Certificate: N/A	10000mL×2,10000mL×4 Shelf Life: 12 months	
76.	M/s MOODY Global Services, Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad	Name of Manufacturer: Getein Biotech, Inc. ADDRESS: No.9 Bofu Road, Luhe District, Nanjing, 211505, China	Brand Name: Getein Generic Name: Activator Applied as: Kit	Deferred for following: Legalized valid FSC shall be submitted

		104	Class. A	
	TT 7 0000 6	LOA	Class: A	
	ELI-00926	Type: Copy		
	R&I Date:	Notarization: yes	Models/Code/sizes (as per	
	02-09-2024	Validity: 09-05-2029	FSC & application:	
	CMS tracking ID:		Sizes:	
	AZH-7S8-GYZY	• FSC	220uL×25, 220uL×50,	
	Fee: 5,000/-	Type: Copy	220uL×100, 1000mL×2,	
	,		500mL×2, 250mL×2,	
		Legalized: yes	1000mL×4, 500mL×4,	
		Issued by: JSMPA	250mLx4.4	
		Valid date: 11-07-2025	230m2x1.1	
		• ISO – Certificate:	Shelf Life:	
		Type: Copy	12 months	
		Notarization: No	12 months	
		Valid till: 25-07-2026	Mi. Ola	
		EC Certificate: N/A	0,0,1	
77.	M/s MOODY Global	Name of Manufacturer:	Brand Name:	Deferred for
1	Services, Office No. 14, 2nd	Getein Biotech, Inc.	Getein	following:
1	Floor, Mujahid Plaza, Blue	ADDRESS: No.9 Bofu Road, Luhe	Generic Name:	Legalized valid
	area, Islamabad		Activator	FSC shall be
1	arca, Islaillauau	District, Nanjing, 211505, China		
1	EL I No.0025	TOL VOICE	Applied as: Kit Class: A	submitted
	ELI No:0025	LOA	Class: A	
		Type: Copy		
	R&I Date:	Notarization: yes	Models/Code/sizes (as per	
	09-09-2024	Validity: 09-05-2029	FSC & application:	
	CMS tracking ID:		Sizes:	
	R95-J26-6AZY	• FSC	220uL×25, 220uL×50,	
	L	Type: Copy	220uL×100, 1000mL×2,	
	Fee: 5,000/-	Legalized: yes	500mL×2, 250mL×2,	
	, 10	Issued by: JSMPA	1000mL×4, 500mL×4,	
			250mLx4.4	
		Valid date: 11-07-2025		
		• ISO – Certificate:	Shelf Life:	
		Type: Copy	12 months	
		Notarization: No	12 Holitis	
		Valid till: 25-07-2026	14. 2.	
			-61	
		EC Certificate: N/A		
78.	MR Medical Pakistan	Name of Manufacturer:	Brand Name:	Approved
1	Private Limited	M/s Shenzhen Mindray Bio-Medical	Mindray	
1	Office no: 1101, 11th floor,		Generic Name:	
1	ISE Tower, Jinnah Avenue,	ADDRESS: Mindray Building, Keji		
1	Blue Area, Islamabad,	12th Road South, High-Tech	_	
1	Pakistan.	Industrial Park, Nanshan, 518057,	Class: A	
1	ELI No:01008	Shenzhen, PEOPLE'S REPUBLIC	CAMBBO 11	
1	151/1 140.01000	OF CHINA	Models/Code/sizes (as per	
	D & I Date:	OF CHINA	· -	
	R&I Date:	TOA	FSC & application:	
1	23-02-2023	LOA	Sizes:	
	CMS tracking ID:	Type: Copy	220uL×25, 220uL×50,	
	7RB-L5L-1MSE	Notarization: yes	220uL×100, 1000mL×2,	
1	Fee: 5,000/-	Validity: 14-04-2027	500mL×2, 250mL×2,	
1			1000mL×4, 500mL×4,	
		• FSC	250mLx4.4	
		Type: Copy		
		Legalized: yes	Shelf Life:	
		Issued by: Germany	12 months	
		assuce by. Commany	<u> </u>	

	T	T 14 02 02 202;	T	T
ſ		Issue date: 02-02-2021		
İ		• ISO – Certificate:		
ı		Type: Copy Notarization: No		
ı		Valid till: 31-08-2026		
1		vanu un. 31-08-2020		
İ		EC Certificate: N/A		
79.	MR Medical Pakistan	Name of Manufacturer:	Brand Name:	Approved.
İ	Private Limited	M/s Shenzhen Mindray Bio-Medical	Mindray	
ı	Office no: 1101, 11th floor,	· · · · · · · · · · · · · · · · · · ·	Generic Name:	
ı	ISE Tower, Jinnah Avenue,	ADDRESS: Mindray Building, Keji	•	
ı	Blue Area, Islamabad,	12th Road South, High-Tech		
ı	Pakistan.	Industrial Park, Nanshan, 518057,	Class: A	
İ	ELI No:01008	Shenzhen, PEOPLE'S REPUBLIC	M. O.	
İ	2072	OF CHINA	Models/Code/sizes (as per	
İ	R&I Date:	LOA	FSC & application:	
İ	23-02-2023	Type: Copy	Sizes: BS-2000M	
İ	CMS tracking ID:	Notarization: yes	Shelf Life:	
i	1GT-NW9-EABQ Fee: 5,000/-	Validity: 14-04-2027	Shelf Life: 10 years	
Ì	1 66. 3,000/-	• FSC	10 years	
Ī		Type: Copy		
İ		Legalized: yes		
İ		Issued by: Germany		
Ī		Issue date: 02-02-2021		
Ī	\	• ISO – Certificate:		
İ		Type: Copy		
İ		Notarization: No		
Ī		Valid till: 31-08-2026		
İ	101.	EC Certificate: N/A		
80.	MR Medical Pakistan	Name of Manufacturer:	Brand Name:	Deferred for
1	Private Limited	M/s Shenzhen Mindray Bio-Medical		Clarification
İ	Office no: 1101, 11th floor,		Generic Name:	for grouping
İ	ISE Tower, Jinnah Avenue,	ADDRESS: Mindray Building, Keji		the applied
İ	Blue Area, Islamabad,	12th Road South, High-Tech		constituents as
İ	Pakistan.	Industrial Park, Nanshan, 518057,		single product
İ	ELI No:01008	Shenzhen, PEOPLE'S REPUBLIC	Class: A	
Ī		OF CHINA		
Í	R&I Date:	70.160	Models/Code/sizes (as per	
i	23-02-2023	LOA	FSC & application:	
i	CMS tracking ID:	Type: Copy	Sizes:	
Í	99M-RZ2-LZQN	Notarization: yes	M-30 E(Cleanser)	
i	Fee: 5,000/-	Validity: 14-04-2027	M-30 R(Rinse)	
Í		Tag O	M-30P (Probe cleanser) Shelf Life:	
i	1	• FSC	Shell Life:	
i	\	Type: Copy		
İ		Legalized: yes		
i	>	Issued by: Germany		
Í		Issue date: 02-02-2021		
i		• ISO – Certificate:		
		T C		A CONTRACTOR OF THE CONTRACTOR
İ	Mo	Type: Copy		
Ĭ	Ple	Notarization: No		
	Me	* - * *		

81.	MR Medical Pakistan Private Limited Office no: 1101, 11th floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad, Pakistan. ELI No:01008 R&I Date: 22-02-2023 CMS tracking ID: D5A-YR7-UHJW Fee: 5,000/-	M/s Shenzhen Mindray Bio-Medical Electronics Co., Ltd. ADDRESS: Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, PEOPLE'S REPUBLIC OF CHINA LOA Type: Copy Notarization: yes Validity: 14-04-2027 • FSC Type: Copy Legalized: No Issued by: Provincial Supervision Body, China Valid: 07-01-2027 • ISO – Certificate: Type: Copy Notarization: No Valid till: 31-08-2026	Brand Name: Mindray Generic Name: BC-RET Hematology Control Applied as: Kit Class: A Models/Code/sizes (as per FSC & application: Sizes: H: 4.5ml ×1, 4.5ml ×6 N: 4.5ml ×1, 4.5ml ×6 L: 4.5ml ×1, 4.5ml ×6 Shelf Life: 14 days	Deferred for submission of valid legalized FSC.
82.	MR Medical Pakistan Private Limited Office no: 1101, 11th floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad, Pakistan. ELI No:01008 R&I Date: 23-02-2023 CMS tracking ID: NPR-D82-DBU6 Fee: 5,000/-	EC Certificate: N/A Name of Manufacturer: M/s Shenzhen Mindray Bio-Medical Electronics Co., Ltd. ADDRESS: Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, PEOPLE'S REPUBLIC OF CHINA LOA Type: Copy Notarization: yes Validity: 14-04-2027 • FSC Type: Copy Legalized: No Issued by: Provincial Supervision Body, China Valid: 26-02-2026 • ISO – Certificate: Type: Copy Notarization: No Valid till: 31-08-2026 EC Certificate: N/A		Deferred for submission of valid legalized FSC.
83.	MR Medical Pakistan Private Limited Office no: 1101, 11th floor, ISE Tower, Jinnah Avenue,	Name of Manufacturer: M/s Shenzhen Mindray Bio-Medical Electronics Co., Ltd.	Brand Name: Mindray Generic Name:	Approved.

	Blue Area, Islamabad, Pakistan. ELI No:01008 R&I Date: 20-12-2022 CMS tracking ID: 2X4-XMW-U82X Fee: 5,000/-	ADDRESS: Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, PEOPLE'S REPUBLIC OF CHINA LOA Type: Copy Notarization: yes Validity: 14-04-2027	Gonadotropin (CLIA) Applied as: Kit	
		 FSC Type: Copy Legalized: Apostille Issued by: Provincial Supervision Body, China Valid: 01-04-2026 ISO – Certificate: Type: Copy Notarization: No Valid till: 31-08-2026 EC Certificate: N/A 	16 HORUS	
84.	MR Medical Pakistan Private Limited Office no: 1101, 11th floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad, Pakistan. ELI No:01008 R&I Date: 22-02-2023 CMS tracking ID: 7VG-Q6Q-RYNH Fee: 5,000/-	Name of Manufacturer: M/s Shenzhen Mindray Bio-Medical Electronics Co., Ltd. ADDRESS: Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, PEOPLE'S REPUBLIC OF CHINA LOA Type: Copy Notarization: yes Validity: 14-04-2027 • FSC Type: Copy Legalized: No Issued by: Provincial Supervision Body, China	Applied as: Kit	Deferred for submission of valid legalized FSC.
	7	Valid: 02-11-2022 • ISO – Certificate: Type: Copy Notarization: No Valid till: 31-08-2026 EC Certificate: N/A		
85.	M/s. A.Feroz & Co., Medicine Street No. 1, Marriot Road, Karachi	Name of Manufacturer:	Brand Name: Supermax-Non-Sterile Latex Examination Gloves, Powdered	Approved.
	ELI No:00066	ADDRESS: Lot 38, Putra Industrial Park, Bukit Rahman Putra, 47000 Sungai Buloh, Selangor,	Generic Name: NonSterile Latex Examination	
	R&I Date:	MALAYSIA Serangor,	Applied as: Family	

	13-03-2020		Class: A	
	CMS tracking ID:	LOA	Class 11	
	NL1-LWH-ZEZG	Type: Copy	Models/Code/sizes (as per	
	Fee: 5,000/-	Notarization: yes	FSC & application:	
	166. 3,000/	Validity: 14-04-2027	Sizes:	
		valuity: 14-04-2027	XS, S, M, L, XL	
		• FSC	Shelf Life:	
			05 years	
		Type: Copy	05 years	
		Legalized: yes		
		Issued by: Ministry of Health		
		Malaysia		
		Valid : 06-07-2027	(6)	
		• ISO – Certificate:	113,00	
		Type: Copy	M_{II} , $O(\cdot)$	
		Notarization: yes	6.	
		Valid till: 06-02-2026	70.5,	
		1 G 40.	OF	
		EC Certificate: N/A		
86.	M/s. A.Feroz & Co.,	Name of Manufacturer:	Brand Name:	Approved.
	Medicine Street No. 1,	M/s Supermax Gloves	Supermax-Non-Sterile Latex	
	Marriot Road, Karachi	Manufacturing SDN BHD (SGM),	Examination Gloves, Powder	
		ADDRESS: Lot 38, Putra Industrial		
	ELI No:00066	Park, Bukit Rahman Putra, 47000	Generic Name:	
		Sungai Buloh, Selangor,	NonSterile Latex Examination	
	R&I Date:	MALAYSIA	Gloves, Powder free	
	13-03-2020		Applied as: Family	
	CMS tracking ID:	LOA	Class: A	
	NL1-LWH-ZEZG	Type: Copy		
	Fee: 5,000/-	Notarization: yes	Models/Code/sizes (as per	
	, 10,	Validity: 25-08-2029	FSC & application:	
			Sizes:	
	· ·	• FSC	XS, S, M, L, XL	
		Type: Copy	Shelf Life:	
		Legalized: yes	05 years	
		Issued by: Ministry of Health		
		Malaysia		
		Valid: 06-07-2027	0,0,1	
		Valid . 00-07-2027	Or	
		• ISO – Certificate: Type: Copy Notarization: yes		
		Type: Copy		
		Notarization: yes		
		valid uii: 00-02-2026		
		EC Certificate: N/A		1

Evaluator: Rana Ahsan-ul-Haq Athar

Agenda Item II (g) DEFERRED CASES IMPORT

S#	Importer Name	Manufacturer Details	Name of MD / Class / Codes	Decision
	~VO.		/ Shelf life / etc.	
1.	M/s Ferozsons Laboratories	Legal Manufacturer:	Brand Name:	Approved
	Limited, P.O. Ferozsons,	Boston Scientific Corporation,	Wallflex TM Esophageal Fully	$Wallflex^{TM}$
	Amangarh, Nowshera-	300, Boston Scientific Way,	Covered RMV Stent System	Esophageal
	KPK, Pakistan.	Marlborough, MA 01752 USA.		Fully Covered

Generic Name: RMVStent **Manufacturing Site:** Polymer-Metal Oesophageal System only. (ELI-00120)Boston Scientific Limited, Stent. Firm will apply separately for Date of R& I Ballybrit Business Park, Ireland. 14-07-2025 Applied as: Family Fully Covered RMVStent • LOA Fee: PKR100,000/-Type: Copy of Notarized Class: C System Longer **Slip** # 9830837763 **Notarization**: Notarized Loop. **Validity:** 30-06-2025 Models/Code/sizes (As per **FSC & Application): Fully Covered RMV Stent** • FSC System **Type:** Copy of apostilled **Issued By:** HPRA • M00516210 Legalization: Apostilled (18/23-25X103) **Issue Date:** 20-11-2024 • M00516220 Validity: Not mentioned. (18/23-25X123) • M00516230 (18/23-25X153) • ISO - Certificate: • M00516240 **Type:** Copy of notarized (23/28X105)**Notarization:** Notarized • M00516250 Validity: 23-03-2027 (23/28X125) • M00516260 (23/28X155)**Fully Covered RMV Stent System Longer Loop** • M00516270 (18/23-25X103) • M00516280 (18/23-25X123) • M00516290 (18/23-25X153) Abdul Director • M00516300 (23/28X105)• M00516310 (23/28X125)• M00516320 (23/28X155)• M00516920 (18/23X153)• M00516930 (23/28X105)• M00516940 (23/28X125)• M00516950 (23/28X155)**Service Life:** 19 Months

2.	U.M. Enterprises	BIO-RAD Laboratories	Platelia Rabbies II	Approved in
۷.	3 Boulevard Raymond	3 Boulevard Raymond Poincare,	Tiateria Rabbies II	* *
	poincare, 92430 Marnes-la-	92430 Marnes-la-Conquette, France	Class A	class C subject
	Coquette, France	92430 Mariles-la-Conquette, Prance	Shel life 12 months	to submission
	Plot No. 12, Sector No. 15,	FSC	2-8°C	of valid,
	Korangi Industrial Area,	Original France	Fee 5000	notarized
	Karachi		ree 3000	LOA.
2		Copy of LOA expiry 31.12.2020	D I	D.f 1 (1)
3.	M/s Alliance Medical, 12-	Name of Manufacturer:	Brand name:	Deferred (last
	B, 1st Floor, Agro Flats,	Brun Medical Co., Ltd., Building	BRUN Ballon Inflation	opportunity)
	Shadman, Lahore	B8, Enterpreneurship and	Device Set	for the
		Innovation Park, 88 Changtang		following:
	ELI-00147	Road, Yunlong Demonstration	Generic Name:	1. submission
		Zone, Zhuzhou City 412000,	Balloon Inflation Device Set	of original
	Date of R& I	China	Mr. Ois	legalized/apost
	27-06-2025	2011.	Applied as: Single	ille FSC and
		• LOA:	70.5.	original,
	Fee: 6,000 /-		Class: A	•
	Slip # 386760094	Type: Copy		notarized LOA
	F 233, 333,	Notarization: By CCPIT		and ISO 13485
		Issue Date: 29-07-2024	Code/sizes (as per FSC &	certificate.
		Validity: 28-07-2027	Application):	2. Clarification
		*3, 60,	BR-BID-130A, BR-BID-	of the
		• FSC: Netherlands	130AL, BR-BID-II26A, BR-	components of
		Type: Copy	BID-II30A, BR-BID-III30A,	Balloon
		Legalization: Apostilled	BR-BID-130B, BR-BID-	Inhalation
	`	Issue Date: 22-07-2024	130BL, BR-BID-II2BA, BR-	Device Sets.
			BID-II30B, BR-BID-III30B,	3. submission
	>	Validity: 12-09-2028	BR-BID-130C, BR-BID-	
			130CL, BR-BID-II26C, BR-	of the fee for
	10,	• ISO – Certificate:	BID-II30C, BR-BID-III30C,	the family and
		Type: Copy	BR-BID-130D, BR-BID-	codes.
	•	Notarization: By CCPIT	130DL, BR-BID-II26D, BR-	4. submission
		Validity: 14-10-2026	BID-II30D, BR-BID-III30D,	of
			BR-BID-130E, BR-BID-	Brochure/catal
		• CE - EU Certificate:	130EL, BR-BID-II26E, BR-	ogue.
			BID-II30E, BR-BID-III30E,	
		Type: Copy	BR-BID-130F, BR-BID-	
		Notarization: By CCPIT	130FL, BR-BID-II26F, BR-	
		Validity: 12-09-2028	BID-II30F, BR-BID-III30F,	
		100-110 11	BR-BID-130,	
		Validity: 12-09-2028	BR-BID-130L, BR-BID-	
			II26, BR-BID-III30, BR-	
		~31, ~61,	BID-140,	
		191 -00	BR-BID-140L, BR-BID-	
		-61 O	II30, BR-BID-IV30	
	1	25-01	1150, DK-DID-1 v 50	
	\			
		42	Service Life: 3 Years	
1	M/a Alliance Madical 12	Nome of Marries street		Defermed (1set
4.	M/s Alliance Medical, 12-	Name of Manufacturer:	Brand name:	Deferred (last
	B, 1 st Floor, Agro Flats,	Brun Medical Co., Ltd., Building	BRUN Manifolds	opportunity)
	Shadman, Lahore	B8, Enterpreneurship and	Camania Nassa	for the
		Innovation Park, 88 Changtang	Generic Name:	following:
	ELI-00147	Road, Yunlong Demonstration	Manifolds	1. submission
		Zone, Zhuzhou City 412000,	A 1. 1 G. 1	of original
	Date of R& I	China	Applied as: Single	legalized/apost
	I	<u> </u>	1	-oapost

27-06-2025

Fee: **31,000**/-

Slip # 3467162744

• LOA:

Type: Copy

Notarization: By CCPIT Issue Date: 29-07-2024 Validity: 28-07-2027

• FSC: Netherlands

Type: Copy

Legalization: Apostille **Issue Date**: 22-07-2024 **Validity**: 12-09-2028

• ISO - Certificate:

Type: Copy

Notarization: By CCPIT Validity: 14-10-2026

• CE - EU Certificate:

Type: Copy

Notarization: By CCPIT Validity: 12-09-2028

Abdul Oadil Stant Directo

Class: B

Code/sizes (as per FSC & Application):

BR-GW018-45S, BR-GW018-45J, BR-GW021-45S, BR-GW021-45J, BR-GW025-45S, BR-GW025-45J, BR-GW018-60S, BR-GW018-60J, BR-GW021-60S, BR-GW021-60J, BR-GW025-60S, BR-GW025-60J, BR-GW018-80S, BR-GW018-80J, BR-GW021-80S, BR-GW021-80J, BR-GW025-80S, BR-GW025-80J, BR-GW018-120S, BR-GW018-120J, BR-GW021-120S, BR-GW021-120J, BR-GW025-120S, BR-GW025-120J, BR-GW018-150S, BR-GW018-150J, BR-GW021-150S, BR-GW021-150J, BR-GW025-150S, BR-GW025-150J, BR-GW018-180S, BR-GW018-180J, BR-GW021-180S, BR-GW021-180J, BR-GW025-180S, BR-GW025-180J, BR-GW018-260S, BR-GW018-260J, BR-GW021-260S, BR-GW021-260J, BR-GW025-260S, BR-GW025-260J, BR-GW032-45S, BR-GW032-45J, BR-GW035-45S, BR-GW035-45J, BR-GW038-45S, BR-GW038-45J, BR-GW032-60S, BR-GW032-60J, BR-GW035-60S, BR-GW035-60J, BR-GW038-60S, BR-GW038-60J, BR-GW032-80S, BR-GW032-80J, BR-GW035-80S, BR-GW035-80J, BR-GW038-80S, BR-GW038-80J, BR-GW032-120S, BR-GW032-120J, BR-GW035-120S, BR-GW035-120J, BR-

GW038-120S, BR-GW038-120J, BR-

GW032-150S, BR-GW032-150J, BR- ille FSC and original, notarized LOA and ISO 13485 certificate.

- 2. submission of the fee for the family and codes.
- 3. submission of Brochure/catalogue.

	<u> </u>
	GW035-150S, BR-GW035- 150J, BR-
	GW038-150S, BR-GW038- 150J, BR-
	GW032-180S, BR-GW032- 180J, BR-
	GW035-180S, BR-GW035- 180J, BR-
diff	GW038-180S, BR-GW038- 180J, BR-
dul Geroli	GW032-260S, BR-GW032- 260J, BR-
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2 09	GWC018-45S, BR- GWC018-45J, BR-
Mougay	GWC021-45S, BR- GWC021-45J, BR-
	GWC025-45S, GWC025-45J, BR-
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Mougay	GWC025-80S, BR- GWC025-80J, BR-
	GWC018-120S, BR- GWC018-120J, BR-

	GWC021-120S, BR-	
	GWC021-120J, BR-	
	GWC025-120S, BR-	
	GWC025-120J, BR-	
	GWC018-150S, BR-	
	GWC018-150J, BR-	
	GWC021-150S, BR-	
	GWC021-150J, BR-	
	GWC025-150S, BR-	
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	GWC025-260S, BR-	
	GWC025-260J, BR-	
	GWC032-45S, BR-	
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Assistant Director. Assistant Director. Assistant Director.	GWC032-60S, BR-	
aist ago	GWC032-60J, BR-	
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707,	GWC038-60S, BR-	
"Nougay,	GWC038-60J, BR-	
Mo	GWC032-80S, BR-	
	GWC032-80J, BR-	
	GWC035-80S, BR-	
	GWC035-80J, BR-	

	GWC038-80S, BR- GWC038-80J, BR-
	GWC032-120S, BR- GWC032-120J, BR-
	GWC035-120S, BR- GWC035-120J, BR-
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dul Geroli	GWC035-150S, BR- GWC035-150J, BR-
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ssistian Dece	GWC032-180S, BR- GWC032-180J, BR-
	GWC035-180S, BR- GWC035-180J, BR-
Monde	GWC038-180S, BR- GWC038-180J, BR-
	GWC032-260S, BR-GWC035-260S, BR-GWC035-260J, BR-
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eistallecell.	NGW021-45S, BR- NGW021-45J, BR-
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	NGW021-60S, BR- NGW021-60J, BR-
	NGW025-60S, BR- NGW025-60J, BR-

	NGW018-80S, BR-NGW018-80J, BR-	
	NGW021-80S, BR-NGW021-80J, BR-	
	NGW025-80S, BR-NGW025-80J, BR-	
	NGW018-120S, NGW018-120J, BR-	
diff	NGW021-120S, BR-NGW021-120J, BR-	
Aul Geroli,	NGW025-120S, BR- NGW025-120J, BR-	
Alodul Qadiini.	NGW018-150S, BR- NGW018-150J, BR-	
esistal Dece.	NGW021-150S, BR- NGW021-150J, BR-	
72,72	NGW025-150S, BR- NGW025-150J, BR-	
Moligian	NGW018-180S, BR- NGW018-180J, BR-	
	NGW021-180S, BR-NGW021-180J, BR-	
diff	NGW025-180S, BR- NGW025-180J, BR-	
Aul Geroli	NGW018-260S, BR-NGW018-260J, BR-	
Abdul Qadili ordani ordani ordani ordani ordani ordani ordani ordani ordani ordani ordani ordani ordani ordani	NGW021-260S, BR- NGW021-260J, BR-	
esistion pece	NGW025-260S, BR- NGW025-260J, BR-	
197,52	NGW032-45S, BR- NGW032-45J, BR-	
Moligia	NGW035-45S, BR- NGW035-45J, BR-	
	NGW038-45S, BR- NGW038-45J, BR-	

	NGW032-60S, NGW032-60J, BR-	BR-
	NGW035-60S, NGW035-60J, BR-	BR-
	NGW038-60S, NGW038-60J, BR-	BR-
	NGW032-80S, NGW032-80J, BR-	BR-
	NGW035-80S, NGW035-80J, BR-	BR-
"Il Osciol.	NGW038-80S, NGW038-80J, BR-	BR-
Abdul Grector	NGW032-120S, NGW032-120J, BR-	BR-
sistaine ceilt	NGW035-120S, NGW035-120J, BR-	BR-
15 29	NGW038-120S, NGW038-120J, BR-	BR-
Policy Salar	NGW032-150S, NGW032-150J, BR-	BR-
	NGW035-150S, NGW035-150J, BR-	BR-
	NGW038-150S, NGW038-150J, BR-	BR-
Assistant Director. Assistant Director. Assistant Director.	NGW032-180S, NGW032-180J, BR-	BR-
Ploof Direct.	NGW035-180S, NGW035-180J, BR-	BR-
-sistal lecell	NGW038-180S, NGW038-180J, BR-	BR-
129	NGW032-260S, NGW032-260J, BR-	BR-
Mougay,	NGW035-260S, NGW035-260J, BR-	BR-
	NGW038-260S, NGW038-260J, BR-	BR-
	NGWC018-45S, NGWC018-45J, BR-	BR-

		NGWC021-45S, BR-NGWC021-45J, BR-	
		NGWC025-45S, BR- NGWC025-45J, BR-	
		NGWC018-60S, BR- NGWC018-60J, BR-	
		NGWC021-60S, BR- NGWC021-60J, BR-	
	dir	NGWC025-60S, BR- NGWC025-60J, BR-	
	Aul Oraciols	NGWC018-80S, BR- NGWC018-80J, NGWC021-	
	Abdul Qadir	80S, BR-NGWC021-80J, BR-NGWC025-80S, BR- NGWC025-80J, BR-	
	esista Dece.	NGWC018-120S, BR- NGWC018-120J, BR-	
	79	NGWC021-120S, BR- NGWC021-120J,	
, one	93.	BR-NGWC025-120S, BR- NGWC025-120J,	
High		BR-NGWC018-150S, BR- NGWC018-150J,	
		BR-NGWC021-150S, BR-NGWC021-150J,	
	Gactor-l	BR-NGWC025-150S, BR- NGWC025-150J,	
	Moder Direct,	BR-NGWC018-180S, BR- NGWC018-180J,	
	sistant cent	BR-NGWC021-180S, BR- NGWC021-180J,	
4	29	BR-NGWC025-180S, BR- NGWC025-180J,	
	Abdul Qadiff	BR-NGWC018-260S, BR- NGWC018-260J,	
Mo		BR-NGWC021-260S, BR- NGWC021-260J,	
		BR-NGWC025-260S, BR- NGWC025-260J,	

BR-NGWC032-45S, BR-NGWC032-45J, BR-NGWC035-45S, BR-NGWC035-45J, BR-NGWC038-45S, BR-NGWC038-45J, BR-NGWC032-60S, BR-NGWC032-60J, BR-NGWC035-60S, BR-NGWC035-60J, BR-NGWC038-60S, BR-NGWC038-60J, BR-NGWC032-80S, BR-NGWC032-80J, BR-NGWC035-80S, BR-NGWC035-80J, BR-NGWC038-80S, BR-NGWC038-80J, BR-NGWC032-120S, BR-NGWC032-120J, BR-NGWC035-120S, BR-NGWC035-120J, BR-NGWC038-120S, BR-NGWC038-120J, BR-NGWC032-150S, BR-NGWC032-150J, BR-NGWC035-150S, BR-NGWC035-150J, BR-NGWC038-150S, BR-NGWC038-150J, BR-NGWC032-180S, BR-NGWC032-180J, BR-NGWC035-180S, BR-NGWC035-180J, BR-NGWC038-180S, BR-NGWC038-180J,

			BR-NGWC032-260S, BR-	
			NGWC032-260J,	
			BR-NGWC035-260S, BR-	
			NGWC035-260J,	
			, , , , , , , , , , , , , , , , , , , ,	
			BR-NGWC038-260S, BR-	
			NGWC038-260J	
			110 W C036-2003	
			Service Life: 3 Years	
_	N/ All: N/ 1: 1 10	27 025 0		D.C. 1 (1)
5.	M/s Alliance Medical, 12-	Name of Manufacturer:	Brand name:	Deferred (last
	B, 1 st Floor, Agro Flats,	Brun Medical Co., Ltd., Building	BRUN Guidewires	opportunity)
	Shadman, Lahore	B8, Enterpreneurship and	113, 0.	for the
		Innovation Park, 88 Changtang	Generic Name:	following:
	ELI-00147	Road, Yunlong Demonstration	Guidewires	1. submission
		Zone, Zhuzhou City 412000,	7 1.5.	of original
	Date of R& I	China	Applied as: Single	legalized/apost
	27-06-2025	Cillia		•
	27-00-2023	- " Mo oille of	Class: B	ille FSC and
	Fee: 31,000 /-	• LOA:		original,
	,	Type: Copy		notarized LOA
	Slip # 98205538650	Notarization: By CCPIT	Code/sizes (as per FSC &	and ISO 13485
		Issue Date: 29-07-2024	Application):	certificate.
		Validity: 28-07-2027	BR-MF 1-ON, BR-MF2-ON,	2. submission
		validity: 20 07 2027		of the fee for
		Taga Maria	BR-MF3-ON, BR-MF 1	
		• FSC: Netherlands	OFF, BR-MF2-OFF, BR-	the family and
		Type: Copy	MF3-OFF	codes.
		Legalization: Apostille		3. submission
	101,	Issue Date: 22-07-2024	Firm has submitted the	of Brochure/
		Validity: 12-09-2028	following codes	catalogue.
		-	BR-GWC025-150J,	
		• ISO – Certificate:	BR-GWC025-150S,	
		Type: Copy	BR-GWC025-260S,	
			BR-GWC025-260J,	
		Notarization: By CCPIT	BR-GWC032-150S,	
		Validity: 14-10-2026	BR-GWC032-150J,	
		(G* \alpha\)	BR-GWC035-150S,	
		• CE - EU Certificate:	BR-GWC035-150J,	
		Type: Copy	BR-GWC038-150S,	
		Notarization: By CCPIT	BR-GWC038-150J,	
		Validity: 12-09-2028	BR-GWC035-260S,	
		, midiej. 12 07 2020	BR-GWC035-260J,	
		No. Co.	BR-GWC038-260S,	
		19.00	BR-GWC038-260J,	
		63 AV	BR-NGW018-45J,	
		200	BR-NGW021-45J,	
			BR-NGW025-45J,	
		21,	BR-NGW018-60J,	
		(0-)	BR-NGW021-60J,	
			BR-NGW025-60J,	
			BR-NGW021-150S,	
			BR-NGW021-150J,	
			BR-NGW025-150S,	
			BR-NGW025-150J,	
			•	
			BR-NGW032-45J,	

			BR-NGW035-45J,	
			BR-NGW038-45J,	
			BR-NGW032-60J,	
			BR-NGW035-60J,	
			BR-NGW038-60J,	
			BR-NGW032-150J,	
			BR-NGW035-150J,	
			BR-NGW038-150J.	
			Service Life: 3 Years	
6.	M/s Alliance Medical, 12-	Name of Manufacturer:	Brand name:	Deferred (last
	B, 1 st Floor, Agro Flats,	Brun Medical Co., Ltd., Building	BRUN Connecting Tubings	opportunity)
	Shadman, Lahore	B8, Enterpreneurship and	(Pressuere Extension Line)	for the
	Shadman, Lanore	Innovation Park, 88 Changtang		following:
	TT 1 001 4F		Generic Name:	-
	ELI-00147	Road, Yunlong Demonstration	Connecting Tubes	1. submission
		Zone, Zhuzhou City 412000,	Connecting Tubes	of original
	Date of R& I	China	Applied as: Single	legalized/apost
	27-06-2025	100-110 -11	PP as single	ille FSC and
	F 21 000/	• LOA:	Class: B	original,
	Fee: 31,000 /-	Type: Copy		notarized LOA
	Slip # 5905805985	Notarization : By CCPIT		and ISO 13485
		Issue Date: 29-07-2024	Code/sizes (as per FSC &	certificate.
		Validity: 28-07-2027	Application):	2. submission
	7	200	BR-CT1.80-10, BR-CT1.80-	of the fee for
	`	• FSC: Netherlands	20, BR-CT1.80-30, BR	the family and
		Type: Copy	CT1.80 60, BR CT1.80 90,	codes.
			BR-CT1.80-120, BR	3. submission
		Legalization: Apostille	CT1.80-150, BR-CT2.00-10,	of Brochure/
	10,	Issue Date: 22-07-2024	BR-CT2.00-20, BR-CT2.00	
		Validity: 12-09-2028	30, BR-CT2.00-60, BR-	catalogue.
	· ·		CT2.00-90, BR-CT2.00-120,	
		• ISO – Certificate:	BR-CT2.00-150, BR	
		Type: Copy	CT2.70-10, BR-CT2.70-20,	
		Notarization: By CCPIT	BR-CT2.70-30, BR-CT2.70-	
		Validity: 14-10-2026	60. BR CT2.70 90. BR	
		0.00	CT2.70-120, BR-CT2.70	
		• CE - EU Certificate:	150, BR-CT3.00-10, BR-	
		Type: Copy	CT3.00-20, BR-CT3.00-30,	
		Notarization: By CCPIT	BR-CT3.00-60, BR-CT3.00-	
			90, BR-CT3.00-120, BR	
		Validity: 12-09-2028	CT3.00-150, BR-CT3.20-10,	
		10° (0)	BR-CT3.20-20, BR-CT3.20	
		19000	30, BR-CT3.20-60, BR	
		65, 0	CT3.20-90, BR-CT3.20-120,	
	7	× 09 ,	BR-CT3.20-150, BR-	
	· ·		CT3.65-10, BR-CT3.65-20,	
		24,	BR-CT3.65-30, BR-CT3.65-	
	2	0,	60, BR-CT3.65-90, BR-	
		7	CT3.65-120, BR-CT3.65-	
	-VO.		150, BR CT4.00 10, BR	
	B.		CT4.00-20, BR-CT4.00-30,	
			BR-CT4.00-60, BR-CT4.00	
			90, BR-CT4.00-120, BR	
			CT4.00-150, BR-CT3.20-	
			51 1100 120, BR C13.20-	

	T	T	100 t DD CTT0 00 t0 t DD	
			20A, BR-CT3.20-60A, BR	
			CT3.20-90A, BR-CT3.20	
			120A,	
			BR-CT3.20-150A,	
			BRCT3.20-180A, BR-	
			CT3.20-200A,	
			BR-CT3.65-20B, BR-	
			CT3.65-60B, BR-CT3.65	
			90B, BR CT3.65 120B,	
			BR CT3.65-150B.	
			BR-CT3.65-180B,	
			BR-CT3.65-200B,	
			BR CT4.00 150S, BR	
			CT4.00-150D.	
		20,, 1	6.	
		0.00	Now firm has applied	
		ay's December's	following codes only.	
		7/11 20.	BR-CT1.80-90, BR-CT1.80-	
		100-110 011	120, BR-CT1.80-150,	
		DD 01. 20.	BR-CT2.00-90, BR-CT2.00-	
		1 47 40	120, BR-CT2.00-150,	
			BR-CT2.70-90, BR-CT2.70-	
		· clor occ	120, BR-CT2.70-150,	
		els Ob	DD CT2 00 00 DD CT2 00	
		650	BR-CT3.00-90, BR-CT3.00-	
		7 03	120, BR-CT3.00-150,	
			BR-CT3.65-90, BR-CT3.65-	
		34,	120, BR-CT3.65-150,	
		0-3		
			CT3.20-120A,	
	"VO.		BR-CT3.20-150A,	
			BRCT3.20-180A, BR-	
			CT3.20-200A,	
			BR-CT3.65-90B, BR-	
			CT3.65-120B,	
			BR-CT3.65-150B,	
			BR-CT3.65-180B,	
			BR-CT3.65-200B,	
		(G' ,0)	BR-C13.03-200B,	
			Service Life: 3 Years	
7.	M/s Alliance Madical 12	Name of Manufacturer:	Brand name:	Defermed (1s-4
/.	M/s Alliance Medical, 12-			Deferred (last
	B, 1 st Floor, Agro Flats,	Brun Medical Co., Ltd., Building	BRUN Introducer Sheath Set	opportunity)
	Shadman, Lahore	B8, Enterpreneurship and	C · N	for the
		Innovation Park, 88 Changtang	Generic Name:	following:
	ELI-00147	Road, Yunlong Demonstration	Introducer Sheath	1. submission
		Zone, Zhuzhou City 412000,		of original
	Date of R& I	China	Applied as: Single	legalized/apost
	27-06-2025			ille FSC and
		270.	Class: B	
	Fee: 31,000 /-	• LOA:		original,
	Slip # 54732192	Type: Copy	Code/sizes (as per FSC &	notarized LOA
	Sup # 54/52192	Notarization: By CCPIT	Application):	and ISO 13485
		Issue Date: 29-07-2024	BR-RA0407,	certificate.
	Bi	Issue Date: 29-07-2024		
	B.			2. submission
	B.	Validity: 28-07-2027	BR-RA0507,	
	B.	Validity: 28-07-2027	BR-RA0507, BR-RA0607	2. submission of the fee for
			BR-RA0507,	

		Γ= -	Γ====	T
		Type: Copy	BR-RA0411,	the family and
		Legalization : Apostille	BR-RA0511	codes.
		Issue Date: 22-07-2024	BR-RA0611,	3. submission
		Validity: 12-09-2028	BR-RA0711,	of Brochure/
			BR-RA0416	catalogue.
		• ISO – Certificate:	BR-RA0516,	
		Type: Copy	BR-RA0616,	
		Notarization: By CCPIT	BR-RA0716	
		Validity: 14-10-2026	BR-RA0423,	
		, undity 11. 10 2020	BR-RA0523,	
		• CE - EU Certificate:	BR-RA0623	
			BR-RA0723,	
		Type: Copy	BR-FA0409, BR-FA0511	
		Notarization: By CCPIT		
		Validity: 12-09-2028	BR-FA0611, BR-FA0711,	
		G- "01"	BR-FA0811	
			BR-FA0911,	
			BR-FA1011,	
		100 Oll 1001.	BR-FA1211	
		Abdul Directer	BR-FA0419,	
		Plogin Direct.	BR-FA0523,	
		isto 300	BR-FA0623	
		GIS OB	BR-FA0723,	
		5-0	BR-FA0823,	
			BR-FA0923	
			BR-FA1023,	
	>	23	BR-FA1223.	
	10,		Service Life: 3 Years	
8.	M/s Alliance Medical, 12-	Name of Manufacturer:	Brand name:	Deferred (last
	B, 1st Floor, Agro Flats,	Brun Medical Co., Ltd., Building	BRUN Angiography	opportunity)
	Shadman, Lahore	B8, Enterpreneurship and	Syringes and Accessories	for the
		Innovation Park, 88 Changtang	113,0.	following:
	ELI-00147	Road, Yunlong Demonstration	Generic Name:	1. submission
		Zone, Zhuzhou City 412000,	Angiography Syringes and	of original
	Date of R& I	China	Accessories	legalized/apost
	27-06-2025			ille FSC and
		• LOA:	Applied as: Single	original,
	Fee: 31,000 /-	Type: Copy	CI D	notarized LOA
	Slip # 871539410213	Notarization: By CCPIT	Class: B	and ISO 13485
	_		C. 1./ (ECC. 6	certificate.
		Issue Date: 29-07-2024	Code/sizes (as per FSC &	
		Validity: 28-07-2027	Application):	
	*	2.0.Y.	BR-AS-CT-200-A01,	of the fee for
		• FSC: Netherlands	BR-AS-CT-200/200-A02,	the family and
		Type: Copy	BR-AS-CT-200-A03,	codes.
	2	Legalization: Apostille	BR-AS-CT-200/200-A04,	3. submission
		Issue Date: 22-07-2024	BR-AS-CT-190-A05,	of Brochure/
	, NO1	Validity: 12-09-2028	BR-AS-CT-200-B01,	catalogue.
	Bi.		BR-AS-CT-200/200-B02,	
	▼	• ISO – Certificate:	BR-AS-CT-200-C01,	
		Type: Copy	BR-AS-CT-100/200-D02, BR-AS-CT-100-D01,	
		Notarization: By CCPIT	BR-AS-CT-200-D01, BR-AS-CT-200-D03,	
			DK-A3-C1-200-D03,	

			I	1
		Validity: 14-10-2026	BR-AS-CT-200-E01,	
			BR-AS-CT-200/200-E02,	
		• CE - EU Certificate:	BR-AS-CT-190/190-A06,	
		Type: Copy	BR-AS-CT-200/200-A08,	
			BR-AS-DSA-150-A01,	
		Notarization: By CCPIT	BR-AS-DSA-200-A03,	
		Validity: 12-09-2028	BR-AS-DSA-60-A05,	
			BR-AS-DSA-150-B01,	
			1	
			BR-AS-DSA-150-B03,	
			BR-AS-CT-200/200-C02,	
			BR-AS-CT-100/100-D04,	
			BR-AS-CT-200/200-D06,	
			BR-AS-CT-60/200-D08,	
			BR-AS-MRI-65-E01,	
			BR-AS-MRI-65/65-E02,	
		000	BR-AS-DSA-130-A07,	
		10, 70,	BR-AS-DSA-150-A09,	
		7(7) °C, '	BR-AS-MRI-65/65-A02,	
		asistant December	BR-AS-MRI-115/115-A04,	
		Ph. O., 20.	BR-AS-MRI-65/115-A06,	
			BR-AS-MRI-60-B01,	
			BR-AS-MRI-60/60-B02,	
		i callo	BR-AS-DSA-120-D01,	
		clo Oo	DD AC MDI 60 D01	
		500	BR-AS-MRI-60-D01,	
		7 03	BR-AS-MRI-60/60-D02, BR-AS-MRI-65/200-E04.	
			BK-AS-WKI-03/200-E04.	
		93'	Service Life: 3 Years	
9.				
	Muhamala Vision 22 A Haman	I I a and Manusfa atumam	Cimadiaa	Deigotad due to
٠.	Mubarak Vision, 32-A Usman	Legal Manufacturer:	Simedice	Rejected due to
<i>)</i> .	Center, Shah Alam Market,	M/s Henan Simedice	Hydrophobic Aspheric Foldable	following
). 		M/s Henan Simedice Biotechnologies Co., Ltd, No. 28,		following reasons:
). 	Center, Shah Alam Market, Lahore.	M/s Henan Simedice Biotechnologies Co., Ltd, No. 28, Floor 7, Unit A, Building 1, No. 8,	Hydrophobic Aspheric Foldable IOL's	following reasons: 1. Fee for the
<i>)</i> .	Center, Shah Alam Market, Lahore. ELI-00045	M/s Henan Simedice Biotechnologies Co., Ltd, No. 28, Floor 7, Unit A, Building 1, No. 8, Guohuai Ave., Hi-Tech Industries	Hydrophobic Aspheric Foldable IOL's (Hydrophobic Aspheric	following reasons: 1. Fee for the family has not
<i>)</i> .	Center, Shah Alam Market, Lahore.	M/s Henan Simedice Biotechnologies Co., Ltd, No. 28, Floor 7, Unit A, Building 1, No. 8, Guohuai Ave., Hi-Tech Industries Development Zone, Zhengzhou,	Hydrophobic Aspheric Foldable IOL's	following reasons: 1. Fee for the family has not been submitted.
, ,	Center, Shah Alam Market, Lahore. ELI-00045	M/s Henan Simedice Biotechnologies Co., Ltd, No. 28, Floor 7, Unit A, Building 1, No. 8, Guohuai Ave., Hi-Tech Industries	Hydrophobic Aspheric Foldable IOL's (Hydrophobic Aspheric	following reasons: 1. Fee for the family has not been submitted. 2. The name of
,).	Center, Shah Alam Market, Lahore. ELI-00045	M/s Henan Simedice Biotechnologies Co., Ltd, No. 28, Floor 7, Unit A, Building 1, No. 8, Guohuai Ave., Hi-Tech Industries Development Zone, Zhengzhou, Henan 450001, P.R. China.	Hydrophobic Aspheric Foldable IOL's (Hydrophobic Aspheric Foldable IOL's)	following reasons: 1. Fee for the family has not been submitted. 2. The name of the device at
, <i>)</i> .	Center, Shah Alam Market, Lahore. ELI-00045	M/s Henan Simedice Biotechnologies Co., Ltd, No. 28, Floor 7, Unit A, Building 1, No. 8, Guohuai Ave., Hi-Tech Industries Development Zone, Zhengzhou, Henan 450001, P.R. China. FSC China validity	Hydrophobic Aspheric Foldable IOL's (Hydrophobic Aspheric	following reasons: 1. Fee for the family has not been submitted. 2. The name of the device at cover note of the
, <i>)</i> .	Center, Shah Alam Market, Lahore. ELI-00045 5152-P	M/s Henan Simedice Biotechnologies Co., Ltd, No. 28, Floor 7, Unit A, Building 1, No. 8, Guohuai Ave., Hi-Tech Industries Development Zone, Zhengzhou, Henan 450001, P.R. China. FSC China validity	Hydrophobic Aspheric Foldable IOL's (Hydrophobic Aspheric Foldable IOL's) Class-C	following reasons: 1. Fee for the family has not been submitted. 2. The name of the device at cover note of the Form 7A is
, <i>)</i> .	Center, Shah Alam Market, Lahore. ELI-00045 5152-P	M/s Henan Simedice Biotechnologies Co., Ltd, No. 28, Floor 7, Unit A, Building 1, No. 8, Guohuai Ave., Hi-Tech Industries Development Zone, Zhengzhou, Henan 450001, P.R. China. FSC China validity	Hydrophobic Aspheric Foldable IOL's (Hydrophobic Aspheric Foldable IOL's)	following reasons: 1. Fee for the family has not been submitted. 2. The name of the device at cover note of the Form 7A is Henan Simedice
	Center, Shah Alam Market, Lahore. ELI-00045 5152-P	M/s Henan Simedice Biotechnologies Co., Ltd, No. 28, Floor 7, Unit A, Building 1, No. 8, Guohuai Ave., Hi-Tech Industries Development Zone, Zhengzhou, Henan 450001, P.R. China. FSC China validity	Hydrophobic Aspheric Foldable IOL's (Hydrophobic Aspheric Foldable IOL's) Class-C Shelf Life: 5 years	following reasons: 1. Fee for the family has not been submitted. 2. The name of the device at cover note of the Form 7A is Henan Simedice Aspheric
	Center, Shah Alam Market, Lahore. ELI-00045 5152-P	M/s Henan Simedice Biotechnologies Co., Ltd, No. 28, Floor 7, Unit A, Building 1, No. 8, Guohuai Ave., Hi-Tech Industries Development Zone, Zhengzhou, Henan 450001, P.R. China. FSC China validity	Hydrophobic Aspheric Foldable IOL's (Hydrophobic Aspheric Foldable IOL's) Class-C Shelf Life: 5 years Models:	following reasons: 1. Fee for the family has not been submitted. 2. The name of the device at cover note of the Form 7A is Henan Simedice Aspheric Foldable IOL's
	Center, Shah Alam Market, Lahore. ELI-00045 5152-P	M/s Henan Simedice Biotechnologies Co., Ltd, No. 28, Floor 7, Unit A, Building 1, No. 8, Guohuai Ave., Hi-Tech Industries Development Zone, Zhengzhou, Henan 450001, P.R. China. FSC China validity	Hydrophobic Aspheric Foldable IOL's (Hydrophobic Aspheric Foldable IOL's) Class-C Shelf Life: 5 years Models: SM60AS	following reasons: 1. Fee for the family has not been submitted. 2. The name of the device at cover note of the Form 7A is Henan Simedice Aspheric Foldable IOL's and as section 4
	Center, Shah Alam Market, Lahore. ELI-00045 5152-P	M/s Henan Simedice Biotechnologies Co., Ltd, No. 28, Floor 7, Unit A, Building 1, No. 8, Guohuai Ave., Hi-Tech Industries Development Zone, Zhengzhou, Henan 450001, P.R. China. FSC China validity	Hydrophobic Aspheric Foldable IOL's (Hydrophobic Aspheric Foldable IOL's) Class-C Shelf Life: 5 years Models: SM60AS SM60AS1	following reasons: 1. Fee for the family has not been submitted. 2. The name of the device at cover note of the Form 7A is Henan Simedice Aspheric Foldable IOL's and as section 4 of the Form 7A
	Center, Shah Alam Market, Lahore. ELI-00045 5152-P	M/s Henan Simedice Biotechnologies Co., Ltd, No. 28, Floor 7, Unit A, Building 1, No. 8, Guohuai Ave., Hi-Tech Industries Development Zone, Zhengzhou, Henan 450001, P.R. China. FSC China validity	Hydrophobic Aspheric Foldable IOL's (Hydrophobic Aspheric Foldable IOL's) Class-C Shelf Life: 5 years Models: SM60AS SM60AS1 SM60AS2	following reasons: 1. Fee for the family has not been submitted. 2. The name of the device at cover note of the Form 7A is Henan Simedice Aspheric Foldable IOL's and as section 4 of the Form 7A is Simedice
· /.	Center, Shah Alam Market, Lahore. ELI-00045 5152-P	M/s Henan Simedice Biotechnologies Co., Ltd, No. 28, Floor 7, Unit A, Building 1, No. 8, Guohuai Ave., Hi-Tech Industries Development Zone, Zhengzhou, Henan 450001, P.R. China. FSC China validity	Hydrophobic Aspheric Foldable IOL's (Hydrophobic Aspheric Foldable IOL's) Class-C Shelf Life: 5 years Models: SM60AS SM60AS1	following reasons: 1. Fee for the family has not been submitted. 2. The name of the device at cover note of the Form 7A is Henan Simedice Aspheric Foldable IOL's and as section 4 of the Form 7A is Simedice Aspheric
	Center, Shah Alam Market, Lahore. ELI-00045 5152-P	M/s Henan Simedice Biotechnologies Co., Ltd, No. 28, Floor 7, Unit A, Building 1, No. 8, Guohuai Ave., Hi-Tech Industries Development Zone, Zhengzhou, Henan 450001, P.R. China. FSC China validity	Hydrophobic Aspheric Foldable IOL's (Hydrophobic Aspheric Foldable IOL's) Class-C Shelf Life: 5 years Models: SM60AS SM60AS1 SM60AS2	following reasons: 1. Fee for the family has not been submitted. 2. The name of the device at cover note of the Form 7A is Henan Simedice Aspheric Foldable IOL's and as section 4 of the Form 7A is Simedice Aspheric Foldable IOL's.
	Center, Shah Alam Market, Lahore. ELI-00045 5152-P	M/s Henan Simedice Biotechnologies Co., Ltd, No. 28, Floor 7, Unit A, Building 1, No. 8, Guohuai Ave., Hi-Tech Industries Development Zone, Zhengzhou, Henan 450001, P.R. China. FSC China validity	Hydrophobic Aspheric Foldable IOL's (Hydrophobic Aspheric Foldable IOL's) Class-C Shelf Life: 5 years Models: SM60AS SM60AS1 SM60AS2	following reasons: 1. Fee for the family has not been submitted. 2. The name of the device at cover note of the Form 7A is Henan Simedice Aspheric Foldable IOL's and as section 4 of the Form 7A is Simedice Aspheric
	Center, Shah Alam Market, Lahore. ELI-00045 5152-P	M/s Henan Simedice Biotechnologies Co., Ltd, No. 28, Floor 7, Unit A, Building 1, No. 8, Guohuai Ave., Hi-Tech Industries Development Zone, Zhengzhou, Henan 450001, P.R. China. FSC China validity	Hydrophobic Aspheric Foldable IOL's (Hydrophobic Aspheric Foldable IOL's) Class-C Shelf Life: 5 years Models: SM60AS SM60AS1 SM60AS2	following reasons: 1. Fee for the family has not been submitted. 2. The name of the device at cover note of the Form 7A is Henan Simedice Aspheric Foldable IOL's and as section 4 of the Form 7A is Simedice Aspheric Foldable IOL's.
	Center, Shah Alam Market, Lahore. ELI-00045 5152-P	M/s Henan Simedice Biotechnologies Co., Ltd, No. 28, Floor 7, Unit A, Building 1, No. 8, Guohuai Ave., Hi-Tech Industries Development Zone, Zhengzhou, Henan 450001, P.R. China. FSC China validity	Hydrophobic Aspheric Foldable IOL's (Hydrophobic Aspheric Foldable IOL's) Class-C Shelf Life: 5 years Models: SM60AS SM60AS1 SM60AS2	following reasons: 1. Fee for the family has not been submitted. 2. The name of the device at cover note of the Form 7A is Henan Simedice Aspheric Foldable IOL's and as section 4 of the Form 7A is Simedice Aspheric Foldable IOL's. 3. Firm has not
	Center, Shah Alam Market, Lahore. ELI-00045 5152-P	M/s Henan Simedice Biotechnologies Co., Ltd, No. 28, Floor 7, Unit A, Building 1, No. 8, Guohuai Ave., Hi-Tech Industries Development Zone, Zhengzhou, Henan 450001, P.R. China. FSC China validity	Hydrophobic Aspheric Foldable IOL's (Hydrophobic Aspheric Foldable IOL's) Class-C Shelf Life: 5 years Models: SM60AS SM60AS1 SM60AS2	following reasons: 1. Fee for the family has not been submitted. 2. The name of the device at cover note of the Form 7A is Henan Simedice Aspheric Foldable IOL's and as section 4 of the Form 7A is Simedice Aspheric Foldable IOL's. 3. Firm has not submitted EU
<i>7.</i>	Center, Shah Alam Market, Lahore. ELI-00045 5152-P	M/s Henan Simedice Biotechnologies Co., Ltd, No. 28, Floor 7, Unit A, Building 1, No. 8, Guohuai Ave., Hi-Tech Industries Development Zone, Zhengzhou, Henan 450001, P.R. China. FSC China validity	Hydrophobic Aspheric Foldable IOL's (Hydrophobic Aspheric Foldable IOL's) Class-C Shelf Life: 5 years Models: SM60AS SM60AS1 SM60AS2	following reasons: 1. Fee for the family has not been submitted. 2. The name of the device at cover note of the Form 7A is Henan Simedice Aspheric Foldable IOL's and as section 4 of the Form 7A is Simedice Aspheric Foldable IOL's. 3. Firm has not submitted EU technical
<i>7.</i>	Center, Shah Alam Market, Lahore. ELI-00045 5152-P	M/s Henan Simedice Biotechnologies Co., Ltd, No. 28, Floor 7, Unit A, Building 1, No. 8, Guohuai Ave., Hi-Tech Industries Development Zone, Zhengzhou, Henan 450001, P.R. China. FSC China validity	Hydrophobic Aspheric Foldable IOL's (Hydrophobic Aspheric Foldable IOL's) Class-C Shelf Life: 5 years Models: SM60AS SM60AS1 SM60AS2	following reasons: 1. Fee for the family has not been submitted. 2. The name of the device at cover note of the Form 7A is Henan Simedice Aspheric Foldable IOL's and as section 4 of the Form 7A is Simedice Aspheric Foldable IOL's. 3. Firm has not submitted EU technical documentation
	Center, Shah Alam Market, Lahore. ELI-00045 5152-P	M/s Henan Simedice Biotechnologies Co., Ltd, No. 28, Floor 7, Unit A, Building 1, No. 8, Guohuai Ave., Hi-Tech Industries Development Zone, Zhengzhou, Henan 450001, P.R. China. FSC China validity	Hydrophobic Aspheric Foldable IOL's (Hydrophobic Aspheric Foldable IOL's) Class-C Shelf Life: 5 years Models: SM60AS SM60AS1 SM60AS2	following reasons: 1. Fee for the family has not been submitted. 2. The name of the device at cover note of the Form 7A is Henan Simedice Aspheric Foldable IOL's and as section 4 of the Form 7A is Simedice Aspheric Foldable IOL's. 3. Firm has not submitted EU technical documentation certificate.
	Center, Shah Alam Market, Lahore. ELI-00045 5152-P	M/s Henan Simedice Biotechnologies Co., Ltd, No. 28, Floor 7, Unit A, Building 1, No. 8, Guohuai Ave., Hi-Tech Industries Development Zone, Zhengzhou, Henan 450001, P.R. China. FSC China validity	Hydrophobic Aspheric Foldable IOL's (Hydrophobic Aspheric Foldable IOL's) Class-C Shelf Life: 5 years Models: SM60AS SM60AS1 SM60AS2	following reasons: 1. Fee for the family has not been submitted. 2. The name of the device at cover note of the Form 7A is Henan Simedice Aspheric Foldable IOL's and as section 4 of the Form 7A is Simedice Aspheric Foldable IOL's. 3. Firm has not submitted EU technical documentation certificate. 4. DoC not
, , , , , , , , , , , , , , , , , , ,	Center, Shah Alam Market, Lahore. ELI-00045 5152-P	M/s Henan Simedice Biotechnologies Co., Ltd, No. 28, Floor 7, Unit A, Building 1, No. 8, Guohuai Ave., Hi-Tech Industries Development Zone, Zhengzhou, Henan 450001, P.R. China. FSC China validity	Hydrophobic Aspheric Foldable IOL's (Hydrophobic Aspheric Foldable IOL's) Class-C Shelf Life: 5 years Models: SM60AS SM60AS1 SM60AS2	following reasons: 1. Fee for the family has not been submitted. 2. The name of the device at cover note of the Form 7A is Henan Simedice Aspheric Foldable IOL's and as section 4 of the Form 7A is Simedice Aspheric Foldable IOL's. 3. Firm has not submitted EU technical documentation certificate. 4. DoC not mentioned.
	Center, Shah Alam Market, Lahore. ELI-00045 5152-P	M/s Henan Simedice Biotechnologies Co., Ltd, No. 28, Floor 7, Unit A, Building 1, No. 8, Guohuai Ave., Hi-Tech Industries Development Zone, Zhengzhou, Henan 450001, P.R. China. FSC China validity	Hydrophobic Aspheric Foldable IOL's (Hydrophobic Aspheric Foldable IOL's) Class-C Shelf Life: 5 years Models: SM60AS SM60AS1 SM60AS2	following reasons: 1. Fee for the family has not been submitted. 2. The name of the device at cover note of the Form 7A is Henan Simedice Aspheric Foldable IOL's and as section 4 of the Form 7A is Simedice Aspheric Foldable IOL's. 3. Firm has not submitted EU technical documentation certificate. 4. DoC not mentioned. 5. copy of the

10.	M/s. Verizon, 60-D, F.C.C.	Legal Manufacturer:	Brand name:	per FSC the applied codes belong to different devices. Floodable IOLs not mentioned in the FSC. 7. In none of the submitted document Foldable Intraocular Lens mentioned. 8. Firm has applied intraocular lens, Preloaded Aspheric Intraocular lens, Toric Lens, Preloaded Toric Lens in single application. 9. Firm has not submitted revised LOA. MDB
	Zahoor Elahi Road,	Richard Wolf GmbH, Pforzheimer Strabe 32 75438	Camera Head, Controller, Remote Control USB &	approved LOGIC 4K
	Gulberg-4, Lahore.	Knittlingen, Germany.	Perforated Basket for Camera	CAMERA
	(ELI- 00087)		Head	HEAD (code
		Manufacturing Sites:	112,0:,	85525942) only subject to
	R&I detail	1.Richard Wolf GmbH, DE-	Generic Name:	submission of
	08-07-2025	75438 Knittlingen, Pforzheimer	Camera Head, Controller,	brand name.
	Fee: 25,000/-	Strabe 32, Germany.	Remote Control USB &	Firm will apply
	Slip: 75267236	2.Merz tronic GmbH, DE-78054	Perforated Basket for Camera	others devices
		Villingen-Schwenningen,	Head	in separate
		Siederstr. 50 Germany.		application.
		3.Kogel GmbH, DE-75038	Applied as: System	
		Oberderdingen,		
		Hagenfeldstrasse 4, Germany.	Class: A	
	1	• LOA	Model/Codes/Sizes (as per	
		Type: Original	application & FSC):	
	A	Notarization: Notarized	• Camera Head	
		Validity: 31-12-2025	85525942	
			85525902	
1	4011			
	W _{Ol}	• FSC	5525933	
	Mol	Type: Original	• Lens	
	Mol	Type: Original Issued By: Govt. Body	• Lens 85261504	
	Mol	Type: Original	• Lens	

		• ISO Certificate Type: Original Notarization: Notarized Validity: 28-11-2027	85261144 85261244 85261272 85261.322 5257141 5257.271 • Camera Controller 5525301 5525201 5525833 85525812 • Manual Remote Control USB 5525401 • Perorated Basket for Camera Head 38002 Service life:	
		-SI 0	Not mentioned.	
11.	M/s. Verizon, 60-D, F.C.C.	Legal Manufacturer:	Brand Name:	MDB
	Zahoor Elahi Road,	Richard Wolf GmbH,	Insufflator 45 Basic FR	approved Insufflator 45
	Gulberg-4, Lahore.	Pforzheimer Strabe 32 75438	45L/Min & Insufflation Tube	Heat FR
	(TX X 0000T)	Knittlingen, Germany.	System	45L/Min (code
	(ELI- 00087)	35 0 1 0		2235021) only
	DOLLA T	Manufacturing Site:	Generic Name:	subject to
	R&I detail	1.Richard Wolf GmbH, DE-	Insufflator & Insufflation	submission of
	08-07-2025	75438 Knittlingen, Pforzheimer	Tube System	brand name.
	Fee: 50,000/-	Strabe 32, Germany.		Firm will apply
	Slip: 75175126850		Applied as: System	others devices
		• LOA	Class P	in separate
		Type: Original	Class: B	application.
		Notarization: Notarized	Model/Codes/Sizes (as per	
		Validity: 31-12-2025	application & FSC):	
		• FSC	• 2235021 (Insufflator 45	
		Type: Original	Heat FR 45L/Min)	
		Issued By: Govt. Body	• 2235001 (Insufflator 45	
		Legalization: Legalized	Basic FR 45L/Min)	
		Issue Date: 26-06-2024	• 2235031 (Insufflator 45	
	\		EVAC+ Heat FR 45L/Min)	
		ISO Certificate	• 2235011 (Insufflator 45	
	>	Type: Original	EVAC FR 45L/Min)	
		Notarization: Notarized	• 8170.101 (Insufflation	
	"Vo.	Validity: 28-11-2027	Tube Set L 2.5M)	
			Service life:	
			Ser vice inc.	

12.	M/s. Verizon, 60-D, F.C.C.	Legal Manufacturer:	Brand Name:	MDB
	Zahoor Elahi Road,	Richard Wolf GmbH,	Panoview Telescope Blue	approved the
	Gulberg-4, Lahore.	Pforzheimer Strabe 32 75438	•	Panoview
	2	Knittlingen, Germany.	Generic Name:	Telescope Blue
	(ELI- 00087)		Medical endoscope	with following
	,	Manufacturing Site:	1	codes:
	R&I detail	1.Richard Wolf GmbH, DE-	Applied as: Family	• Telescope
	08-07-2025	75438 Knittlingen, Pforzheimer	,	Blue 0° Ø
	Fee: 50,000/-	Strabe 32, Germany.	Class: B	4mm WL
	Slip: 61802386	2.Henke-Sass, Wolf GmbH, DE-	5400 Z	298mm.
	Shp. 01002300	78532 Tuttlingen, Keltenstrabe	Model/Codes/Sizes (as per	• Telescope
		1, Germany.	application & FSC):	Blue 12° Ø
		3.Richard Wolf, Betriebsstatte	• 8654.531 (Telescope Blue	4mm WL
		Berlin, DE-10553 Berlin	12° Ø 4MM WL 298MM)	298mm.
		Reuchlinstr. 11, Germany.		• Telescope
		Reachinisti. 11, Germany.	• 8654.522 (Telescope Blue	Blue 30° Ø
		104 1111 261	30° Ø 4MM WL 299MM)	4mm WL
		• LOA	• 8650.515 (Telescope Blue	299mm.
		Type: Original	70° Ø 4MM WL 303MM)	Telescope Blue
		Notarization: Notarized	• 8650.514 (Telescope Blue	70° Ø 4mm
		Validity: 31-12-2025	0° Ø 4MM WL 298MM)	WL 303mm.
		-151-00	• 8934462 (Telescope 30° Ø	
		• FSC	10MM WL 305MM)	Firm will apply
		Type: Original	• 89344416 (Telescope 0° Ø	other in
		Issued By: Govt. Body	10MM WL 440MM)	separate
		Legalization: Legalized	• 89344436 (Telescope 50° Ø	application.
		Issue Date: 26-06-2024	10MM WL 440MM)	
			• 8934461 (Telescope 0° Ø	
		• ISO Certificate	10MM WL 305MM)	
		Type: Original	• 89344426 (Telescope 30° Ø	
		Notarization: Notarized	10MM WL 440MM)	
		Validity: 28-11-2027	• 8934463 (Telescope 50° Ø	
		2.5	10MM WL 305MM)	
			• 8935462 (Telescope Ø	
		O'o of all	5.5MM WL 300MM)	
		10.	• 8935461 (Telescope Ø	
		40"	5.5MM WL 300MM)	
		700 UII - 61,	5.514111 (11 500141141)	
		Apqril Oscilla	Service life:	
			Not mentioned.	
13.	M/s. Verizon, 60-D, F.C.C.	Legal Manufacturer:	Brand name:	Deferred (last
10.	Zahoor Elahi Road,	Richard Wolf GmbH,	Suction tube, irrigation tube	opportunity)
	Gulberg-4, Lahore.	Pforzheimer Strabe 32 75438	set & Irrigation pump system	for the
		Knittlingen, Germany.	pamp system	followings:
	(ELI- 00087)			1. submission
	(Manufacturing Sites:	Generic Name:	of the Brand
	R&I detail	1. Kurt Semrau GmbH, DE-78532	Suction tube, irrigation tube	name.
	08-07-2025	Tuttlingen, Gansacker 64,	set & Irrigation pump system	2. Justification
	Fee: 50,000/-	Germany.	set a migation pump system	of the
	Slip: 49008141332	2.Richard Wolf GmbH, DE-	Applied as: System	grouping.
	5.p. 17000171332	75438 Knittlingen, Pforzheimer	Tappieu us. System	3. submission
		Strabe 32, Germany.	Class: B	of the
		Strace 32, Germany.	C1400. 12	or unc

	Ī	2300 M 30 11 C 34 1''	I	1 1. /
		3.W.O.M. World of Medicine	M 11/0 1 /01	brochure/
		GmbH, DE-10587 Berlin,	Model/Codes/Sizes (as per	catalogue.
		Salzufer 8, Germany	application & FSC):	
			• 8171402 (Suction Tube)	
		• LOA	• 2216001 (LAP	
		Type: Original	Suction/Irrigation Pump)	
		Notarization: Notarized	• 817123 (Irrigation Tube)	
		Validity: 31-12-2025	• 8385.901 (Suction	
			Irrigation Handle)	
		• FSC	• 4171223 (Irrigation Tube	
		Type: Original	Set Spike L 3M)	
		Issued By: Govt. Body	• 4171225	
		Legalization: Legalized	(Suction/Irrigation Tube	
		Issue Date: 26-06-2024	Set L 3M)	
		000	• 8171223 (Irrigation Tube	
		• ISO Certificate	_	
		Type: Original	Set Spike)	
		Notarization: Notarized	Service life:	
		Validity: 28-11-2027		
1 /	M/a Variant 60 D ECC		Not mentioned.	Defermed /1- (
14.	M/s. Verizon, 60-D, F.C.C. Zahoor Elahi Road,	Legal Manufacturer: Richard Wolf GmbH,	Brand Name:	Deferred (last
	· · · · · · · · · · · · · · · · · · ·		Unit Cart, Unit Cart Base &	opportunity) for the
	Gulberg-4, Lahore.	Pforzheimer Strabe 32 75438	Flexon Port System	
	(EL L. 00097)	Knittlingen, Germany.	Comonia Name	followings:
	(ELI- 00087)	Many 6- 4 6:4	Generic Name:	1. submission
	D01 1-4-9	Manufacturing Site:	Unit Cart, Unit Cart Base &	of the Brand
	R&I detail	1. Richard Wolf GmbH, DE-	Flexon Port System	name.
	08-07-2025	75438 Knittlingen, Pforzheimer	Amailia di ana Casadana	2. Justification
	Fee: 25,000/-	Strabe 32, Germany	Applied as: System	of the
	Slip: 78805408660	2.ITD GmbH Office Neubiberg,		grouping.
		DE-85579 Neubiberg,	Class: A	3. submission
		Lilienthalstr. 19, Germany.	M LVC L C	of the
			Model/Codes/Sizes (as per	
		• LOA	application & FSC):	catalogue and
		Type: Original	• Unit Cart	FSC.
		Notarization: Notarized	32116011 (Unit Cart)	
		Validity: 31-12-2025	82116015 (Unit Cart	
		Dr. O., No.	Premium Electr. 220-230 V	
		• FSC	AC)	
		Type: Original	• Unit Cart Base Electr. 220-	
		Issued By: Govt. Body	240V AC	
		Legalization: Legalized	32116014	
	1	Issue Date: 26-06-2024	• Flexon-Port	
			32116103 (Flexon-Port	
	4	• ISO Certificate	350+400 (103CM))	
		Type: Original	32116058 (Flexon-Port 300	
		Notarization: Notarized	(58CM))	
		Validity: 28-11-2027	32116068 (Flexon-Port 400	
			(68CM))	
			32116093 (Flexon-Port	
			350+300 (93CM))	

			Service life:	
			Not mentioned.	
15.	Applicant Name:	Name of Manufacturer:	Brand name:	Approved.
	Akbar Biotech, Plot No. 5-C, Mezzanine Floor, Bukhari Commercial, Lane No. 06, Phase 06, DHA, Karachi	M/s Human Biosciences Inc. 940 Clopper Road, Gaithersburg, MD 20878, USA	Medifil II Particles Medifill II Collagen Particle Generic Name:	
			Collagen Particles	
	ELI-01304	LOA Validity: 30-04-2027 (Copy)	Collagen Based Wound Care Dressing	
	Date of R&I 26-06-2025	FSC: USA Validity: 18-03-2027(Copy)	W130.0	
	Fee Details:		Class-D	
	Paid Fee: 62,000/- Fee Challan No:	ISO Validity: 28-11-2027 (Copy)	Shelf life: 5 Years	
	25496997	EU QA/ EC Certificate	Models/ Specification	
		atan cent	Applied as Single	
16.	Applicant Name:	Name of Manufacturer:	Brand name:	Approved.
	Akbar Biotech, Plot No. 5-C, Mezzanine Floor, Bukhari	M/s Human Biosciences Inc. 940 Clopper Road, Gaithersburg, MD	SkinTemp II	
	Commercial, Lane No. 06, Phase 06, DHA, Karachi	20878, USA LOA Validity:	Generic Name: Collagen Sheets	
	ELI-01304	30-04-2027 (Copy)	Class-D	
	Date of R&I 26-06-2025	FSC: USA Validity: 18-03-2027(Copy)	Shelf life: 5 Years	
	Fee Details: Paid Fee: 62,000/-	ISO Validity: 28-11-2027 (Copy)	Models/ Specification	
	Fee Challan No: 6371025106	EU QA/ EC Certificate	1052	
17.	Applicant Name:	Name of Manufacturer:	Brand name:	Approved subject to
	Akbar Biotech, Plot No. 5-C, Mezzanine Floor, Bukhari	M/s Human Biosciences Inc. 940 Clopper Road, Gaithersburg, MD	Collatek Collagen Gel	submission of shelf life
	Commercial, Lane No. 06, Phase 06, DHA, Karachi	20878, USA	Generic Name: Collagen Wound Dressing	studies.
	ELI-01304	LOA Validity: 30-04-2027 (Copy)	Class-D	
	Date of R&I 26-06-2025	FSC: USA	Shelf life: 3 Years	
	Fee Details:	Validity: 18-03-2027(Copy)	Models/ Specification	
	Paid Fee: 62,000/- Fee Challan No:	ISO Validity: 28-11-2027 (Copy)		
	24443048499	EU QA/ EC Certificate		

18. Iqbal and Company, Legal Manufacturer: Brand Name: Approved **Duo-Flow** MEDICAL COMPONENETS INC Alfalah Manzil Opp. National **Duo-Flow Soft-line** Soft-line Police Foundation, Street No. DBA-Medcomp Catheter Set Catheter Set 26, Sector, E-11/4, Islamabad, T73M - 7F X 7CM DUO-T73M - 7F X Pakistan. Address: 7CM DUO-FLOW® SOFT-LINE® 1499 DELP DRIVE FLOW® SOFT-**DOUBLE LUMEN** ELI-00117 HARLEYSVILLE, PA 19438, USA. **LINE® HEMODIALYSIS DOUBLE** CATHETER BASIC SET Date of R&I LOA Validity: 31-12-2025 (Copy) **LUMEN** T73MGL - 7F X 7CM 28-04-2025 **HEMODIALYS DUO-FLOW® SOFT-**FSC: USA IS CATHETER Fee Details: Validity: 27-05-2026 (notarized) LINE® DOUBLE LUMEN **BASIC** SET Paid Fee: 62030/-**HEMODIALYSIS** only. Firm will ISO Validity: 28-09-2025 Fee Challan No: **CATHETER BASIC SET** apply other in 0349520396 separate T74M - 7F X 10CM DUO-EC validity: 26-05-2024 application. FLOW® SOFT-LINE® (Copy) DOUBLE LUMEN **MDB HEMODIALYSIS** constituted the CATHETER BASIC SET following sub-T74MGL - 7F X 10CM committee for **DUO-FLOW® SOFT**evaluation of the LINE® DOUBLE LUMEN devices that **HEMODIALYSIS** require CATHETER BASIC SET registration of devices T94M - 9F X 12CM DUOas family of the FLOW® SOFT-LINE® sets. **DOUBLE LUMEN** 1. Ms. Tazeen **HEMODIALYSIS** Saeed Bukhari. CATHETER BASIC SET Biomedical T94MGL - 9F X 12CM Engineer **DUO-FLOW® SOFT-**(Chairperson). LINE® DOUBLE LUMEN Abdul Oadill Hant Directo 2. Ms. Sadaf **HEMODIALYSIS** Ahmad CATHETER BASIC SET (coordinator). T96M - 9F X 15CM DUO-Muhammad Ashfaq FLOW® SOFT-LINE® (Member). **DOUBLE LUMEN HEMODIALYSIS** CATHETER BASIC SET T96MGL - 9F X 15CM **DUO-FLOW® SOFT-**LINE® DOUBLE LUMEN **HEMODIALYSIS** CATHETER. Double Lumen Hemodialysis Catheter Set Class D Shelf Life: 5 Years

			Applied as: Family	
			M 11/6 '6' '	
10	M/s AMD HIZ Estamais	NI CNA CA	Models/ Specification	A 1
19.	M/s AMB HK Enterprises (Pvt.) Ltd., 2 nd Floor Plaza	Name of Manufacturer:	Brand name: Sure-Guard	Approved
	, ,	Guangdong Zhongai Medical	Sure-Guard	
	60, Commercial Block-K	Technology Co. Ltd., No.1	Generic Name:	
	Phase-1, DHA, Lahore.	Shaping Village, Baidu Town,	Sterile Hollow Fiber	
	TV 7 000 62	Meixian District 514700	Dialyzer (Low Flux)	
	ELI-00863	Meizhou, Guangdong, China.	Dialyzer (Zow Tian)	
	D (CDC I	• LOA:	Applied as: Single	
	Date of R& I	Not submitted.		
	27-06-2025	Trot sustinition.	Class: C	
	Fee: 31,000 /-	• FSC	M_{II} , O :	
	Slip # 5218031569	Type: Copy	6.6	
	Shp # 3210031307	Issued By: MPA	Code/sizes (as per FSC &	
		Legalization: Not Legalized	Application):	
		Validity: 17-11-2025	V-16L	
		valuity: 17-11-2023	V-17L	
		IGO C 4:0" 4	V-18L	
		• ISO – Certificate:	V-19L	
		Type: Copy	V-20L	
		Notarization: Not Notarized	Chale Lie a 2 V	
	7	Validity: 31-08-2026	Shelf Life: 3 Years	
	\	777 25 27 27 28 28		
		• EU QMS Certificate:		
	2	Type: Copy		
		Notarization: Not Notarized		
20	16/ 11/0 11/1 5	Validity: 27-09-2028		
20.	M/s AMB HK Enterprises	Name of Manufacturer:	Brand name:	Approved.
	(Pvt.) Ltd., 2 nd Floor Plaza	Guangdong Zhongai Medical	Sure-Guard	
	60, Commercial Block-K	Technology Co. Ltd., No.1	Generic Name:	
	Phase-1, DHA, Lahore.	Shaping Village, Baidu Town,	Sterile Hollow Fiber	
	EI I 000/2	Meixian District 514700	Dialyzer (High Flux)	
	ELI-00863	Meizhou, Guangdong, China.		
	Date of R& I	• LOA:	Applied as: Single	
	27-06-2025	Not submitted.		
	2, 00 2023	Edd O	Class: C	
	Fee: 31,000 /-	• FSC		
	Slip # 94194435	Type: Copy	Codoloinos (se ses ESC 9	
	_	Issued By: MPA	Code/sizes (as per FSC &	
		Legalization : Not Legalized	Application):	
	1	Validity: 17-11-2025	V-16H V-17H	
	\	190 G	V-17H V-18H	
		• ISO – Certificate:	V-19H	
	λ.	Type: Copy	V-20H	
		Notarization: Not Notarized		
	Wo.	Validity: 31-08-2026	Shelf Life: 3 Years	
		ELLOME Continues		
		• EU QMS Certificate:		
		Type: Copy Notarization: Not Notarized		
		Validity: 27-09-2028		
		* anuity. 41-07-2020		

DEFERRED CASES (LOCAL MANUFACTURING)

Name & Address of Establishment	Name of Medical Devices With Size	Decision	
 Caraway Diagnostics, Plot No. 12, Street N-3, National industrial Zone Rawat, Rawalpindi (ELM-0092) [958-6L] License permits the manufacture of following medical devices in Liquid Section for IVD Products; 1. Diluent for Hematology Analyzer, 2. Cleaning Solution for hematology analyzer 3. Lyse (IVD) 4. Reagent for quantitative determination of Hemoglobin (Hb) 5Reagent for quantitative determination of Total Protein 6. Reagent for quantitative determination of Creatinine 7. Reagent for quantitative determination for Bilirubin. D. No. 13158 dated 15-05-2025. 	Cleaner -CA Analyzer System Cleaner "Probe / Flow Cell Cleaner" "Maintenance Wash Solution" Ingredients: Detergents<1.0 % Buffers<1.0% Preservatives<0.5% Stabilizers<0.5% in ion free water. Class: A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 7408981643	Approved subject to verification of the formulation/ composition of approved Analyzer System Cleaner "Probe/Flow Cell Cleaner" "Maintenance Wash Solution"	

DEFERRED CASES OF IMPORT

DEFERRED CASES OF IMPORT		(MS) 9:9:1 AM		
Importer Name	Manufacturer Details	Name of MD / Class / Codes / Shelf life / etc.	Decision	
Kokab Enterprises	Manufacturer:	Belzer UW Cold	Board approved the Belzer	
No. G-56, Billys	Preservation Solutions Inc.	Storage Solution	UW Cold Storage Solution	
Shoppers Galleria,	1099 Proctor Drive, Elkhorn,	0,	(University of Wisconsin	
Gulistan-e-jauhar,	WI 53121 USA	Generic Name:	Solution). The Board	
Block 18, Karachi	401, 601,	(University of	Authorized Chairman	
(ELI-00544)	Carnamedica Sp. ZO. O. ul. Olszynki Grochowskiej 21 lok. U6, 04-281 Warsaw,	Wisconsin Solution)	MDB to give personal hearing to the M/s Healthline Pharmaceuticals	
Evaluator:	Poland	Class D	currently known as Diligent	
AD-IV	103,		Health Solution for de-	
[3599]	Exported by: Bridge to Life Limited 1 Filament Walk LU 311 (The Light Bulb) Wandsworth, England SW 18 4GQ United Kingdom.	Shelf life 24 months	registration of his product, before issuance of Registration letter.	

Name	Name: Shams Scientific Traders,
Address of Importer	Address of Importer: 22-Y-J Madina Town, Faisalabad
Detail of ELM/ELI	ELI: 00459
Name	(LEGAL MANUFACTEURER)
Address of Manufacturer	Healgen Scientific LLC, 3818 Fuqua Street, Houston, TX 77047, USA.
	Manufacturing site:
	Zhejiang Orient Gene Biotech Co., Ltd.,3787, East Yangguang Avenue, Dipu
	Street Anji 313300 Huzhou Zhejiang, China.
Brand Name	Healgen
	(H. Pylori Ab Rapid Test Cassette (Feces)
	Pinns has such missed at the second makes Cata (Daily 1).
	Firm has submitted that correct name of the device is
Country of origin FSC	Healgen (H. Pylori Ag Rapid Test Cassette (Feces) FSC Spain Date of issue 03-11-2023
Country of origin FSC	(Original and attested, already submitted)
Class of medical device	B
Stability data/ service life	Shelf Life: 24 Months
Documents submitted	Marketing Authorization Letter: LOA valid till 18-02-2024 (Original and notarized, already submitted)
Marketing Authorization	LOA vand un 16-02-2024 (Original and notarized, affeady submitted)
Letter:	Production Quality Management System Certificate (ISO 13485)
Letter.	valid till 08-02-2025
Production Quality	
Management System Certificate	Full Quality Assurance Certificate or Equivalent:
(ISO 13485)	N/A
Full Quality Assurance	Design Examination: N/A
Certificate or Equivalent:	
Design Examination	Declaration of Conformity (Doc): Provided
Declaration of Conformity (Doc):	W2.0.
Codes/ sizes/models	GCHP-602a (DoC)
Decision	Approved
DCCISIOII	Approved

POST LICENSE VARIATION (CHANGE OF MANAGEMENT)

Importer name	Existing Management	Proposed Management	Decision
M/s Gulf Marketing	1.Muhammad Shafiq, Gulf	Muhammad Shafiq, Gulf	The MDB deferred the case and
International, 11B/2	House 11B/2, Mohallah	House 11B/2, Mohallah	decided that current
Mohallah Satellite	Satel.lite Town, Saidpur	Satel.lite Town, Saidpur	management will submit the
town, Abdullah Jan	Road, Rawalpindi.	Road, Rawalpindi.	succession or transfer of shares
Masjid Street Near	CNIC:61101-2035270-1	CNIC:61101-2035270-1	to the legal heirs and from the
Kali Tanki, Said Pur	2. Mr. Muhammad Shabbir		legal heirs to the proposed
Road Rawalpindi.	P/O khas Bhola Mosa	Akifa Batool, House	management from the civil
	Tehsil Sumbrial Distt.	No.11-B/2, Block-	court, magistrate/civil judge.
ELI-00194, dated 18-	Sialkot	B,Satellite Town, Saidpur	Till the approval of the
10-2018	CNIC No.	Road, Rawalpindi.	management, all other
	61101-2026893-1	CNIC:33100-9963420	application of the firm will not
Change of			be entertained.
Management			

Deferred Cases for Import

S. No	Company Name	Name of Manufacturer and Documents details	Name of Medical Device	Decision.
1.	Global Clinical Cura 18, Mian Iqbal Road Westridge 1, Rawalpindi ELI: 00196 [3724] Evaluator: DD-1	Legal Manufacturer: M/s Beijing Wantai Biological Pharmacy Enterprises Co., Ltd, No. 31 Kexueyuan Road Changping District Beijing P.R China FSC: China Valid till: 2023/03/22. ISO 13485 valid upon 18-01-2025	Diagnostic kit for T cell infected with Mycobacterium Tuberculosis (TB-IGRA) Codes & sizes: Class-C Shelf Life: 12 months Fee: 50000 Date of Application:02-02-2023	Deferred Final opportunity of submission of documents. • Justification for not submission of reply since 2024. • The validity of FSC & Notarized CE has been expired so the case cannot be approved for the subject kits the decision of 65th meeting held on 25-26th January, 2024 is reiterated.
		anday, Abdul Oadi		

ADDITIONAL AGENDA

Item No. 1: <u>DEFERRED CASES AGENDA FOR ENLISTMENT OF IMPORTED MEDICAL</u> <u>DEVICES</u>

DEFERRED CASES IMPORT

Rana Ahsan-ul-Haq Athar – Deputy Director

СH	Immoutou Nones	Manufacturar Datail	Name of MD / Class / Callet	Decision
S#	Importer Name	Manufacturer Details	Name of MD / Class / Codes	Decision
			/ Shelf life / etc.	
22.	Applicant Name:	Name of Manufacturer:	Brand name:	Approved
		M/s GreatBatch Medical, 2300 Berkshire Lane North,	Myopore	
	· · · · · · · · · · · · · · · · · · ·		W. 23.3.	
	Road, Westridge 1, Rawalpindi	Minneapolis, MN 55441 USA	Generic Name:	
	Rawaipindi	USA	Sutureless Pacing Lead	
	ELI-00109	LOA Validity: 31-12-2026 (Copy)	Class-D	
	ELI-00109	31-12-2020 (Copy)	Ch -1f 1:f-, 2 V	
	Date of R&I	FSC: USA	Shelf life: 3 Years	
	04-07-2025	Validity: validity 04.2026	Models/ Specification	
			511210 (25cm), 511211	
	Fee Details:	ISO 13485 Validity:	(35mm), 511212 (54 cm)	
	Paid Fee: 62,000/- Fee Challan No:	10.12.2027		
	3683919435	EU QA/ EC Certificate		
	3003717133	28-02-2026		
		Design examination		
		certificate notarized		•
		15.09.2029	11/2/.9:	
23.	Applicant Name:	Name of Manufacturer:	Brand name:	Approved
	Global Marketing	Abbott Medical 15900	Allows DE	
	Services, 111, Hali	Valley View Court, Sylmar,	Allure RF	
	Road, Westridge 1,	California-91342, USA	Generic Name:	
	Rawalpindi	100 OIII	Cardiac Resynchronization	
		Manufacturing site: Abbott	Therapy Pacemaker	
		Medical (Also Known as		
	ELI-00109	ST, Jude Medical) 15900	Class-D	
	Data af DOI	Valley View Court, Sylmar,		
	Date of R&I 10-06-2025	California, USA	Shelf life: 18 months	
	10-00-2023	Abbott Medical (Also		
	Fee Details:	Known as ST, Jude	Models/ Specification	
	Paid Fee: 62,000/-	Medical) Plot No. 102,	PM 3222	
	Fee Challan No:	Lebuhraya Kampung Jawa,		
	401504968	Bayan Lepas, Industrial		
		Zone, 11900 Penang,		
		Malaysia, Country,		
		Malaysia		

		Abbott Medical (Also know as ST Jude Medical) Puerto Rico, LLC Lot a Interior No. 2 RD Km 67.5 Santana Industrial Park, Arecibo, PR USA LOA Validity: 31-12-2026 (Copy) FSC: USA Validity: 31-03-2027 (Copy) ISO Validity: 31-03-2028 (Copy) EU QA/ EC Certificate Validity: 14-08-2027	in 10/15, 9:9:1 h	
24.	Applicant Name: Global Marketing	Name of Manufacturer: Abbott Medical 15900	Brand name: Optisure	Approved
	Services, 111, Hali Road, Westridge 1,	Valley View Court, Sylmar, California-91342, USA	•	
	Rawalpindi	Manufacturing site: Abbott	Generic Name: Defibrillation Leads	
	ELI-00109	Medical (Also Known as ST, Jude Medical) 15900	Class-D	
		Valley View Court, Sylmar, California, USA	Shelf life: 3 Years	
	Date of R&I 10-06-2025	Abbott Medical (Also	Models/ Specification	
	Fee Details:	Know as ST, Jude Medical) Plot No. 102, Lebuhraya	1	
	Paid Fee: 100000/- Fee Challan No:	Kampung Jawa, Bayan Lepas, Industrial Zone,	11/51.9:11	
	15622816060	11900 Penang, Malaysia, Country, Malaysia	101-1052, 3.	
		Abbott Medical (Also know	101,001	
		as ST Jude Medical) Puerto Rico, LLC Lot a Interior	of,	
		No. 2 RD Km 67.5 Santana Industrial Park, Arecibo, PR USA		
		LOA Validity: 31-12-2026 (Copy)		
		FSC: USA Validity: 05-09-2026 (Copy)		
	Moll	ISO Validity: 31-03-2028 (Copy)		
		EU QA/ EC Certificate		
		Validity: 14-08-2027 DE Validity: 23-05-2029		

	T	T		1
25.	Muslim Scientific	Legal Manufacturer:	CC TD-4116	The board
	Corporation, 3 Syed Moj	Taidoc Technology	(CC Advance Glucometer+	deliberated on the
	Darya Road 3 rd Floor of	Corporation 127, Wugong	strips)	matter and decided
	Building	2nd Road, Wugu District,		to put a hold on the
		New Taipei City, Taiwan	Class-C	renewal application
	Warehouse Address:	248		* *
	House # 57 PAF Colony		Shelf life: AS per stability study	and shall grant the
	Zarar Shaheed Road,			firm 06 months
	Lahore			time for shifting of
				premesis to a new
	ELI: 00431			location. The board
	3036-P		~ ^ ^	shall conduct the
	13-06-2022		1/2/0://	inspection and
			(1/1/1 0:3	shall decide
		20		renewal application
			V., Vis.	in the light of new
			70. UO.	findings at new
		90, 6		location.

Monday, 29 December, 2025, 9:9:1 AM