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

<u>DECISIONS OF 109th MEETING OF THE MEDICAL DEVICE BOARD (MDB)</u> <u>HELD ON 20-11-2025 (MANUAL APPLICATION AGENDA PART-II)</u>

109th 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 20th November, 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.	1200-160	
1.	Dr. Babar Khan, Director, Medical Devices & Medicated Cosmetics, Drug Regulatory Authority of Pakistan, Islamabad.	Chairman
2.	Mr M Salik Zahid, Chief Drugs Inspector, Nominee of	Member
	DGHS Baluchistan	(attended meeting through videolink)
3.	Prof Dr Saqib Shafi Sheikh, Interventional Cardiologist, 98 Babar block, New Garden Town, Lahore	Member (attended meeting through videolink)
4.	Prof. Dr. Mehmood Ahmad, Former Dean, Islamia University, Bahawalpur, House No. 144-D, St. No.14, OPF Housing Scheme, Phase-1, Khayaban Jinnah, Near Raiwind Road, Lahore.	Member (attended meeting through videolink)
5.	Abdul Aleem Awan, Assistant Prof. Pharmacy Department, Abbottabad University of Science & Technology, Havelian.	Member (attended meeting through videolink)
6.	Dr. Farid Khan, Senior Consultant Neuro Surgery/Director Trauma & Emergency/Focal Person MSDS, Primary & Secondary Healthcare Department, Punjab.	Member (attended meeting through videolink)
7.	Dr. Ayesha Ali, Department of Pharmacy, Pakistan Institute of Medical Sciences, Islamabad (Hospital Pharmacist).	Member
8.	Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad.	Member
9.	Mr. Wajahat Ali, Biomedical Engineer, Liaquat College of Medicine and Dististry & Darul Sehat Hospital, Karachi.	Member (attended meeting through videolink)
10.	Ms. Tazeen Saeed Bukhari, Biomedical Engineer	Co-Opted Expert (attended meeting through videolink)
11.	Mr. Ayyaz Ahmed, Additional Director (MD&MC), DRAP, Islamabad.	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.

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

DEPUTY DIRECTOR-IX (MR. MUHAMMAD AMIN)

(FRESH CASES-ELI)

S.#	Name of Establishment	Name of	Decision
	*O/,	Qualified	
		Technical	
		Person	
1.	M/s AF Solutions Pakistan	Danish Sarfraz	Approved
	Office and Godown:	Pharm D	, 0,-
	Office No. 516-A, 1st Floor, Jeff Heights,		6.
	Main Boulevard, Gulberg-III, Lahore	G, 10, 1	9.
2.	M/s Aria Pharma (SMC Pvt) Ltd.,	Kashif Rehman	Approved
	100	Khan	
	Office and godown:	N. '60, ,	
	A-18, Eastern Industrial Zone, Port Qasim	Pharm D	
	Authority, Karachi		
3.	M/s Lepharma & Diagnostic (Private)	Sadaf Hidayat	Approved
	Limited		
	V-08 V	Pharm D	
	Office and Godown:		
	Block-D, Unit 5, 8th Floor, Lakson Square		
	Building-1, Sarwar Shaheed Road, Saddar,		
	South Saddar Town, Karachi		
4.	M/s Medical Advantages,	Hafiz Shaikh	Approved
		Muhammad	
	Office and godown:	Shaheryar	
		-	

	Plot No. 4-C, Suit No. 02, 20th Commercial	BS (Bio Medical	
	Street, Phase II (Extension), DHA, Karachi	Engineer)	
5.	M/s Awais Enterprises	Faheem Amad Khan	Approved
	Office:		
	Shop No. 19, Block-A, Malik Syed Akbar Plaza, Bara Bazar, Khyber Bara, Peshawar	Microbiology	apli
	Godown:		6)31
	Afridi House Godown No. 2, Chugal Pura Ring Road, Peshawar	21 211	113.35.
6.	M/s Qureshi Trading Agency (Pvt) Ltd.,	Ms. Arwa Shahid	Approved
	Office and Godown:	Pharm D	
	House No. 2632V40, Backside Multan Art Council Al Raheem Colony Nishter,	Oir or	
	Multan.	70	
7.	M/s Gastro specialty care,	eu.	Keeping in view of the statement and recommendations submitted by the
	Office/Godown: Masood Hospital 99, Garden Block Garden Town, Lahore,		inspector, The Board decided to reject
	Punjab 54600 Lahore		the application for establishment license to import medical devices.
8.	M/s Khalil Sons (Private) Limited, A-18, Eastern Industrial Zone, Port Qasim		The board considered the report of the inspector and observed the major
	Authority, Karachi		shortcomings in warehouse. It is further
	Bu		observed that the firm initially applied on Plot No CP 1/21, Port Operation
			Zone, Port Qasim Authority but later on changed to A-18, Eastern Industrial
		dir (Zone, Port Qasim Authority, Karachi
		G'0,01	without intimation of Medical Devices Board. The inspector conducted the
		100 JO	inspection of the firm at A-18, Eastern Industrial Zone, Port Qasim Authority,
	AD	Diner,	Karachi and reported major
	Assistant Assistant	emi	shortcomings at the premises. Keeping in view of the above, the board decided
	esisoe		to reject the application for establishment license to import medical
	P. 28		devices.

Item No. I(B)::

Subject: ESTABLISHMENT LICENSE TO IMPORT MEDICAL DEVICES –

INSPECTION THEREOF OF M/S MODERN TRADING COMPANY, LAHORE

It is submitted that an inspection of M/s Modern Trading Company, located at 15-S-256 Al-Faisal Town, Bahar Shah Road, Block-C, Lahore Cantt (near Saka Honda Center), Lahore, was conducted by Mr. Abdul Rashid Shaikh, Additional Director, DRAP Lahore, on 01-08-2025, wherein the storage facility of the firm was recommended.

However, the case of the said firm was discussed in the 89th meeting of the MDB. During the meeting, the firm requested additional time, which was placed before the Board for consideration. The Board, however, rejected the application on the grounds that the firm was still not ready despite having applied for grant of an import licence. The Board decided that the firm may submit a fresh application on the prescribed form, along with the prescribed fee and all required documents.

It is therefore submitted that, as the case was rejected in the 89th meeting, the received inspection report may be treated as null and void.

The case is placed before the MDB for consideration.

Decision: The board noticed that the establishment license to import medical devices of the firm was rejected in 89th meeting of the board. However, the Deputy Director DRAP Lahore inspected the premises inadvertently without knowing decision of the board. Therefore, report was considered null and void and advised the firm to apply afresh for establishment license to import medical devices.

Item No. II (a): <u>DEFERRED APPLICATION FOR REGISTRATION / ENLISTMENT OF MEDICAL DEVICE FOR IMPORT.</u>

DEFERRED CASES MINUTES

IHSAN-UL-HAQ ATHAR, DEPUTY DIRECTOR-VIII

S#	Importer Name	Manufacturer Details	Name of MD / Class / Codes / Shelf life / etc.	Decision
1.	Health Tec,	SCW Medicath Ltd,	Angiographic Catheter	Approved in class B.
	H. No. 10-B, Valley Road, St. 24, Opposite Rehmania	Address: No. 4, Baolong 6th Road, Baolong	Peripheral angiographic Catheter	
	Masjid, Westridge 1, Rawalpindi,	Industrial Town,	Class-C	
	Pakistan.	Longgang District, Shenzhen, 518116	Shelf life: 12 Months	
	ELI-00046	Guangdong, P.R. China.	(Model and specification	
	Date of R&I 22/4/2025	FSC: China.	as per FSC)	

		Walidian 25 11 2026		
	Fee Details: Paid Fee: 62,000/-	Validity: 25-11-2026. (Apostille)		
		LOA Validity:		
	Fee Challan No: 73333755806	26/08/2029 (copy)		
		EU Quality		
		Management System		1
		Certificate (MDR)		(2)
		validity 26-09-2029.		5
		(copy)	ill (Miles)	5
			0, 16, 0	
		ISO Validity: 08-07-2027 (copy)	0,000,000	
2.	M/s. Health Tec,	Name of	Brand Name:	Deferred for submission of:
	H. No. 10-B, Valley	Manufacturer:	HT-Burette Set	1. Notarized LOA with name,
	Road, St. 24,	Ultra Med A/S, 64,	Generic Name:	model/sizes of the product.
	Opposite Rehmania	Nakhla El-Motaiy	Measured Volume Fluid	2. clarification that product
	Masjid, Westridge 1,	Triomphe Square,	Administration Set	name in FSC (Egypt) is HT-
	Rawalpindi,	Heliopolis Cairo, Egypt	Applied as: Set	Burette Set Measured Volume
	Pakistan.	LOA	Class: B	Fluid Administration Set and
	(ELI-00046)	Type: Original	Models/Code/sizes (as per	codes not mentioned in it.
		Notarization:	FSC & application	
	R&I Date: 03-06-	Legalized	Model:	Spain not valid (issue date
	2025	Issue Date: 27-03-2025	FSC issued by Egyptian	
	Fee: 31000/-	Validity: 1 year	Drug Authority does not	device as per FSC spain is
	Slip # 949961765141	• FSC	declare any Model or Sizes.	Ultrmed Burette Set Measured
		Type: Original	Shelf Life: 5 years (Room	Volume Fluid Administration Set-1016. The codes are 1016-
		i. Issued By: Egyptian Drug Authority	temperature)	100 and 1016-150.
		Legalization: Legalized	All ((A, O)	4. clarify that name & address
		Iggue Deter 07 04 2025	020 11 6.	of the manufacturer declared in
		Validity: 07-04-2027	G, 40, 400,	FSC, DoC etc is "Ultra for
		validity: 07 04 2027	1000	medical products co.
		ii. Issued by: AEMPS		((ULTRAMED)) U.M.I.C)
		of Spain)	S.A.E, Paret No. (304:310) &
		Type: Copy	Jitecto, Sobs,	Part No. (312 – Industrial
		Legalization: Legalized	31,	Area, Arab E1 Awamer.
		Issue Date: 06-11-2019		5. The fee for the family has
		Validity: N/A		not been submitted.
		, 00		
		• ISO – Certificate:		
		Type: Original		
		Notarization:		
	14	Legalized Validity: 26-05-2024		
3.	M/s. Health Tec,	Name of	Brand Name:	Deferred for submission of:
	H. No. 10-B, Valley	Manufacturer:	HT-Latex Foley Balloon	1. Notarized LOA with name,
	Road, St. 24,		Catheter	model/sizes of the product.

	Opposite Rehmania	Ultra Med A/S, 64,	Generic Name:	2. clarification that product
	Masjid, Westridge 1,	Nakhla El-Motaiy	Indwelling Urinary	name in FSC (Egypt) is Silicon
	Rawalpindi,	,	Catheter	coated Latex Folly Balloon
	Pakistan.	Triomphe Square, Heliopolis Cairo, Egypt		•
		1	Applied as: Set	Catheter 2 Way and 3 way
	(ELI-00046)	LOA	Class: B	Code not mentioned in FSC.
	DOI D 4 02.06	Type: Original	Models/Code/sizes (as per	3. clarification that FSC of
	R&I Date: 03-06-	Notarization:	FSC & application	•
	2025	Legalized	Model:	28.10.2019). The name of
	Fee: 31000/-	Issue Date: 27-03-2025	Silicon Coated Latex Foley	device as per FSC Spain is
	Slip # 638591659997	Validity: 1 year	Balloon Catheter 2 way and	Ultrmed silicon coated latex
		• FSC	3 way	Foley balloon catheter 2-way
		Type: Original		and 3-way-3006. Multiple
		i. Issued By: Egyptian	**FSC issued by Egyptian	sizes/types and codes
		Drug Authority	Drug Authority does not	
		Legalization : Legalized	declare any further Model	4. clarify that name & address
		Issue Date: 07-04-2025	or Sizes.	of the manufacturer declared in
		Validity: 07-04-2027	Shelf Life: 5 years (Room	FSC, DoC etc is "Ultra for
		*3	temperature)	medical products co.
		ii. Issued by: AEMPS	0	((ULTRAMED)) U.M.I.C)
		of Spain		S.A.E, Paret No. (304:310) &
		Type: Copy		Part No. (312 – Industrial
		Legalization: Legalized		Area, Arab E1 Awamer.
		Issue Date: 06-11-2019		5. The fee for the family has
		Validity: N/A		not been claimed but fee
		VO.		voucher not attached.
		• ISO – Certificate:		
		Type: Original		
		Notarization:		
		Legalized	191	6.5
		Validity: 20-05-2026	111 (1911)	5
4.	M/s. Health Tec,	Name of	Brand Name:	Deferred for submission of:
	H. No. 10-B, Valley	Manufacturer:	HT-Surgical Gloves	1. Notarized LOA with name,
	Road, St. 24,	Ultra Med A/S, 64,	(Powder free)	model/sizes of the product.
	Opposite Rehmania	Nakhla El-Motaiy	Generic Name:	2. clarification that product
	Masjid, Westridge 1,	Triomphe Square,	Surgical Gloves (Powder	name in FSC (Egypt) is
	Rawalpindi,	Heliopolis Cairo, Egypt	free)	Surgical Gloves Powder free
	Pakistan.	LOA	Applied as: Set	and codes not mentioned in it.
	(ELI-00046)	Type: Original	Class: B	3. clarification that FSC of
		Notarization:	Models/Code/sizes (as per	Spain not valid (issue date
	R&I Date: 03-06-	Legalized	FSC & application:	28.10.2019). The name of
	2025	Issue Date: 27-03-2025	6.5, 7.0, 7.5, 8.0, 8.5	device as per FSC Spain is HT-
	Fee: 31000/-	Validity: 1 year	**FSC issued by Egyptian	Surgical Gloves (Powder free)
	Slip # 2664028627	• FSC	Drug Authority does not	-9013/PF – with multiple
		Type: Original	declare any Sizes.	codes/sizes mentioned in it.
	A	i. Issued By: Egyptian	Shelf Life: 5 years	4. clarify that name & address
		Drug Authority	·	of the manufacturer declared in
		Legalization : Legalized		FSC, DoC etc is "Ultra for
		Issue Date: 07-04-2025		medical products co.
		Validity: 07-04-2027		((ULTRAMED)) U.M.I.C)
		•		· · · · · · · · · · · · · · · · · · ·

				S.A.E, Paret No. (304:310) &
		ii. Issued by: AEMPS		Part No. (312 – Industrial
		of Spain		Area, Arab E1 Awamer.
		Type: Copy		5. The fee for the family has
		Legalization: Legalized		not been submitted.
		Issue Date: 06-11-2019		not been submitted.
		Validity: N/A		
		valuity. WA		
		• ISO – Certificate:		
		Type: Original		6.5
		Notarization:	iil (Mi)	5
		Legalized	001. 16. 0	
		Validity: 20-05-2026	0.0	
5.	M/s. Health Tec,	Name of	Brand Name:	Deferred for submission of:
3.	H. No. 10-B, Valley	Manufacturer:	HT-Blood Administration	1. Notarized LOA with name,
	Road, St. 24,		Set	model/sizes of the product.
	Opposite Rehmania	Nakhla El-Motaiy	Generic Name:	2. clarification that product
	Masjid, Westridge 1,	Triomphe Square,	Blood Administration Set	name in FSC (Egypt) is Blood
	Rawalpindi,	Heliopolis Cairo, Egypt	Applied as: Set	Administration Set.
	Pakistan.	LOA	Class: B	3. clarification that FSC of
	(ELI-00046)	Type: Original		
	(EL1-00040)	Notarization:	Models/Code/sizes (as per FSC & application	Spain not valid (issue date
	D 9-1 Dotos 02 06	Legalized	FSC & application Model:	
	R&I Date: 03-06-2025	Issue Date: 27-03-2025		device as per FSC Spain is Ultrmed Blood Transfusion
			FSC issued by Egyptian	
	Fee: 31000/-	Validity: 1 year	Drug Authority does not	
	Slip # 2318455592	• FSC	declare any Model or Sizes.	4. clarify that name & address
		Type: Original	Shelf Life: 5 years (Room	of the manufacturer declared in
		i. Issued By: Egyptian	temperature)	FSC, DoC etc is "Ultra for
		Drug Authority		medical products co.
		Legalization: Legalized		((ULTRAMED)) U.M.I.C)
		Issue Date: 07-04-2025	20. 11 . 2.	S.A.E, Paret No. (304:310) &
		Validity: 07-04-2027	G. "U, "U,D,	Part No. (312 – Industrial
		:: Iggred by AEMDC	Jilecto, Sosso,	Area, Arab E1 Awamer. 5. The fee for the family has
		ii. Issued by: AEMPS		not been submitted.
		of Spain)''-0\''	not been submitted.
		Type: Copy		
			3(1)	
		Issue Date: 06-11-2019	0	
		Validity: N/A		
		• ISO – Certificate:		
		Type: Original		
		Notarization:		
		Legalized		
		Validity: 26-05-2024		
6.	M/s. Health Tec,	Name of	Brand Name:	Deferred for submission of:
0.	H. No. 10-B, Valley	Manufacturer:	Silicon Foley Balloon	1. Notarized LOA with name,
	Road, St. 24,	manuactui (i	Catheter	model/sizes of the product.
	21000, 50, 27,			model sizes of the product.

	Unnocite Rehmania	Ultra Med A/S, 64,	Generic Name:	2. clarification that product
	Opposite Rehmania Masjid, Westridge 1,	Nakhla El-Motaiy	Indwelling Urinary	name in FSC (Egypt) is Silicon
1	Rawalpindi,	Triomphe Square,	Catheter	Foley Balloon Catheter 2-
	Pakistan.	Heliopolis Cairo, Egypt	Applied as: Set	way/3-Way and codes not
		1	Class: B	mentioned in it.
	(ELI-00046)	LOA		
	DOI D 4 02.06	Type: Original	Models/Code/sizes (as per	
	R&I Date: 03-06-	Notarization:	FSC & application	•
	2025	Legalized	Model:	28.10.2019). The name of
	Fee: 31000/-	Issue Date: 27-03-2025	Silicon Foley Balloon	1
	Slip # 450645153	Validity: 1 year	Catheter 2 way and 3 way	Ultrmed All silicon, Silicon
		• FSC		Foley balloon catheter 2-way
		Type: Original	**FSC issued by Egyptian	
		i. Issued By: Egyptian	Drug Authority does not	-
		Drug Authority	declare any further Model	
		Legalization: Legalized	or Sizes.	FSC, DoC etc is "Ultra for
		Issue Date: 07-04-2025	Shelf Life: 5 years (Room	medical products co.
		Validity: 07-04-2027	temperature)	((ULTRAMED)) U.M.I.C)
		401		S.A.E, Paret No. (304:310) &
		ii. Issued by: AEMPS	0.	Part No. (312 – Industrial
		of Spain		Area, Arab E1 Awamer.
		Type: Copy		5. The fee for the family has
		Legalization: Legalized		not been submitted.
		Issue Date: 06-11-2019		6. Firm need to apply 2-way
		Validity: N/A		and 3-way separately.
		000		
		• ISO – Certificate:		
		Type: Original		A DIV
		Type: Original Notarization:		al All
		Notarization:	,(8)	6:31 All
			iir (MS)	55:31 AII
7.	M/s. Health Tec,	Notarization: Legalized	Brand Name:	Deferred for submission of:
7.	M/s. Health Tec, H. No. 10-B, Valley	Notarization: Legalized Validity: 20-05-2026	Brand Name: Ultramed Urine Collection	
7.	H. No. 10-B, Valley	Notarization: Legalized Validity: 20-05-2026 Name of Manufacturer:	Ultramed Urine Collection	1. Notarized LOA with name,
7.	H. No. 10-B, Valley	Notarization: Legalized Validity: 20-05-2026 Name of		
7.	H. No. 10-B, Valley Road, St. 24, Opposite Rehmania	Notarization: Legalized Validity: 20-05-2026 Name of Manufacturer: Ultra Med A/S, 64, Nakhla El-Motaiy	Ultramed Urine Collection Bag Generic Name:	 Notarized LOA with name, model/sizes of the product. clarification that product
7.	H. No. 10-B, Valley Road, St. 24, Opposite Rehmania Masjid, Westridge 1,	Notarization: Legalized Validity: 20-05-2026 Name of Manufacturer: Ultra Med A/S, 64, Nakhla El-Motaiy Triomphe Square,	Ultramed Urine Collection Bag Generic Name: Urine Collection Bag	 Notarized LOA with name, model/sizes of the product. clarification that product name in FSC (Egypt) is Urine
7.	H. No. 10-B, Valley Road, St. 24, Opposite Rehmania	Notarization: Legalized Validity: 20-05-2026 Name of Manufacturer: Ultra Med A/S, 64, Nakhla El-Motaiy	Ultramed Urine Collection Bag Generic Name:	 Notarized LOA with name, model/sizes of the product. clarification that product
7.	H. No. 10-B, Valley Road, St. 24, Opposite Rehmania Masjid, Westridge 1, Rawalpindi, Pakistan.	Notarization: Legalized Validity: 20-05-2026 Name of Manufacturer: Ultra Med A/S, 64, Nakhla El-Motaiy Triomphe Square, Heliopolis Cairo, Egypt LOA	Ultramed Urine Collection Bag Generic Name: Urine Collection Bag Applied as: Set Class: B	 Notarized LOA with name, model/sizes of the product. clarification that product name in FSC (Egypt) is Urine Collection Bag with non-return Valve.
7.	H. No. 10-B, Valley Road, St. 24, Opposite Rehmania Masjid, Westridge 1, Rawalpindi,	Notarization: Legalized Validity: 20-05-2026 Name of Manufacturer: Ultra Med A/S, 64, Nakhla El-Motaiy Triomphe Square, Heliopolis Cairo, Egypt	Ultramed Urine Collection Bag Generic Name: Urine Collection Bag Applied as: Set Class: B Models/Code/sizes (as per	 Notarized LOA with name, model/sizes of the product. clarification that product name in FSC (Egypt) is Urine Collection Bag with non-return Valve. clarification that FSC of
7.	H. No. 10-B, Valley Road, St. 24, Opposite Rehmania Masjid, Westridge 1, Rawalpindi, Pakistan.	Notarization: Legalized Validity: 20-05-2026 Name of Manufacturer: Ultra Med A/S, 64, Nakhla El-Motaiy Triomphe Square, Heliopolis Cairo, Egypt LOA Type: Original Notarization:	Ultramed Urine Collection Bag Generic Name: Urine Collection Bag Applied as: Set Class: B Models/Code/sizes (as per FSC & application	 Notarized LOA with name, model/sizes of the product. clarification that product name in FSC (Egypt) is Urine Collection Bag with non-return Valve.
7.	H. No. 10-B, Valley Road, St. 24, Opposite Rehmania Masjid, Westridge 1, Rawalpindi, Pakistan. (ELI-00046) R&I Date: 03-06-	Notarization: Legalized Validity: 20-05-2026 Name of Manufacturer: Ultra Med A/S, 64, Nakhla El-Motaiy Triomphe Square, Heliopolis Cairo, Egypt LOA Type: Original Notarization: Legalized	Ultramed Urine Collection Bag Generic Name: Urine Collection Bag Applied as: Set Class: B Models/Code/sizes (as per	 Notarized LOA with name, model/sizes of the product. clarification that product name in FSC (Egypt) is Urine Collection Bag with nonreturn Valve. clarification that FSC of Spain not valid (issue date 28.10.2019). The name of
7.	H. No. 10-B, Valley Road, St. 24, Opposite Rehmania Masjid, Westridge 1, Rawalpindi, Pakistan. (ELI-00046) R&I Date: 03-06- 2025	Notarization: Legalized Validity: 20-05-2026 Name of Manufacturer: Ultra Med A/S, 64, Nakhla El-Motaiy Triomphe Square, Heliopolis Cairo, Egypt LOA Type: Original Notarization: Legalized Issue Date: 27-03-2025	Ultramed Urine Collection Bag Generic Name: Urine Collection Bag Applied as: Set Class: B Models/Code/sizes (as per FSC & application Capacity: 2000ml	 Notarized LOA with name, model/sizes of the product. clarification that product name in FSC (Egypt) is Urine Collection Bag with non-return Valve. clarification that FSC of Spain not valid (issue date 28.10.2019). The name of device as per FSC Spain is the
7.	H. No. 10-B, Valley Road, St. 24, Opposite Rehmania Masjid, Westridge 1, Rawalpindi, Pakistan. (ELI-00046) R&I Date: 03-06-2025 Fee: 31000/-	Notarization: Legalized Validity: 20-05-2026 Name of Manufacturer: Ultra Med A/S, 64, Nakhla El-Motaiy Triomphe Square, Heliopolis Cairo, Egypt LOA Type: Original Notarization: Legalized Issue Date: 27-03-2025 Validity: 1 year	Ultramed Urine Collection Bag Generic Name: Urine Collection Bag Applied as: Set Class: B Models/Code/sizes (as per FSC & application Capacity: 2000ml **FSC issued by Egyptian	1. Notarized LOA with name, model/sizes of the product. 2. clarification that product name in FSC (Egypt) is Urine Collection Bag with non-return Valve. 3. clarification that FSC of Spain not valid (issue date 28.10.2019). The name of device as per FSC Spain is the name of device as per FSC
7.	H. No. 10-B, Valley Road, St. 24, Opposite Rehmania Masjid, Westridge 1, Rawalpindi, Pakistan. (ELI-00046) R&I Date: 03-06- 2025	Notarization: Legalized Validity: 20-05-2026 Name of Manufacturer: Ultra Med A/S, 64, Nakhla El-Motaiy Triomphe Square, Heliopolis Cairo, Egypt LOA Type: Original Notarization: Legalized Issue Date: 27-03-2025 Validity: 1 year • FSC	Ultramed Urine Collection Bag Generic Name: Urine Collection Bag Applied as: Set Class: B Models/Code/sizes (as per FSC & application Capacity: 2000ml **FSC issued by Egyptian Drug Authority does not	1. Notarized LOA with name, model/sizes of the product. 2. clarification that product name in FSC (Egypt) is Urine Collection Bag with nonreturn Valve. 3. clarification that FSC of Spain not valid (issue date 28.10.2019). The name of device as per FSC Spain is the name of device as per FSC Spain is Ultrmed Urine
7.	H. No. 10-B, Valley Road, St. 24, Opposite Rehmania Masjid, Westridge 1, Rawalpindi, Pakistan. (ELI-00046) R&I Date: 03-06-2025 Fee: 31000/-	Notarization: Legalized Validity: 20-05-2026 Name of Manufacturer: Ultra Med A/S, 64, Nakhla El-Motaiy Triomphe Square, Heliopolis Cairo, Egypt LOA Type: Original Notarization: Legalized Issue Date: 27-03-2025 Validity: 1 year • FSC Type: Original	Ultramed Urine Collection Bag Generic Name: Urine Collection Bag Applied as: Set Class: B Models/Code/sizes (as per FSC & application Capacity: 2000ml **FSC issued by Egyptian Drug Authority does not declare any further Model	1. Notarized LOA with name, model/sizes of the product. 2. clarification that product name in FSC (Egypt) is Urine Collection Bag with non-return Valve. 3. clarification that FSC of Spain not valid (issue date 28.10.2019). The name of device as per FSC Spain is the name of device as per FSC Spain is Ultrmed Urine Collection Bag (adult urine
7.	H. No. 10-B, Valley Road, St. 24, Opposite Rehmania Masjid, Westridge 1, Rawalpindi, Pakistan. (ELI-00046) R&I Date: 03-06-2025 Fee: 31000/-	Notarization: Legalized Validity: 20-05-2026 Name of Manufacturer: Ultra Med A/S, 64, Nakhla El-Motaiy Triomphe Square, Heliopolis Cairo, Egypt LOA Type: Original Notarization: Legalized Issue Date: 27-03-2025 Validity: 1 year • FSC Type: Original i. Issued By: Egyptian	Ultramed Urine Collection Bag Generic Name: Urine Collection Bag Applied as: Set Class: B Models/Code/sizes (as per FSC & application Capacity: 2000ml **FSC issued by Egyptian Drug Authority does not declare any further Model or Sizes.	1. Notarized LOA with name, model/sizes of the product. 2. clarification that product name in FSC (Egypt) is Urine Collection Bag with non-return Valve. 3. clarification that FSC of Spain not valid (issue date 28.10.2019). The name of device as per FSC Spain is the name of device as per FSC Spain is Ultrmed Urine Collection Bag (adult urine collection bag with non-return
7.	H. No. 10-B, Valley Road, St. 24, Opposite Rehmania Masjid, Westridge 1, Rawalpindi, Pakistan. (ELI-00046) R&I Date: 03-06-2025 Fee: 31000/-	Notarization: Legalized Validity: 20-05-2026 Name of Manufacturer: Ultra Med A/S, 64, Nakhla El-Motaiy Triomphe Square, Heliopolis Cairo, Egypt LOA Type: Original Notarization: Legalized Issue Date: 27-03-2025 Validity: 1 year • FSC Type: Original i. Issued By: Egyptian Drug Authority	Ultramed Urine Collection Bag Generic Name: Urine Collection Bag Applied as: Set Class: B Models/Code/sizes (as per FSC & application Capacity: 2000ml **FSC issued by Egyptian Drug Authority does not declare any further Model or Sizes. Shelf Life: 5 years (Room	1. Notarized LOA with name, model/sizes of the product. 2. clarification that product name in FSC (Egypt) is Urine Collection Bag with nonreturn Valve. 3. clarification that FSC of Spain not valid (issue date 28.10.2019). The name of device as per FSC Spain is the name of device as per FSC Spain is Ultrmed Urine Collection Bag (adult urine collection bag with non-return valve (push/pull connecter)).
7.	H. No. 10-B, Valley Road, St. 24, Opposite Rehmania Masjid, Westridge 1, Rawalpindi, Pakistan. (ELI-00046) R&I Date: 03-06-2025 Fee: 31000/-	Notarization: Legalized Validity: 20-05-2026 Name of Manufacturer: Ultra Med A/S, 64, Nakhla El-Motaiy Triomphe Square, Heliopolis Cairo, Egypt LOA Type: Original Notarization: Legalized Issue Date: 27-03-2025 Validity: 1 year FSC Type: Original i. Issued By: Egyptian Drug Authority Legalization: Legalized	Ultramed Urine Collection Bag Generic Name: Urine Collection Bag Applied as: Set Class: B Models/Code/sizes (as per FSC & application Capacity: 2000ml **FSC issued by Egyptian Drug Authority does not declare any further Model or Sizes.	1. Notarized LOA with name, model/sizes of the product. 2. clarification that product name in FSC (Egypt) is Urine Collection Bag with non-return Valve. 3. clarification that FSC of Spain not valid (issue date 28.10.2019). The name of device as per FSC Spain is the name of device as per FSC Spain is Ultrmed Urine Collection Bag (adult urine collection bag with non-return valve (push/pull connecter)). 4. clarify that name & address
7.	H. No. 10-B, Valley Road, St. 24, Opposite Rehmania Masjid, Westridge 1, Rawalpindi, Pakistan. (ELI-00046) R&I Date: 03-06-2025 Fee: 31000/-	Notarization: Legalized Validity: 20-05-2026 Name of Manufacturer: Ultra Med A/S, 64, Nakhla El-Motaiy Triomphe Square, Heliopolis Cairo, Egypt LOA Type: Original Notarization: Legalized Issue Date: 27-03-2025 Validity: 1 year • FSC Type: Original i. Issued By: Egyptian Drug Authority	Ultramed Urine Collection Bag Generic Name: Urine Collection Bag Applied as: Set Class: B Models/Code/sizes (as per FSC & application Capacity: 2000ml **FSC issued by Egyptian Drug Authority does not declare any further Model or Sizes. Shelf Life: 5 years (Room	1. Notarized LOA with name, model/sizes of the product. 2. clarification that product name in FSC (Egypt) is Urine Collection Bag with nonreturn Valve. 3. clarification that FSC of Spain not valid (issue date 28.10.2019). The name of device as per FSC Spain is the name of device as per FSC Spain is Ultrmed Urine Collection Bag (adult urine collection bag with non-return valve (push/pull connecter)).

		• ISO – Certificate: Type: Original Notarization: Legalized Validity: 20-05-2026-		medical products co. ((ULTRAMED)) U.M.I.C) S.A.E, Paret No. (304:310) & Part No. (312 – Industrial Area, Arab E1 Awamer. 5. The fee for the family has not been submitted.
8.	M/s Health Solutions. 28-B, Second floor, Zeenat Medicine Market, North Napier Road, Karachi. (ELI-01153) D.O.I: 07-09-2023 Dy. No.: 15745 DRAP (R&I) Dated: 18-09-2024 Fee Challan No.: 07048226510 7 PKR: 50000/- Dated: 30-07-2024	Legal Manufacturer: M/s Shandong Haidike Medical Products Co. Ltd. Manufacturer Address: Tianfu Road, Dongcheng District, Shan County, 274300, Heze City, Shandong Province, China. ISO 13485 Certificate validity: 19-04-2026 EC Certificate validity: 09-04-2024 LOA Validity: 30-12-2027 FSC Validity: China (country of origin): 14-02-2025	Suigly Suicon Surgical Sutures Polyglycolic Acid Surgical Suture with Needle (PGA) USP Suture Size: 12-0, 11-0, 10-0, 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3, 4, 5. Needle Shape: Round Bodied, Straight, Curve, Cutting, Reverse Cutting, Taper Cutting, Non cutting. Needle Curvature: ½ Circle, 3/8 circle, straight & double spatulated. Class: D Shelf life: 05 years	Approved with Brand name SUICARE.
	la.	FSC (MHRA-UK) Dated 23-02-2019		31
9.	M/s Health Solutions. 28-B, Second floor, Zeenat Medicine Market, North Napier Road, Karachi. (ELI-01153) D.O.I: 07-09-2023 Dy. No.: 15744 DRAP (R&I) Dated: 18-09-2024 Fee Challan No.: 838593134 PKR: 50000/- Dated: 30-07-2024	Legal Manufacturer: M/s Shandong Haidike Medical Products Co. Ltd. Manufacturer Address: Tianfu Road,	Suicon Surgical Sutures Silk Braided Surgical Suture with needle USP Suture Size: 12-0, 11-0, 10-0, 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3, 4, 5. Needle Shape: Round Bodied, Straight, Curve, Cutting, Reverse Cutting. Needle Curvature: ½ Circle, 3/8 circle, straight. Class: D Shelf life: 05 years	Approved with Brand name SUICARE.

		Dated 23-02-2019		
10.	M/s Health Solutions. 28-B, Second floor, Zeenat Medicine Market, North Napier Road, Karachi. (ELI-01153) D.O.I: 07-09-2023 Dy. No.: 15747 DRAP (R&I) Dated: 18-09-2024 Fee Challan No.: 7798811089 PKR: 50000/- Dated: 09-08-2024	Legal Manufacturer: M/s Shandong Haidike Medical Products Co. Ltd. Manufacturer Address: Tianfu Road, Dongcheng District, Shan County, 274300, Heze City, Shandong Province, China. ISO 13485 Certificate validity: 19-04-2026 EC Certificate validity: 09-04-2024 LOA Validity: 30-12-2027 FSC Validity: China (country of origin): 14-02-2025 FSC (MHRA-UK)	Suicon Surgical Sutures Suilene Polypropylene Monofilament Surgical Suture with Needle USP Suture Size: 12-0, 11-0, 10-0, 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3, 4, 5. Needle Shape: Round Bodied, Straight, Curve, Cutting, Reverse Cutting, Taper cutting and non- cutting. Needle Curvature: ½ Circle, 3/8 circle, straight, Double Needle. Class: D Shelf life: 05 years	Approved with Brand name SUICARE.
11.	M/s Health Solutions. 28-B, Second floor, Zeenat Medicine Market, North Napier Road, Karachi. (ELI-01153) D.O.I: 07-09-2023 Dy. No.: 15746 DRAP (R&I) Dated: 18-09-2024 Fee Challan No.: 06434554213 PKR: 50000/- Dated: 09-08-2024	Dated 23-02-2019 Legal Manufacturer: M/s Shandong Haidike Medical Products Co. Ltd. Manufacturer Address: Tianfu Road, Dongcheng District, Shan County, 274300, Heze City, Shandong Province, China. ISO 13485 Certificate validity: 19-04-2026 EC Certificate validity: 09-04-2024 LOA Validity: 30-12-2027 FSC Validity: China (country of origin): 14-02-2025 FSC (MHRA-UK) Dated 23-02-2019.	Suicon Surgical Sutures Suicryl Polyglactin 910 (PGLA) Surgical Suture with Needle USP Suture Size: 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3, 4, 5. Needle Shape: Round Bodied, Straight, Curve, Cutting, Reverse Cutting, Taper cutting. Needle Curvature: ½ Circle, 3/8 circle, straight. Class: D Shelf life: 05 years	Approved with Brand name SUICARE.
12.	ZYBIO MEDICAL PAKISTAN (SMC- PRIVATE) LIMITED	LEGAL MANUFACTEURER Zybio Inc.	High Density Lipoprotein Cholesterol (HDL-C) Kit (Enzymatic Method) Codes:	Approved subject to submission of fee for the family.

	Address of Importer House No 323, street No 66, Sector I8/3, Islamabad Fee Amount & Fee Submission Date: Rs. 31,000/- 20/02/2025 Deposit Slip No: 55312531	Company Address: No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China Marketing Authorization Letter (original): Validity Date: 23-11- 2028 FSC: China (Original) Issuance Date: 03-11-2026 Production Quality Management System Certificate (ISO 13485) (Original) Validity Date: 29-11- 2026	REF (as per IFU) 01.09.02. 03.EC.01 01.09.02. 03.EC.02	Specificatio n (as per FSC) R1 30 mL × 3 R2 10 mL × 3 Calibrator 1 Level × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1 R1 45 mL × 2 R2 15 mL × 2 Calibrator 1 Level × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1	
	W.	5,	Shelf Life: 1 Class:B	8 months	1 AM
13.	ZYBIO MEDICAL PAKISTAN (SMC-PRIVATE) LIMITED Address of Importer House No 323, street No 66, Sector I8/3, Islamabad Fee Amount & Fee Submission Date: Rs. 31,000/-20/2025 Deposit Slip No: 1668763579	LEGAL MANUFACTEURER Zybio Inc. Company Address: No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China Marketing Authorization Letter (original): Validity Date: 23-11- 2028 FSC: China (Original) Issuance Date: 03-11-2026	Total Bilirul Kit(Vanadat Method) Codes: REF (as per IFU) 01.09.00. 21.EC.01 01.09.00. 21.EC.03	Specifica tion (as per FSC) R1 30 mL × 3 R2 7.5 mL × 3 R1 48 mL × 2 R2 12 mL × 2	Approved subject to submission of fee for the family.

		1	Classin			
		Production Quality Management System Certificate (ISO 13485) (Original) Validity Date: 29-11- 2026	Class:B		AM	
14.	ZYBIO MEDICAL PAKISTAN (SMC- PRIVATE) LIMITED	LEGAL MANUFACTEURER Zybio Inc. Company Address:	(ALT) Kit (E Method) Codes:	(A)	Approved subject submission of fee for family.	to the
	Address of Importer House No 323, street No 66, Sector I8/3,	No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District,	REF (as per IFU)	Specificat ion (as per FSC)		
	Fee Amount & Fee Submission Date:	400082 Chongqing, People's Republic of China Marketing	01.09.00.0 5.EC.01	R1 30 mL × 3 R2 7.5 mL × 3		
	Rs. 31,000/- 20/02/2025 Deposit Slip No:	Authorization Letter (original): Validity Date: 23-11- 2028	01.09.00.0 5.EC.03	R1 48 mL × 2 R2 12 mL × 2		
	83172362105	FSC: China (Original) Issuance Date: 03-11-2026	Shelf Life: 18	8 months	5:31 AM	
		Production Quality Management System Certificate (ISO 13485) (Original) Validity Date: 29-11- 2026	Class:B	50522.		
15.	ZYBIO MEDICAL PAKISTAN (SMC- PRIVATE) LIMITED	LEGAL MANUFACTEURER Zybio Inc. Company Address:	Aspartate Aminotransfe Kit (Enzymat Codes: REF (as		Approved subject submission of fee for family.	to the
	Address of Importer House No 323, street No 66, Sector I8/3, Islamabad	No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China	per IFU)	on (as per FSC)		
	Fee Amount & Fee Submission Date: Rs. 31,000/-	Cimiu				

	20/02/2025 Deposit Slip No: 58368205383	Marketing Authorization Letter (original): Validity Date: 23-11- 2028 FSC: China (Original) Issuance Date: 03-11-2026 Production Quality Management System Certificate (ISO 13485) (Original) Validity Date: 29-11-	01.09.00. 16.EC.01 01.09.00. 16.EC.02 Shelf Life: 1	R1 30 mL × 3 R2 7.5 mL × 3 R1 48 mL × 2 R2 12 mL × 2	55:31 AM
16.	ZYBIO MEDICAL PAKISTAN (SMC- PRIVATE) LIMITED Address of Importer House No 323, street No 66, Sector I8/3, Islamabad Fee Amount & Fee Submission Date: Rs. 31,000/- 20/02/2025 Deposit Slip No: 89357770	LEGAL MANUFACTEURER Zybio Inc. Company Address: No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China Marketing Authorization Letter (original): Validity Date: 23-11- 2028 FSC: China (Original) Issuance Date: 03-11-2026 Production Quality Management System Certificate (ISO 13485) (Original) Validity Date: 29-11-	Urea (UREAGLDH Meth Codes: REF (as per IFU) 01.09.01. 06.EC.01 01.09.01. 06.EC.02	Specificati on (as per FSC) R1 30 mL × 3 R2 7.5 mL × 3 R1 48 mL × 2 R2 12 mL × 2	Approved subject to submission of fee for the family.
17.	ZYBIO MEDICAL PAKISTAN (SMC- PRIVATE) LIMITED Address of Importer	LEGAL MANUFACTEURER Zybio Inc. Company Address: No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing,	Alkaline Pho (ALP) Kit (I Method) Codes: REF (as per IFU)	_	Approved subject to submission of fee for the family.

	House No 323, street No 66, Sector I8/3, Islamabad Fee Amount & Fee Submission Date: Rs. 31,000/- 20/02/2025 Deposit Slip No: 056101453	People's Republic of China Marketing Authorization Letter (original): Validity Date: 23-11-2028 FSC: China (Original) Issuance Date: 03-11-2026 Production Quality Management System Certificate (ISO 13485) (Original) Validity Date: 29-11-2026	01.09.01.0 6.EC.01 01.09.01.0 6.EC.02 Shelf Life: 18	R1 30 mL × 3 R2 7.5 mL × 3 R1 48 mL × 2 R2 12 mL × 2	35:31 AM
18.	ZYBIO MEDICAL PAKISTAN (SMC- PRIVATE) LIMITED Address of Importer House No 323, street No 66, Sector I8/3, Islamabad Fee Amount & Fee Submission Date: Rs. 31,000/- 20/02/2025 Deposit Slip No: 056101453	LEGAL MANUFACTEURER Zybio Inc. Company Address: No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China Marketing Authorization Letter (original): Validity Date: 23-11- 2028 FSC: China (Original) Issuance Date: 03-11-2026 Production Quality Management System Certificate (ISO 13485) (Original) Validity Date: 29-11- 2026	per IFU) 01.09.0 0.04.EC .01	Specificat ion (as per FSC) R 30 mL × 6 R 60 mL × 2	Approved subject to submission of fee for the family.
19.	ZYBIO MEDICAL PAKISTAN (SMC- PRIVATE) LIMITED	LEGAL MANUFACTEURER Zybio Inc.	Low Density Cholesterol ((Enzymatic M Codes:	LDL-C) Kit	Approved subject to submission of fee for the family.

	Address of Importer House No 323, street No 66, Sector I8/3, Islamabad Fee Amount & Fee Submission Date: Rs. 31,000/-20/2/2025 Deposit Slip No: 3632546296	Company Address: No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China Marketing Authorization Letter (original): Validity Date: 23-11- 2028 FSC: China (Original) Issuance Date: 03-11-2026 Production Quality Management System Certificate (ISO 13485) (Original) Validity Date: 29-11- 2026	REF (as per IFU) 01.09.02. 00.EC.01 01.09.02. 00.EC.02	Specificatio n (as per FSC) R1 30 mL × 3 R2 10 mL ×3 Calibrator 1 Level × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1 R1 45 mL × 2 R2 15 mL × 2 Calibrator 1 Level × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1	55:31 AM
20.	ZYBIO MEDICAL	LEGAL	Shelf Life: 1 Class:B Glycated He		Approved subject to
20.	ZYBIO MEDICAL PAKISTAN (SMC- PRIVATE) LIMITED Address of Importer House No 323, street No 66, Sector I8/3, Islamabad Fee Amount & Fee Submission Date: Rs. 31,000/- 20/02/2025 Deposit Slip No: 44943347	LEGAL MANUFACTEURER Zybio Inc. Company Address: No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China Marketing Authorization Letter (original): Validity Date: 23-11- 2028 FSC: China (Original) Issuance Date: 03-11-2026	Glycated He (HbA1c) Kit (Immunotur Method) Codes: REF (as per IFU) 01.09.06.0 3.EC.01	Specificat ion (as per FSC)	Approved subject to submission of fee for the family.

		Production Quality Management System Certificate (ISO 13485) (Original) Validity Date: 29-11- 2026	01.09.06.0 3.EC.02	1.0 mL × 1 R1 15 mL × 2 R2 10 mL × 1 Lyse 50 mL × 2 Calibrator 5 Levels × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1	5:31 AM
21.	ZYBIO MEDICAL PAKISTAN (SMC-	LEGAL MANUFACTEURER	Class:B Magnesium (M (Xylidyl Blue)	•	Approved subject to submission of fee for the
	PRIVATE) LIMITED Address of Importer	Zybio Inc. Company Address: No. 45, Shilin Avenue,	Codes: REF (as per IFU)	Specificati on (as per	family.
	•			FSC)	1
	House No 323, street No 66, Sector I8/3, Islamabad	Tiaodeng Town, Dadukou District, 400082 Chongqing,	01.09.0C.02 .EC.01	FSC) R 30 mL × 6	55:31
	House No 323, street No 66, Sector I8/3, Islamabad Fee Amount & Fee	Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China	.EC.01 01.09.0C.02 .EC.02	R 30 mL ×	55:31
	House No 323, street No 66, Sector I8/3, Islamabad	Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China Marketing Authorization Letter (original):	.EC.01 01.09.0C.02	R 30 mL × 6 R 60 mL × 2 R 30 mL × 6	55.31
	House No 323, street No 66, Sector I8/3, Islamabad Fee Amount & Fee Submission Date: Rs. 31,000/- 20/02/2025 Deposit Slip No:	Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China Marketing Authorization Letter (original): Validity Date: 23-11- 2028	.EC.01 01.09.0C.02 .EC.02 01.09.0C.02	R 30 mL × 6 R 60 mL × 2 R 30 mL ×	55.3
	House No 323, street No 66, Sector I8/3, Islamabad Fee Amount & Fee Submission Date: Rs. 31,000/- 20/02/2025	Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China Marketing Authorization Letter (original): Validity Date: 23-11- 2028 FSC: China (Original) Issuance Date: 03-11-2026	.EC.01 01.09.0C.02 .EC.02 01.09.0C.02	R 30 mL × 6 R 60 mL × 2 R 30 mL × 6 Calibrator 1 Level × 1.0 mL × 1 R 60 mL ×2 Calibrator 1 Level×	
	House No 323, street No 66, Sector I8/3, Islamabad Fee Amount & Fee Submission Date: Rs. 31,000/- 20/02/2025 Deposit Slip No:	Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China Marketing Authorization Letter (original): Validity Date: 23-11- 2028 FSC: China (Original) Issuance Date:	.EC.01 01.09.0C.02 .EC.02 01.09.0C.02 .EC.03	R 30 mL × 6 R 60 mL × 2 R 30 mL × 6 Calibrator 1 Level × 1.0 mL × 1 R 60 mL ×2 Calibrator 1 Level× 1.0mL×1	

22.	ZYBIO MEDICAL	LEGAL	Hematology Analyzer	Approved Hamatalass
44.	PAKISTAN (SMC-	LEGAL MANUFACTEURER	1	Approved Hematology
	`	Zybio Inc.	Models: (as per FSC) Z50	Analyzer Models: Z50.
	PRIVATE)	Zybio Inc.		
	LIMITED	Company Address:	Z52	The firm will apply
		No. 45, Shilin Avenue,	Shelf Life: 18 months	Hematology Analyzer
	Address of Importer	Tiaodeng Town,		Models: Z52 separately
	House No 323, street	Dadukou District,	Class:B	through online portal for
	No 66, Sector I8/3,	400082 Chongqing,		registration.
	Islamabad	People's Republic of		
		China		10°
	Fee Amount & Fee	Cimia	111 (1911)	5
	Submission Date:	Marketing	00, 16, 0	
	Rs. 50,000/-	Authorization Letter	0.00	
	·	(original):		
	20/02/2025	Validity Date: 23-11-	10, 10,	
		2028		
	Deposit Slip No:	_520	orsque 10/22	
	4635111056	FSC: China (Original)		
		Issuance Date:		
		03-11-2026		
		Production Quality		
		Management System		
		Certificate (ISO		
		13485) (Original)		
		Validity Date: 29-11-		
		2026		
23.	ZYBIO MEDICAL	LEGAL	Hematology Analyzer	Approved Hematology
	PAKISTAN (SMC-	MANUFACTEURER	Models: (as per FSC)	Analyzer
	PRIVATE)	Zybio Inc.	1. Z3	Models: Z3.
	LIMITED		2. Z31	The firm will apply online
		Company Address:	3. Z30	separately for each model.
	Address of Importer	No. 45, Shilin Avenue,	4. Z3 CRP	3 - 4
	House No 323, street	Tiaodeng Town,	5. Z30 CRP	
	No 66, Sector I8/3,	Dadukou District,	6. Z31 CRP	
	Islamabad	400082 Chongqing,	Shelf Life: 18 months	
	Islamadad	People's Republic of	Shell Life. To months	
	Foo Amount & Foo	China		
	Fee Amount & Fee Submission Date:	40)	Class:B	
	Rs. 50,000/-	Marketing	0	
	13. 30,000/-	Authorization Letter		
	20/02/2025	(original):		
	20/02/2023	Validity Date: 23-11-		
	Deposit Slip No:	2028		
	116164750586	ECC. China (Oniainal)		
	11010-750500	FSC: China (Original)		
	A	Issuance Date: 03-11-2026		
		03-11-2020		
		Production Quality		
		Management System		
<u></u>		wranagement System		

		Certificate (ISO 13485) (Original) Validity Date: 29-11- 2026				
24.	ZYBIO MEDICAL PAKISTAN (SMC- PRIVATE)	LEGAL MANUFACTEURER Zybio Inc.	Lipase (LPS) (Colorimetric		Approved subject submission of fee for family.	to the
	LIMITED Address of Importer House No 323, street No 66, Sector I8/3,	Company Address: No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District,	REF (as per IFU)	Specificati on (as per FSC)	rainity.	
	Fee Amount & Fee Submission Date:	400082 Chongqing, People's Republic of China	01.09.0B .01.EC.0	R1 30 mL × 3 R2 10 mL × 3		
	Rs. 31,000/- 20/02/2025	Marketing Authorization Letter (original): Validity Date: 23-11- 2028	anio	Calibrator 1 Level × 1.0 mL × 1		
	Deposit Slip No: 71809609647	FSC: China (Original) Issuance Date:	01.09.0B	Control 2 Levels × 1.0 mL × 1		
	M	03-11-2026 Production Quality Management System	.01.EC.0 2	R1 45 mL $\times 2 mtext{R2}$ $15 mtext{mL} imes 2$ Calibrator	.31 AM	
		Certificate (ISO 13485) (Original) Validity Date: 29-11- 2026	Qadir	1 Level × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1	75°.5°.	
		Alodul	Shelf Life: 1 Class:B			
25.	ZYBIO MEDICAL	LEGAL MANUFACTEURER	Total Protein		Approved subject	to
	PAKISTAN (SMC- PRIVATE) LIMITED	Zybio Inc. Company Address:	(Biuret Methods) REF (as per IFU)	Specificat ion (as	submission of fee for family.	the
	Address of Importer House No 323, street No 66, Sector I8/3,	No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing,	01.09.00.2 3.EC.01	per FSC) R 30 mL × 6		
	Islamabad Fee Amount & Fee Submission Date:	People's Republic of China	01.09.00.2 3.EC.02 Shelf Life: 1	$ \begin{array}{ c c }\hline R 60 \text{ mL}\\ \times 2\\\hline 8 \text{ months}\\ \end{array} $		
	Rs. 31,000/-					

	20/02/2025 Deposit Slip No: 71809609647	Marketing Authorization Letter (original): Validity Date: 23-11- 2028 FSC: China (Original) Issuance Date: 03-11-2026 Production Quality Management System Certificate (ISO 13485) (Original) Validity Date: 29-11- 2026	Class:B	1025.	55:31 AM
26.	ZYBIO MEDICAL PAKISTAN (SMC- PRIVATE) LIMITED	LEGAL MANUFACTEURER Zybio Inc.	Gamma-Gluta Transferase (C (Enzymatic M	GGT) Kit	Approved subject to submission of fee for the family.
	Address of Importer House No 323, street No 66, Sector I8/3, Islamabad	Company Address: No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of	REF (as per IFU)	Specificat ion (as per FSC)	
	Fee Amount & Fee Submission Date: Rs. 31,000/-	China Marketing Authorization Letter	3.EC.01	× 3 R2 7.5 mL × 3	-31 AM
	20/02/2025 Deposit Slip No:	(original): Validity Date: 23-11- 2028	3.EC.02	$\begin{array}{ccc} R1 & 48 & \text{HL} \\ \times & 2 & R2 \\ 12 & \text{mL} \times \\ & 2 & \end{array}$	55.
	7380613052	FSC: China (Original) Issuance Date: 03-11-2026	Shelf Life: 18 Class:B	months	
		Production Quality Management System Certificate (ISO 13485) (Original) Validity Date: 29-11- 2026	Suppe		
27.	ZYBIO MEDICAL	LEGAL	Triglyceride (•	Approved subject to
	PAKISTAN (SMC- PRIVATE)	MANUFACTEURER Zybio Inc.	(Enzymatic M		submission of fee for the family.
	LIMITED	2,010 1110	REF (as	Specifica	ranniy.
		Company Address: No. 45, Shilin Avenue,	per IFU)	tion (as per FSC)	
	Address of Importer	Tiaodeng Town,	01.09.02.0	R1 30	
		Dadukou District, 400082 Chongqing,	2.EC.01	$mL \times 3$	

	House No 323, street No 66, Sector I8/3, Islamabad Fee Amount & Fee Submission Date: Rs. 31,000/- 20/02/2025 Deposit Slip No: 51681194097	People's Republic of China Marketing Authorization Letter (original): Validity Date: 23-11- 2028 FSC: China (Original) Issuance Date: 03-11-2026 Production Quality Management System Certificate (ISO 13485) (Original) Validity Date: 29-11- 2026	01.09.02.0 2.EC.02 Shelf Life: 1 Class:B	mL × 2 R2 12 mL × 2	35:31 AM
28.	ZYBIO MEDICAL PAKISTAN (SMC- PRIVATE) LIMITED Address of Importer House No 323, street No 66, Sector I8/3, Islamabad	LEGAL MANUFACTEURER Zybio Inc. Company Address: No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of	C-Reactive F (Immunoture Method) REF (as per IFU) 3011001		Approved C-Reactive Protein (CRP) Kit (Latex Enhanced Immunoturbidimetric Method) subject to submission of fee for the family.
	Fee Amount & Fee Submission Date: Rs. 62,000/- 20/02/2025 Deposit Slip No: 699990640	People's Republic of China Marketing Authorization Letter (original): Validity Date: 23-11- 2028 FSC: China (Original) Issuance Date: 03-11-2026 Production Quality Management System Certificate (ISO 13485) (Original) Validity Date: 29-11- 2026	3011001	0.4mLx25, R2 1.5mLx1 100T: R1 0.4mLx10 0, R2 3.0mLx2 25T: R1 0.4mLx25, R2 1.5mLx1 (including Cal 6 levels x1 x 0.5mL, Con 2 levels x1x0.5mL)	

		Assistant on day, on day, on day, on day, on the day, of the day, of the day,	3011004 3011005 3011006 Shelf Life: 13	25T: R1 0.4mLx25, R2 1.5mLx1(i ncluding Con 2 levels x1x0.5mL) 100T: R1 0.4mLx10 0, R2 3mLx2 (including Cal 6 levels x1x1.0mL, Con 2 levels x1x1.0mL) 100T: R1 0.4mLx10 0, R2 3mLx2(including Cal 6 levels x1x1.0mL, Con 2 levels x1x1.0mL)	5:31 AM
29.	ZYBIO MEDICAL PAKISTAN (SMC-PRIVATE) LIMITED Address of Importer House No 323, street No 66, Sector I8/3, Islamabad Fee Amount & Fee Submission Date: Rs. 31,000/- 20/02/2025 Deposit Slip No: 51681194097	LEGAL MANUFACTEURER Zybio Inc. Company Address: No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China Marketing Authorization Letter (original): Validity Date: 23-11- 2028 FSC: China (Original)	Class:C Lactate Dehy	rdrogenase Rate Method)) Specificati on (as per FSC) R1 30 mL × 3 R2 7.5 mL × 3 R1 48 mL × 2 R2 12 mL × 2	Approved subject to submission of fee for the family.

30.	ZYBIO MEDICAL	Issuance Date: 03-11-2026 Production Quality Management System Certificate (ISO 13485) (Original) Validity Date: 29-11- 2026 LEGAL	Total Chala	starel (CHOL)	Approved subject	to
30.	PAKISTAN (SMC-	MANUFACTEURER		sterol (CHOL) atic Method)	Approved subject submission of fee for	to the
	PRIVATE)	Zybio Inc.	REF (as	Specification	family.	
	LIMITED	Company Address:	per IFU)	(as per FSC)		
	Address of Importer House No 323, street No 66, Sector I8/3, Islamabad	No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China	ingcit	2010		
	Fee Amount & Fee Submission Date:		01.09.02.	R1 30 mL × 3		
	Rs. 31,000/-	Marketing Authorization Letter (original):	10.EC.01	R2 7.5 mL × 3		
	20/02/2025	Validity Date: 23-11-	01.09.02.	R1 48 mL × 2		
	Deposit Slip No:	2028	10.EC.02	R2 12 mL \times 2	<u> </u>	
	48737124	FSC: China (Original)	Shelf Life: 1	18 months		
	B.	Issuance Date: 03-11-2026	Class:B	.(5)	31 AM	
		Production Quality Management System Certificate (ISO 13485) (Original) Validity Date: 29-11- 2026	O. adir	3052, 03	50	
31.	ZYBIO MEDICAL	LEGAL	Glucose (Gl	*	Approved subject	to
	PAKISTAN (SMC-	MANUFACTEURER Zybio Inc.	(Hexokinase		submission of fee for	the
	PRIVATE) LIMITED	Company Address:	REF (as per IFU)	Specificatio n (as per FSC)	family.	
	Address of Importer	No. 45, Shilin Avenue, Tiaodeng Town,	1080201	R1 30 mL ×		
	House No 323, street No 66, Sector I8/3,	Dadukou District,	1000201	1 R2		
	Islamabad	400082 Chongqing,		$7.5 \text{ mL} \times 1$		
		People's Republic of China	1080202	R1 30 mL ×		
	Fee Amount & Fee	D,		3 R2		
	Submission Date: Rs. 31,000/-	Marketing Authorization Letter (original):		$7.5 \text{ mL} \times 3$		
	20/02/2025	(original).				

	Deposit Slip No: 0044365032	Validity Date: 23-11-2028 FSC: China (Original) Issuance Date: 03-11-2026 Production Quality Management System Certificate (ISO 13485) (Original) Validity Date: 29-11-2026	Shelf Life: 1 Class:B	R1 48 mL × 2 R2 12 mL × 2 8 months	55:31 AM
32.	Fabnos Traders Pvt Ltd building 26-c, 3rd floor, Touheed commercial area, street no 26 phase v Dha, Karachi (ELI-00750)	Zimmer Dental, Inc: 1900 Aston Ave Carlsbad, California 92008-7308, USA Manufacturng Site: Biomet 3i Dental Iberica, S.L.U, Spain, C-Islas Baleares, 50 Pol. Ind. Fuente De Jarro, Paterna, Valencia, 46988 Spain.	Zimmer Dental (Abutment) Angled Applied Codes: A5H20/6 (ABUT 20 DEG 5,7MM IMP HEX-LOCK) AH20/4 (ABUT 20 DEG SCR-V 3.5 MM IMP) AH20S (SCR REPLACEMENT SCR-V 20 DEG ABUT INT HEX) AH20W/5 (ABUT 20DEG SCR-V 4.5MM IMP)		Deferred with final opportunity for submission of fee for the family, annexures as per form 7A and undertaking on the stamp paper.
33.	Fabnos Traders (Pvt) Ltd Address: Building no 26, 3rd floor, Touheed commercial area, 26th street, Phase V DHA, Karachi. (ELI-00750	Zimmer Dental, Inc: 1900 Aston Ave Carlsbad, California 92008-7308, USA Manufacturng Site: Biomet 3i Dental Iberica, S.L.U, Spain, C-Islas Baleares, 50 Pol. Ind. Fuente De Jarro, Paterna, Valencia, 46988 Spain.	Zimmer Der (Healing Co	ntal	Deferred with final opportunity for submission of fee for the family, annexures as per form 7A and undertaking on the stamp paper. Clarification for the name of device as the name of device is Healing collars for taped screw-Vent and Screw-Vent Implants.
34.	Fabnos Traders (Pvt) Ltd Address: Building no 26, 3rd floor, Touheed commercial area, 26th street, Phase V DHA, Karachi.	Zimmer Dental, Inc: 1900 Aston Ave Carlsbad, California 92008-7308, USA Manufacturng Site: Biomet 3i Dental Iberica, S.L.U, Spain, C-Islas Baleares, 50	Zimmer Der (Hex Lock A	ntal Abutment Abutment)	Deferred with final opportunity for submission of fee for the family, annexures as per form 7A and undertaking on the stamp paper. Clarification is required that The codes HLTS2 and MHLAS does not belong to ABUT HEX-LOCK FLARE.

		Pol. Ind. Fuente De		
	(ELL 00750			
	(ELI-00750	Jarro, Paterna, Valencia,		
2.5	E1 E 1 (D.)	46988 Spain.	D	D C 1 11 C 1
35.	Fabnos Traders (Pvt)	Dentis Co., Ltd., Korea	Dentis	Deferred with final
	Ltd		s-Clean Healing Abutment	opportunity for submission of
	Address: Building no	Addresses:		fee for the family, annexures as
	26, 3rd floor,	1. HQ: 99 Seongseoseo-	Codes:	per form 7A and undertaking
	Touheed commercial	ro, Dalseo-gu, Daegu,	• DSH4510	on the stamp paper.
	area, 26th street,	Republic of Korea.	• DSH4515	Clarification is required as The
	Phase V DHA,		• DSH4520	name of device as per FSC is
	Karachi.	2. Factory address: 1F,	• DSH4525	•
		B-dong, 6, Yulam-ro,	• DSH4535	Implant, endosseous,
	(ELI-00750	Dong-gu, Daegu,	• DSH4545	superstructure.
	`	Republic of korea	• DSH4555	
		1	• DSH5510	
		Tel: +82-53-582-2804	• DSH5515	
		Fax. +82-53-583-2806	• DSH5520	
		E-mail:	• DSH5525	
		http://www.dentis.co.kr	• DSH5535	
		http://www.dehtis.eo.ki	• DSH5545	
		LOA:	• DSH5555	
		Issuance date: 01-03-	• DSH6515	
		2023		
			• DSH6520	
		Valid Till: 28-02-2026	• DSH6525	
			• DSH6535	
		Country of Origin	• DSH6545	
		(Korea) FSC:	• DSH6555	
		Date of Issuance: 13-	• DSH7515	al AM
		03-2023	• DSH7520	1
			• DSH7525	0
		ISO Certificate:	• DSH7535	(2)
		Issuance date: 02-04-	• DSH7545	30,
		2022	• DSH7555	
		Validi till: 02-04-2025	• DSHS4010	
			• DSHS4015	
		CE Certificate:	• DSHS4020	
		Initial date: 16-07-2019	• DSHS4025	
		Validi till: 27-05-2024	• DSHS4035	
			• DSHS4045	
36.	Fabnos Traders (Pvt)	Dentis Co., Ltd., Korea	s-Clean SQ-SL Fixture	Deferred with final
	Ltd		3)	opportunity for submission of
1	Address: Building no	Addresses:	Codes:	fee for the family, annexures as
1	26, 3rd floor,	1. HQ: 99 Seongseoseo-	DSSFN3507S	· · · · · · · · · · · · · · · · · · ·
1	Touheed commercial	ro, Dalseo-gu, Daegu,	DSSFN3508S	per form 7A and undertaking
1	area, 26th street,	Republic of Korea.	DSSFN3510S	on the stamp paper.
1	Phase V DHA,	republic of Ixolea.	DSSFN3510S DSSFN3512S	Clarification/justification is
1	Karachi.	2. Factory address: 1F,	DSSFN3512S DSSFN3514S	required as The name of device
1	ixaraciii.	B-dong, 6, Yulam-ro,	DSSFR4007S	as per FSC is Implant,
	(ELL 00750			endosseous, fixture and The
	(ELI-00750	Dong-gu, Daegu,	DSSFR4008S	codes DSSFW6006S
1		Republic of korea	DSSFR4010S	DSSFW7006S
1		TE 1 00 50 500 000 1	DSSFR4012S	
		Tel: +82-53-582-2804	DSSFR4014S	DSSFW8006S are not present
		Fax. +82-53-583-2806	DSSFR4507S	in FSC.

		E-mail:	DCCED4500C	
			DSSFR4508S	
		http://www.dentis.co.kr	DSSFR4510S	
			DSSFR4512S	
		LOA:	DSSFR4514S	
		Issuance date: 01-03-	DSSFR5007S	
		2023	DSSFR5008S	
		Valid Till: 28-02-2026	DSSFR5010S	5:31 AM
			DSSFR5012S	
		Country of Origin	DSSFR5014S	
		(Korea) FSC:	DSSFW6007S	~ · · · · · · · · · · · · · · · · · · ·
		Date of Issuance: 13-	DSSFW6008S	, (a)
		03-2023	DSSFW6010S	5
		03 2023	DSSFW6012S	
		ISO Certificate:	DSSFW7007S	
		Issuance date: 02-04-		
			DSSFW7008S	
		2022	DSSFW7010S	
1		Validi till: 02-04-2025	DSSFW7012S	
1			DSSFW8007S	
1		CE Certificate:	DSSFW8008S	
		Initial date: 16-07-2019	DSSFW8010S	
		Validi till: 27-05-2024	DSSFW8012S	
			DSSFW6006S	
		V~ -0, V	DSSFW7006S	
		, 00	DSSFW8006S	
37.	Fabnos Traders (Pvt)	Dentis Co., Ltd., Korea	Dentis s-Clean TiN Partial	Deferred with final
	Ltd	200	Coating Couple Abutment	opportunity for submission of
	Address: Building no	Addresses:	g in g	fee for the family, annexures as
	26, 3rd floor,	1. HQ: 99 Seongseoseo-	Model no:	
	Touheed commercial	ro, Dalseo-gu, Daegu,	DSCA4510HPCTS	per form 7A and undertaking
	area, 26th street,	Republic of Korea.	DSCA4510NPCTS	on the stamp paper.
	Phase V DHA,	Republic of Rolea.	DSCA4510H7PCTS	Clarification/justification is
	Karachi.	2 Footowy address, 1F	DSCA4510N7PCTS	required as The name of device
	Karaciii.	2. Factory address: 1F,		as per FSC is Implant,
	/ELL 00750	B-dong, 6, Yulam-ro,	DSCA4515HPCTS	endosseous, superstructure.
	(ELI-00750	Dong-gu, Daegu,	DSCA4515NPCTS	
		Republic of korea	DSCA4515H7PCTS	
			DSCA4515N7PCTS	
		Tel: +82-53-582-2804	DSCA4520HPCTS	
		Fax. +82-53-583-2806	DSCA4520NPCTS	
		E-mail:	DSCA4520H7PCTS	
		http://www.dentis.co.kr	DSCA4520N7PCTS	
		:610	DSCA4525HPCTS	
		LOA:	DSCA4525NPCTS	
		Issuance date: 01-03-	DSCA4525H7PCTS	
		2023	DSCA4525N7PCTS	
		Valid Till: 28-02-2026	DSCA4535HPCTS	
		3/1	DSCA4535NPCTS	
		Country of Origin	DSCA4535H7PCTS	
		(Korea) FSC:	DSCA4535N7PCTS	
		Date of Issuance: 13-	DSCA4545HPCTS	
		03-2023	DSCA4545NPCTS	
		03-2023	DSCA4545H7PCTS	
		ISO Certificate:	DSCA4545N7PCTS	
			DSCA4545N/PCTS DSCA4555HPCTS	
		Issuance date: 02-04-	DSCA4333FC18	

202	22	DSCA4555NPCTS
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l va	inai tiii: 02-04-2025	DSCA4555H7PCTS
		DSCA4555N7PCTS
	E Certificate:	DSCA5510HPCTS
	tial date: 16-07-2019	DSCA5510NPCTS
Va	ılidi till: 27-05-2024	DSCA5510H7PCTS
		DSCA5510N7PCTS
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		DSCA5520HPCTS
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		DSCA5520H7PCTS
		DSCA5520N7PCTS
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	707	DSCA6535N7PCTS
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			DSCA6555N7PCTS	
			DSCA6510HPCTS	
			DSCA6510NPCTS	
38.	Fabnos Traders (Pvt)	Dentis Co., Ltd., Korea	DENTIS	Deferred with final
	Ltd		s-Clean TiN Half Coating	opportunity for submission of
	Address: Building no	Addresses:	Angled Abutment	fee for the family, annexures as
	26, 3rd floor,	1. HQ: 99 Seongseoseo-		per form 7A and undertaking
	Touheed commercial	ro, Dalseo-gu, Daegu,	Model no:	on the stamp paper.
	area, 26th street,	Republic of Korea.	DSAA45151HCTS	Clarification/justification is
	Phase V DHA,		DSAA45151NHCTS	required as The name of device
	Karachi.	2. Factory address: 1F,	DSAA45152HCTS	•
		B-dong, 6, Yulam-ro,	DSAA45152NHCTS	
	(ELI-00750	Dong-gu, Daegu,	DSAA45154HCTS	endosseous, superstructure.
		Republic of korea	DSAA45154NHCTS	
			DSAA55151HCTS	
		Tel: +82-53-582-2804	DSAA55151NHCTS	
		Fax. +82-53-583-2806	DSAA55152HCTS	
		E-mail:	DSAA55152NHCTS	
		http://www.dentis.co.kr	DSAA55154HCTS	
		SIS SIC	DSAA55154NHCTS	
		LOA:	DSAA65151HCTS	
		Issuance date: 01-03-	DSAA65151NHCTS	
		2023	DSAA65152HCTS	
		Valid Till: 28-02-2026	DSAA65152NHCTS	
		70-7	DSAA65154HCTS	
		Country of Origin	DSAA65154NHCTS	
		(Korea) FSC:	DSAA45251HCTS	
		Date of Issuance: 13-	DSAA45251NHCTS	al AM
		03-2023	DSAA45252HCTS	21
			DSAA45252NHCTS	,·)
		ISO Certificate:	DSAA45254HCTS	70.
		Issuance date: 02-04-	DSAA45254NHCTS	9
		2022	DSAA55251HCTS	
		Validi till: 02-04-2025	DSAA55251NHCTS	
			DSAA55252HCTS	
		CE Certificate:	DSAA55252NHCTS	
		Initial date: 16-07-2019	DSAA55254HCTS	
		Validi till: 27-05-2024	DSAA55254NHCTS	
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		0	DSAA65254NHCTS	
39.	Biosorin (Private)	Legal Manufacturer &	RealStar Filovirus Screen	Approved.
	Limited,	Manufacturing Site:	RT-PCR Kit 1.0	
	, '	Altona Diagnostics	Filovirus Screen RT-PCR	
	19-Usman Block,	GmbH, Bertrand	Kit 1.0	
	Main Boulevard New	Lecointe		
	Garden Town Lahore	Morkenstr.Be 12 22767		
	- Pakistan.	Hamburg Germany.	Shelf Life: 15 months	
			Class: D	
	l	<u> </u>	<u>i</u>	ı

	ELI-00186			
	LLI-00100	FSC:		
		Germany Free Sale Certificate (FSC) issued on 22-06-2023.	Codes/Sizes: 441013	
		ISO 13485 validity date: 23-04-2026	Fee vide slip No. 887919916.: 62,000/-	AN
		LOA valid upto 31-12-2024.	IIIS)	15.6V
40.	Biosorin (Private) Limited,	Manufacturing Site:	RealStar Zika Virus RT-PCR Kit 1.0 Zika Virus RT-PCR Kit 1.0	Approved
	19-Usman Block, Main Boulevard New	GmbH, Bertrand	Zika viius K1-1 CK Kit 1.0	
	Garden Town Lahore - Pakistan.	Morkenstr.Be 12 22767 Hamburg Germany.	Shelf Life: 15 months Class: C	
	ELI-00186	FSC: Germany Free Sale Certificate (FSC) issued on 22-06-2023.	Codes/Sizes: 591013	
		ISO 13485 validity date: 23-04-2026	Fee vide slip No. 50517565737: Rs.62,000/-	
	N	LOA valid upto 31-12-2024.		AM
41.	Biosorin (Private) Limited,	Manufacturing Site: Altona Diagnostics	RealStar WNV RT-PCR Kit 2.0 West Nile virus (WNV)	Approved.
	19-Usman Block, Main Boulevard New Garden Town Lahore	II	RT-PCR Kit 2.0	
	- Pakistan. ELI-00186	Hamburg Germany. FSC:	Shelf Life: 18 months Class: C	
	ELI-00180	Germany Free Sale Certificate (FSC) issued on 22-06-2023.	Codes/Sizes: 322013	
		ISO 13485 validity date: 23-04-2026	Fee vide slip No. 56126841590: Rs. 62,000/-	
		LOA valid upto 31-12-2024.		
42.	Biosorin (Private) Limited, 19-Usman Block, Main	Legal Manufacturer: M/s Esco Medical Technologies, UAB,	MIRI IVF incubators (MIRI® TL Family)	Deferred for following: 1. clarification that the name of the device as per FSC
	Boulevard New	Draugystes g, 19, Kaunas, Lithuania	(MIRI ® TL6, MIRI ® TL12)	Multiroom IVF.

	C1			2
	Garden Town, Lahore.	FSC: Lithuania validity	Class-B	2. submission of original, notarized CE certificate
	ELI: 00186	01-09-2027 LOA issuance 09-01-	Shelf LifeL N/A	apostille/ legalized FSC of RRA
	25,000/-	2023		3. Firm will apply both models
		ISO 13485 validity 01- 09-2025		separately.
43.	Biosorin (Private) Limited, 19-Usman Block, Main Boulevard New Garden Town, Lahore. ELI: 00186 25,000/-	Legal Manufacturer: M/s Esco Medical Technologies, UAB, Draugystes g, 19, Kaunas, Lithuania FSC: Lithuania validity 01-09-2027 LOA issuance 09-01- 2023	Dish for MRI TL® (Culture Coin) Class-B Shelf Life: 2 years Model: Culture Coin	Deferred for the submission of original, notarized CE certificate or apostille/ legalized FSC of RRA
		ISO 13485 validity 01- 09-2025	3	
44.	Quality Medical Services, H-49. Gordon College Road Rawalpindi ELI: 00123	Legal Manufacturer: CONWELL MEDICAL CO., LTD. 2F, No. 127- 3, 1st Road, Taichung Industrial Park, Situn District, Taichung 407270, Taiwan FSC: TAIWAN Validity: 31/OCT/2026 LOA Validity: 31/OCT/2024	Conwell Medical –CO Limited Knee, ankle and foot, wrist Series Class A Shelf Life: 5 years	Approved only Supper Elastic Knee support. Firm will apply online separately for each product.
45.	Lab Medikal Solutions Pvt.Ltd Office No 14/1-A Main Harley Street Rawalpindi. ELI-00694 1121-C 23-12-2022	Legal Manufacturer: Guangzhou Wondfo Biotech Co, Ltd. No.8 Lizhishan Road, Science City, Luogang District 510663, Guangzhou P.R China.	Wondfo (Blood Gas analyzer, reagent pack, Test card and Control) Class-B Shelf life: not provided Codes: FSC is not provided	Deferred with final opportunity for the following: 1. submission of original, notarized LOA with valid dates. 2. Original, valid and attested FSC in any reference country or FQA certificate. 3. Declaration of conformity. 4. Firm will apply Blood Gas Analyzer Reagents Pack, Blood Gas Analyzer Control, Blood Gas Analyzer Test Card and Blood Gas analyzer separately.

46.	Lab Medikal Solutions Pvt.Ltd Office No 14/1-A Main Harley Street Rawalpindi. ELI-00694 1688-C 23-12-2022	Guangzhou Wondfo Biotech Co, Ltd.	Wondfo Optical coagulation Analyzer Prothrombin Time kit Activated Partial Thrombin Time Reagent kit Fibrinogen Reagent kit Activated Clotting Time Reagent kit Thrombin Time Reagent kit Class-C Shelf life: Codes: FSC is not provided	Deferred with final opportunity for the following: 1. submission of original, notarized LOA with valid dates. 2. Original, valid and attested FSC in any reference country or FQA certificate. 3. Declaration of conformity. 4. clarification/ justification that firm has applied Optical coagulation analyzer and multiple kits in single application.
47.	Alfa Scientific Store, 24-Maclogen Road, Lahore. ELI-00148 6075-P 31,000/-	Zhejiang Orient Gene Biotech Co, Ltd 3787#, East Yangguang Avenue, Dipu Street, Anji, 313300 Zhejiang, China. Original FSC: Belgium. Date of Issuance: 13-05- 2022. FSC: Germany. Date of Issuance: 31-08- 2022.	Orient Gene HCG Pregnancy Rapid Test-Midstream Class-B Shelf Life: 24 Months Code: GAHCG-103a-1T GAHCG-103b-1T GAHCG-103b-2T GAHCG-103d-1T GAHCG-103d-2T	Deferred with final opportunity for the following: 1. clarification that name as per label is BioCheck (for in vitro diagnostic use). 2. clarification that label contains "that reagent made in USA".
48.	Alfa Scientific Store, 24-Maclogen Road, Lahore.	Legal Manufacturer: Zhejiang Orient Gene Biotech Co, Ltd 3787#, East Yangguang	HBsAg Rapid Test (Serum / Plasma) (Cassette) Class-D	Rejected due to following: 1. The product/ device not mentioned in submitted EC Design Examination

	ELI-00148 6066-P 62,000/-	Avenue, Dipu Street, Anji, 313300 Zhejiang, China. Original FSC: China. Date of Validity: 30-10-2025. LOA validity 25-02-2030 ISO 13485 validity 16-03-2027 CE certificate validity 26-05-2025 DE certificate validity 26-05-2025.	Shelf Life: 24 Months	Certificate, EC FQA and FSC china. 2. Firm has not submitted original documents 3. label contains "that reagent made in USA".
49.	Alfa Scientific Store, 24-Maclogen Road, Lahore. ELI-00148 6067-P 62,000/-	Legal Manufacturer: Zhejiang Orient Gene Biotech Co, Ltd 3787#, East Yangguang Avenue, Dipu Street, Anji, 313300 Zhejiang, China. Original FSC: China. Date of Validity: 30-10- 2025. LOA validity 25-02- 2030 ISO 13485 validity 16- 03-2027 CE certificate validity 26-05-2025 DE certificate validity 26-05-2025	Immunodeficiency Virus Rapid Test Class-D Shelf Life: 24 Months Size: 40 tests/lit GCHIV-302a	Deferred for the following: 1. The product/ device name is The product name Healgen HIV ½ Human Immunodeficiency Virus Rapid Test (Serum/Plasma) in submitted EC Design Examination Certificate, EC FQA and FSC Belgium. 2. label contains "that reagent made in USA". 3. The firm will submit revised application as per brand name mentioned EC Design Examination Certificate, EC FQA and FSC Belgium.
50.	Roys & Roys International, 1st Floor Rehman Centre-2, Service Lane Ring Road, Near Askari-11, Lahore. ELI-00708 7150-P 31,000/-	Legal Manufacturer: Changsha Sinocare Inc. 265 Guyuan Roas, Hi- Tech Zone, Changsha, Hunan Province, 410205, People's Republic of China. Original FSC: China Date of Validity: 14-03- 2026. LOA validity 07-02- 2027 ISO 13485 validity 31- 01-2028		Approved in class B

51.	M/s Global Health	Enzymes	Enzymes tests, also known	Approved as cluster with brand
31.	Care Private	Elizymes	as enzyme marker tests, are	name IVO-CHEM.
	Limited, Plot No.	α-Amylase (α-AMY)	used to measure the levels	nume I v & CIIZIVI.
	3A, N4, RCC	Assay Kit, Creatine	of specific enzymes in the	
	Industrial Area	Kinase (CK) Assay Kit,	blood, which can provide	
	Rawat, Islamabad	Creatine Kinase MB	valuable information about	
	Rawai, Islamabaa	(CK-MB) Assay Kit	organ function, disease	
		and Lactate	progression, and treatment	
	Approved Sections:	Dehydrogenase (LDH)	effectiveness.	0.
	1. Assembling		criccuveness.	6.5
	Filling Packaging,	Assay Kit	11/1/19	5
	Labelling & Testing	Shelf Life: α-Amylase	911, 11, 0	
	of Reagents Kits	(α-AMY) Assay Kit and	000000	
	2. Cutting	Creatine Kinase MB	6 40.	
	Assembling	(CK-MB) Assay Kit: 12	100	
	Packaging Labelling	months		
	& Testing of Rapid	Creatine Kinase (CK)	700,	
	Test Kits	Assay Kit and	The same of the sa	
	3. Assembling	Lactate Dehydrogenase:	3,	
	Section (Patient Monitor, Vital Sign	13 months	, -	
	Monitor, ECG	0500		
	Machine Ultrasound,	Class: B		
	Arm Blood Pressure	R & I Details: File		
	Monitor, Nebulizer,	submitted on		
	Infrared	05/06/2025		
	Thermometer,	03/00/2023		
	Syringe Infusion	Rs. 25,000/-		AM
	Pump & Pulse	Ks. 25,000/-		
	Oximeter)	Slip No: 3815349909	1191	(S.)
		Shp 100. 30133 19909	(1/1/2)	
		Fee Submitted on:	911 / (1, 0)	
		02/06/2025	0000000	
			5 40, 23	
52.	M/s Global Health	Liver Function Tests	100	Approved as cluster with brand
	Care Private	Alonino	Liver function tests are	name IVO-CHEM.
	Limited, Plot No.	Alanine	Liver function tests are intended to assess the	
	3A, N4, RCC	Aminotransferase		
	Industrial Area	(ALT) Assay Kit,	overall health of the liver by	
	Rawat, Islamabad	Aspartate	measuring specific	
		Aminotransferase	substances in the blood.	
	Approved Sections:	(AST)/SGOT) Assay	These tests can help	
	1. Assembling Filling	Kit, Alkaline	diagnose liver disease,	
	Packaging,	Phosphatase (ALP)	monitor its progression, and	
	Labelling & Testing of Reagents Kits	Assay Kit, γ-	assess the effectiveness of	
	2. Cutting	Glutamyltransferase	treatments.	
	Assembling	(GGT) Assay Kit, Total		
	Packaging Labelling	Bilirubin (TBIL) Assay		
	& Testing of Rapid	Kit, Direct Bilirubin		
	0 · · · · · · · ·	., = ==================================		

	T TZ':	(DDH.) A W.	Г	T
	Test Kits	(DBIL) Assay Kit		
	3. Assembling	Shelf Life: 12 Months		
	Section (Patient Monitor, Vital Sign	Shell Elie. 12 Wolling		
	Monitor, ECG	Class: B		
	Machine Ultrasound,			
	Arm Blood Pressure	R & I Details: File		
	Monitor, Nebulizer,	submitted on		
	Infrared	05/06/2025		
	Thermometer,			~.C2\
	Syringe Infusion	Rs. 25,000/-		10·
	Pump & Pulse	Slip No. 60709227		
	Oximeter)	Slip No: 69798237	0, 16, 0	
53.	M/s Global Health	Serology Tests	Serology tests are used to	Approved as cluster with brand
	Care Private		detect antibodies in the	name IVO-CHEM.
	Limited, Plot No.	Antistreptolysin O	blood, indicating exposure	name i v o erizivi.
	3A, N4, RCC	(ASO) Assay Kit,	to a specific disease or	
	Industrial Area	Rheumatoid Factor (RF)	infection	
	Rawat, Islamabad	Assay Kit, C-reactive	micetion	
	Rawat, Islamabaa	Protein (CRP) Assay	3	
	Approved Sections:	Kit Kit)	
	1. Assembling Filling	Kit		
	Packaging,	Shelf Life: 13 months		
	Labelling & Testing			
	of Reagents Kits	Class: B		
	2. Cutting	R & I Details: File		<u> </u>
	Assembling	submitted on		5:31 AM
	Packaging Labelling	05/06/2025		
	& Testing of Rapid	03/00/2023		
	Test Kits	Rs. 25,000/-	.61	7.5
	3.Assembling	KS. 25,000/-		70.
	Section (Patient	C1: N - 44445 (20	411 (19, 0)	
	Monitor, Vital Sign	Slip No: 44445638	200	
	Monitor, ECG		G, *0, ~0,5,	
	Machine Ultrasound,		CC 00	
	Arm Blood Pressure	200		
	Monitor, Nebulizer, Infrared			
	Thermometer,	, 7/	oliecio 50/2	
	Syringe Infusion	401		
	Pump & Pulse	.\5*C		
	Oximeter)	100 CO		
54.	M/s Global Health	Lipid Profile Test	A lipid profile test, also	Approved as cluster with brand
	Care Private	- , 00	known as a lipid panel, is a	name IVO-CHEM.
	Limited, Plot No.	Total Cholesterol	blood test used to measure	
	3A, N4, RCC	(CHO) Assay Kit and	cholesterol and triglyceride	
	Industrial Area	Triglycerides (TG)	levels. It's primarily	
	Rawat, Islamabad	Assay Kit	intended to assess	
	,	-	cardiovascular health,	
	Approved Sections:		identify risk factors for	
	1.Assembling Filling		heart disease and stroke,	
	1.1.1.0.001111111111111111111111111111	<u> </u>	man discuse and stroke,	l

	Packaging,	Shelf Life: 12 months	and monitor treatment	
	Labelling & Testing	Shell Life. 12 months	effectiveness for high	
	of Reagents Kits	Class: B	cholesterol	
	2. Cutting		Cholesterol	
	Assembling	R & I Details: File		
	Packaging Labelling	submitted on		
	& Testing of Rapid	05/06/2025		
	Test Kits			
		Rs. 25,000/-		1
	3.Assembling Section (Patient	Ks. 23,000/-		0
	`	G1: N 062511504041	191	6.9
	Monitor, Vital Sign	Slip No: 863511594841	111 1111	5
	Monitor, ECG		91, 16, 0	
	Machine Ultrasound,		00 11 6	
	Arm Blood Pressure		0.8dir 1 (MIS)	
	Monitor, Nebulizer,			
	Infrared	100		
	Thermometer,			
	Syringe Infusion		700	
	Pump & Pulse	-21		
	Oximeter)			
55.	M/s Global Health	Renal Function Tests	Renal function tests are	Approved as cluster with brand
	Care Private	Creatining (CDEA E)	intended to evaluate the	name IVO-CHEM.
	Limited, Plot No.	Creatinine (CREA-E)	health and function of the	
	3A, N4, RCC	Assay Kit, Urea	kidneys, which play a	
	Industrial Area	(UREA) Assay Kit,	crucial role in filtering	
	Rawat, Islamabad	Albumin (ALB) Assay	waste and excess fluid	
		Kit, Total Protein (TP)	from the blood. These tests	
		Assay Kit, Uric Acid	help diagnose, monitor,	
	Approved Sections:	(UA) Assay Kit, Urine	and manage various kidney	
	1. Assembling Filling		conditions, including	0
	Packaging,	Microalbumin (UMA)	chronic kidney disease	6.9
	Labelling & Testing	Assay Kit)		5
	of Reagents Kits	Shelf Life: 12 months	(CKD).	
	2. Cutting	Shell Life: 12 months	00 000	
	Assembling	Class: B	G 70, 713.	
	Packaging Labelling	2300.2	100 00	
	& Testing of Rapid	R & I Details: File	Jilecr Son	
	Test Kits	submitted on	7. 6,	
	3.Assembling	05/06/2025		
	Section (Patient	Rs. 25,000/-		
	Monitor, Vital Sign	Slip No: 09464377012		
	Monitor, ECG			
	Machine Ultrasound,	P aV		
	Arm Blood Pressure	, 00		
	Monitor, Nebulizer,	.1.		
	Infrared			
	Thermometer,	000		
	Syringe Infusion			
	Pump & Pulse			
	Oximeter)			

56.	Ophth Pharma (Pvt)	B.T Plain Catgut Suture	R T Plain Catout suture is a	The Board deferred the case
50.	Ltd., Plot No. 241,	D.1 1 min Cargar Surare	natural, absorbable sterile	
	Sector 24, Korangi	Class: D		i. List of all materials of
	Industrial Area,	Shelf Life: 60 Months	complies with the	animal, human, microbial or
	Karachi	Fee: 25000	-	
			requirements of the United	•
	(ELM-0055)	Fee Slip No.	State pharmacopoeia and	
		793975159758	European pharmacopoeia.	the manufacturing process of
		Sizes: 0,1,2,2/0,3/0,4/0,	INDICATIONS	the medical device.
			Plain Catgut suture is	
			indicated for use in general	concerning the selection of
			soft tissue approximation	sources or donors
			and / or ligation especially	iii. Detailed information on
			in General surgery,	the harvesting, processing,
			Gastrointestinal surgery,	preservation, testing and
		1000	Gynecology, Obstetrics,	handling of tissues, cells and
			Urology,	substances
			Ophthalmic surgery.	iv. Process full description of
			300	the system for record keeping
		15° 00		allowing traceability from
		62,00		sources to the finished medical
		A-0.		device
57	0.1.1.11 (D. ()		T . N	<u> </u>
57.	Ophth Pharma (Pvt.)	Surgimesh	Transparent, Non absorbable, mono-filament	Approved
	Ltd	Dellarenten	polypropylene indicated in	
	Plot No. 241, Sector	Polypropylene Monofilament Knitted	Inguinal hernia. Incisional	
	24, Korangi	non-absorbable mesh	hernia. Reconstruction of	Dla.
	Industrial Area,	undyed	chest wall.	
	Karachi Pakistan	unayea	.6)	~·3'
	License No.	Class:		NO.
	ELM-0055	Class D	All (B. O.	
	ELMI-0055		20.	
	Surgical Suture	Shelf-life: 5 years	G, *0, ~0,0,0	
	Surgical Suture Section		Cr. Oo	
	Section	Sizes:	10	
	Ligature section.	6 x 11 cm (1 x 3)	olifecto, 505	
	Ligature section.	15 x 15 cm (1 x 3)	70	
		30 x 30 cm (1 x 3)		
		46		
			/	
		Fee Challan No.		
		Slip No. 15662641		

Item No. II (b):

DEFERRED CASES MINUTES

MR. KHALID MAHMOOD, DEPUTY DIRECTOR

a	T	3.5 0	N	D
S#	Importer Name	Manufacturer Details	Name of MD / Class / Codes / Shelf life / etc.	Decision
1.	Applicant:	(Legal Manufacturer)	Disposable Feeding	Deferred with final opportunity
	M/s Safe Health	Name: M/S. Suzhou	Bag Venous TM	for submission of valid FSC,
	Pakistan Bizcon.	Yaxin Medical	500ml,1000 ml, 1200 ml	LOA & clarification of class of
	Office No. 25, 2nd	Products Co., Ltd.	& 1500 ml	product as Disposable Feeding
	Floor, Dilkusha	No. 12, Zhonghua	Generic:	Bags are classified as a Class IIa
	Chamber, Marston	Road, Mudu Town,	Enteral Feeding set	medical device according to the
	Road, Karachi	Suzhou, Peoples		EU Medical Device Regulation
		Republic of China	Class-A	(MDR) under Eudamed. Proof of
	(ELI- 00275)	FSC Validity: 08-10-2025		fee submission.
	Track ID:		Shelf life: 05 years	
	PDS-58W-A1R8	Letter of	Storage Conditions:	
	Fee: PKR 5000/-	authorization:	Room temperature	
	Slip: 8401979738	Issuance date: 25-02-	1	
	Dated: 09-09-2021	2024		
		Expiry date:		
	10	Not mentioned		
2.	Applicant:	(Legal Manufacturer)	Disposable Chest	Deferred with final opportunity
	M/s Safe Health	Name: M/S. Suzhou	Drainage Bottle	for final submission of valid
	Pakistan Bizcon.	Yaxin Medical	(System) Single	FSC, LOA & clarification of
	Office No. 25, 2nd	Products Co., Ltd.	Chamber, Two	class of product as Disposable
	Floor, Dilkusha	No. 12, Zhonghua	Chambers & Three	Feeding Bags are classified as a
	Chamber, Marston	Road, Mudu Town,	Chambers - Venous TM	Class IIb medical device
	Road, Karachi	Suzhou, Peoples	100	according to the EU Medical
		Republic of China	Class-A	Device Regulation (MDR) under
	(ELI- 00275)		70°	Eudamed. Proof of fee
		FSC Validity:	Letter of	submission.
	Track ID:	08-10-2025	authorization:	
	PDS-58W-A1R8	-G13-G0	Issuance date: 25-02-	
		0500	2024	
	Fee: PKR 5000/-	7,00	Expiry date: Not	
	Slip: 2043614	V208 D	mentioned	
	Dated: 06-10-2020	(6)		
		0.00	Shelf life: 05 years	
	401		Storage Conditions:	
	Pur		Room temperature	
3.	M/S. Safe Health	Legal Manufacturer:	Venous Disposable	Deferred with final opportunity
٦.	Pakistan Bizcon.	Legai Manufacturel.	Biopsy Needle.	for final submission of valid
	i akistali Dizcoli.		Diopsy recuie.	101 IIIai suullissiuli ul vallu

	Address: Office # 25, 2 nd Floor, Dilkusha Chamber, Marston Road, Karachi 74700. Pakistan ELI-00275 R&I details 9 th May 2025 Fee Rs. 30,000.00 through slip no. 851977932085 Date 12-05-2025	M/S. Chamfond Biotech Co., Ltd. 2/F Building E, Sino Danish Eco Life Science Pak, Jiangbei, New Area, Nanjing Jiangsu, CN 21032, China. LOA: Issuance: 01-03-2025 FSC: Validity: 11-05-2025 ISO-13485: Validity: 12-07-2027	Class-B Shelf Life: 5 years Sizes: G-8, 9, 11, 13, 15, 16, 18 Models: BN, MAB, CF, CB, MA	FSC, LOA & CE regarding subject medical device. The ISO certification validity to be expired on 12-07-2027 may also be provided. Proof of fee submission.
4.	M/S. Safe Health Pakistan Bizcon. Address: Office # 25, 2nd Floor, Dilkusha Chamber, Marston Road, Karachi 74700. Pakistan ELI-00275 R&I details 20th May 2025 Fee Rs. 30,000.00 through slip no. 8618708376 Date 12-05-2025	Legal Manufacturer: M/S. Jiangsu Jianzhiyuan Medical Instrument Technology Co., Ltd. Floor 2, Building 102, No. 198 East Wuzhou Road, Development Zone, Yangzhou City. China. LOA: Validity: 30-09-2029 FSC: Validity: 20-09-2025 ISO-13485: Validity: 20-10-2025 CE validity 26-05-2024	•	Deferred with final opportunity as submitted document is merely a general letter which is ambiguous. No valid CE marked Provided. Medical device Regulation (China). Provision of Valid LOA and FSC of any RRA. Clarification of classification and differential fee required to be paid.
5.	M/S. Safe Health Pakistan Bizcon. Office No. 25, 2 nd Floor, Dilkusha Chamber, Marston Road, Karachi (ELI-00275)	Legal Manufacturer: M/S. Zheijiang Runqiang Medical Instruments Co., Ltd. Manufacturing Site: No. 618, Dade Road, Jiaxing Xiuzhou Distric, 314031 Jianxing City, Peoples Republic of China.	Venous Extension Set (Pressure Tube) Class B (E) Shelf Life: 05 years Codes/Sizes: As per FSC	Deferred with final opportunity as submitted document is merely a general letter instead of provision of Valid LOA and FSC of any RRA. Clarification of classification and differential fee required to be paid. Further the valid FSC, LOA & CE certificate with valid certificate of ISO 13485.

	FSC: Validity:	
	Germany 14-07-2025.	
	<u>LOA</u>	
	Validity: 01-01-2025	
	EC Certificate	
	Validity: 06-05-2025	
	<u>ISO 13485</u>	
	Validity: 06-05-2023	1

Item No. II (c). ENLISTMENT/REGISTRATION OF MEDICAL DEVICES FOR IMPORT.

Dr. Hanif Ullah (Deputy Director-IX)

New application:

Item N	Item No. II (c). ENLISTMENT/REGISTRATION OF MEDICAL DEVICES FOR IMPORT.				
Dr. Ha	anif Ullah (Deputy D	irector-IX)			
Now o	pplication:		25		
new a	ppiication.				
		1290,16			
S. #	Name of Firm(s)	Manufacturer's detail	Name of Medical	Decision	
		, 7/2	Device		
1.	Reliable Medical	Manufacturer:	Brand Name:	Deferred for:	
	Supply, Office No.	Shandong Huge Dental	Zirking	English translation of the	
	204, 2nd Floor,	Material Corporation, No.	Generic Name:	issuing authority of the FSC is	
	Makkah Tower,	68 Shanhai Road,	Zirconia Block	required.	
	Namak Mandi	Danggang District,	Applied as: Single	There are many shades and	
	Peshawar	Rizhao City, Shandong	Class: B	specifications of the device in	
		Province, 276800 P.R.	Models/Code/sizes	the FSC. The firm has applied	
	ELI-00618	China	(as per FSC &	as single. Selection /	
	R&I Date:	LOA	application:	clarification is required.	
	21.05.2025	Type: Copy	HT	Notarized LOA and ISO	
	Fee: 31000/-	Notarization: No	Shelf Life: 10 years	certificate are required.	
	Slip #10966332402	Validity: 11.05.2028		Legalized FSC in the country of	
		FSC1 (for zirconia block)	11 . 11/2 013	Origin is required.	
		Type: Copy		Notarized CE Certificate / EU	
		Issued by: NIL	·0/ -0/3,	QMS certificate (MDR) is	
		Legalization: No	00 h	required.	
		Validity: 08.10.2026			
		FSC2 (for zirconia block			
		and coloring liquid)			
		Type: Copy			
		Issued by: NIL			
		Legalization: No			
		Validity: 20.10.2026			
		, 00			
		ISO – Certificate			
	A	Type: copy			
		Legalization: No			
	~VO,	Validity: 20.02.2026			
	B.	CE certificate / EU QMS			
		certificate (MDR):			
		Type: Copy			

		Legalization: No		
		Validity: 26.03.2029		
2.	Reliable Medical	Manufacturer:	Brand Name: NIL	Deferred for:
	Supply, Office No.	Shandong Huge Dental	Generic Name:	Submission of brand name.
	204, 2nd Floor,	Material Corporation, No.	Glass Ionomer	English translation of the
	Makkah Tower,	68 Shanhai Road,	Cement Applied as:	issuing authority of the FSC is
	Namak Mandi	Danggang District,	Single	required.
	Peshawar	Rizhao City, Shandong	Class: B	There are many codes of the
		Province, 276800 P.R.	Models/Code/sizes	device in the FSC. The firm has
	ELI-00618	China	(as per FSC &	applied as single. Selection /
	R&I Date:	LOA	application:	clarification is required.
	21.05.2025	Type: Copy	Luting I, Luting II /	Notarized LOA and ISO
	Fee: 31000/-	Notarization: No	Lufill HS, Filling I,	certificate are required.
	Slip #140095465	Validity: 11.05.2028	Filling II	Legalized FSC in the country of
	1	FSC1 (for Luting I,	Shelf Life: NIL	Origin is required.
		Luting II / Lufill HS)	A 1	Notarized CE Certificate / EU
		Type: Copy	3	QMS certificate (MDR) is
		Issued by: NIL		required.
		Legalization: No		Conclusive report for shelf life
		Validity: 16.05.2026		verification / stability studies is
		FSC2 (for Filling I,		required.
		Filling II)		1
		Type: Copy		
		Issued by: NIL		
	~0	Legalization: No		
	10/	Validity: 20.07.2026		5:31 AM
	No.	ISO – Certificate		
	Y	Type: copy		á ('
		Legalization: No	(6)	2:3
		Validity: 20.02.2026		3
		CE certificate / EU QMS	1, 1, 0, 0	
		certificate (MDR):	-(1)	
		Type: Copy	(0, 71%,	
		Legalization: No	00	
		Validity: 26.03.2029	-5.	
3.	Reliable Medical	Name of Manufacturer:	Brand Name: NIL	Deferred for:
	Supply, Office No.	Zhejiang QL Biotech Co.,	Generic Name:	Submission of brand name.
	204, 2nd Floor,	Ltd.,	Typhoid Ab Rapid	Notarized LOA and ISO
	Makkah Tower,	Address: Room No. 501,	Test	certificate are required.
	Namak Mandi		Applied as: kit	Legalized FSC in the country of
	Peshawar	Chuangye Rd,	Class: C	Origin is required.
		Qingshanhu Sub-District,	Models/Code/sizes	Legalized FSC in reference
	ELI-00618	Lin 'an District,	(as per FSC &	country or notarized CE
	R&I Date:	Hangzhou, China	application:	Certificate / EU QMS
	21.05.2025	LOA	NIL	certificate (MDR) is required.
	Fee: 62000/-	Type: Copy	Shelf Life: 2 years	• • • • • • • • • • • • • • • • • • • •
	Slip # 2814790550	Notarization: No		
	· •	Validity: 28.04.2030		
		variatty: 20.01.2030		

		Type: Copy		
		Issued by: China Chamber		
		of Commerce for Import		
		and Export of Medicines		
		_		
		and Health Product		
		Legalization: No		
		Validity: two years from		
		11.06.2024		
		ISO – Certificate	.6)	···
		Type: copy		O.
		Legalization: No	10, 52,	
		Validity: 30.08.2027		
		CE certificate / EU QMS	·0/ ·0/2,	
		certificate (MDR):	200 h	
		Type: Not submitted		
		Legalization: NIL		
		Validity: NIL	0	
4.	Reliable Medical		Brand Name: NIL	Deferred for:
	Supply, Office No.	Zhejiang QL Biotech Co.,	Generic Name:	Submission of brand name.
	204, 2nd Floor,		Malaria pf/pv Rapid	Notarized LOA and ISO
	Makkah Tower,	Address: Room No. 501,	Test	certificate are required.
	Namak Mandi		Applied as: kit	Legalized FSC in the country of
	Peshawar	Chuangye Rd,	Class: C	Origin is required.
	ELI-00618	Qingshanhu Sub-District,	Models/Code/sizes	Legalized FSC in reference
	R&I Date:		(as per FSC &	country or notarized CE
	21.05.2025	Hangzhou, China	application:	Certificate / EU QMS
	Fee: 62000/-	LOA	NIL	certificate (MDR) is required.
	Slip #34574792560	Type: Copy	Shelf Life: 2 years	certificate (WIDK) is required.
	Shp #34374772300	Notarization: No	Shell Elic. 2 years	·
				O.
		Validity: 28.04.2030	11 . 112. 013	
		FSC		
		Type: Copy	0,000	
		Issued by: China Chamber	700	
		of Commerce for Import		
		and Export of Medicines		
		and Health Product	0,	
		Legalization: No		
		Validity: two years from		
		11.06.2024		
		ISO – Certificate		
		Type: copy		
		Legalization: No		
	A	Validity: 30.08.2027		
	- 2	CE certificate / EU QMS		
	4 000	certificate (MDR):		
		Type: Not submitted		
		Legalization: NIL		
		Validity: NIL		
		validity. INIL		

5.	Hi Diagnostic	Manufacturer:	Brand Name:	Deferred for:
<i>J</i> .	Traders, 21/2	VivaChek Biotech	Hemoglobin Meter	Model has not been mentioned
	Gulshan-e-Kareem	(HangZhou) Co., Ltd.,	Generic Name:	in the FSC. Clarification is
	Colony, Jamshaid	Level 2, Block 2, 146 East	Hemoglobin Meter	required.
	Tareen Road,	Chaofeng Rd., Yuhang	Applied as: Single	The firm has applied as single;
	Multan Koau,	Economy Development	Class: B	however, the device is system in
	ELI-01028	1	Models/Code/sizes	
	R&I Date:	Zone, Hangzhou 311100		
		Zhejiang P.R. China LOA	(as per FSC &	required.
	21.05.2025		application: VOM01	2:0
	Fee: 62000/-	Type: Copy Notarization: China		
	Slip #5229751477		Shelf Life: NA	
		council for the Promotion		
		of International Trade	(O, ~U,S,	
		China Chamber of International Commerce	00	
		Validity: 01.12.2029	31,	
		FSC Type: Conv		
		Type: Copy		
		Issued by: Zhejiang		
		Medical Product		
		Administration		
		Legalization: Apostilled		
		the notarization of China		
		council for the Promotion		
		of International Trade China Chamber of		
				of AM
		International Commerce		4 1
		Validity: 28.10.2026 ISO – Certificate	.6	
				(a) ·
		Type: copy		
		Legalization: China		
		council for the Promotion of International Trade	0, 0,0,	
			100 V	
		China Chamber of		
		International Commerce		
		Validity: 02.03.2027		
		CE certificate / EU QMS		
		certificate (MDR):		
		Type: Not submitted		
		Legalization: NIL		
6.	JF International,	Validity: NIL Name of Manufacturer:	Brand Name:	Deferred for:
0.	4th Floor, 10C, 6th	Bionet Co., Ltd.,	Brand Name: Bionet	
	Sunset Commercial	Address: 5F, 61, Digital-	Generic Name:	Stamp paper shall be issued in the name of the firm / signatory.
	Lane, Phase 2 Ext,	, , , , ,		
		Ro 31-Gil, Guro-Gu,	Electrocardiographi	Legalized FSC in the country of
	DHA, Karachi	Seoul Republic of Korea	c Analyzer	origin with validity is required.
	EL 1 00246	08375	Applied as: System Class: B	Shelf life verification / stability
	ELI-00246	Sub Assambly units	Class: D	studies report is required.
		Sub Assembly unit:		

	R&I Date:	Bionet Co., Ltd., #401,	Models/Code/sizes	Clarification regarding
	21.05.2025	34LS-ro 91 beon-gil,	(as per FSC &	variation in the address of
			` •	
	Fee: 31000/-	Dongan-gu, Anyang-Si,	application:	manufacturer in Form and FSC
	Slip #361428689	Gyeonggi-do	Cardio7	etc.
			Shelf Life: 10 years	
		LOA		
		Type: Copy of notarized		
		LOA submitted for		1
		CardioTouch3000		
		Notarization: No		G.
		Validity: 01.01.2030		
		FSC	1. 16. 0.	
		Type: Copy	101,052,01;	
		Issued by: National	in the	
		Institute of Medical	1, 15,	
		Devices Safety	4	
		Information, South Korea	3),	
		Legalization: Apostille		
		_		
		Validity: NIL		
		ISO – Certificate:		
		Type: Copy of the		
		notarized certificate		
		submitted for		
	2	CardioTouch3000		
		Notarization: No		
	VVO),	Validity: 19.10.2026		
		CE certificate / EU QMS		
	,	certificate (MDR)		05
		Type: Copy of notarized	.(9)	2.3
		certificate submitted for		3
		CardioTouch3000	1, 17, 01,	
		Notarization: No	4116	
		Validity: 26.05.2024	(O, ~U;o,	
		Extended till 31.12.2028	00	
		for class IIa devices.		
7.	BioMax	Manufacturer:	Brand Name: CLIA	Deferred for:
/ .	International, P-	Nanjing Poclight	Kits for Poclight	Submit properly filled Form-
	150, Street No. 8,	Biotechnology Co., Ltd.,	5000	7A.
		South Side, 2nd Floor,	Generic Name:	
	1 1			Blank stamp paper without declaration has been submitted.
	Hospital, Near	Building A02,	Dry	
	Daewoo Terminal	Biopharmaceutical Valley	Chemiluminescence	Valid, legalized FSC of the
	Akbarabad,	Accelerator (Phase III),	Immunoassay	applied product mentioning the
	Faisalabad	No. 142 Huakang Road,	analyzer and Test	issuing authority in English is
		Jiangbei New District,	Kit	required.
	ELI-00950	Nanjing City, Jiangsu	Applied as: Cluster	The brand name shall be
	R&I Date:	Province, 210000, P.R.	Class: B	mentioned in the LOA.
	22.05.2025	China	Models/Code/sizes	For class B devices, the firm
	Fee: 50000/-		(as per FSC &	shall apply in relevant grouping
	Slip #43034064098	LOA	application:	/ clusters separately.
1		I.		

Notarization: Apostilled the notarization of CCPTI Validity: 28.02.2028 FSC Type: Copy Issued by: NIL Legalization: Apostilled the notarization of CCPTI Validity: 24.05.2026 ISO - Certificate: Type: Copy Notarization: Apostilled the notarization of CCPTI Validity: 24.05.2026 ISO - Certificate: Type: Copy Notarization: Apostilled the notarization of CCPTI Validity: 20.06.2027 CE certificate (MDR) Type: Not submitted Notarization: NIL Validity: NIL Validity: NIL Validity: NIL Notarization: Apostilled the notarization of CCPTI Validity: 20.06.2027 CE certificate (MDR) Type: Not submitted Notarization: NIL Validity: NIL Validity: NIL Notarization: NIL Validity: NIL Notarization: NIL Validity: NIL Notarization: NIL Validity: NIL Notarization: NIL Validity: NIL Notarization: NIL Validity: NIL Notarization: NIL Validity: NIL Notarization: NIL Validity: NIL Notarization: Apostilled the notarization of CCPTI	I		Type: Original	Krebs Von den	Moraovar alass C madical
the notarization of CCPIT Validity: 28.02.2028 FSC Type: Copy Issued by: NIL Legalization: Apostilled the notarization of CCPIT Validity: 24.05.2026 ISO - Certificate: Type: Copy Notarization: Apostilled the notarization of CCPIT Validity: 20.06.2027 CE certificate (MDR) Type: Not submitted Notarization: NIL Validity: NIL					
Validity: 28.02.2028 FSC Type: Copy Issued by: NIL Legalization: Apostilled the notarization of CCPIT Validity: 24.05.2026 ISO — Certificate: Type: Copy Notarization: Apostilled the notarization of CCPIT Validity: 24.05.2026 ISO — Certificate: Type: Copy Notarization: Apostilled the notarization of CCPIT Validity: 20.06.2027 CE certificate / EU QMS certificate (MDR) Type: Not submitted Notarization: NIL Validity: NIL Vali			1		
FSC Type: Copy Issued by: NIL Legalization: Apostilled the notarization of CCPIT Validity: 24.05.2026 ISO - Certificate: Type: Copy Notarization: Apostilled the notarization of CCPIT Validity: 20.06.2027 CE certificate (FU QMS certificate (MDR) Type: Not submitted Notarization: NIL Validity: NIL				_	I
Type: Copy Issued by: NIL Legalization: Apostilled the notarization of CCPIT Validity: 24.05.2026 ISO - Certificate: Type: Copy Notarization: Apostilled the notarization of CCPIT Validity: 20.06.2027 CE certificate (MDR) Type: Not submitted Notarization: NIL Validity: NIL Validity: NIL Validity: NIL Vali				* *	_
Issued by: NIL Legalization: Apostilled the notarization of CCPIT Validity: 24.05.2026 ISO — Certificate: Type: Copy Notarization: Apostilled the notarization of CCPIT Validity: 24.05.2026 ISO — Certificate: Type: Copy Notarization: Apostilled the notarization of CCPIT Validity: 20.06.2027 CE certificate / EU QMS certificate / MDR) Type: Not submitted the notarization of CCPIT Heparin Binding Protein Test Kit, Hemoglobin A1c Test Kit, Total Thyroxine Test Kit, Notarization: NIL Validity: NIL Val				•	_
Legalization: Apostilled the notarization of CCPIT Validity: 24.05.2026 ISO – Certificate: Type: Copy Notarization: Apostilled the notarization of CCPIT Validity: 20.06.2027 CE certificate (MDR) Type: Not submitted Notarization: NIL Memoglobin A1c certificate (MDR) Type: Not submitted Notarization: NIL Nalidity: NIL Free thyroxine Test Kit, Hemoglobin A1c Stimulating Hormone Test Kit, Creatine kinase MB Test Kit, Interleukin-6 Test Ki			Type: Copy	Serum Amyloid A	Legalized FSC in reference
the notarization of CCPIT Validity: 24.05.2026 ISO — Certificate: Type: Copy Notarization: Apostilled the notarization of CCPIT Validity: 20.06.2027 CE certificate / EU QMS certificate (MDR) Type: Not submitted Notarization: NIL Validity: NIL Va			Issued by: NIL	Test Kit, High	country or notarized CE
the notarization of CCPIT Validity: 24.05.2026 ISO – Certificate: Type: Copy Notarization: Apostilled the notarization of CCPIT Validity: 20.06.2027 CE certificate / EU QMS certificate (MDR) Type: Not submitted Notarization: NIL Validity: NIL Va			Legalization: Apostilled	Sensitive Cardiac	Certificate / EU OMS
Validity: 24.05.2026 ISO – Certificate: Type: Copy Notarization: Apostilled the notarization of CCPIT Validity: 20.06.2027 CE certificate / EU QMS certificate (MDR) Type: Not submitted Notarization: NIL Validity: NIL Validity: NIL			_	Toponin T Test Kit.	
ISO - Certificate: Type: Copy Notarization: Apostilled the notarization of CCPIT Validity: 20.06.2027 CE certificate / EU QMS certificate (MDR) Type: Not submitted Notarization: NIL Validity: NIL Validity: Nil Validity Nil Validity: Nil Validity: Nil Validity Nil Validi				•	(**************************************
Type: Copy Notarization: Apostilled the notarization of CCPIT Validity: 20.06.2027 CE certificate (MDR) Type: Not submitted Notarization: NIL Validity: NIL Test Kit, Total Thyroxine Test Kit, Myoglobin Test Kit, Myoglobin Test Kit, Myoglobin Test Kit, Free thyroxine Test Kit, Myoglobin Test Kit, Thyroid Stimulating Hormone Test Kit, Creatine kinase MB Test Kit, Interleukin-6 Test Kit, 19tpe Natriuretic Peptide Test Kit, 25 Hydroxy vitamin D Test Kit, 25 Hydroxy vitamin D Test Kit, 10-dimer Test Kit, 1					
Notarization: Apostilled the notarization of CCPIT Validity: 20.06.2027 CE certificate / EU QMS certificate (MDR) Type: Not submitted Notarization: NIL Validity: NIL Free thyroxine Test Kit, Usildity: NIL Free thyroxine Test Kit, Usilding Normone Te					
the notarization of CCPIT Validity: 20.06.2027 CE certificate (MDR) Type: Not submitted Notarization: NIL Validity: NIL Validity: Nil Validity: Nil Validity: Nil Validity: Nil Validity: Nil Validity: Validity Validity: Almonglobin Alc Validity: Validity Validity: Validity Validity: Almonglobin Alc Validity: Validity Validity: Nil Validity: Validity Validity: Nil Validity: Nil Validity: Nil Validity: Nil Validity: Nil Validity: Nil Validity: Test Kit, Myoglobin Validity Validity Test Kit, Throid Test Kit, Throid Test Kit, Total Tribroidal Thirodichyronine Test Kit, Total Tribroidal Tribroidal Thyroxine Test Kit, Interleukin-6 Test Kit, Total Tribroidal Thyroxine Test Kit, Interleukin-6 Test Kit, Total Tribroidal Thyroxine Test Kit, Alt Creatine Alt Ni					
Validity: 20.06.2027 CE certificate / EU QMS certificate (MDR) Type: Not submitted Notarization: NIL Validity: NIL Validity:			_		
CE certificate / EU QMS certificate (MDR) Type: Not submitted Notarization: NIL Validity: NIL Validity: Nil Validity: Nil Validity: Nil Validity: Nil Validity: Nil Validity: Nil Validity: Nil Validity: Nil Validity: Nil Validity: Nil Validity: Nil Validity: Nil Validity: Nil Validity: Nil Validity: Nil Validity: Nil Validity: Nil Validity: Nil Validity: Nil Noglobin Test Kit, Total Thyroxine Test Kit, Notal Not					
Certificate (MDR) Type: Not submitted Notarization: NIL Validity: NIL Free thyroxine Test Kit, Myoglobin Test Kit, Thyroid Stimulating Hormone Test Kit, Thyroid Test Kit, Thyroid Stimulating Hormone Test Kit, Thoral Thyroxine Test Kit, Theat Tite, Thyroid Stimulating Hormone Test Kit, Thoral Thyroxine Test Kit, Thoral					
Type: Not submitted Notarization: NIL Validity: NIL Validity: NIL Tree thyroxine Test Kit, Myoglobin Test Kit, Thyroid Stimulating Hormone Test Kit, Creatine kinase MB Test Kit, Interleukin-6 Test Kit, Interleukin-6 Test Kit, 25 Hydroxy vitamin D Test Kit, Prolactin Test Kit, Total Triiodothyronine Test Kit, Total Triiodothyronine Test Kit, D-dimer Test Kit, Total Triiodothyronine Test Kit, D-dimer Test Kit, D-dimer Test Kit, Total Triiodothyronine Test Kit, D-dimer Test Ki				O .	
Notarization: NIL Validity: NIL Notarization: NIL Free thyroxine Test Kit, Thyroid Stimulating Hormone Test Kit, Creatine kinase MB Test Kit, Interleukin-6 Test Kit, B type Natriuretic Peptide Test Kit, 25 Hydroxy vitamin D Test Kit, Total Triitodothyronine Test Kit, D-dimer Test Kit, Shelf Life: 5 years Namufacturer: Shenzhen Sinseng Ground Floor, A1- 198, Block 13-A, Railway Society, Railway Society, Karachi Ltd., Room No. 801, Railway Society, Karachi Low Carbon Industrial Park, Shangcun Community, Gongming R&I Date: Community, Gongming R&I Date: Street, Guangming District, Shenzhen P.R. Fee: 31000/- China Nyoglobin Test Kit, Free thyroxine Test Kit, Free thyroxine Test Kit, Interleukin-6 Test Kit, Interleukin-6 Test Kit, Interleukin-6 Test Kit, Detention Peptide Test Kit, D-dimer Test Kit, Shelf Life: 5 years Shenzhen Sinseng Submission of brand name. Submitsion of brand name. Submi			· ·		
Validity: NIL Free thyroxine Test Kit, Thyroid Stimulating Hormone Test Kit, Creatine kinase MB Test Kit, Interleukin-6 Test Kit, B type Natriuretic Peptide Test Kit, 25 Hydroxy vitamin D Test Kit, Total Tritiodothyronine Test Kit, Total Tritiodothyronine Test Kit, Total Tritiodothyronine Test Kit Shelf Life: 5 years 8. Koncept Technologies, Ground Floor, A1- 198, Block 13-A, Railway Society, Karachi Lid., Room No. 801, Railway Society, Karachi Low Carbon Industrial Park, Shangeun ELI-00767 R&I Date: 26.05.2025 District, Shenzhen P.R. Fee: 31000/- Validity: NIL Free thyroxine Test Kit, Thyroid Stimulating Hormone Test Kit, Interleukin-6 Test Kit, B type Natriuretic Peptide Test Kit, 25 Hydroxy vitamin D Test Kit, Total Tritiodothyronine Test Kit, Total Tritiodothyronine Test Kit, Enterly Peptide Test Kit, 25 Hydroxy vitamin D Test Kit, Polactin Test Kit, Throid Stimulating Hormone Test Kit, Interleukin-6 Test Kit, B type Natriuretic Peptide Test Kit, 25 Hydroxy vitamin D Test Kit, Polactin Test Kit, 25 Hydroxy vitamin D Test Kit, 10tal Tritiodothyronine Test Kit, 25 Hydroxy vitamin D Test Kit, Total Tritiodothyronine Test Kit Shelf Life: 5 years Submission of brand name. Submission of brand name. Submission of brand name. Submission of brand name. Subm			Type: Not submitted	Thyroxine Test Kit,	
Kit, Thyroid Stimulating Hormone Test Kit, Creatine kinase MB Test Kit, Interleukin-6 Test Kit, B type Natriuretic Peptide Test Kit, 25 Hydroxy vitamin D Test Kit, Prolactin Test Kit, Prolactin Test Kit, D-dimer Test Kit, D-dimer Test Kit Shelf Life: 5 years 8. Koncept Technologies, Ground Floor, A1- 198, Block 13-A, Railway Society, Karachi ELI-00767 R&I Date: ELI-00767 R&I Date: Street, Guangming EXTECT. Guangming EXTECT. Guangming EXTECT. Guangming EXTECT. Guangming EXTECT. Guangming EXTECT. Guangming District, Shenzhen P.R. Class: B Models/Code/sizes Kit, Thyroid Stimulating Hormone Test Kit, Creatine kinase MB Test Kit, Interleukin-6 Test Kit, Stept Groude Test Kit, D-dimer Test Kit, Shelf Life: 5 years Brand Name: NIL Generic Name: Submission of brand name. Submission of brand name. Submission of brand name. Submist properly filled Form- 7A. Stamp paper shall be issued in the name of the firm / signatory. The firm has submitted ISO certificate with a different address of the manufacturer and without information about the manufacturing facility for the			Notarization: NIL	Myoglobin Test Kit,	
8. Koncept Technologies, Ground Floor, Al- 198, Block 13-A, Railway Society, Karachi ELI-00767 R&I Date: 26.05.2025 Stimulating Hormone Test Kit, Creatine kinase MB Test Kit, Interleukin-6 Test Kit, B type Natriuretic Peptide Test Kit, 25 Hydroxy vitamin D Test Kit, Total Triodothyronine Test Kit, D-dimer Test Kit, Shelf Life: 5 years Brand Name: NIL Generic Name: Generic Name: Submission of brand name. Submits properly filled Form- 7A. Stamp paper shall be issued in the name of the firm / signatory. The firm has submitted ISO certificate with a different address of the manufacturer and without information about the manufacturing facility for the			Validity: NIL	Free thyroxine Test	
8. Koncept Technologies, Ground Floor, A1- 198, Block 13-A, Railway Society, Karachi ELI-00767 R&I Date: 26.05.2025 Stimulating Hormone Test Kit, Creatine kinase MB Test Kit, Interleukin-6 Test Kit, B type Natriuretic Peptide Test Kit, 25 Hydroxy vitamin D Test Kit, Prolactin Test Kit, D-dimer Test Kit, Belf Life: 5 years Brand Name: NIL Generic Name: Submission of brand name. Submission of brand name. Submit properly filled Form-7A. Stamp paper shall be issued in the name of the firm / signatory. The firm has submitted ISO certificate with a different address of the manufacturer and without information about the manufacturing facility for the			Do CV	Kit, Thyroid	
8. Koncept Test Kit, Technologies, Ground Floor, A1-198, Block 13-A, Railway Society, Karachi Karachi ELI-00767 Community, Gongming R&I Date: 26.05.2025 Pistrict, Shenzhen P.R. Class: B Manufacturer and without information about the Fee: 31000/- Hormone Test Kit, Creatine kinase MB Test Kit, Interleukin-6 Test Kit, Interleukin-6 Test Kit, Interleukin-6 Test Kit, Determed Test Kit, 25 Hydroxy vitamin D Test Kit, Prolactin Test Kit, Total Triiodothyronine Test Kit, Dedimer Test Kit, Dedimer Test Kit Shelf Life: 5 years Brand Name: NIL Generic Name: Submission of brand name. Submit properly filled Form-14. Submit properly filled Form-14. Stamp paper shall be issued in the name of the firm / signatory. The firm has submitted ISO certificate with a different address of the manufacturer and without information about the manufacturing facility for the			, 00	=	
8. Koncept Technologies, Ground Floor, A1-198, Block 13-A, Railway Society, Karachi Low Carbon Industrial Park, Shangcun ELI-00767 Community, Gongming R&I Date: 26.05.2025 Past Kit, Step Natriuretic Peptide Test Kit, Deferred for: Submission of brand name. Submitted ISO Certificate with a different address of the manufacturer and without information about the manufacturing facility for the			1.0	- C	
8. Koncept Test Kit, D-dimer Test Kit, D-dimer Test Kit, D-dimer Test Kit Shelf Life: 5 years 8. Koncept Shenzhen Sinseng Ground Floor, A1-198, Block 13-A, Railway Society, Karachi Low Carbon Industrial Park, Shangcun Community, Gongming R&I Date: 26.05.2025 Pier: 4, Shenzhen P.R. Fee: 31000/- Railway Society Fee: 31000/- Railway Society Pier: 4, Shenzhen P.R. China Railway Society Pier: 4, Shenzhen P.R. China Railway Society Pier: 4, Submission of brand name. Submission of brand name. Submit properly filled Form-3100 the name of the firm / signatory. The firm has submitted ISO certificate with a different address of the manufacturer and without information about the manufacturing facility for the			03,	· ·	
8. Koncept Test Kit, D-dimer Test Kit, D-dimer Test Kit, D-dimer Test Kit, Shelf Life: 5 years 8. Koncept Shenzhen Sinseng Ground Floor, A1-198, Block 13-A, Railway Society, Karachi Low Carbon Industrial Park, Shangcun Community, Gongming R&I Date: 26.05.2025 Pier: 4, Shenzhen P.R. Fee: 31000/- Railway Society Fee: 31000/- Railway Society Pier: 4, Shenzhen P.R. China Natriuretic Peptide Test Kit, 25 Hydroxy vitamin D Test Kit, Prolactin Trest Kit, D-dimer Test Kit Shelf Life: 5 years Brand Name: NIL Generic Name: Submission of brand name. Submit properly filled Form-3100 The firm / signatory. Hu Lyse (SXHA) Stamp paper shall be issued in the name of the firm / signatory. DIFF Lyse (SXHA) Community, Gongming Street, Guangming Applied as: Cluster Class: B without information about the manufacturing facility for the		~0			A
8. Koncept Test Kit, D-dimer Test Kit, D-dimer Test Kit, D-dimer Test Kit, Shelf Life: 5 years 8. Koncept Shenzhen Sinseng Ground Floor, A1-198, Block 13-A, Railway Society, Karachi Low Carbon Industrial Park, Shangcun Community, Gongming R&I Date: 26.05.2025 Pier: 4, Shenzhen P.R. Fee: 31000/- Railway Society Fee: 31000/- Railway Society Pier: 4, Shenzhen P.R. China Natriuretic Peptide Test Kit, 25 Hydroxy vitamin D Test Kit, Prolactin Trest Kit, D-dimer Test Kit Shelf Life: 5 years Brand Name: NIL Generic Name: Submission of brand name. Submit properly filled Form-3100 The firm / signatory. Hu Lyse (SXHA) Stamp paper shall be issued in the name of the firm / signatory. DIFF Lyse (SXHA) Community, Gongming Street, Guangming Applied as: Cluster Class: B without information about the manufacturing facility for the				ĺ ,	
8. Koncept Test Kit, D-dimer Test Kit, D-dimer Test Kit, D-dimer Test Kit, Shelf Life: 5 years 8. Koncept Shenzhen Sinseng Ground Floor, A1-198, Block 13-A, Railway Society, Karachi Low Carbon Industrial Park, Shangcun Community, Gongming R&I Date: 26.05.2025 Pier: 4, Shenzhen P.R. Fee: 31000/- Railway Society Fee: 31000/- Railway Society Pier: 4, Shenzhen P.R. China Natriuretic Peptide Test Kit, 25 Hydroxy vitamin D Test Kit, Prolactin Trest Kit, D-dimer Test Kit Shelf Life: 5 years Brand Name: NIL Generic Name: Submission of brand name. Submit properly filled Form-3100 The firm / signatory. Hu Lyse (SXHA) Stamp paper shall be issued in the name of the firm / signatory. DIFF Lyse (SXHA) Community, Gongming Street, Guangming Applied as: Cluster Class: B without information about the manufacturing facility for the					
8. Koncept Technologies, Ground Floor, A1-198, Block 13-A, Railway Society, Karachi Low Carbon Industrial Park, Shangcun ELI-00767 R&I Date: 26.05.2025 Fee: 31000/- Round Floor, China Test Kit, 25 Hydroxy vitamin D Test Kit, Prolactin Test Kit, D-dimer Test Kit Shelf Life: 5 years Brand Name: NIL Generic Name: Submission of brand name. Submission of br					
8. Koncept Technologies, Ground Floor, A1- 198, Block 13-A, Railway Society, Karachi ELI-00767 R&I Date: 26.05.2025 Pee: 31000/- Brak Kit, Prolactin Test Kit, Total Triiodothyronine Test Kit, D-dimer Test Kit Shelf Life: 5 years Brand Name: NIL Generic Name: Submission of brand name. Submit properly filled Form- 7A. Stamp paper shall be issued in the name of the firm / signatory. The firm has submitted ISO certificate with a different address of the manufacturer and without information about the manufacturing facility for the					· · · · · · · · · · · · · · · · · · ·
8. Koncept					(D)*
8. Koncept Test Kit, D-dimer Test Kit Shelf Life: 5 years 8. Koncept Technologies, Ground Floor, A1- 198, Block 13-A, Railway Society, Karachi ELI-00767 R&I Date: ELI-00767 R&I Date: Fee: 31000/- REST Kit, Total Triiodothyronine Test Kit, D-dimer Test Kit Shelf Life: 5 years Brand Name: NIL Generic Name: Submission of brand name. Submission of brand name. Submit properly filled Form- 7A. Stamp paper shall be issued in the name of the firm / signatory. The firm has submitted ISO certificate with a different address of the manufacturer and without information about the Models/Code/sizes Test Kit, Total Triiodothyronine Test Kit, D-dimer Test Kit Shelf Life: 5 years Submission of brand name. Submit properly filled Form- 7A. The firm has submitted ISO certificate with a different address of the manufacturer and without information about the Models/Code/sizes					
8. Koncept Manufacturer: Shenzhen Sinseng Ground Floor, A1-198, Block 13-A, Railway Society, Karachi ELI-00767 Community, Gongming R&I Date: Street, Guangming R&I Date: Street, Guangming 26.05.2025 Fee: 31000/- 8. Koncept Manufacturer: Shenzhen Sinseng Ground Name: NIL Generic Name: Submission of brand name. LH LYSE (HAS Submit properly filled Form-7A. Stamp paper shall be issued in the name of the firm / signatory. The firm has submitted ISO certificate with a different address of the manufacturer and without information about the Models/Code/sizes manufacturing facility for the					
8. Koncept Technologies, Ground Floor, A1- 198, Block 13-A, Railway Society, Karachi ELI-00767 R&I Date: Community, Gongming R&I Date: 26.05.2025 Pee: 31000/- Manufacturer: Shenzhen Sinseng Generic Name: Ceneric Name: Submission of brand name. Submit properly filled Form- Applied as: Cluster Class: B Models/Code/sizes Manufacturer: Submission of brand name. Submit properly filled Form- Street, Guangming Applied as: Cluster Class: B Models/Code/sizes Manufacturer Submission of brand name. Submit properly filled Form- Streme Submit properly filled Form- Applied as: Cluster Class: B Models/Code/sizes			O.		
8. Koncept Technologies, Ground Floor, A1- 198, Block 13-A, Railway Society, Karachi ELI-00767 R&I Date: Carbon Date: Carbon Date: Carbon Low Carbon Industrial Park, Shangcun Community, Gongming R&I Date: Carbon Low Carbon P.R. China Test Kit Shelf Life: 5 years Brand Name: NIL Generic Name: Submission of brand name. Submit properly filled Form- Submit properly filled Form- Applied as: Cluster Carbon Industrial Carbon Industrial Carbon Industrial Carbon Industrial Community, Gongming Applied as: Cluster Class: B Models/Code/sizes Manufacturer and Submits properly filled Form- Abure Submit properly filled Form- Submit properly filled Form- Submit properly filled Form- Abure Carbon Industrial Carbon Indus					
8. Koncept Technologies, Ground Floor, A1- 198, Block 13-A, Railway Society, Karachi ELI-00767 R&I Deferred for: Generic Name: LH LYSE (HAS Submit properly filled Form- 198, Shenzhen Sinseng Low Carbon Industrial Park, Shangcun Community, Gongming R&I Date: Street, Guangming 26.05.2025 District, Shenzhen P.R. Fee: 31000/- Shelf Life: 5 years Brand Name: NIL Generic Name: Submission of brand name. LH LYSE (HAS Submit properly filled Form- 7A. LH LYSE (SXHA 610) The firm has submitted ISO certificate with a different address of the manufacturer and without information about the Models/Code/sizes manufacturing facility for the			40, 6	Test Kit, D-dimer	
8. Koncept Technologies, Ground Floor, A1- 198, Block 13-A, Railway Society, Karachi ELI-00767 R&I Deferred for: Submission of brand name. LH LYSE (HAS Submit properly filled Form- 310) LH LYSE (SXHA 610) District, Shenzhen P.R. Fee: 31000/- Manufacturer: Brand Name: NIL Generic Name: Submission of brand name. Submit properly filled Form- 7A. Stamp paper shall be issued in the name of the firm / signatory. The firm has submitted ISO certificate with a different address of the manufacturer and without information about the manufacturing facility for the				Test Kit	
Technologies, Ground Floor, A1- 198, Block 13-A, Railway Society, Karachi ELI-00767 R&I Date: ELI-00767 R&I Date: Fee: 31000/- Technologies, Ground Floor, A1- 198, Block 13-A, Railway Society, Building C, Guancheng Low Carbon Industrial Park, Shangcun Community, Gongming District, Shenzhen P.R. China Generic Name: LH LYSE (HAS 310) TA. Stamp paper shall be issued in the name of the firm / signatory. The firm has submitted ISO certificate with a different address of the manufacturer and without information about the manufacturing facility for the			W * V W	Shelf Life: 5 years	
Technologies, Ground Floor, A1- 198, Block 13-A, Railway Society, Karachi ELI-00767 R&I Date: Community, Gongming R&I Date: Submission of brand name. Submission of brand name. LH LYSE (HAS) 310) TA. LH LYSE (SXHA) 610) DIFF LYSE (SXHA) 610) The firm has submitted ISO certificate with a different address of the manufacturer and without information about the manufacturing facility for the	8.	Koncept	Manufacturer:	Brand Name: NIL	Deferred for:
Ground Floor, A1- 198, Block 13-A, Railway Society, Karachi ELI-00767 R&I Date: 26.05.2025 Fee: 31000/- Building C, Guancheng Low Carbon Industrial Park, Shangcun Community, Gongming District, Shenzhen P.R. China LH LYSE (HAS 310) LH LYSE (SXHA 610) DIFF LYSE (SXHA 610) Applied as: Cluster Class: B Models/Code/sizes LH LYSE (HAS 310) TA. Stamp paper shall be issued in the name of the firm / signatory. The firm has submitted ISO certificate with a different address of the manufacturer and without information about the manufacturing facility for the		•	Shenzhen Sinseng	Generic Name:	Submission of brand name.
198, Block 13-A, Railway Society, Railway Society, Karachi ELI-00767 R&I Date: 26.05.2025 Fee: 31000/- District, Shenzhen P.R. Common No. 801, Building C, Guancheng Low Carbon Industrial Park, Shangcun Community, Gongming Class: B District, Shenzhen P.R. China 310) LH LYSE (SXHA) 610) Applied as: Cluster Class: B Models/Code/sizes 7A. Stamp paper shall be issued in the name of the firm / signatory. The firm has submitted ISO certificate with a different address of the manufacturer and without information about the manufacturing facility for the		<u> </u>		LH LYSE (HAS	Submit properly filled Form-
Railway Society, Karachi Railway Society, Karachi ELI-00767 R&I Date: 26.05.2025 Fee: 31000/- Railway Society, Karachi Building C, Guancheng LH LYSE (SXHA 610) DIFF LYSE (SXHA 610) Applied as: Cluster Class: B Models/Code/sizes LH LYSE (SXHA 610) Certificate with a different address of the manufacturer and without information about the manufacturing facility for the		,		,	
Karachi Low Carbon Industrial Park, Shangcun ELI-00767 Community, Gongming R&I Date: Street, Guangming 26.05.2025 District, Shenzhen P.R. Fee: 31000/- Community, Gongming District, Shenzhen P.R. China 610) DIFF LYSE (SXHA) 610) Certificate with a different address of the manufacturer and without information about the manufacturing facility for the				/	
Park, Shangcun ELI-00767 Community, Gongming R&I Date: Street, Guangming Diff LYSE (SXHA 610) Applied as: Cluster Class: B The firm has submitted ISO certificate with a different address of the manufacturer and without information about the Models/Code/sizes			0 7	,	
ELI-00767 Community, Gongming R&I Date: Street, Guangming 26.05.2025 District, Shenzhen P.R. Fee: 31000/- China Community, Gongming Applied as: Cluster Class: B Without information about the manufacturing facility for the		12uruviii		/	
R&I Date: Street, Guangming 26.05.2025 District, Shenzhen P.R. China Applied as: Cluster Class: B without information about the manufacturing facility for the		ELI 00767		`	
26.05.2025 District, Shenzhen P.R. Class: B without information about the Models/Code/sizes manufacturing facility for the				/	
Fee: 31000/- China Models/Code/sizes manufacturing facility for the					
Slip LOA (as per FSC & kits.					
		Slip	LOA	(as per FSC &	kits.
#116729815049 application:		#116729815049		application:	

		Type: Copy of notarized	LH LYSE (HAS	The firm has submitted FSC of
		LOA	310)	Germany with a different
		Apostilled the	LH LYSE (SXHA	address of the manufacturer,
		notarization of CCPIT	610)	without validity date and
		Validity: 5 years from	DIFF LYSE (SXHA	without information about the
		01.02.2025	610)	applied kits. Clarification along
		FSC	Shelf Life: 18	with FSC legalized in the
		Type: NIL	months	reference country is required.
		Issued by: NIL		Valid, legalized FSC of the
		Legalization: NIL		applied product mentioning the
		Validity: NIL		issuing authority in English is
		ISO – Certificate:	1. 16. 0.	required.
		Type: Copy of notarized	101,1052,01;	The brand name shall be
		Notarization: CCPIT	10-01	mentioned in Form-7A.
		Validity: 29.11.2025	7	The firm has applied for LH
		CE certificate / EU QMS		LYSE (HAS 310), which Lyse
		certificate (MDR)	0,	(HAS 310) in the label.
		Type: Not submitted		Clarification is required. The
		Notarization: NIL		requisite fee for cluster shall be
		Validity: NIL		submitted.
		03.0		The DOC does not contain the
		, 0,0		applied devices.
9.	Koncept	Manufacturer:	Brand Name: NIL	Deferred for:
	Technologies,	Shenzhen Sinseng	Generic Name:	Submission of brand name.
	Ground Floor, A1-	Medical Technology Co.,	Diluent (HAS 310)	Submit properly filled Form-
	198, Block 13-A,	Ltd., Room No. 801,	Diluent (SXHA	7A.
	Railway Society,	Building C, Guancheng	610)	Stamp paper shall be issued in
	Karachi	Low Carbon Industrial	Applied as: Cluster	the name of the firm / signatory.
		Park, Shangcun	Class: B	The firm has submitted ISO
	ELI-00767	Community, Gongming	Models/Code/sizes	certificate with a different
	R&I Date:	Street, Guangming	(as per FSC &	address of the manufacturer and
	26.05.2025	District, Shenzhen P.R.	application:	without information about the
	Fee: 31000/-	China	Diluent (HAS 310)	manufacturing facility for the
	Slip #3762065322	LOA	Diluent (SXHA	kits.
		Type: Copy of notarized	610)	The firm has submitted FSC of
		LOA	Shelf Life: 18	Germany with a different
		Apostilled the	months	address of the manufacturer,
		notarization of CCPIT		without validity date and
		Validity: 5 years from		without information about the
		01.02.2025		applied kits. Clarification along
		FSC		with FSC legalized in the
		Type: NIL		reference country is required.
		Issued by: NIL		Valid, legalized FSC of the
	~0	Legalization: NIL		applied product mentioning the
	40//	Validity: NIL		issuing authority in English is
		ISO – Certificate:		required.
	-	Type: Copy of notarized		The brand name shall be
		Notarization: CCPIT		mentioned in Form-7A.
		Validity: 29.11.2025		

		CE certificate / EU QMS certificate (MDR) Type: Not submitted Notarization: NIL Validity: NIL		The firm has applied for LH LYSE (HAS 310), which Lyse (HAS 310) in the label. Clarification is required. The requisite fee for cluster shall be submitted. The DOC does not contain the applied devices.
10.	Highnoon Laboratories Limited, 17.5 Km, Multan Road, Lahore ELI-00646 R&I Date: 31.07.2023 Fee: 5,000/- Slip #7130204351 This evaluation is based on the on- line data submitted through E-App. Tracking ID: XL4- 4SJ-JURJ	Manufacturer: Mis Taian Dalu Medical Instrument Co. Ltd. West part of Yitianmen street, Hi- Tech Zone Taian, Shandong, China LOA Type: scanned copy Notarization in Chinese with English translation. Validity: 5 years from 15.02.2022 FSC Type: scanned copy Issued by: NIL Legalization: NIL Validity: 14.01.2026 ISO – Certificate: Type: Scanned copy Notarization: No Validity: 21.10.2027 CE certificate / EU QMS certificate (MDR) Type: NIL Notarization: NIL Validity: NIL	Brand Name: Powerhaler Generic Name: Dry Powder Inhaler Applied as: Single Class: A Models/Code/sizes (as per FSC & application: DL-D05 Shelf Life: 36 months	Deferred for: The application form has been signed by Director Regulatory Affairs. Authorization letter for the signatory is required. The LOA contains two models ((Dl-D04, (Dl-D07) other than the applied model (Dl-D05). Clarification is required. Scanned copy of the notarized and valid ISO certificate is required Variation in the address of manufacturer in ISO certificate vs other documents shall be clarified. Declaration on stamp paper to be issued in the name of the firm / signatory is required. Valid, legalized FSC of the applied product mentioning the issuing authority in English is required. DOC shall be submitted on the letter head of the manufacturer.
11.	Highnoon Laboratories Limited, 17.5 Km, Multan Road, Lahore ELI-00646 R&I Date: 17.03.2022 Fee: 5,000/- Slip #83059332595 This evaluation is based on the on- line data submitted through E-App.	Manufacturer: Mis Taian Dalu Medical Instrument Co. Ltd. West part of Yitianmen street, Hi- Tech Zone Taian, Shandong, China LOA Type: scanned copy Notarization in Chinese with English translation. Validity: 5 years from 15.02.2022 FSC	Brand Name: ROTAFLO Generic Name: Dry Powder Inhaler Applied as: Single Class: A Models/Code/sizes (as per FSC & application: DL-D07 Shelf Life: 36 months	Deferred for: The application form has been signed by Director Regulatory Affairs. Authorization letter for the signatory is required. Scanned copy of the notarized and valid ISO certificate is required Variation in the address of manufacturer in ISO certificate vs other documents shall be clarified. Declaration on stamp paper to be issued in the name of the firm / signatory is required.

	Tracking ID: R4V-NYZ-J4QM	Type: scanned copy Issued by: NIL Legalization: NIL Validity: 14.01.2026 ISO – Certificate: Type: Scanned copy Notarization: No Validity: 21.10.2027 CE certificate / EU QMS certificate (MDR) Type: NIL Notarization: NIL Validity: NIL	W (MIS)	Valid, legalized FSC of the applied product mentioning the issuing authority in English is required. The brand name is Free-breath in DOC. Clarification is required.
12.	Highnoon Laboratories Limited, 17.5 Km, Multan Road, Lahore ELI-00646 R&I Date: 10.05.2022 Fee: 5,000/- Slip #7396113710 This evaluation is based on the online data submitted through E-App. Tracking ID: MX9- 8G7-QJ5W	Manufacturer: Mis Taian Dalu Medical Instrument Co. Ltd. West part of Yitianmen street, Hi- Tech Zone Taian, Shandong, China LOA Type: scanned copy Notarization in Chinese with English translation. Validity: 5 years from 15.02.2022 FSC Type: scanned copy Issued by: NIL Legalization: NIL Validity: 14.01.2026 ISO – Certificate: Type: Scanned copy Notarization: No Validity: 21.10.2027 CE certificate / EU QMS certificate (MDR) Type: NIL Notarization: NIL Validity: NIL	Brand Name: REVOLIZER Generic Name: Dry Powder Inhaler Applied as: Single Class: A Models/Code/sizes (as per FSC & application: DL-D07 Shelf Life: 36 months	Deferred for: The firm has applied the same model (DL-D07) twice. Clarification is required. The application form has been signed by Director Regulatory Affairs. Authorization letter for the signatory is required. Scanned copy of the notarized and valid ISO certificate is required Variation in the address of manufacturer in ISO certificate vs other documents shall be clarified. Declaration on stamp paper to be issued in the name of the firm / signatory is required. Valid, legalized FSC of the applied product mentioning the issuing authority in English is required. The brand name is Free-breath in DOC. Clarification is required. DOC shall be submitted on the letter head of the manufacturer.
13.	M/S Hospital Supply Corporation, 42 Darul Aman Housing Society, Block 7 & 8, Karachi ELI-00005	Manufacturer: Zhejiang Kindly Medical Devices Co., LTD Address: No.758, 5th Binhai Road, Binhai Industrial Park, Longwan District 325025	Brand Name: YMS Infusion Set Generic Name: Scalp Vein Set Applied as: Single Class: B Models/Code/sizes (as per FSC & application:	Deferred for: The firm shall submit the renewal status of ELI. The firm shall apply as grouping with submission of requisite fee. The fee deposited vide Slip #2045103 Dated 24.06.2025

	R&I Date:	Wenzhou, Zhejiang	270 260 250	Diff Equ. 12 500/
		LOA	27G, 26G, 25G.	Diff. Fee: 12,500/-
	25.06.2020		24G, 23G. 22G,	Slip# 34110862712
	Fee: 12,500/-	Type: scanned copy	21G, 20G, 19G,	Dated: 28.12.2021 is meant or
	Slip #2045103	Notarization: No	18G	renewal of registration (as
	Dated 24.06.2025	Validity: 31.12.2025	(With	drug).
	Diff. Fee: 12,500/-	FSC	corresponding size /	Scanned copy of the notarized
	Slip# 34110862712	Type: scanned copy	caliber in FSC)	and ISO certificate and CE
	Dated: 28.12.2021	Issued by: Zhejiang	Shelf Life: 36	certificate are required
	This evaluation is	Medical Products	months	Declaration on stamp paper to
	based on the on-	Administration		be issued in the name of the
	line data submitted	Legalization: NIL		firm / signatory is required.
	through E-App.	Validity: 14.01.2026		Valid, legalized FSC of the
	Tracking ID: TRX-	ISO – Certificate:	000	applied product mentioning the
	1LZ-A145	Type: Scanned copy		issuing authority in English is
		Notarization: No	7,9	required.
		Validity: 31.10.2026	1	Shelf life verification report is
		CE certificate / EU QMS	0,	required.
		certificate (MDR)		The sterilization site has not
		Type: scanned copy		been mentioned in the ISO
		Notarization: NIL		certificate and CE certificate.
		Validity: 14.04.2026		certificate and CL certificate.
14.	Global Biotech	Manufacturer:	Brand Name:	Deferred for:
14.	Medical Devices	Curatia Medical Limited.	EXTesia Introducer	Properly filled application
	(Private) Limited.	Site 1 (other than	Sheath Set	Form shall be submitted.
	First Floor of Plot	sterilization)	Generic Name:	The sheath and dilators vary in
	No 35-N/3,	No. 198 Xiangjiang Road,	Introducer Sheath	size / caliber. Similarly, the
	PECHS Block-6,	e. e	Set	
	Near Rohail	New District, Suzhou,		guide wire varies in caliber,
	Khund Society,	China	Applied as: Single	type (spring, polymer jacket),
	Karachi.	Site 2 (Sterilization	Class: B	and tip shape (straight, J,
	ELI-01292	process)	Models/Code/sizes	angled). Likewise, the entry
	R&I Date:	Name: Goals Sterilization	(as per FSC &	needle varies in type (IV
	03.12.2024	Co., Ltd	application: (551	catheter. metallic needle) and
	Fee: 31,000/-	Address: East of	codes)	size. Moreover, the last 20
	Slip #594093568	Renkangtang, South of 07	2IS040521PSI,	codes (from 2IS040500000 to
	This evaluation is	provincial road, Xinfeng	2IS040525PSI,	2IS072500000) does not
	based on the on-	Town, Nanhu District	2IS040535PSI,	contain guided wire, entry
	line data submitted	LOA	2IS040521PAI,	needle scalpel and syringe. The
	through E-App.	Type: scanned copy	2IS040525PAI,	firm shall apply as grouping
	Tracking ID: 1DG-	Notarization: Yes, CCPIT	2IS040535PAI,	with submission of requisite
	UEZ-T6M8	Validity: 04.07.2026	2IS040518SSN,	fee.
	OLL-TUNIO	FSC	2IS040521SSN,	The application form has been
		Type: scanned copy	2IS040525SSN,	signed by authorized person for
	A	Issued by: Jiangsu	2IS040535SSN,	Regulatory Affairs.
	20	Medical Products	2IS040518SJN,	Authorization letter for the
		Administration	2IS040521SJN,	signatory is required.
		Legalization: apostilled	2IS040525SJN,	Declaration on stamp paper to
		the notarization of CCPIT	2IS040535SJN,	be issued in the name of the firm
		Validity: 03.07.2026	2IS040721PSI,	/ signatory is required.
		ISO – Certificate:	2IS040725PSI,	, signatory is required.
		150 - Certificate.	215070723151,	

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Type: Scanned copy	2IS040735PSI,	Scanned copy of the notarized
Notarization: Yes, CCPIT	2IS040721PAI,	CE certificate are required
Validity: 31.07.2026	2IS040725PAI,	Shelf life verification report is
CE certificate / EU QMS	2IS040735PAI,	required.
certificate (MDR)	2IS040718SSN,	The sterilization site has not
Type: scanned copy	2IS040721SSN,	been mentioned in the ISO
Notarization: No	2IS040725SSN,	certificate and CE certificate.
(notarized the statement	2IS040735SSN,	
of manufacturer, not the	2IS040718SJN,	
certificate)	2IS040721SJN,	(D)
Validity: 26.05.2024	2IS040725SJN,	
Extended till 31.12.2028	2IS040735SJN,	
, Gr	2IS041021PSI,	
	2IS041025PSI,	
100 - 110	2IS041035PSI,	
Ø5 . O	2IS041021PAI,	
1 2/1 20	2IS041025PAI,	
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100	2IS041618SSN,	
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	2IS041635SSN,	
	2IS041618SJN,	
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GIS - CO	2IS041625SJN,	
K5 00	2IS041635SJN,	
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	2IS042518SSN,	
	2IS042521SSN,	
	2IS042525SSN,	
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Monday, and Monday	Shelf Life: 36
	months
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15. Global Biotech Manufacturer: Brand Name: Deferred for: Medical Devices Curatia Medical Limited. Navaio PTA Properly filled application (Private) Limited. **Balloon Dilatation** Form shall be submitted. Site 1 (other than First Floor of Plot Catheter English translation of the sterilization) No 35-N/3. No. 198 Xiangjiang Road, Generic Name: issuing authority in FSC is PECHS Block-6. New District, Suzhou, **Balloon Dilatation** required. Near Rohail China Catheter The scanned copy of the FSC Khund Society, Site 2 (Sterilization Applied as: Single varies from the attachments Karachi. process) Class: B and notarization. ELI-01292 Name: Goals Sterilization Models/Code/sizes The models vary in balloon R&I Date: Co., Ltd (as per FSC & size (OD x length), catheter 03.12.2024 Address: East of application: length, balloon nominal Fee: 31,000/-Catheter Length Renkangtang, South of 07 pressure, rated burst pressure, Slip #206211973099 provincial road, Xinfeng maximum guide wire lumen (80cm) This evaluation is Town, Nanhu District 21005040, and catheter OD. The firm shall based on the on-LOA 21005060, apply as grouping with line data submitted Type: scanned copy submission of requisite fee. 21005080, through E-App. Notarization: Yes, CCPIT The application form has been 21006040, Tracking ID: Validity: 04.07.2026 signed by authorized person for 21006060, MUY-P46-TGEL FSC Regulatory Affairs. 21006080, Type: scanned copy Authorization letter for the 21007040, Issued by: NIL 21007060, signatory is required. Legalization: apostilled Declaration on stamp paper to 21007080, the notarization of CCPIT be issued in the name of the 21008040, Validity: 15.01.2026 21008060, firm / signatory is required. ISO – Certificate: 21008080, Scanned copy of the notarized Type: Scanned copy CE certificate are required. 21009040, Notarization: Yes, CCPIT The sterilization site has not 21009060, Validity: 31.07.2026 been mentioned in the ISO 21009080, CE certificate / EU QMS 21010040, certificate and CE certificate. certificate (MDR) 21010060, Type: scanned copy 21010080. Notarization: No Catheter (notarized the statement Length (100cm) of manufacturer, not the 21205040, certificate) 21205060, Validity: 26.05.2024 21205080. Extended till 31.12.2028 21206040, 21206060, 21206080, 21207040. 21207060, 21207080, 21208040, 21208060, 21208080, 21209040, 21209060, 21209080,

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16.	Global Biotech	Manufacturer:	Brand Name: Vela	Deferred for:
10.	Medical Devices	manufucturor.	RX PTA Balloon	Properly filled application
	(Private) Limited.		Dilatation Catheter	Form shall be submitted.
	(1 11 vaic) Lillicu.		Difatation Catheter	romi shan de sudmitted.

First Floor of Plot Curatia Medical Limited. Generic Name: English translation of the No 35-N/3, No. Site 1 (other than Balloon Dilatation issuing authority in FSC is PECHS Block-6, sterilization) Catheter required. Near Rohail 198 Xiangjiang Road, Applied as: Single The scanned copy of the FSC Khund Society, New District, Suzhou, Class: B varies from the attachments Karachi. China Models/Code/sizes and notarization. ELI-01292 Site 2 (Sterilization (as per FSC & The models vary in balloon R&I Date: process) application: Size (OD x Length), rated burst 03.12.2024 Name: Goals Sterilization Balloon Length pressure, and catheter OD. The Fee: 31,000/-Co., Ltd (10mm)firm shall apply as grouping Slip #1306741949 Address: East of 21510140, with submission of requisite This evaluation is Renkangtang, South of 07 22010140. fee. based on the online data submitted provincial road, Xinfeng 22510140, The application form has been Town, Nanhu District through E-App. 23010140, signed by authorized person for Tracking ID: LOA 23510140, Regulatory Affairs. BUA-Z8Z-9PV3 Type: scanned copy 24010140. Authorization letter for the Notarization: Yes, CCPIT Balloon Length signatory is required. Validity: 04.07.2026 Declaration on stamp paper to (20mm)**FSC** 21520140, be issued in the name of the Type: scanned copy 22020140, firm / signatory is required. Issued by: NIL 22520140, Scanned copy of the notarized Legalization: apostilled 23020140, CE certificate are required. the notarization of CCPIT The sterilization site has not 23520140, Validity: 15.01.2026 24020140. been mentioned in the ISO ISO – Certificate: Balloon Length certificate and CE certificate. Type: Scanned copy (30mm)Notarization: Yes, CCPIT 21530140, Validity: 31.07.2026 22030140, CE certificate / EU OMS 22530140, certificate (MDR) 23030140, Type: scanned copy 23530140, Notarization: No 24030140. (notarized the statement **Balloon Length** of manufacturer, not the (40mm) certificate) 21540140, Validity: 26.05.2024 22040140, Extended till 31.12.2028 22540140, 23040140, 23540140, 24040140. Shelf Life: 2 years

ADDITIONAL AGENDA 109TH MEETING OF MDB

Item No. I(A): <u>APPLICATIONS FOR GRANT OF ADDITIONAL SECTION FOR LOCAL</u> MANUFACTURING (ELM)

(Additional Section -ELM)

S.#	Name and Address of Establishment	Name of Production Incharge	Name of QC Incharge	Decision
1.	M/s Sayyad Healthcare Limited, Plot No. 37, Allama Iqbal Industrial City, Faisalabad (ELM- 0079)	Muhammad Fayyaz	Moshin Ali Altaf	The Board approved the following additional section to manufacture medical devices. 1.Disposable Syringes Section

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

S.#	Name of Establishment	Name of Qualified	Name of Management	Decision
	2010	Technical Person		
	10			
1.	Electromed Corporation,	Ms. Zartaj	Said Ur Rehman	Approved
	Office/Godown: 53 Mall		Razi Ur Rehman	,
	Avenue, 54 The Mall, Near	Bs Microbiology	Zaki Ur Rehman	~
	Panorama Shopping Center		Shoaib Rizwan Usmani	
	, LAHORE	dill	16,0:2	
		00	(" -61	
	ELI-00163	16 10), 713,	

Item No. II: CASES OF M/S PERFECT TRADERS (ELI-01394)

Muhammad Ashfaq - 0Deputy Director-VI

S. No.	Name of Applicant(s)	Name of Manufacturer	Medical Device	Decision
1.	M/s Perfect	Name of	Brand Name:	Deferred due to following
	Traders, 72 Harley	Manufacturer:	Pro Sun	deficiencies in the application;
	Street Lane No.2, Rawalpindi. (ELI-01394)	Beijing Chong Lang Rehabilitation Aids Co., Ltd, 7-2-401,	Generic Name: Prosthetic Knee Joint	1. Copy of filled, signed & stamped application form, has not been submitted.
	Date of R& I 11-04-2025 Fee: 6,000/- Slip # 937914403	Liando U Valley 4 Yard, Renhe Town, Shunyi District, Beijing, 101399, China	Applied as: Single Class: A	 2. LOA has not been notarized. 3. Validity Period or validity date has not been mentioned on LOA. 4. LOA has been issued by Beijing Chonglang

	<u> </u>		Model:	Rehabilitation Accessory Co.,
		LOA	X5-T	Ltd., Room 401, Unit 2,
		Type: Copy	23.0 1	Building 7, Lianhe U valley 4
		Notarization: Not	Shelf Life: 36	yard, Renheyuan 2 street,
		Notarization: Not Notarized	Months	Renhe town, Shunyi District,
			IVIOHUIS	Beijing, China while
		Issue Date: 06-03-		manufacturer mentioned on
		2025		FSC is Beijing Chong Lang
		Validity: Not		Rehabilitation Aids Co., Ltd, 7-
		mentioned	_	2-401, Liando U Valley 4 Yard,
			, C	Renhe Town, Shunyi District,
		• FSC (UK)		Beijing, 101399, China.
		Type: Copy	111 1111	5.FSC (UK) has not been
		Issued By: MHRA	00, 11	legalized.
		Legalization: Not	Sciol Jobs	6. ISO certificate submitted has
		legalized	and all	been issued by CAB not found
		Validity: 19-06-2029	18h, Uh,	in NANDO data base.
		• ISO – Certificate:	GC, JO,	7. ISO certificate has not been notarized.
		Type: Copy	700	8. Stability studies data has not
		Notarization: Not		been submitted.
		Notarization: Not		9. Undertaking on stamp paper
		Validity: 22-08-2026		has not been submitted.
	,	vanuity. 22-08-2020		m n
		7 08		The Board directed to rectify the
		U		above-mentioned deficiencies for
		44		further processing the application.
2.	M/s Perfect	Name of	Brand Name:	Deferred due to following
	Traders, 72 Harley	Manufacturer:	Pro Sun	deficiencies in the application;
	Street Lane No.2,	Beijing Chong Lang	G	1. Copy of filled, signed &
	Rawalpindi.	Rehabilitation Aids	Generic Name:	stamped application form, has
	(ELI-01394)	Co., Ltd, 7-2-401,	Prosthetic Knee Joint	not been submitted.
	Date of R& I	Liando U Valley 4	40	2. LOA has not been notarized.
	11-04-2025	Yard, Renhe Town,	Applied as: Single	3. Validity Period or validity date has not been mentioned on
	11 01 2023	Shunyi District,	Tappired as. Single	LOA.
	Fee: 6,000/-	Beijing, 101399,	Class: A	4. LOA has been issued by
	Slip #	China	" (N)	Beijing Chonglang
	372118529489		Model:	Rehabilitation Accessory Co.,
		LOA	X4-T	Ltd., Room 401, Unit 2,
		Type: Copy	-1.	Building 7, Lianhe U valley 4
		Notarization: Not	Shelf Life: 36	yard, Renheyuan 2 street,
		Notarized	Months	Renhe town, Shunyi District,
		Issue Date: 06-03-		Beijing, China while
		2025		manufacturer mentioned on
		Validity: Not		FSC is Beijing Chong Lang
		mentioned		Rehabilitation Aids Co., Ltd, 7-
		, 00		2-401, Liando U Valley 4 Yard,
		• FSC (UK)		Renhe Town, Shunyi District,
		Type: Copy		Beijing, 101399, China.
	-0	Issued By: MHRA		5. FSC (UK) has not been legalized.
		Legalization: Not		6. ISO certificate submitted has
		legalized		been issued by CAB not found
	1/4	Validity: 19-06-2029		in NANDO data base.
				7. ISO certificate has not been
	i .	i	•	
		• ISO – Certificate:		notarized.

		Type: Copy		8. Stability studies data has not
				been submitted.
		Notarization: Not		
		Notarized		9. Undertaking on stamp paper
		Validity: 22-08-2026		has not been submitted.
				The Board directed to rectify the
				above-mentioned deficiencies for
				further processing the application.
3.	M/s Perfect	Name of	Brand Name:	Deferred due to following
	Traders, 72 Harley	Manufacturer:	Pro Sun	deficiencies in the application;
	Street Lane No.2,	Beijing Chong Lang		1. Copy of filled, signed &
	Rawalpindi.	Rehabilitation Aids	Generic Name:	stamped application form, has
	(ELI-01394)		Prosthetic Knee Joint	not been submitted.
	(=== ======)	Co., Ltd, 7-2-401,	- 1/1/1	2. LOA has not been notarized.
		Liando U Valley 4	20, 77	
	Date of R& I	Yard, Renhe Town,	Applied as: Single	3. Validity Period or validity date
	11-04-2025	Shunyi District,	Applied as. Single	has not been mentioned on
	11-04-2023	Beijing, 101399,	Class: A	LOA.
	Fact 6 000/	China	Class. A	4. LOA has been issued by
	Fee: 6,000/-	"NP" (1)	Model	Beijing Chonglang
	Slip # 71013168	LOA	Model:	Rehabilitation Accessory Co.,
			XQ-4	Ltd., Room 401, Unit 2,
		Type: Copy		Building 7, Lianhe U valley 4
		Notarization: Not	Shelf Life: 36	yard, Renheyuan 2 street,
		Notarized	Months	Renhe town, Shunyi District,
		Issue Date: 06-03-		Beijing, China while
		2025		manufacturer mentioned on
		Validity: Not		FSC is Beijing Chong Lang
		mentioned		Rehabilitation Aids Co., Ltd, 7-
		mentioned		2-401, Liando U Valley 4 Yard,
		EGG (IIIZ)		Renhe Town, Shunyi District,
		• FSC (UK)		Beijing, 101399, China.
		Type: Copy		5.FSC (UK) has not been
		Issued By: MHRA		legalized.
		Legalization: Not		6. ISO certificate submitted has
		legalized		been issued by CAB not found
		Validity: 19-06-2029		in NANDO data base.
			7/11 ' [1]	7. ISO certificate has not been
		• ISO – Certificate:		notarized.
				8. Stability studies data has not
		Type: Copy	1 4 4 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	been submitted.
		Notarization: Not	100° UV	9. Undertaking on stamp paper
		Notarized		has not been submitted.
		Validity: 22-08-2026	160, JO.	The Board directed to rectify the
			700	above-mentioned deficiencies for
		407		
	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		D 137	further processing the application.
4.	M/s Perfect	Name of	Brand Name:	Deferred due to following
	Traders, 72 Harley	Manufacturer:	Pro Sun	deficiencies in the application;
	Street Lane No.2,	Beijing Chong Lang		1. Copy of filled, signed &
	Rawalpindi.	Rehabilitation Aids	Generic Name:	stamped application form, has
	(ELI-01394)	Co., Ltd, 7-2-401,	Prosthetic Foot	not been submitted.
		Liando U Valley 4		2. LOA has not been notarized.
		Yard, Renhe Town,	Applied as: Single	3. Validity Period or validity date
	Date of R& I	Shunyi District,		has not been mentioned on
	11-04-2025	-	Class: A	LOA.
		Beijing, 101399,		4. LOA has been issued by
	Fee: 6,000/-	China	Model:	Beijing Chonglang
	Slip # 8484982336		J3-M	Rehabilitation Accessory Co.,
		LOA		Ltd., Room 401, Unit 2,
L	_1	I .	I .	1,

		Type: Copy	Shelf Life: 36	Building 7, Lianhe U valley 4
		Notarization: Not	Months	yard, Renheyuan 2 street,
		Notarization: Not Notarized	MIOHUIS	Renhe town, Shunyi District,
				Beijing, China while
		Issue Date : 06-03-		manufacturer mentioned on
		2025		FSC is Beijing Chong Lang
		Validity: Not		Rehabilitation Aids Co., Ltd, 7-
		mentioned		2-401, Liando U Valley 4 Yard,
				Renhe Town, Shunyi District,
		• FSC (UK)		Beijing, 101399, China.
		Type: Copy	. 6	5. FSC (UK) has not been
		Issued By: MHRA		legalized.
		Legalization: Not		6. ISO certificate submitted has
		legalized	201, 17,	been issued by CAB not found
		Validity: 19-06-2029	0 11 6	in NANDO data base.
		(unaity: 1) 00 202)	40, 713	7. ISO certificate has not been
		• ISO – Certificate:	00, 00,	notarized.
		Type: Copy		8. Stability studies data has not
		Notarization: Not		been submitted.
			700	9. Undertaking on stamp paper
		Notarized		has not been submitted.
		Validity: 22-08-2026	*	The Board directed to rectify the
		- Cl - CU		above-mentioned deficiencies for
		5 0		further processing the application.
5.	M/s Perfect	Name of	Brand Name:	Deferred due to following
	Traders, 72 Harley	Manufacturer:	Pro Sun	deficiencies in the application;
	Street Lane No.2,	Beijing Chong Lang		1. Copy of filled, signed &
	Rawalpindi.	Rehabilitation Aids	Generic Name:	stamped application form, has
	(ELI-01394)	Co., Ltd, 7-2-401,	Prosthetic Foot	not been submitted.
	10),	Liando U Valley 4		2. LOA has not been notarized.
		Yard, Renhe Town,	Applied as: Single	3. Validity Period or validity date
	Date of R& I	Shunyi District,		has not been mentioned on
	11-04-2025	Beijing, 101399,	Class: A	LOA.
	E 6000/	China		4. LOA has been issued by
	Fee: 6,000/-	Cillin	Model:	Beijing Chonglang
	Slip # 7696282671	LOA	J7	Rehabilitation Accessory Co.,
		Type: Copy	0 4	Ltd., Room 401, Unit 2,
			Shelf Life: 36	Building 7, Lianhe U valley 4
		Notarization: Not	Months	yard, Renheyuan 2 street,
		Notarized		Renhe town, Shunyi District, Beijing, China while
		Issue Date: 06-03-		Beijing, China while manufacturer mentioned on
		2025	700	FSC is Beijing Chong Lang
		Validity: Not		Rehabilitation Aids Co., Ltd, 7-
		mentioned		2-401, Liando U Valley 4 Yard,
		6/3-00		Renhe Town, Shunyi District,
		• FSC (UK)		Beijing, 101399, China.
		Type: Copy		5.FSC (UK) has not been
		Issued By: MHRA		legalized.
		Legalization: Not		6. The Model applied (J7), has
	20	legalized		not been mentioned in FSC
	~0	Validity: 19-06-2029		(UK) as well as DOC.
	40//			7. ISO certificate submitted has
		• ISO – Certificate:		been issued by CAB not found
		Type: Copy		in NANDO data base.
		Notarization: Not		8. ISO certificate has not been
		Notarized		notarized.

Validity: 22-08-2026	9. Stability studies data has not
	been submitted.
	10. Undertaking on stamp
	paper has not been submitted.
	The Board directed to rectify the
	above-mentioned deficiencies for
	further processing the application.

Monday, of December, 2025, 9:35:37 AM Assistant Director, 2025, 9:35:37 AM Assistant