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

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#### <u>DECISIONS OF 105<sup>th</sup> MEETING OF THE MEDICAL DEVICE BOARD (MDB)</u> HELD ON 23-10-2025 (MANUAL APPLICATION)

105th 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 16th October, 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.		40, 0, 19
1.	Dr. Babar Khan, Director, Medical Devices	30.0
	& Medicated Cosmetics, Drug Regulatory	Chairman
	Authority of Pakistan, Islamabad.	108
2.	Mr. Salik Zahid, CDI, Nominee of DGHS	Member
	Balochistan	(attended meeting through videolink)
3.	Prof Dr Saqib Shafi Sheikh, Interventional	Member
	Cardiologist, 98 Babar block, New Garden	(attended meeting through videolink)
	Town, Lahore	
4.	Prof. Dr. Mehmood Ahmad, Former Dean,	Member
	Islamia University, Bahawalpur, House	(attended meeting through videolink)
	No. 144-D, St. No.14, OPF Housing	
	Scheme, Phase-1, Khayaban Jinnah, Near	
	Raiwind Road, Lahore.	a Y
5.	Abdul Aleem Awan, Assistant Prof.	Member
	Pharmacy Department, Abbottabad	(S)G.
	University of Science & Technology,	18/11/2.5
	Havelian.	91, 16, 1
6.	Prof. Dr. Farid Khan, Senior Consultant	Member
	Neuro Surgery/Director Trauma &	(attended meeting through videolink)
	Emergency/Focal Person MSDS, Primary	30 . 1
	& Secondary Healthcare Department,	ell'
	Punjab.	.0
7.	Dr. Ayesha Ali, Department of Pharmacy,	Member
	Pakistan Institute of Medical Sciences,	
0	Islamabad (Hospital Pharmacist).	V 1
8.	Mr. Luqman Ali, System Analyst, Pakistan	Member
0	Institute of Medical Sciences, Islamabad.	)/ 1
9.	Mr. Wajahat Ali, Biomedical Engineer,	Member
	Liaquat College of Medicine and Dististry	(attended meeting through videolink)
	& Darul Sehat Hospitaol, Karachi.	
10	Due C Du M Nie Lean Al L Du de C	M 1
10.	Prof Dr M Nadeen Ahmed, Department of	Member
	Radiology, Agha Khan University	(attended meeting through videolink)
	Hospital, Karachi.	

11.	Ms. Tazeen Saeed Bukhari, Biomedical	Co-Opted Expert
	Engineer	(attended meeting through videolink)
12.	Mr. Ayyaz Ahmed, Additional Director (MD&MC), DRAP, Islamabad.	Member-cum-Secretary
13.		

Sr.No.	NAME OF EVALUATOR	DESIGNATION
1.	Mr. Saadat Ali Khan	Deputy Director-I
2.	Mr. Waqar Ahmad	Deputy Director-II
3.	Mst. Sadaf Ahmad	Deputy Director-III
4.	Mr. Dr. Ghayoor Ahmad	Deputy Director-IV
5.	Mr. Muhammad Ashfaq	Deputy Director-VI
6.	Mr. Hafiz Muhammad Asif Iqbal	Deputy Director-VII
7.	Mr.Rana Ahsan-ul-Haq Athar	Deputy Director-VIII
8.	Mr. Muhammad Amin	Deputy Director-IX
9.	Mr. Ammar Ashraf Awan	Deputy Director-X
10.	Mr.Dr. Hanif Ullah	Deputy Director-XI

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

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

#### (FRESH CASES-ESTABLISHMENT LICENSE IMPORT)

S.#	Name of Establishment	Name of Qualified Technical Person	Decision
		"" (MI2,5:5	•
1.	M/s Science&technologies,	Kifayat Ullah Medical Laboratory Technology	Approved
	office/Godown: office No. FLT 257C 2nd	10 x0 01	
	floor Opposite Zain Marriage Hall	(1) CCC JO.	
	Khayaban-e-Sir Syed Rawalpindi		
	Rawalpindi	AL ID	A 1
2.	M/s Ahmed Traders, Shop No # 3	Ahmad Raza	Approved
	Office/ Godown: Al Ashraf Plaza,	Pharm-D	
	Opposite to the Educator School , Range		
	Road, Rawalpindi, Cantt.		
	D	•	
3.	M/s Endo Urology Solution,	Muhammad Shoaib Akmal	Approved
	Office/Codewn W.O. 24 C. Communical	Dashelon of Coiones in Dischamistary	
	Office/Godown: W-0, 24-C, Commercial Area, Hasmi Garden, Bahawalpur.	Bachelor of Science in Biochemistry	
	7 Hea, Hashii Garden, Banawarpar.		
4.	M/s oriental and Co,	Muhammad Amir	Rejected. The board
	Office	BS Biomedical Engineering	considered the report and
	House # 986 Block 4, 1st Floor Shah		observed that the firm is
	Faisal Colony Karachi.		not interested in

	Godowon: Shop No. 1 & 2 House NO. A-3, Rizwia Housing Project, Al-Falah Society, Karachi		obtaining establishment license to import medical devices therefore it was decided to reject application of the firm to obtain establishment license to import medical devices
5.	M/s Zonya Ipex, 43, Sector-2, street 12, HBCHS, Hub river road, Karachi.	Shariq shoukat BS Biomedical Engineering	Rejected. The board considered the report and observed that the firm is not interested in obtaining establishment license to import medical devices therefore it was decided to reject application of the firm to obtain establishment license to import medical devices.

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

#### (FRESH RENEWAL CASES- ESTABLISHMENT LICENSE IMPORT)

10

S.#	Name of Establishment	Name of Qualified Technical Person	Name of Management	Decision
1.	M/s 3J Diagnostices, Office: Office No. 5, 2 <sup>nd</sup> Floor, Liberty Plaza, Opposite Rawalpindi General Hospital (RGH), Murree road, Rawalpindi  Godown: Office No. 9, 2 <sup>nd</sup> Floor, Liberty Plaza, Opposite Rawalpindi General Hospital (RGH), Murree road, Rawalpindi  ELI-00325	Mukhtiar Ahmad Medical Lab technologist	Johnson John	Approved
2.	M/s Meher Enterprises, Office: First Floor Az-Zainab Court Campbell Street Karachi Godown: A-IV 1st Floor, Azzainab Court, Campell Street, Karachi.  Additional godown: A-VI 1st Floor, Azzainab Court, Campell Street, Karachi.  ELI-00241	Shah Noor Bashir Pharm-D	Muhammad Anwar Idrees	Approved

	T		T	T .
3.	M/s Qualitron Corporation Office/Godown: E-172, Block 2, Tariq Road, P.E.C.H.S., Karachi ELI-00550	Muhammad Umair Pharm-D	Shahzad Tazam Shaikh	Approved
4.	M/s UNIQUE VISUAL SYSTEM Office/Godown: L-18, Block 17, 2nd Floor, Gulshan-e-Iqbal, Karachi. ELI-00449	Samia Faisal Hada Pharm-D	MUHAMMAD JAVED Mr. Abdul Samad Mr. Muhammad Raees	Approved
5.	M/s UDL DISTRIBUTION (PVT) LTD  Office: 1-D-13, SECTOR 30, KORANGI INDUSTRIAL AREA, KARACHI.  Godown: S-8/A Translyari Quarters, S.I.T.E Near Gul Bai In Line of Meezan Bank Head Office, KARACHI  ELI-00073	Amna Pharm-D	Tahir Khaliq Arshad Abdullah Nasir Abdullah Ahsan Khaliq	Approved
6.	M/s. Al Qazi Marketing Group  Office/Godown: 10-11-E, Karachi Market, Khyber Bazar, Peshawar, Pakistan	Saif Ullah Pharm-D	Ihsan-ul-Haq Inam-ul-Haq	Approved
	ELI-00540			
7.	M/s. Heartec  Office/ Godown: First Floor, 734 Shadman 1 inside Alam Audiology Clinic, Faisalabad  ELI-00375	Touqeer Hanif BS Hons in Medical Laboratory Technology	Saima Afzaa	Approved
8.	M/s. Global Marketing Services  Office: 111,Hali Road Westridge 1 Cantt Rawalpindi,Pakistan  Godown: plot. no. 36A, PSIC, SIE, Taxila Rawalpindi  ELI-00109	Wajiha Saleem Pharmacist	Zafar Mahmood Muhammad Ayub Naheed Dilshad	Approved
9.	M/s. Digionics Pvt Ltd Office/Godown: 15 Shadman, Jail Road, Lahore ELI-00371	Shanzaib Bint-e- Naeem Pharm D	Riaz Masood Abbasi Qasim Masood	Approved

10.	M/s. Bristol Mayer Biotech	Ume Kalsoom	Abdul Razaq Khan	Approved
	Pakistan (Pvt) Ltd		Zaheer Ahmed khan	
	Office / Godown: 73-B, Guldasht	Pharm-D	Munawer Ali Tariq	
	Town, Zarrar Shaheed Road,			
	Lahore Cantt			
	ELI-00093			
11.	M/s Friends Traders,	Syed Ahmed Shah	Asad Ullah Khan Lodhi	Approved
	Office: Peshawar Medical Centre Hussain Plaza, Shoba Chowk	Bio-Medical Engineer		3/4
	Near Khyber Bazar Peshawar	Dio Medicai Engineer		
	Cala		(5) (6)	
	Godown: Lodhi Katrage, Old Bara Road,			
	University Town, Peshawar			
12	ELI- 00457	Muhammad Raza	Syed Masood Akhtar	A
12.	M/s. Zaidi Traders, Office/ Godown	Zaidi,	Zaidi	Approved
		Doctor of Medical	Syed Yousaf Raza Zaidi	
	F-263, Satellite Town, Rawalpindi.	Laboratroy Sciences		
	Kawaipindi.	Wr. Wr		
	EX 1 000220	0. 18,		
13.	ELI-000328 M/s K.M Enterprises,	Noor Safia	Khalid Mehmood	Approved. The
13.	03.0		Tillana Maninova	firm shall submit
	Office/Godown: KM Mansion	Pharm-D		undertaking that
	605-D block M.A Johar Town Lahore.			the premesis shall not be used for
	6000			residential
	ELI-00054			purposes and inpectors can enter
	1/No			premesis without
			10	hindrance.
14.	M/s AA Enterprizes,	Abu Bakar Siddique Bs Bio medical	Muhammad Waqas	Deferred for approval of
	Offce: 57, 15-16 First Floor Mobi	Engineering	WIII VS.	technical staff and
	Plaza, Haider Road, Saddar,	0011		undertaking that
	Rawalpindi	$G_{\alpha}$	J.5.	the premesis shall not be used for
	Godown:	odul omber	O	residential
	Plot No. 4, House No. 286/4, Main Peshawar Road, Rawalpindi	o dillo		purposes and
	Westridge, Adjacent to Am-Anglo	* N. 700.		inpectors can enter premesis without
	School, Near Polo Ground,	our our		hindrance
	Rawalpindi.	0.010.		
	ELI-00525	40		
15.	M/s. Meritorious Business	Muhammad Haris	Mohammad raza jaffary	Approved
	Solutions (Pvt.) Ltd. Office/Godown: Office # 202,	Mustaib Bio Medical Engineer		
	2nd Floor, 153-D, Block-D, Civic			
	Center, Phase-4, Bahria Town,			
	Rawalpindi.			
	ELI-00208			

16.	M/s. ANWAR & SONS	Gohar Abid Pharmacist	Tahir Mahmood Khan	Approved
	Office: Apt #10, Safari Villas 2 Commercial Complex, Phase 7 Bahria Town, Rawalpindi	T Harmacist		
	Godown: LG 1 & 2, Asian Business Centre, GT Road (Main Gate Bahria Town Phase 7)			M
	ELI-00017		.90	
17.	M/s. Blazon Diagnostic	Muhammad Asif	Ahmar Zaman Khan	Approved
	Office no. 102, Muhammadia Plaza, Gordon College, Road	Pharm-D	W1215:2	
	Godown: Blazon House No.45, 46, 47, Rawalpindi cricket stadium, Double road, Rawalpindi	odul Oracion	1052,	
	ELI-00307	al all		
18.	M/s. Bilal Enterprises Office no 8, Commercial Complex, Safari Villas 2, Bahria Town Phase 7, Rawalpindi  Godown: B-41, Street No. 27, Sector F,	Muhammad Aqib Shahzad Pharmacist	Shagufta Naz	The board considered the findings of the insepector and found gross viloations of the Medical Devices
	DHA Phase 1, Islamabad ELI-00327		6) 61/8	Rules 2017 and Drap Act 2012. Therefore the board decided to issue show cause notice to the firm.
19.	M/s. Promed International	Arooj Khalid alvi	Ahmed Jamal	The board
	Office/Godown:	Pharmacist	(12,1)	considered the findings of the insepector and
	Cb-6349, Amar Pak Plaza, Jhelum Road, Rawalpindi, Pakistan ELI-00000	Pharmacist		found gross viloations of the Medical Devices Rules 2017 and Drap Act 2012. Therefore the board decided to issue show cause notice to the firm.
	Lunegay,			

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

#### **Deferred Renewal Cases:**

S.#	Name of Establishment	Name of Qualified Technical Person	Name of Management	Decision
1.	M/s Bay G Pharma, House No.		Abdul Farooq	Approved
	103A, A-Block, Satellite Town,	Ms. Bushra Ansari		
	Rawalpindi (ELI- 00016)		Abdul Shakoor Awan	
		Pharm-D	10	
			(5) (6:1)	
2.	M/s Promax Technology	Fariha Khan	Akhter Ehsan	Approved
	Pakistan, Suite No. 13, 2 <sup>nd</sup> Floor		// //	
	Majeed Plaza Bank Road,	Pharm-D	6	
	Saddar Rawalpindi	, G , o	33.	
	_	(1) -610	) ·	
	(ELI – 00014)	1000 1100		

#### REGISTRATION OF MEDICAL DEVICES FOR IMPORT

Fresh Application Submitted in Hard (Evaluator Ammar Ashraf Deputy Director MDMC)

S. No.	Name of Applicant(s)	Name of Manufacturer	Medical Device	Decision
1.	Farshine Medical Technology	Name of Manufacturer:	Brand Name:	Approved.
	Co. Pvt., Ltd., Office No. 3,	Farshine Medical Technology Co.	Farshine	Firm shall submit
	2nd Floor, Plot No. 20-D,	Ltd.,	Generic Name:	undertaking that
	Sharja Plaza, G10 Markaz,	Address:	Craniomaxillofacial	the applied product
	Islamabad	No. 58 Jinshui West Road,	Internal Fixation	will are compatible
		Ningxiang High-Tech Industrial	System	and will only be
	ELI-01434	Park, Changsha City, Hunan	Applied as: Family	used with the
		Province, China	Class: C	Farshine system
	<b>R&amp;I Date:</b> 01-07-2025	LOA	Models/Code/sizes	
	<b>Fee:</b> Rs. 100,000 vide deposit	Type: Copy	(as per FSC &	
	slip no. 78960163728	Notarization: Notarized	application	
		Validity: 18-03-2030		
		• FSC	IDW01, IDW02,	
		Type: Copy	IDW03	
		Issued By: Hunan Medical Product		
		Administration	Shelf Life: 5year	
		Legalization: Apostille		
		Validity: 07-04-2027		
	_ C	Free sale:		
		ISO – Certificate:		
	· ·	Type: Copy		
		Notarization: Yes		
	20	Validity: 07-04-2028		
	460			
		<b>CE certificate:</b> Notarized copy of		
		CE certificate, valid till 27-05-2024		
		has been submitted along with		

2.	M/s Link Traders, Office No.1& 2, Mezzanine Floor, Ahmad Trade Center, 2- B Commercial Area Nazimabad No, 2 Karachi.	declaration from M/s Farshine Medical Technology Co. Ltd., " that we have engaged 3 <sup>rd</sup> party (Uden Adriatic d.o.o) a notified body on 05-12-2020 for regulation on medical devices. They are in process for the renewal of our CE certificate.  Name of Manufacturer: Ortus Medi-Tech Co., Ltd. 203, Building C4, Tong Fu Yu Industrial Park, FuPing Road, Pin Di, Longgang 518117 Shenzhen, P.R. China.	Brand name: ORTUS  Generic Name: Disposable Peripheral Guide Wire	Approved
	(ELI- 00727)  R&I detail 25-08-2022  Fee: 20,000/- Slip: 23050005309  Fee: 11,000/- Slip: 783236993	• LOA Type: Copy Attested By: CCPIT Validity: 01-06-2027  • FSC (China)	Applied as: Family Class: B  Model/Codes/Sizes as Per FSC (Germany) and	
	Fee: 21,200/- Slip: 2033558701	Type: Copy Issued By: Market Supervision Administration Legalization: Not Legalized Validity: 28-02-2025  • FSC (Germany) Type: Copy of legalized Issued By: M/o Justice and Consumer Protection Legalization: Legalized Issue Date: 05-04-2017 Validity: Not mentioned  • ISO Certificate Type: Copy Notarization: Not	application:  OM-GW-P14150S OM-GW-P14180S OM-GW-P18150S OM-GW-P18180S OM-GW-P25150S OM-GW-P25180S OM-GW-P28150S OM-GW-P28150S OM-GW-P32150J OM-GW-P32150S OM-GW-P32150S OM-GW-P32150S OM-GW-P32150S OM-GW-P32260S OM-GW-P35150J OM-GW-P35260J	
	<b>S</b>	Validity: 06-08-2025  • CE Certificate Type: Copy Notarization: Not notarized Validity: 31-12-2028	<ul> <li>OM-GW-P35150S</li> <li>OM-GW-P35260S</li> <li>OM-GW-P38150J</li> <li>OM-GW-P38150S</li> <li>OM-GW-P38260S</li> <li>OM-GW-P38180S</li> <li>OM-GW-P38260J</li> </ul> Shelf life: <ul> <li>3 Years</li> </ul>	
3.	M/s Link Traders, Office No.1& 2, Mezzanine Floor, Ahmad Trade Center, 2- B Commercial Area Nazimabad No, 2 Karachi.	Name of Manufacturer: Ortus Medi-Tech Co., Ltd. 203, Building C4, Tong Fu Yu Industrial Park, FuPing Road, Pin Di, Longgang 518117 Shenzhen, P.R. China.	Brand name: ORTUS  Generic Name: Disposable Hemostasis Valve Kit	Approved
	(ELI- 00727)			

		- 104	Applied as: Kit	
	DOT 1 4 11	• LOA	Applied as. Kit	
	R&I detail	<b>Type:</b> Copy		
	25-08-2022	Attested By: CCPIT	Class: A	
	Fee: 5,000/-	Validity: 01-06-2027		
	Slip: 8571577773	,	Model/Codes/Sizes	
	Shp. 0371377773	Fig. (Cit.)		
		• FSC (China)	as Per FSC:	
		<b>Type:</b> Copy	HV01, HV02 & HV03	
		<b>Issued By:</b> Market Supervision		
		Administration	Shelf life:	
			5 Years	
		Legalization: Not Legalized	3 Tears	
		Validity: 28-02-2025	~ ^0	
		• FSC (Germany)	(3,7,2).	
		<b>Type:</b> Copy of legalized		
		<b>Issued By:</b> M/o Justice and		
		Consumer Protection	יפה	
		Legalization: Legalized		
		Issue Date: 05-04-2017	, .	
		Validity: Not mentioned		
		by " D Wo		
		• ISO Certificate		
		<b>Type:</b> Copy		
		Notarization: Not		
		Validity: 06-08-2025		
4.	Farshine Medical Technology	Name of Manufacturer:	Brand Name:	Approved.
	Co. Pvt., Ltd., Office No. 3,	Farshine Medical Technology Co.	Farshine	Firm shall submit
	2nd Floor, Plot No. 20-D,	Ltd.,	Generic Name:	undertaking that
		Address:	Craniomaxillofacial	•
	Sharja Plaza, G10 Markaz,			the applied product
	Islamabad	No. 58 Jinshui West Road,	Internal Fixation	will are compatible
		Ningxiang High-Tech Industrial	System	and will only be
	ELI-01434	Park, Changsha City, Hunan	<b>Applied as:</b> Family	used with the
		Province, China	Class: C	Farshine system
	<b>R&amp;I Date:</b> 01-07-2025	LOA	Models/Code/sizes	T disimile system
	<b>Fee:</b> Rs. 100,000 vide deposit	_		
	· •	Type: Copy	(as per FSC &	
	slip no. 381024934787	Notarization: Notarized	application	
		<b>Validity:</b> 18-03-2030		
		• FSC	JDW07, JDW06,	
		Type: Copy	JDW05, JDW04,	
			JDW03, JDW02	
		<b>Issued By:</b> Hunan Medical Product	35 11 03, 35 11 02	
		Administration	G1 107.10	
		<b>Legalization</b> : Apostille	Shelf Life: 5year	
		Validity: 07-04-2027		
		Free sale:		
		ISO – Certificate:		
	C	<b>Type:</b> Copy		
	Dis	Notarization: Yes		
		Validity: 07-04-2028		
	4	<b>CE certificate:</b> Notarized copy of		
		* *		
	20	CE certificate, valid till 27-05-2024		
	60	has been submitted along with		
		declaration from M/s Farshine		
		Medical Technology Co. Ltd.,		
		"that we have engaged 3 <sup>rd</sup> party		ļ ,
1				
		(Uden Adriatic d.o.o) a notified		
		body on 05-12-2020 for regulation		
	<u> </u>		l	

		on medical devices. They are in		
		process for the renewal of our CE		
		certificate.		
_	E 1' M 1' 1 T 1 1		D 137	A 1
5.	Farshine Medical Technology	Name of Manufacturer:	Brand Name:	Approved.
	Co. Pvt., Ltd., Office No. 3,	Farshine Medical Technology Co.	Farshine	Firm shall submit
	2nd Floor, Plot No. 20-D,	Ltd.,	Generic Name:	undertaking that
	Sharja Plaza, G10 Markaz,	Address:	3D-Printed Titanium	the applied product
	Islamabad	No. 58 Jinshui West Road,	Porous Artifical	will are compatible
		Ningxiang High-Tech Industrial	Vertebral Replacment	and will only be
	ELI-01434	Park, Changsha City, Hunan	Applied as: Family	used with the
		Province, China	Class: C	Farshine system
	<b>R&amp;I Date:</b> 01-07-2025	LOA	Models/Code/sizes	
	Fee: Rs. 100,000 vide deposit	Type: Copy	(as per FSC &	
	slip no. 381024934787	Notarization: Notarized	application	
		Validity: 18-03-2030		
		• FSC	JCV-01, JCV-02,	
		Type: Copy	JCV-03, JCV-04	
		<b>Issued By:</b> Hunan Medical Product	Shelf Life: 5year	
		Administration	,	
		Legalization: Apostille		
		Validity: 07-04-2027		
		Free sale:		
		ISO – Certificate:		
	. 6	Type: Copy		
		Notarization: Yes		
		Validity: 07-04-2028		
		<b>CE certificate:</b> Notarized copy of		
		CE certificate, valid till 27-05-2024		
	COL	has been submitted along with		
		declaration from M/s Farshine		
		Medical Technology Co. Ltd.,		
		"that we have engaged 3 <sup>rd</sup> party	. 0,	
	Ť	(Uden Adriatic d.o.o) a notified		
		body on 05-12-2020 for regulation	191.6	
		on medical devices. They are in		
		process for the renewal of our CE		
		certificate.	6	
6.	Farshine Medical Technology	Name of Manufacturer:	Brand Name:	Approved.
1	Co. Pvt., Ltd., Office No. 3,	Farshine Medical Technology Co.	Farshine	Firm shall submit
1	2nd Floor, Plot No. 20-D,	Ltd.,	Generic Name:	undertaking that
	Sharja Plaza, G10 Markaz,	Address:	Craniomaxillofacial	the applied product
	Islamabad	No. 58 Jinshui West Road,	Internal Fixation	will are compatible
	1514IIIIIOUU	Ningxiang High-Tech Industrial	System	and will only be
	ELI-01434	Park, Changsha City, Hunan	<b>Applied as:</b> Family	used with the
	DDI VITOT	Province, China	Class: C	Farshine system
	<b>R&amp;I Date:</b> 01-07-2025	LOA	Models/Code/sizes	raisinne system
	<b>Fee:</b> Rs. 100,000 vide deposit	Type: Copy	(as per FSC &	
	± V	Notarization: Notarized	_ · · · -	
	slip no. 7252837416		application	
	10	Validity: 18-03-2030	IMO09 IMO07	
	600	• FSC	JMQ08, JMQ07,	
		Type: Copy	JMQ06, JMQ05,	
		<b>Issued By:</b> Hunan Medical Product	JMQ04, JMQ03,	
		Administration	JMQ02, JMQ01	
	▼	Legalization: Apostille	Shelf Life: 5 year	
		Validity: 07-04-2027		
		· · · · · · · · · · · · · · · · · · ·		

		Free sale:		
		ISO – Certificate:		
		Type: Copy Notarization: Yes		
		Validity: 07-04-2028		
		•		
		<b>CE certificate:</b> Notarized copy of		
		CE certificate, valid till 27-05-2024		
		has been submitted along with declaration from M/s Farshine		
		Medical Technology Co. Ltd.,		
		"that we have engaged 3 <sup>rd</sup> party	0,	
		(Uden Adriatic d.o.o) a notified	1/0	
		body on 05-12-2020 for regulation	(5) (6.)	
		on medical devices. They are in		
		process for the renewal of our CE	, / L	
		certificate.	6	
7.	Farshine Medical Technology	Name of Manufacturer:	Brand Name:	Approved.
/ .	Co. Pvt., Ltd., Office No. 3,	Farshine Medical Technology Co.	Farshine	Firm shall submit
	2nd Floor, Plot No. 20-D,	Ltd.,	Generic Name:	undertaking that
	Sharja Plaza, G10 Markaz,	Address:	Craniomaxillofacial	the applied product
	Islamabad	No. 58 Jinshui West Road,	Internal Fixation	will are compatible
		Ningxiang High-Tech Industrial	System	and will only be
	ELI-01434	Park, Changsha City, Hunan	<b>Applied as:</b> Family	used with the
		Province, China	Class: C	Farshine system
	<b>R&amp;I Date:</b> 01-07-2025	LOA	Models/Code/sizes	Tursinine system
	Fee: Rs. 100,000 vide deposit	Type: Copy	(as per FSC &	
	slip no. 27829315931	Notarization: Notarized	application	
		Validity: 18-03-2030		
	-0:00	• FSC	INQ01, INQ02	
	.(5	Type: Copy	Shelf Life: 5year	
		Issued By: Hunan Medical Product		
		Administration	0-	
	•	Legalization: Apostille	~ ~~	
		Validity: 07-04-2027	191.6.	
		Free sale:		
		ISO – Certificate:		
		Type: Copy	661	
		Notarization: Yes		
		Validity: 07-04-2028	·	
		CE certificate: Notarized copy of		
		CE certificate, valid till 27-05-2024		
		has been submitted along with		
		declaration from M/s Farshine		
		Medical Technology Co. Ltd.,		
		"that we have engaged 3rd party		
	N.	(Uden Adriatic d.o.o) a notified		
	Y~	body on 05-12-2020 for regulation		
	. 1	on medical devices. They are in		
		process for the renewal of our CE		
		certificate.		
8.	Farshine Medical Technology	Name of Manufacturer:	Brand Name:	Approved.
	Co. Pvt., Ltd., Office No. 3,	Farshine Medical Technology Co.	Farshine	Firm shall submit
	2nd Floor, Plot No. 20-D,	Ltd.,	Generic Name:	undertaking that
	Sharja Plaza, G10 Markaz,	Address:		the applied product
1	Islamabad			will are compatible

		No. 58 Jinshui West Road,	Craniomaxillofacial	and will only be
	ELI-01434	Ningxiang High-Tech Industrial	Internal Fixation	used with the
	EDI UITOT	Park, Changsha City, Hunan	System	Farshine system
	Del D-4 01 07 2025	· ·	•	raisiiile systeiii
	<b>R&amp;I Date:</b> 01-07-2025	Province, China	Applied as: Single	
	<b>Fee:</b> Rs. 62,000 vide deposit	LOA	Class: C	
	slip no. 7912139354	<b>Type:</b> Copy	Models/Code/sizes	
		Notarization: Notarized	(as per FSC &	
		Validity: 18-03-2030	application	
		• FSC	**	
			LHAQ01	
		Type: Copy	2111201	
		Issued By: Hunan Medical Product	Shelf Life: 5year	
		Administration	Shell Life: Syear	
		Legalization: Apostille	7.3	
		Validity: 07-04-2027	7. V. P.	
		Free sale:		
		ISO – Certificate:	201	
		Type: Copy		
		Notarization: Yes		
		Validity: 07-04-2028		
		<b>CE certificate:</b> Notarized copy of		
		CE certificate, valid till 27-05-2024		
		has been submitted along with		
		declaration from M/s Farshine		
		Medical Technology Co. Ltd.,		
		"that we have engaged 3 <sup>rd</sup> party		
		(Uden Adriatic d.o.o) a notified		
		body on 05-12-2020 for regulation		
	20	on medical devices. They are in		
	450.	process for the renewal of our CE		
		certificate.		
9.	Farshine Medical Technology	Name of Manufacturer:	Brand Name:	Approved.
	Co. Pvt., Ltd., Office No. 3,	Farshine Medical Technology Co.	Farshine	Firm shall submit
	2nd Floor, Plot No. 20-D,	Ltd.,	Generic Name:	undertaking that
	Sharja Plaza, G10 Markaz,	Address:	Spinal Internal	the applied product
	Islamabad	No. 58 Jinshui West Road,		will are compatible
	Islamada	Ningxiang High-Tech Industrial		-
	ELI 01424			and will only be
	ELI-01434		Class: C	used with the
		Province, China	Models/Code/sizes	Farshine system
	<b>R&amp;I Date:</b> 01-07-2025	LOA	(as per FSC &	
	Fee: Rs. 100,000 vide deposit	Type: Copy	application	
	slip no. 7254983183	Notarization: Notarized		
		Validity: 18-03-2030	RCA01,RCA02,	
		• FSC	RCA03, RCA04,	
			RCA05	
		Type: Copy	Shelf Life: 5year	
		<b>Issued By:</b> Hunan Medical Product	Shen Life: Syear	
	De	Administration		
		Legalization: Apostille		
		Validity: 07-04-2027		
		Free sale:		
	Xo	ISO – Certificate:		
	460			
		Type: Copy		
		Notarization: Yes		
		Validity: 07-04-2028		
	, and the second	<b>CE certificate:</b> Notarized copy of		
		CE certificate, valid till 27-05-2024		
		<b>CE certificate:</b> Notarized copy of		

10.	Farshine Medical Technology Co. Pvt., Ltd., Office No. 3, 2nd Floor, Plot No. 20-D, Sharja Plaza, G10 Markaz, Islamabad ELI-01434  R&I Date: 01-07-2025 Fee: Rs. 62,000 vide deposit slip no. 965331199	has been submitted along with declaration from M/s Farshine Medical Technology Co. Ltd., "that we have engaged 3 <sup>rd</sup> party (Uden Adriatic d.o.o) a notified body on 05-12-2020 for regulation on medical devices. They are in process for the renewal of our CE certificate.  Name of Manufacturer: Farshine Medical Technology Co. Ltd., Address: No. 58 Jinshui West Road, Ningxiang High-Tech Industrial Park, Changsha City, Hunan Province, China LOA Type: Original Notarization: Notarized Validity: 18-03-2030  FSC Type: Original Issued By: Hunan Medical Product Administration Legalization: Apostille Validity: 07-04-2027 Free sale: ISO – Certificate: Type: Original Notarization: Yes Validity: 07-04-2028 CE certificate, valid till 27-05-2024 has been submitted along with declaration from M/s Farshine Medical Technology Co. Ltd., "that we have engaged 3 <sup>rd</sup> party (Uden Adriatic d.o.o) a notified body on 05-12-2020 for regulation	Brand Name: Farshine Generic Name: 3D-Printed Titanium Porous Interbody Fusion Cage System Applied as: Single Class: C Models/Code/sizes (as per FSC & application CV-I Shelf Life: 5year	Approved. Firm shall submit undertaking that the applied product will are compatible and will only be used with the Farshine system
		(Uden Adriatic d.o.o) a notified body on 05-12-2020 for regulation on medical devices. They are in process for the renewal of our CE certificate.		
11.	Farshine Medical Technology Co. Pvt., Ltd., Office No. 3, 2nd Floor, Plot No. 20-D, Sharja Plaza, G10 Markaz, Islamabad	Name of Manufacturer: Farshine Medical Technology Co. Ltd., Address: No. 58 Jinshui West Road, Ningxiang High-Tech Industrial	Brand Name: Farshine Generic Name: Craniomaxillofacial Internal Fixation System	Approved. Firm shall submit undertaking that the applied product will are compatible and will only be
	<b>R&amp;I Date:</b> 01-07-2025 <b>Fee:</b> Rs. 62,000 vide deposit slip no. 965331199	Park, Changsha City, Hunan Province, China LOA Type: Copy Notarization: Notarized Validity: 18-03-2030	Applied as: Single Class: C Models/Code/sizes (as per FSC & application IMQ01	used with the Farshine system

		• FSC	Shelf Life: 5year	
		Type: Copy Issued By: Hunan Medical Product Administration Legalization: Apostille Validity: 07-04-2027 Free sale: ISO – Certificate: Type: Copy Notarization: Yes Validity: 07-04-2028 CE certificate: Notarized copy of CE certificate, valid till 27-05-2024 has been submitted along with declaration from M/s Farshine Medical Technology Co. Ltd., "that we have engaged 3 <sup>rd</sup> party (Uden Adriatic d.o.o) a notified body on 05-12-2020 for regulation on medical devices. They are in process for the renewal of our CE certificate.		
12.	Farshine Medical Technology Co. Pvt., Ltd., Office No. 3, 2nd Floor, Plot No. 20-D, Sharja Plaza, G10 Markaz, Islamabad  ELI-01434  R&I Date: 01-07-2025 Fee: Rs. 100,000 vide deposit slip no. 655397348	Name of Manufacturer: Farshine Medical Technology Co. Ltd., Address: No. 58 Jinshui West Road, Ningxiang High-Tech Industrial Park, Changsha City, Hunan Province, China LOA Type: Copy Notarization: Notarized Validity: 18-03-2030 • FSC Type: Copy Issued By: Hunan Medical Product Administration Legalization: Apostille Validity: 07-04-2027 Free sale: ISO – Certificate: Type: Copy Notarization: Yes Validity: 07-04-2028 CE certificate: Notarized copy of CE certificate, valid till 27-05-2024 has been submitted along with declaration from M/s Farshine Medical Technology Co. Ltd., "that we have engaged 3 <sup>rd</sup> party (Uden Adriatic d.o.o) a notified body on 05-12-2020 for regulation on medical devices. They are in	Brand Name: Farshine Generic Name: 3D-Printed Titanium Porous Interbody Fusion Cage System Applied as: Family Class: C Models/Code/sizes (as per FSC & application ZCV-01, ZCV-02, ZCV-03, ZCV-04 Shelf Life: 5year	Approved. Firm shall submit undertaking that the applied product will are compatible and will only be used with the Farshine system

		process for the renewal of our CE		
13.	Farshine Medical Technology Co. Pvt., Ltd., Office No. 3, 2nd Floor, Plot No. 20-D, Sharja Plaza, G10 Markaz, Islamabad  ELI-01434  R&I Date: 01-07-2025 Fee: Rs. 100,000 vide deposit slip no. 51415510053	Name of Manufacturer: Farshine Medical Technology Co. Ltd., Address: No. 58 Jinshui West Road, Ningxiang High-Tech Industrial Park, Changsha City, Hunan Province, China LOA Type: Copy Notarization: Notarized Validity: 18-03-2030 • FSC Type: Copy Issued By: Hunan Medical Product Administration Legalization: Apostille Validity: 07-04-2027 Free sale: ISO – Certificate: Type: Copy Notarization: Yes Validity: 07-04-2028 CE certificate: Notarized copy of CE certificate, valid till 27-05-2024 has been submitted along with declaration from M/s Farshine Medical Technology Co. Ltd., "that we have engaged 3 <sup>rd</sup> party (Uden Adriatic d.o.o) a notified body on 05-12-2020 for regulation on medical devices. They are in	Brand Name: Farshine Generic Name: Craniomaxillofacial Internal Fixation System Applied as: Family Class: C Models/Code/sizes (as per FSC & application JNQ01. JNQ02, JNQ03 Shelf Life: 5year	Approved. Firm shall submit undertaking that the applied product will are compatible and will only be used with the Farshine system
14.	Farshine Medical Technology Co. Pvt., Ltd., Office No. 3, 2nd Floor, Plot No. 20-D, Sharja Plaza, G10 Markaz, Islamabad ELI-01434  R&I Date: 01-07-2025 Fee: Rs. 620,000 vide deposit slip no. 94188296496	process for the renewal of our CE certificate.  Name of Manufacturer: Farshine Medical Technology Co. Ltd., Address: No. 58 Jinshui West Road, Ningxiang High-Tech Industrial Park, Changsha City, Hunan Province, China LOA Type: Copy Notarization: Notarized Validity: 18-03-2030 • FSC Type: Copy Issued By: Hunan Medical Product Administration Legalization: Apostille Validity: 07-04-2027 Free sale:	Brand Name: Farshine Generic Name: Craniomaxillofacial Internal Fixation System Applied as: Family Class: C Models/Code/sizes (as per FSC & application THAQ01 Shelf Life: 5year	Approved. Firm shall submit undertaking that the applied product will are compatible and will only be used with the Farshine system

		ICO C4°6° 4		
15.	Farshine Medical Technology Co. Pvt., Ltd., Office No. 3, 2nd Floor, Plot No. 20-D, Sharja Plaza, G10 Markaz, Islamabad ELI-01434  R&I Date: 01-07-2025 Fee: Rs. 62,000 vide deposit slip no. 88588450	ISO – Certificate: Type: Copy Notarization: Yes Validity: 07-04-2028 CE certificate: Notarized copy of CE certificate, valid till 27-05-2024 has been submitted along with declaration from M/s Farshine Medical Technology Co. Ltd., "that we have engaged 3rd party (Uden Adriatic d.o.o) a notified body on 05-12-2020 for regulation on medical devices. They are in process for the renewal of our CE certificate.  Name of Manufacturer: Farshine Medical Technology Co. Ltd., Address: No. 58 Jinshui West Road, Ningxiang High-Tech Industrial Park, Changsha City, Hunan Province, China LOA Type: Copy Notarization: Notarized Validity: 18-03-2030 • FSC Type: Copy Issued By: Hunan Medical Product Administration Legalization: Apostille Validity: 07-04-2027 Free sale: ISO – Certificate: Type: Copy Notarization: Yes	Brand Name: Farshine Generic Name: 3D-Printed Titanium Porous Interbody Fusion Cage System Applied as: Single Class: C Models/Code/sizes (as per FSC & application JZ01 Shelf Life: 5year	Approved. Firm shall submit undertaking that the applied product will are compatible and will only be used with the Farshine system
	Thurse	Issued By: Hunan Medical Product Administration Legalization: Apostille Validity: 07-04-2027 Free sale: ISO – Certificate: Type: Copy	15,72:5:48 25,	
		on medical devices. They are in process for the renewal of our CE certificate.		
16.	Farshine Medical Technology	Name of Manufacturer:	Brand Name:	Approved.
	Co. Pvt., Ltd., Office No. 3,	Farshine Medical Technology Co.	Farshine	Firm shall submit
	2nd Floor, Plot No. 20-D,	Ltd.,	Generic Name:	undertaking that
	Sharja Plaza, G10 Markaz,	Address:	3D-Printed Titanium	the applied product
	Islamabad	No. 58 Jinshui West Road,	Porous Interbody	will are compatible
		Ningxiang High-Tech Industrial	Fusion Cage System	and will only be
			- solon ougo o jotolii	and will only be

	ELI-01434	Park, Changsha City, Hunan	Applied as: Single	used with the
		Province, China	Class: C	Farshine system
	<b>R&amp;I Date:</b> 01-07-2025	LOA	Models/Code/sizes	,
	Fee: Rs. 62,000 vide deposit	<b>Type:</b> Copy	(as per FSC &	
	slip no. 665668978476	Notarization: Notarized	application	
		Validity: 18-03-2030	YZ01	
		• FSC	Shelf Life: 5year	
		Type: Copy	,	
		<b>Issued By:</b> Hunan Medical Product		
		Administration		
		Legalization: Apostille	. 05	
		<b>Validity:</b> 07-04-2027		
		Free sale:	151.6.	
		ISO – Certificate:		
		Type: Copy		
		Notarization: Yes	561	
		Validity: 07-04-2028		
		<b>CE certificate:</b> Notarized copy of	V	
		CE certificate, valid till 27-05-2024		
		has been submitted along with		
		declaration from M/s Farshine		
		Medical Technology Co. Ltd.,		
		"that we have engaged 3 <sup>rd</sup> party		
		(Uden Adriatic d.o.o) a notified		
	<b>N</b> 9	body on 05-12-2020 for regulation		
		on medical devices. They are in		
		process for the renewal of our CE		
		certificate.		
17.	Farshine Medical Technology	Name of Manufacturer:	Brand Name:	Approved.
	Co. Pvt., Ltd., Office No. 3,	Farshine Medical Technology Co.	Farshine	Firm shall submit
	2nd Floor, Plot No. 20-D,	Ltd.,	Generic Name:	undertaking that
	Sharja Plaza, G10 Markaz,	Address:	3D-Printed Titanium	the applied product
	Islamabad	No. 58 Jinshui West Road,	Porous Interbody	will are compatible
		Ningxiang High-Tech Industrial	Fusion Cage System	and will only be
	ELI-01434	Park, Changsha City, Hunan	<b>Applied as:</b> Family	used with the
		Province, China	Class: C	Farshine system
	<b>R&amp;I Date:</b> 01-07-2025	LOA	Models/Code/sizes	
	Fee: Rs. 100,000 vide deposit	Type: Copy	(as per FSC &	
	slip no. 5299626801	Notarization: Notarized	application	
		<b>Validity:</b> 18-03-2030	MSS-01, MSS-02,	
		• FSC	MSS-03, MSS-04,	
		T	MSS-05, MSS-06	
		<b>Type:</b> Copy		
		Issued By: Hunan Medical Product	Shelf Life: 5year	
		Issued By: Hunan Medical Product		
	<b>N</b> S	<b>Issued By:</b> Hunan Medical Product Administration		
	P <sup>G</sup>	<b>Issued By:</b> Hunan Medical Product Administration <b>Legalization</b> : Apostille		
	PS	Issued By: Hunan Medical Product Administration Legalization: Apostille Validity: 07-04-2027		
	PS NOW	Issued By: Hunan Medical Product Administration Legalization: Apostille Validity: 07-04-2027 Free sale:		
	AS AS	Issued By: Hunan Medical Product Administration Legalization: Apostille Validity: 07-04-2027 Free sale: ISO – Certificate:		
	Ne Asi	Issued By: Hunan Medical Product Administration Legalization: Apostille Validity: 07-04-2027 Free sale: ISO – Certificate: Type: Copy		
	Aursday	Issued By: Hunan Medical Product Administration Legalization: Apostille Validity: 07-04-2027 Free sale: ISO – Certificate: Type: Copy Notarization: Yes		
	Ahursday	Issued By: Hunan Medical Product Administration Legalization: Apostille Validity: 07-04-2027 Free sale: ISO – Certificate: Type: Copy Notarization: Yes Validity: 07-04-2028		

		declaration from M/s Farshine Medical Technology Co. Ltd., "that we have engaged 3 <sup>rd</sup> party (Uden Adriatic d.o.o) a notified body on 05-12-2020 for regulation on medical devices. They are in process for the renewal of our CE certificate.		
18.	Farshine Medical Technology Co. Pvt., Ltd., Office No. 3, 2nd Floor, Plot No. 20-D, Sharja Plaza, G10 Markaz, Islamabad ELI-01434  R&I Date: 01-07-2025 Fee: Rs. 100,000 vide deposit slip no. 050984835496	Name of Manufacturer: Farshine Medical Technology Co. Ltd., Address: No. 58 Jinshui West Road, Ningxiang High-Tech Industrial Park, Changsha City, Hunan Province, China LOA Type: Copy Notarization: Notarized Validity: 18-03-2030 • FSC Type: Copy Issued By: Hunan Medical Product Administration Legalization: Apostille Validity: 07-04-2027 Free sale: ISO – Certificate: Type: Copy Notarization: Yes Validity: 07-04-2028 CE certificate: Notarized copy of CE certificate, valid till 27-05-2024 has been submitted along with declaration from M/s Farshine Medical Technology Co. Ltd., "that we have engaged 3 <sup>rd</sup> party (Uden Adriatic d.o.o) a notified body on 05-12-2020 for regulation on medical devices. They are in process for the renewal of our CE certificate.	Brand Name: Farshine Generic Name: 3D-Printed Titanium Porous Artificial Vertebral Replacement Applied as: Family Class: C Models/Code/sizes (as per FSC & application YCV-01, YCV-02, YCV-03, YCV-04, YCV-05 Shelf Life: 5year	Approved. Firm shall submit undertaking that the applied product will are compatible and will only be used with the Farshine system
19.	Farshine Medical Technology Co. Pvt., Ltd., Office No. 3, 2nd Floor, Plot No. 20-D, Sharja Plaza, G10 Markaz, Islamabad  ELI-01434  R&I Date: 01-07-2025  Fee: Rs. 62,000 vide deposit slip no. 121049907825	Name of Manufacturer: Farshine Medical Technology Co. Ltd., Address: No. 58 Jinshui West Road, Ningxiang High-Tech Industrial Park, Changsha City, Hunan Province, China LOA Type: Copy Notarization: Notarized Validity: 18-03-2030 • FSC	Brand Name: Farshine Generic Name: 3D-Printed Titanium Porous Interbody Fusion Cage System Applied as: Single Class: C Models/Code/sizes (as per FSC & application LN-01 Shelf Life: 5year	Approved. Firm shall submit undertaking that the applied product will are compatible and will only be used with the Farshine system

		Type: Copy Issued By: Hunan Medical Product Administration Legalization: Apostille Validity: 07-04-2027 Free sale: ISO – Certificate: Type: Copy Notarization: Yes Validity: 07-04-2028 CE certificate: Notarized copy of CE certificate, valid till 27-05-2024 has been submitted along with declaration from M/s Farshine Medical Technology Co. Ltd., "that we have engaged 3 <sup>rd</sup> party (Uden Adriatic d.o.o) a notified body on 05-12-2020 for regulation on medical devices. They are in process for the renewal of our CE certificate.	NS \2:5:\8	
20.	Farshine Medical Technology Co. Pvt., Ltd., Office No. 3, 2nd Floor, Plot No. 20-D, Sharja Plaza, G10 Markaz, Islamabad  ELI-01434  R&I Date: 01-07-2025 Fee: Rs. 100,000 vide deposit slip no. 26853109172	Name of Manufacturer: Farshine Medical Technology Co. Ltd., Address: No. 58 Jinshui West Road, Ningxiang High-Tech Industrial Park, Changsha City, Hunan Province, China LOA Type: Copy Notarization: Notarized Validity: 18-03-2030 • FSC Type: Copy Issued By: Hunan Medical Product Administration Legalization: Apostille Validity: 07-04-2027 Free sale: ISO – Certificate: Type: Copy Notarization: Yes Validity: 07-04-2028 CE certificate: Notarized copy of CE certificate, valid till 27-05-2024 has been submitted along with declaration from M/s Farshine Medical Technology Co. Ltd., "that we have engaged 3 <sup>rd</sup> party (Uden Adriatic d.o.o) a notified body on 05-12-2020 for regulation on medical devices. They are in process for the renewal of our CE certificate.	Brand Name: Farshine Generic Name: 3D-Printed Titanium Porous Interbody Fusion Cage System Applied as: Family Class: C Models/Code/sizes (as per FSC & application LV-I, LV-II, LV-III Shelf Life: 5 year	Approved. Firm shall submit undertaking that the applied product will are compatible and will only be used with the Farshine system

21.	Farshine Medical Technology	Name of Manufacturer:	Brand Name:	Approved.
21.	Co. Pvt., Ltd., Office No. 3,	Farshine Medical Technology Co.	Farshine	Firm shall submit
	2nd Floor, Plot No. 20-D,		Generic Name:	
		Ltd.,		U
	Sharja Plaza, G10 Markaz,	Address:	3D-Printed Porous	the applied product
	Islamabad	No. 58 Jinshui West Road,	Hip System	will are compatible
		Ningxiang High-Tech Industrial	<b>Applied as:</b> Family	and will only be
	ELI-01434	Park, Changsha City, Hunan	Class: C	used with the
		Province, China	Models/Code/sizes	Farshine system
	<b>R&amp;I Date:</b> 01-07-2025	LOA	(as per FSC &	Turbillio system
	<b>Fee:</b> Rs. 100,000 vide deposit	Type: Copy	application	
	slip no. 63815712761	Notarization: Notarized	HJ-I, HJ-II, HJ-III,	
	shp no. 03013712701			
		Validity: 18-03-2030	HJ-IV	
		• FSC	Shelf Life: 5 year	
		<b>Type:</b> Copy	V. V.	
		<b>Issued By:</b> Hunan Medical Product		
		Administration	101	
		Legalization: Apostille		
		<b>Validity:</b> 07-04-2027		
		Free sale:		
		ISO – Certificate:		
		Type: Copy		
		Notarization: Yes		
		Validity: 07-04-2028		
		CE certificate: Notarized copy of		
		CE certificate, valid till 27-05-2024		
	V~	has been submitted along with		
		declaration from M/s Farshine		
	20	Medical Technology Co. Ltd.,		
	460	"that we have engaged 3 <sup>rd</sup> party		
		(Uden Adriatic d.o.o) a notified		
		body on 05-12-2020 for regulation		
		on medical devices. They are in	. 95	
		process for the renewal of our CE		
		certificate.	151.6.	
22.	Farshine Medical Technology	Name of Manufacturer:	Brand Name:	Approved.
	Co. Pvt., Ltd., Office No. 3,	Farshine Medical Technology Co.	Farshine	Firm shall submit
	2nd Floor, Plot No. 20-D,	Ltd.,	Generic Name:	undertaking that
	Sharja Plaza, G10 Markaz,	Address:	3D-Printed Titanium	the applied product
	Islamabad	No. 58 Jinshui West Road,	Porous Artificial	will are compatible
	151amavau	Ningxiang High-Tech Industrial	Vertebral	-
	ELI 01/2/			and will only be
	ELI-01434	Park, Changsha City, Hunan	Replacement	used with the
	DOID 4 01 07 2027	Province, China	<b>Applied as:</b> Single	Farshine system
	<b>R&amp;I Date:</b> 01-07-2025	LOA	Class: C	
	<b>Fee:</b> Rs. 100,000 vide deposit	Type: Copy	Models/Code/sizes	
	slip no. 972932766	Notarization: Notarized	(as per FSC &	
1	20	Validity: 18-03-2030	application	
1	<b>Y</b>	• FSC	CV	
		Type: Copy	Shelf Life: 5year	
1		Issued By: Hunan Medical Product		
	20			
	-60	Administration		
		Legalization: Apostille		
		<b>Validity:</b> 07-04-2027		
		Free sale:		
	*	ISO – Certificate:		
1		Type: Copy		
1	İ	-JPU COPJ	<u> </u>	

		Notarization: Yes Validity: 07-04-2028 CE certificate: Notarized copy of CE certificate, valid till 27-05-2024 has been submitted along with declaration from M/s Farshine Medical Technology Co. Ltd., "that we have engaged 3 <sup>rd</sup> party (Uden Adriatic d.o.o) a notified body on 05-12-2020 for regulation on medical devices. They are in process for the renewal of our CE certificate.	S) 5.18	SM
23.	Farshine Medical Technology Co. Pvt., Ltd., Office No. 3, 2nd Floor, Plot No. 20-D, Sharja Plaza, G10 Markaz, Islamabad ELI-01434  R&I Date: 01-07-2025 Fee: Rs. 100,000 vide deposit slip no. 448267529195	Name of Manufacturer: Farshine Medical Technology Co. Ltd., Address: No. 58 Jinshui West Road, Ningxiang High-Tech Industrial Park, Changsha City, Hunan Province, China LOA Type: Copy Notarization: Notarized Validity: 18-03-2030 • FSC Type: Copy Issued By: Hunan Medical Product Administration Legalization: Apostille Validity: 07-04-2027 Free sale: ISO – Certificate: Type: Copy Notarization: Yes Validity: 07-04-2028 CE certificate: Notarized copy of CE certificate, valid till 27-05-2024 has been submitted along with declaration from M/s Farshine Medical Technology Co. Ltd., "that we have engaged 3 <sup>rd</sup> party (Uden Adriatic d.o.o) a notified body on 05-12-2020 for regulation on medical devices. They are in process for the renewal of our CE certificate.	Brand Name: Farshine Generic Name: Spinal Internal Fixation System Applied as: Family Class: C Models/Code/sizes (as per FSC & application RLP01, RLP02, RLP03, RLP06, RLP08 Shelf Life: 5year	Approved. Firm shall submit undertaking that the applied product will are compatible and will only be used with the Farshine system
24.	Farshine Medical Technology Co. Pvt., Ltd., Office No. 3, 2nd Floor, Plot No. 20-D, Sharja Plaza, G10 Markaz, Islamabad ELI-01434	Name of Manufacturer: Farshine Medical Technology Co. Ltd., Address: No. 58 Jinshui West Road, Ningxiang High-Tech Industrial Park, Changsha City, Hunan Province, China	Brand Name: Farshine Generic Name: Craniomaxillofacial Internal Fixation System Applied as: Single Class: C	Approved. Firm shall submit undertaking that the applied product will are compatible and will only be used with the Farshine system

	<b>R&amp;I Date:</b> 01-07-2025	LOA	Models/Code/sizes	
	Fee: Rs. 62,000 vide deposit	Type: Copy	(as per FSC &	
	slip no. 321766868049	Notarization: Notarized	application	
	sup no. 321/00808049		аррисации	
		<b>Validity:</b> 18-03-2030	DII 1 001	
		• FSC	DHAQ01	
		<b>Type:</b> Copy		
		<b>Issued By:</b> Hunan Medical Product	Shelf Life: 5 year	
		Administration		
		Legalization: Apostille		
		<b>Validity:</b> 07-04-2027		
		Free sale:	. 95	
		ISO – Certificate:		
			151.6.	
		Type: Copy		
		Notarization: Yes	, / L	
		<b>Validity:</b> 07-04-2028	6	
		CE certificate: Notarized copy of		
		CE certificate, valid till 27-05-2024		
		has been submitted along with		
		declaration from M/s Farshine		
		Medical Technology Co. Ltd.,		
		"that we have engaged 3 <sup>rd</sup> party		
		(Uden Adriatic d.o.o) a notified		
		body on 05-12-2020 for regulation		
		on medical devices. They are in		
		process for the renewal of our CE		
		certificate.		
25.	M/s Martin Dow Specialties	Name of Manufacturer:	Brand Name:	Approved
23.	(Pvt) Limited	Legal Manufacturer:	Autoimmune Diabetes	ripproved
	7th Floor, Nice Trade Orbit	ShenzhenEver-Blue Biotech Co.,	Multi Control	
	Building, 44-A&B, Block-6,	Ltd,	Multi Control	
	_		Generic Name:	
	PECHS, Razi Road, Shahrah- e-Faisal, Karachi	Address: Building 1, YHLO		
		Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang	Immunoassay	
	(ELI-00160)		Controls	
	DOID (	District, Shenzhen, Guangdong	(Negative: 2 x 2.0ml)	
	R&I Date:		(Positive: 2 x 2.0ml)	
	10-07-2025	Manufacturing Site:		
	<b>Fee:</b> 31,000/-	Commissioned Production	Applied as: Kit	
	<b>Slip</b> # 83157121383	Enterprise):		
		SHENZHEN YHLO BIOTECH	Class: B	
		CO., LTD. Address: Building 2,		
		YHLO Biopark, Baolong 2nd	Models/Code/sizes	
		Road, Baolong Subdistrict,	(as per FSC &	
		Longgang	application:	
		District, Shenzhen, Guangdong	CC829	
		518116 China		
	N.		<b>Shelf Life:</b> 48 Months	
		LOA		
	4	Type: Copy		
		Notarization: No		
	7.0-	Validity: 31-12-2025		
	.45	•		
		• FSC		
		Type: Copy		
		<b>Issued By:</b> Provincial supervision		
		body (Country of Origin)		
		body (Country of Origin)		

		RRA FSC issued by Australian Government (TGA) Legalization: No Validity: 20-12-2026 (Country of Origin FSC) Date of Issue: 21-01-2025 (RRA FSC)  • ISO – Certificate: Type: Copy Notarization: No Validity: 14-11-2025  CE certificate: N/A	NS) 7:5:18	SIN
26. `	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah- e-Faisal, Karachi (ELI-00160)  R&I Date: 17-07-2025 Fee: 31,000/- Slip # 7526832805	Name of Manufacturer: SHENZHEN YHLO BIOTECH CO., LTD, Address: Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China  LOA Type: Copy Notarization: No Validity: 31-12-2025  • FSC Type: Copy Issued By: Provincial supervision body (Country of Origin) RRA FSC issued by Australian Government (TGA) Legalization: No Validity: 12-01-2026 (Country of Origin FSC) Date of Issue: 21-01-2025 (RRA FSC)  • ISO – Certificate: Type: Copy Notarization: No Validity: 09-06-2028 CE certificate: N/A	Brand Name: iFlash-17 α-OH-P  Generic Name: Chemiluminescent Immunoassay (2 x 50 Tests/Kit)  Applied as: Kit  Class: B  Models/Code/sizes (as per FSC & application: C86061  Shelf Life: 18 Months	Approved
27.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah- e-Faisal, Karachi (ELI-00160)  R&I Date:	Name of Manufacturer: SHENZHEN YHLO BIOTECH CO., LTD, Address: Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China	Brand Name: iFlash- Androstenedione  Generic Name: Chemiluminescent Immunoassay (2 x 50 Tests/Kit)	Approved

Fee: 31,000/- Slip # 426434124    Notarization: No Validity: 31-12-2025		17 07 2025	IOA	Applied as: W'	
Slip # 426434124  Notarization: No Validity: 31-12-2025		17-07-2025	LOA	Applied as: Kit	
Validity: 31-12-2025   FSC   Type: Copy   Issued By: Provincial supervision body (Country of Origin)   RRA FSC issued by Australian Government (TGA)   Legalization: No   Validity: 12-01-2025 (RRA FSC)			1		
## FSC Type: Copy   Issued By: Provincial supervision body (Country of Origin)   RR FSC issued by Australian Government (TGA)   Legalization: No Validity: 12-01-2026 (Country of Origin)   RR FSC issued by Australian Government (TGA)   Legalization: No Validity: 12-01-2025 (RRA FSC)    ### ISSO - Certificate: Type: Copy Notarization: No Validity: 09-06-2028   Name of Manufacturer: SHENZHEN YHLO BIOTECH (CO. LTD, Address: Building 1, 1 YHLO Biograf, Baolong 2nd Road, Baolong 2n		<b>Slip</b> # 426434124	Notarization: No	Models/Code/sizes	
Type: Copy Issued By: Provincial supervision body (Country of Origin) RRA FSC Issued by Australian Government (TGA) Legalization: No Validity: 2-01-2026 (Country of Origin FSC) Date of Issue: 21-01-2025 (RRA FSC)  **ISO - Certificate: Type: Copy Notarization: No Validity: 9-06-2028 CE certificate: N/A  **Approved**  Approved**  Approved*  A			Validity: 31-12-2025	(as per FSC &	
Type: Copy Issued By: Provincial supervision body (Country of Origin) RRA FSC Issued by Australian Government (TGA) Legalization: No Validity: 2-01-2026 (Country of Origin FSC) Date of Issue: 21-01-2025 (RRA FSC)  **ISO - Certificate: Type: Copy Notarization: No Validity: 9-06-2028 CE certificate: N/A  **Approved**  Approved**  Approved*  A			• FSC	application:	
Ssued By: Provincial supervision body (Country of Origin)   RRA FSC issued by Australian Government (TGA)   Legalization: No Validity: 12-01-2026 (Country of Origin FSC)   Date of Issue: 21-01-2025 (RRA FSC)					
body (Country of Origin) RRA FSC issued by Australian Government (TGA) Legalization: No Validity: 12-01-2026 (Country of Origin FSC) Date of Issue: 21-01-2025 (RRA FSC)  **ISO - Certificate: Type: Copy Notarization: No Validity: 09-06-2028 CE certificate: NA  Approved				C00002	
RRA FSC issued by Australian Government (TGA) Legalization: No Validity: 12-01-2026 (Country of Origin FSC) Date of Issue: 21-01-2025 (RRA FSC)  • ISO - Certificate: Type: Copy Notarization: No Validity: 09-06-2028 CE certificate: Name of Manufacturer: SHENZ/HEN YHLO BIOTECH Th Floor, Nice Trade Orbit Building: 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi (ELI-00160)  R&I Date: 17-07-2025 Fee: 31,0004 Slip # 148876279103  Validity: 31-12-2025 • FSC Type: Copy Issued By: Provincial supervision body (Country of Origin) RRA FSC issued by Australian Government (TGA) Legalization: No Validity: 12-01-2026 (Country of Origin FSC) Date of Issue: 21-01-2025 (RRA FSC)  • ISO - Certificate: Type: Copy Notarization: No Validity: 12-01-2026 (Country of Origin FSC) Date of Issue: 21-01-2025 (RRA FSC)  • ISO - Certificate: Type: Copy Notarization: No Validity: 09-06-2028 (CE certificate: N/A) Name of Manufacturer: Brand Name: Approved				Chalf I for 10 Manda	
Government (TGA) Legalization: No Validity: 12-01-2026 (Country of Origin FSC) Date of Issue: 21-01-2025 (RRA FSC)  • ISO - Certificate: Type: Copy Notarization: No Validity: 19-06-2028 CE certificate: N/A Approved  ### Address: Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang (ELI-00160)  ### R&I Date: 17-07-2025 Fee: 31,000/- Slip # 148876279103  ### Address: Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China  ### Applied as: Kit  LOA Type: Copy Issued By: Provincial supervision body (Country of Origin) District Shenzhen, Guangdong Sisued By: Provincial supervision body (Country of Origin) RRA FSC issued by Australian Government (TGA) Legalization: No Validity: 12-01-2025 (RRA FSC) Date of Issue: 21-01-2025 (RRA FSC)  • ISO - Certificate: Type: Copy Notarization: No Validity: 12-01-2025 (RRA FSC)  • ISO - Certificate: Type: Copy Notarization: No Validity: 09-06-2028 CE certificate: N/A  Approved  #### App				Shelf Life: 18 Months	
Legalization: No Validity: 12-01-2026 (Country of Origin FSC) Date of Issue: 21-01-2025 (RRA FSC)  • ISO – Certificate: Type: Copy Notarization: No Validity: 09-06-2028  ZE.  M/s Martin Dow Specialties (Pvt) Limited The Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah- e-Faisal, Karachi (ELI-00160)  R&I Date: 17-07-2025 Fee: 31,000/- Slip # 148876279103  LOA Type: Copy Notarization: No Validity: 31-12-2025 (FSC Type: Copy Issued By: Provincial supervision body (Country of Origin) Issued By: Provincial supervision body (Country of Origin) RRA FSC issued by Australian Government (TGA) Legalization: No Validity: 12-01-2025 (RRA FSC) Date of Issue: 21-01-2025 (RRA FSC)  • ISO – Certificate: Type: Copy Notarization: No Validity: 09-06-2028 CE certificate: N/A  29.  M/s Martin Dow Specialties Name of Manufacturer:  Brand Name: Approved iFlash – AMH Chemiluminescent Inluminescent Inluminescen			<b>RRA FSC</b> issued by Australian		
Validity: 12-01-2026 (Country of Origin FSC) Date of Issue: 21-01-2025 (RRA FSC)  • ISO - Certificate: Type: Copy Notarization: No Validity: 09-06-2028 CE certificate: N/A  28. M/s Martin Dow Specialties (Pv1) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah- e-Faisal, Karachi (ELI-00160) Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China  R&I Date: 17-07-2025 Fee: 31,000'- Slip # 148876279103  Notarization: No Validity: 31-12-2025 • FSC Type: Copy Issued By: Provincial supervision body (Country of Origin) RRA FSC issued by Australian Government (TGA) Legalization: No Validity: 12-01-2026 (Country of Origin PSC) Date of Issue: 21-01-2025 (RRA FSC)  • ISO - Certificate: Type: Copy Notarization: No Validity: 12-01-2026 (Country of Origin PSC) Date of Issue: 21-01-2025 (RRA FSC)  • ISO - Certificate: Type: Copy Notarization: No Validity: 09-06-2028 CE certificate: N/A  29. M/s Martin Dow Specialties Name of Manufacturer: Brand Name: Approved			Government (TGA)		
Validity: 12-01-2026 (Country of Origin FSC) Date of Issue: 21-01-2025 (RRA FSC)  • ISO - Certificate: Type: Copy Notarization: No Validity: 09-06-2028 CE certificate: N/A  28. M/s Martin Dow Specialties (Pv1) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah- e-Faisal, Karachi (ELI-00160) Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China  R&I Date: 17-07-2025 Fee: 31,000'- Slip # 148876279103  Notarization: No Validity: 31-12-2025 • FSC Type: Copy Issued By: Provincial supervision body (Country of Origin) RRA FSC issued by Australian Government (TGA) Legalization: No Validity: 12-01-2026 (Country of Origin PSC) Date of Issue: 21-01-2025 (RRA FSC)  • ISO - Certificate: Type: Copy Notarization: No Validity: 12-01-2026 (Country of Origin PSC) Date of Issue: 21-01-2025 (RRA FSC)  • ISO - Certificate: Type: Copy Notarization: No Validity: 09-06-2028 CE certificate: N/A  29. M/s Martin Dow Specialties Name of Manufacturer: Brand Name: Approved			Legalization: No	. %	
Origin FSC) Date of Issue: 21-01-2025 (RRA FSC)  • ISO - Certificate: Type: Copy Notarization: No Validity: 09-06-2028 CE certificate: N/A  Name of Manufacturer: Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah e-Faisal, Karachi (ELI-00160)  R&I Date: 17-07-2025 Fee: 31,000- Slip # 148876279103  Notarization: No Validity: 31-12-2025 • FSC Type: Copy Issued By: Provincial supervision body (Country of Origin) RAA FSC Issued by Australian Government (TGA) Legalization: No Validity: 12-01-2026 (Country of Origin FSC) Date of Issue: Type: Copy Notarization: No Validity: 12-01-2025 (RRA FSC)  • ISO - Certificate: Type: Copy Notarization: No Validity: 12-01-2025 (CRA FSC)  • ISO - Certificate: Type: Copy Notarization: No Validity: 12-01-2025 (CRA FSC)  • ISO - Certificate: Type: Copy Notarization: No Validity: 09-06-2028 CE-certificate: Type: Copy Notarization: No Validity: 09-06-2028 Chemiuminoassay (2 x 50 Tests/Kit) Chemiuminoassay (2 x 50 Te			_		
Date of Issue: 21-01-2025 (RRA FSC)  • ISO – Certificate: Type: Copy Notarization: No Validity: 09-06-2028 CE certificate: N/A Name of Manufacturer: (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah- c-Faisal, Karachi (EL1-00160)  R&I Date: 17-07-2025 Fee: 31,000/- Slip # 148876279103  LOA Type: Copy Notarization: No Validity: 31-12-2025 • FSC Type: Copy Issued By: Provincial supervision body (Country of Origin) RRA FSC issued by Australian Government (TGA) Legalization: No Validity: 21-01-2026 (Country of Origin FSC) Date of Issue: 21-01-2025 (RRA FSC) • ISO – Certificate: Type: Copy Notarization: No Validity: 21-01-2025 (REA FSC) • ISO – Certificate: Type: Copy Notarization: No Validity: 09-06-2028 CE  Evertificate: N/A  Physoved  Approved  Approved  Approved  Approved  Approved				12,70,	
SIO - Certificate: Type: Copy Notarization: No Validity: 09-06-2028   SHENZHEN YHLO BIOTECH (Pv) Limited (7th Floor, Nice Trade Orbit Building, 44-A&B, Block 6, PECHS, Razi Road, Shahrah-c-Faisal, Karachi (EL-00160)   Sill of China (EL					
ISO - Certificate:   Type: Copy     Notarization: No     Validity: 09-06-2028     CE certificate: N/A     Name of Manufacturer:     SHENZHEN YHLO BIOTECH     7th Floor, Nice Trade Orbit     Building, 44-A&B, Block-6,     PECHS, Razi Road, Shahrah-e-Faisal, Karachi     (ELI-00160)     R&I Date:     17-07-2025     Fee: 31,000/-     Slip # 148876279103     Slip # 148876279103     Sisued By: Provincial supervision     body (Country of Origin)     Susued By: Provincial supervision     body (Country of Origin)     CRAFE     Steep By: Provincial supervision     Steep By: Provincial supervision     Steep By: Provincial supervision     Shelf Life: 18 Months     Shel					
Type: Copy Notarization: No Validity: 09-06-2028 CE certificate: N/A  Name of Manufacturer: SHENZHEN YHLO BIOTECH 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah- e-Faisal, Karachi (ELI-00160)  R&I Date: 17-07-2025 Fee: 31,000/- Slip # 148876279103  Notarization: No Validity: 31-12-2025 - FSC Type: Copy Issued By: Provincial supervision body (Country of Origin) RSC Type: Copy Issued By: Provincial supervision body (Country of Origin) RRA FSC issued by Australian Government (TGA) Legalization: No Validity: 12-01-2026 (Country of Origin FSC) Date of Issue: 21-01-2025 (RRA FSC)  • ISO - Certificate: Type: Copy Notarization: No Validity: 09-06-2028 CE certificate: Type: Copy Notarization: No Validity: 09-06-2028 CE certificate: Type: Copy Notarization: No Validity: 09-06-2028 CE certificate: N/A Name of Manufacturer:  Brand Name:  Brand Name:  Approved			(RRA FSC)	6	
Type: Copy Notarization: No Validity: 09-06-2028 CE certificate: N/A  Name of Manufacturer: SHENZHEN YHLO BIOTECH The Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah- e-Faisal, Karachi (ELI-00160)  R&I Date: 17-07-2025 Fee: 31,000/- Slip # 148876279103  Notarization: No Validity: 31-12-2025 • FSC Type: Copy Issued By: Provincial supervision body (Country of Origin) RSC Seed by Australian Government (TGA) Legalization: No Validity: 12-01-2026 (Country of Origin FSC) Date of Issue: 21-01-2025 (RRA FSC)  • ISO - Certificate: Type: Copy Notarization: No Validity: 09-06-2028 CE certificate: N/A Name of Manufacturer:  Brand Name:  Approved			0,00	U.S.,	
Notarization: No Validity: 09-06-2028   CE certificate: N/A			• ISO – Certificate:		
Notarization: No Validity: 09-06-2028   CE certificate: N/A			Type: Copy		
Validity: 09-06-2028   CE certificate: N/A					
CE certificate: N/A   Amount of Manufacturer:   Brand Name:   Approved					
Name of Manufacturer:   SHENZHEN YHLO BIOTECH   SHENZHEN YHLO BIOTECH   SHENZHEN SHENZHEN YHLO BIOTECH   SHENZHE					
CPvt Limited   Third Floor, Nice Trade Orbit   Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrahe-Faisal, Karachi (ELI-00160)   Dispark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China   Applied as: Kit	20	M/s M-s-A-s D C + F4		D 1 N	A
7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah- e-Faisal, Karachi (ELI-00160)  R&I Date: 17-07-2025 Fee: 31,000/- Slip # 148876279103  LOA Type: Copy Notarization: No Validity: 12-01-2025 (Country of Origin) FSC Date of Issue: 21-01-2025 (RRA FSC)  ISO — Certificate: Type: Copy Notarization: No Validity: 12-01-2025 (RRA FSC)  ISO — Certificate: Type: Copy Notarization: No Validity: 19-01-2025 (Country of Origin) FSC Date of Issue: 21-01-2025 (RRA FSC)  ISO — Certificate: Type: Copy Notarization: No Validity: 09-06-2028 CE certificate: N/A  PSC M/s Martin Dow Specialties  Name of Manufacturer: Brand Name:  Generic Name: Chemiluminescent Immunoassay (2 x 50 Tests/Kit)  Shelf Life: 18 Months  Generic Name: Chemiluminescent Immunoassay (2 x 50 Tests/Kit)  Shelf Life: 18 Months  Generic Name: Chemiluminescent Immunoassay (2 x 50 Tests/Kit)  Applied as: Kit  Shelf Life: 18 Months  Shelf Life: 18 Months  Shelf Life: 18 Months	28.	_			Approved
Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi (ELI-00160)  R&I Date: 17-07-2025 Fee: 31,000/- Slip # 148876279103  Notarization: No Validity: 31-12-2025 FSC Type: Copy Issued By: Provincial supervision body (Country of Origin) FSC issued by Australian Government (TGA) Legalization: No Validity: 12-01-2026 (Country of Origin FSC) Date of Issue: 21-01-2025 (RRA FSC)  ISO — Certificate: Type: Copy Notarization: No Validity: 09-06-2028 CE certificate: N/A  PApproved  Address: Building 1, YHLO Biopark, Baolong 2nd Road, Baolong 2nd Road, Chemiluminescent Immunoassay (2 x 50 Tests/Kit)  Applied as: Kit  Class: B  Models/Code/sizes (as per FSC & application: C86316  Shelf Life: 18 Months				iFlash – AMH	
PECHS, Razi Road, Shahrahe-Faisal, Karachi (ELI-00160)  R&I Date: 17-07-2025 Fee: 31,000/- Slip # 148876279103  Notarization: No Validity: 31-12-2025 FSC Type: Copy Issued By: Provincial supervision body (Country of Origin) FSC issued by Australian Government (TGA) Legalization: No Validity: 12-01-2026 (Country of Origin FSC) Date of Issue: 21-01-2025 (RRA FSC)  ISO — Certificate: Type: Copy Notarization: No Validity: 09-06-2028 CE certificate: N/A  PECH Shark Rad, Shahrahe-Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 51816 China  Applied as: Kit  Class: B  Class: B  Models/Code/sizes (as per FSC & application: C86316  Shelf Life: 18 Months  Shelf Life: 18 Months  FSC issued by Australian Government (TGA) Legalization: No Validity: 12-01-2026 (Country of Origin FSC) Date of Issue: 21-01-2025 (RRA FSC)  ISO — Certificate: Type: Copy Notarization: No Validity: 09-06-2028 CE certificate: N/A  Pagnoved					
e-Faisal, Karachi (ELI-00160)  R&I Date: 17-07-2025 Fee: 31,000/- Slip # 148876279103  Notarization: No Validity: 31-12-2025 FSC Type: Copy Issued By. Provincial supervision body (Country of Origin) FSC Sisued by Australian Government (TGA) Legalization: No Validity: 12-01-2026 (Country of Origin FSC) Date of Issue: 21-01-2025 (RRA FSC)  ISO — Certificate: Type: Copy Notarization: No Validity: 09-06-2028 CE certificate: N/A  PSC issued by Australian Government (TGA) Legalization: No Validity: 12-01-2025 (RRA FSC)  ISO — Certificate: Type: Copy Notarization: No Validity: 09-06-2028 CE certificate: N/A  Pand Name: Approved		Building, 44-A&B, Block-6,	Address: Building 1, YHLO	Generic Name:	
e-Faisal, Karachi (ELI-00160)  R&I Date: 17-07-2025 Fee: 31,000/- Slip # 148876279103  REST Date: 17-07-2025 Fee: 31,000/- Slip # 148876279103  ROMAN FSC issued by Australian Government (TGA) Legalization: No Validity: 12-01-2026 (Country of Origin PSC) Date of Issue: 21-01-2025 (RRA FSC)  ISO — Certificate: Type: Copy Notarization: No Validity: 09-06-2028 CE certificate: N/A  Pappiled as: Kit  Applied as: Kit  Applied as: Kit  Class: B  Models/Code/sizes (a per FSC & application: C86316  Shelf Life: 18 Months  Shelf Life: 18 Months  FSC issue of Jasue: 21-01-2025 (RRA FSC)  Page of Issue: 21-01-2025 (RRA FSC)		PECHS, Razi Road, Shahrah-	Biopark, Baolong 2nd Road,	Chemiluminescent	
(ELI-00160)  District, Shenzhen, Guangdong 518116 China  R&I Date: 17-07-2025 Fee: 31,000/- Slip # 148876279103  Notarization: No Validity: 31-12-2025 FSC Type: Copy Issued By: Provincial supervision body (Country of Origin) RRA FSC issued by Australian Government (TGA) Legalization: No Validity: 12-01-2026 (Country of Origin FSC) Date of Issue: 21-01-2025 (RRA FSC)  Date of Issue: 21-01-2025 (RRA FSC)  ISO — Certificate: Type: Copy Notarization: No Validity: 09-06-2028 CE certificate: N/A  PSC issued by Australian Government (TGA) Legalization: No Validity: 09-06-2028 CE certificate: N/A  PSO — M/s Martin Dow Specialties  Name of Manufacturer: Brand Name: Approved		e-Faisal, Karachi		Immunoassav	
R&I Date: 17-07-2025 Fee: 31,000/- Slip # 148876279103  Notarization: No Validity: 31-12-2025 FSC Type: Copy Issued By: Provincial supervision body (Country of Origin) FSC issued by Australian Government (TGA) Legalization: No Validity: 12-01-2026 (Country of Origin FSC) Date of Issue: 21-01-2025 (RRA FSC)  ISO — Certificate: Type: Copy Notarization: No Validity: 09-06-2028 CE certificate: N/A  Pand Name: Approved				•	
R&I Date: 17-07-2025 Fee: 31,000/- Slip # 148876279103  Notarization: No Validity: 31-12-2025 • FSC Type: Copy Issued By: Provincial supervision body (Country of Origin) FSC issued by Australian Government (TGA) Legalization: No Validity: 12-01-2026 (Country of Origin FSC) Date of Issue: 21-01-2025 (RRA FSC)  • ISO — Certificate: Type: Copy Notarization: No Validity: 19-06-2028 CE certificate: N/A  29. M/s Martin Dow Specialties  Name of Manufacturer: Brand Name: Approved		(EEI-00100)		(2 X 50 Tests/Test)	
17-07-2025   LOA   Type: Copy   Class: B   Models/Code/sizes (as per FSC & application: No Validity: 31-12-2025   See FSC   Type: Copy   Issued By: Provincial supervision body (Country of Origin)   RRA FSC issued by Australian Government (TGA)   Legalization: No Validity: 12-01-2026 (Country of Origin FSC)   Date of Issue: 21-01-2025 (RRA FSC)		Del Deter	310110 Cililla	Applied on Vit	_ \
Fee: 31,000/- Slip # 148876279103  Type: Copy Notarization: No Validity: 31-12-2025 • FSC Type: Copy Issued By: Provincial supervision body (Country of Origin) RRA FSC issued by Australian Government (TGA) Legalization: No Validity: 12-01-2026 (Country of Origin FSC) Date of Issue: 21-01-2025 (RRA FSC)  • ISO — Certificate: Type: Copy Notarization: No Validity: 09-06-2028 CE certificate: N/A  Page M/s Martin Dow Specialties  Type: Copy Notarization: No Validity: 09-06-2028 CE certificate: N/A  Page M/s Martin Dow Specialties  Type: Copy Notarization: No Validity: 09-06-2028 CE certificate: N/A  Page M/s Martin Dow Specialties  Rodels/Code/sizes (as per FSC & application: C86316  Shelf Life: 18 Months  Shelf Life: 18 Months  Shelf Life: 18 Months			T 0.4	Applied as: Kit	
Slip # 148876279103  Notarization: No Validity: 31-12-2025  FSC Type: Copy Issued By: Provincial supervision body (Country of Origin) RRA FSC issued by Australian Government (TGA) Legalization: No Validity: 12-01-2026 (Country of Origin FSC) Date of Issue: 21-01-2025 (RRA FSC)  ISO - Certificate: Type: Copy Notarization: No Validity: 09-06-2028 CE certificate: N/A  Models/Code/sizes (as per FSC & application: C86316  Shelf Life: 18 Months  Fig. 18 Months  Shelf Life: 18 Months				-	
Validity: 31-12-2025 • FSC Type: Copy Issued By: Provincial supervision body (Country of Origin) RRA FSC issued by Australian Government (TGA) Legalization: No Validity: 12-01-2026 (Country of Origin FSC) Date of Issue: 21-01-2025 (RRA FSC)  • ISO - Certificate: Type: Copy Notarization: No Validity: 09-06-2028 CE certificate: N/A  29. M/s Martin Dow Specialties  Name of Manufacturer:  Brand Name: Approved			'=	Class: B	
• FSC Type: Copy Issued By: Provincial supervision body (Country of Origin) RRA FSC issued by Australian Government (TGA) Legalization: No Validity: 12-01-2026 (Country of Origin FSC) Date of Issue: 21-01-2025 (RRA FSC)  • ISO – Certificate: Type: Copy Notarization: No Validity: 09-06-2028 CE certificate: N/A  29. M/s Martin Dow Specialties Name of Manufacturer: Brand Name: Approved		<b>Slip</b> # 148876279103	Notarization: No	.C.)	
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Type: Copy Issued By: Provincial supervision body (Country of Origin) RRA FSC issued by Australian Government (TGA) Legalization: No Validity: 12-01-2026 (Country of Origin FSC) Date of Issue: 21-01-2025 (RRA FSC)  • ISO — Certificate: Type: Copy Notarization: No Validity: 09-06-2028 CE certificate: N/A  29. M/s Martin Dow Specialties  Type: Copy Name of Manufacturer: Brand Name: Approved			• FSC	(as per FSC &	
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Government (TGA) Legalization: No Validity: 12-01-2026 (Country of Origin FSC) Date of Issue: 21-01-2025 (RRA FSC)  • ISO – Certificate: Type: Copy Notarization: No Validity: 09-06-2028 CE certificate: N/A  29. M/s Martin Dow Specialties Name of Manufacturer: Brand Name: Approved				Shen Life: 18 Months	
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29. M/s Martin Dow Specialties Name of Manufacturer: Brand Name: Approved			I		
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(rvi) Limited 1Flasn – Folate	27.	_	rame of Manufacturer;		Approved
	<u></u>	(FVI) Limited		11 Tasii – Folate	

	7th Floor, Nice Trade Orbit	SHENZHEN YHLO BIOTECH		
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	Building, 44-A&B, Block-6,	CO., LTD,	Generic Name:	
	PECHS, Razi Road, Shahrah-	Address: Building 1, YHLO	Chemiluminescent	
	e-Faisal, Karachi	Biopark, Baolong 2nd Road,	Immunoassay	
	(ELI-00160)	Baolong Subdistrict, Longgang	(2 x 50 Tests/Kit)	
		District, Shenzhen, Guangdong		
	R&I Date:	518116 China	Applied as: Kit	
	17-07-2025	310110 Cililia	Applied as. 1010	
		104	Clares D	
	<b>Fee:</b> 31,000/-	LOA	Class: B	
	<b>Slip</b> # 44570875	Type: Copy		
		Notarization: No	Models/Code/sizes	<b>Y</b>
		<b>Validity:</b> 31-12-2025	(as per FSC &	
		• FSC	application:	
		Type: Copy	C86318	
			200310	
		<b>Issued By:</b> Provincial supervision	Shelf Life: 18 Months	
		body (Country of Origin)	Shell Life: 18 Months	
		RRA FSC issued by Australian		
		Government (TGA)		
		Legalization: No		
		<b>Validity:</b> 12-01-2026 (Country of		
		Origin FSC)		
		<b>Date of Issue</b> : 21-01-2025		
		(RRA FSC)		
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		Type: Copy		
		Notarization: No		
		Validity: 09-06-2028		
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		CE acadicianda NI/A		
20	75/ 75 (1 D G (14)	CE certificate: N/A	D IN	A 1
30.	M/s Martin Dow Specialties	Name of Manufacturer:	Brand Name:	Approved
30.	(Pvt) Limited	Name of Manufacturer: SHENZHEN YHLO BIOTECH	iFlash-25-OH	Approved
30.	7	Name of Manufacturer: SHENZHEN YHLO BIOTECH CO., LTD,		Approved
30.	(Pvt) Limited	Name of Manufacturer: SHENZHEN YHLO BIOTECH	iFlash-25-OH	Approved
30.	( <b>Pvt</b> ) <b>Limited</b> 7th Floor, Nice Trade Orbit	Name of Manufacturer: SHENZHEN YHLO BIOTECH CO., LTD, Address: Building 1, YHLO	iFlash-25-OH	Approved
30.	(Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-	Name of Manufacturer: SHENZHEN YHLO BIOTECH CO., LTD, Address: Building 1, YHLO Biopark, Baolong 2nd Road,	iFlash-25-OH Vitamin D Generic Name:	Approved
30.	(Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah- e-Faisal, Karachi	Name of Manufacturer: SHENZHEN YHLO BIOTECH CO., LTD, Address: Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang	iFlash-25-OH Vitamin D  Generic Name: Chemiluminescent	Approved
30.	(Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-	Name of Manufacturer: SHENZHEN YHLO BIOTECH CO., LTD, Address: Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong	iFlash-25-OH Vitamin D  Generic Name: Chemiluminescent Immunoassay	Approved
30.	(Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah- e-Faisal, Karachi (ELI-00160)	Name of Manufacturer: SHENZHEN YHLO BIOTECH CO., LTD, Address: Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang	iFlash-25-OH Vitamin D  Generic Name: Chemiluminescent	Approved
30.	(Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah- e-Faisal, Karachi (ELI-00160)  R&I Date:	Name of Manufacturer: SHENZHEN YHLO BIOTECH CO., LTD, Address: Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China	iFlash-25-OH Vitamin D  Generic Name: Chemiluminescent Immunoassay (2 x 50 Tests/Kit)	Approved
30.	(Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah- e-Faisal, Karachi (ELI-00160)  R&I Date: 17-07-2025	Name of Manufacturer: SHENZHEN YHLO BIOTECH CO., LTD, Address: Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China LOA	iFlash-25-OH Vitamin D  Generic Name: Chemiluminescent Immunoassay	Approved
30.	(Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah- e-Faisal, Karachi (ELI-00160)  R&I Date:	Name of Manufacturer: SHENZHEN YHLO BIOTECH CO., LTD, Address: Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China LOA Type: Copy	iFlash-25-OH Vitamin D  Generic Name: Chemiluminescent Immunoassay (2 x 50 Tests/Kit)	Approved
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30.	(Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah- e-Faisal, Karachi (ELI-00160)  R&I Date: 17-07-2025 Fee: 31,000/-	Name of Manufacturer: SHENZHEN YHLO BIOTECH CO., LTD, Address: Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China  LOA Type: Copy Notarization: No	iFlash-25-OH Vitamin D  Generic Name: Chemiluminescent Immunoassay (2 x 50 Tests/Kit)  Applied as: Kit	Approved
30.	(Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah- e-Faisal, Karachi (ELI-00160)  R&I Date: 17-07-2025 Fee: 31,000/-	Name of Manufacturer: SHENZHEN YHLO BIOTECH CO., LTD, Address: Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China  LOA Type: Copy Notarization: No Validity: 31-12-2025	iFlash-25-OH Vitamin D  Generic Name: Chemiluminescent Immunoassay (2 x 50 Tests/Kit)  Applied as: Kit  Class: B	Approved
30.	(Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah- e-Faisal, Karachi (ELI-00160)  R&I Date: 17-07-2025 Fee: 31,000/-	Name of Manufacturer: SHENZHEN YHLO BIOTECH CO., LTD, Address: Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China  LOA Type: Copy Notarization: No Validity: 31-12-2025 • FSC	iFlash-25-OH Vitamin D  Generic Name: Chemiluminescent Immunoassay (2 x 50 Tests/Kit)  Applied as: Kit Class: B  Models/Code/sizes	Approved
30.	(Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah- e-Faisal, Karachi (ELI-00160)  R&I Date: 17-07-2025 Fee: 31,000/-	Name of Manufacturer: SHENZHEN YHLO BIOTECH CO., LTD, Address: Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China  LOA Type: Copy Notarization: No Validity: 31-12-2025 • FSC Type: Copy	iFlash-25-OH Vitamin D  Generic Name: Chemiluminescent Immunoassay (2 x 50 Tests/Kit)  Applied as: Kit Class: B  Models/Code/sizes (as per FSC &	Approved
30.	(Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah- e-Faisal, Karachi (ELI-00160)  R&I Date: 17-07-2025 Fee: 31,000/-	Name of Manufacturer: SHENZHEN YHLO BIOTECH CO., LTD, Address: Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China  LOA Type: Copy Notarization: No Validity: 31-12-2025 • FSC Type: Copy Issued By: Provincial supervision	iFlash-25-OH Vitamin D  Generic Name: Chemiluminescent Immunoassay (2 x 50 Tests/Kit)  Applied as: Kit Class: B  Models/Code/sizes (as per FSC & application:	Approved
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30.	(Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah- e-Faisal, Karachi (ELI-00160)  R&I Date: 17-07-2025 Fee: 31,000/-	Name of Manufacturer: SHENZHEN YHLO BIOTECH CO., LTD, Address: Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China  LOA Type: Copy Notarization: No Validity: 31-12-2025 • FSC Type: Copy Issued By: Provincial supervision body (Country of Origin) RRA FSC issued by Australian	iFlash-25-OH Vitamin D  Generic Name: Chemiluminescent Immunoassay (2 x 50 Tests/Kit)  Applied as: Kit  Class: B  Models/Code/sizes (as per FSC & application: C86319	Approved
30.	(Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah- e-Faisal, Karachi (ELI-00160)  R&I Date: 17-07-2025 Fee: 31,000/-	Name of Manufacturer: SHENZHEN YHLO BIOTECH CO., LTD, Address: Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China  LOA Type: Copy Notarization: No Validity: 31-12-2025 • FSC Type: Copy Issued By: Provincial supervision body (Country of Origin)	iFlash-25-OH Vitamin D  Generic Name: Chemiluminescent Immunoassay (2 x 50 Tests/Kit)  Applied as: Kit Class: B  Models/Code/sizes (as per FSC & application:	Approved
30.	(Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah- e-Faisal, Karachi (ELI-00160)  R&I Date: 17-07-2025 Fee: 31,000/-	Name of Manufacturer: SHENZHEN YHLO BIOTECH CO., LTD, Address: Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China  LOA Type: Copy Notarization: No Validity: 31-12-2025 • FSC Type: Copy Issued By: Provincial supervision body (Country of Origin) RRA FSC issued by Australian	iFlash-25-OH Vitamin D  Generic Name: Chemiluminescent Immunoassay (2 x 50 Tests/Kit)  Applied as: Kit  Class: B  Models/Code/sizes (as per FSC & application: C86319	Approved
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30.	(Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah- e-Faisal, Karachi (ELI-00160)  R&I Date: 17-07-2025 Fee: 31,000/-	Name of Manufacturer: SHENZHEN YHLO BIOTECH CO., LTD, Address: Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China  LOA Type: Copy Notarization: No Validity: 31-12-2025 • FSC Type: Copy Issued By: Provincial supervision body (Country of Origin) RRA FSC issued by Australian Government (TGA) Legalization: No Validity: 12-01-2026 (Country of Origin FSC)	iFlash-25-OH Vitamin D  Generic Name: Chemiluminescent Immunoassay (2 x 50 Tests/Kit)  Applied as: Kit  Class: B  Models/Code/sizes (as per FSC & application: C86319	Approved
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30.	(Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah- e-Faisal, Karachi (ELI-00160)  R&I Date: 17-07-2025 Fee: 31,000/-	Name of Manufacturer: SHENZHEN YHLO BIOTECH CO., LTD, Address: Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China  LOA Type: Copy Notarization: No Validity: 31-12-2025 • FSC Type: Copy Issued By: Provincial supervision body (Country of Origin) RRA FSC issued by Australian Government (TGA) Legalization: No Validity: 12-01-2026 (Country of Origin FSC) Date of Issue: 21-01-2025 (RRA FSC)	iFlash-25-OH Vitamin D  Generic Name: Chemiluminescent Immunoassay (2 x 50 Tests/Kit)  Applied as: Kit  Class: B  Models/Code/sizes (as per FSC & application: C86319	Approved
30.	(Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah- e-Faisal, Karachi (ELI-00160)  R&I Date: 17-07-2025 Fee: 31,000/-	Name of Manufacturer: SHENZHEN YHLO BIOTECH CO., LTD, Address: Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China  LOA Type: Copy Notarization: No Validity: 31-12-2025 • FSC Type: Copy Issued By: Provincial supervision body (Country of Origin) RRA FSC issued by Australian Government (TGA) Legalization: No Validity: 12-01-2026 (Country of Origin FSC) Date of Issue: 21-01-2025	iFlash-25-OH Vitamin D  Generic Name: Chemiluminescent Immunoassay (2 x 50 Tests/Kit)  Applied as: Kit  Class: B  Models/Code/sizes (as per FSC & application: C86319	Approved
30.	(Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah- e-Faisal, Karachi (ELI-00160)  R&I Date: 17-07-2025 Fee: 31,000/-	Name of Manufacturer: SHENZHEN YHLO BIOTECH CO., LTD, Address: Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China  LOA Type: Copy Notarization: No Validity: 31-12-2025 • FSC Type: Copy Issued By: Provincial supervision body (Country of Origin) RRA FSC issued by Australian Government (TGA) Legalization: No Validity: 12-01-2026 (Country of Origin FSC) Date of Issue: 21-01-2025 (RRA FSC)	iFlash-25-OH Vitamin D  Generic Name: Chemiluminescent Immunoassay (2 x 50 Tests/Kit)  Applied as: Kit  Class: B  Models/Code/sizes (as per FSC & application: C86319	Approved

		Notarization: No		
		Validity: 09-06-2028		
		CE certificate: N/A		
31.	M/s Martin Dow Specialties	Name of Manufacturer:	Brand Name:	Approved
31.	(Pvt) Limited	SHENZHEN YHLO BIOTECH	iFlash-Anti-TSHR	Approved
	7th Floor, Nice Trade Orbit	CO., LTD,	II Iasii-Alia-TSTIK	
	Building, 44-A&B, Block-6,	Address: Building 1, YHLO	Generic Name:	
	PECHS, Razi Road, Shahrah-	Biopark, Baolong 2nd Road,	Chemiluminescent	
	e-Faisal, Karachi	-	Immunoassay	_ \
		Baolong Subdistrict, Longgang	(2 x 50 Tests/Kit)	
	(ELI-00160)	District, Shenzhen, Guangdong	(2 x 30 Tests/Kit)	
	DOLD 4	518116 China	Applied on Vit	
	<b>R&amp;I Date:</b>	7.04	Applied as: Kit	
	17-07-2025	LOA	Claus D	
	Fee: 31,000/-	Type: Copy	Class: B	
	<b>Slip#</b> 375652935	Notarization: No		
		Validity: 31-12-2025		
		• FSC	Models/Code/sizes	
		Type: Copy	(as per FSC &	
		<b>Issued By:</b> Provincial supervision	application:	
		body (Country of Origin)	C86049-S	
		RRA FSC issued by Australian	Shelf Life: 18 Months	
		Government (TGA)	Shell Bile. 10 Months	
		Legalization: No		
		<b>Validity:</b> 12-01-2026 (Country of		
		Origin FSC)		
	· ·	<b>Date of Issue</b> : 21-01-2025		
		(RRA FSC)		
	70-	• ISO – Certificate:		
	450	Type: Copy		
		Notarization: No		
		Validity: 09-06-2028		
		CE certificate: N/A		
32.	M/s Vertex Medical Pvt.	Name of Manufacturer:	Brand Name:	Deferred for
	Ltd.	ArjoHuntleigh AB	Sara Combilizer and S	clarification for
	<b>Address</b> : 401-402, Block – F,	Address:	ara Stedy, Sara Stedy	applying different
	Johar Town, Lahore	Hans Michelsensgatan 10 211 20	Compact	products and
	(ELI-0000150)	Malmo Sweden	Generic Name:	models in the same
		10,00	Standing and Raising	application shall be
	R&I Date:	LOA	AidApplied as:	provided.
	17-06-2021	Type: Copy	Single	•
	<b>Fee:</b> 5,000/-	Notarization: Legalized		
	<b>Slip</b> # 50441495384	Validity: 31-12-2025	Class: A	
	The second secon	• FSC		
		Type: Copy	Models/Code/sizes	
		Issued By: Swedish Medical	(as per FSC &	
		Products Agency	application:	
		Legalization: Legalized	Sara Stedy NTB2000	
		Issued date: 12-07-2023	Sara Stedy Compact	
		\ 10	NTB 3000	
	200	• ISO – Certificate:	Shelf Life: 10 years	
	.45	Type: Copy	Shell Life. 10 years	
		Notarization: Notarized		
		Validity: 05-01-2027		
		CE certificate: N/A		
				<del></del>

33.	M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore (ELI-0000150)	Name of Manufacturer: ArjoHuntleigh AB Address: Hans Michelsensgatan 10 211 20 Malmo Sweden	Brand Name: Concerto Generic Name: Shower Trolley Class: A	Approved
	<b>R&amp;I Date:</b> 17-06-2021 <b>Fee:</b> 5,000/- <b>Slip#</b> 8517158444	Type: Copy Notarization: Legalized Validity: 31-12-2025 • FSC Type: Copy Issued By: Swedish Medical Products Agency Legalization: Legalized Issued date: 12-07-2023 • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 05-01-2027 CE contilinates NA	Models/Code/sizes (as per FSC & application: Concentro: BABxxX-XX Shelf Life: 10 years	
34.	M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore (ELI-0000150)  R&I Date: 17-06-2021 Fee: 5,000/- Slip# 988217621186	CE certificate: N/A  Name of Manufacturer: ArjoHuntleigh AB Address: Hans Michelsensgatan 10 211 20 Malmo Sweden  LOA Type: Copy Notarization: Legalized Validity: 31-12-2025 • FSC Type: Copy Issued By: Swedish Medical Products Agency Legalization: Legalized Issued date: 12-07-2023 • ISO – Certificate: Type: Copy Notarization: Notarized	Brand Name: Carevo Generic Name: Shower Trolley Class: A  Models/Code/sizes (as per FSC & application: BAC11xX-XX Shelf Life: 10 years	Approved
35.	M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore (ELI-0000150)  R&I Date: 17-06-2021 Fee: 5,000/- Slip# 988217621186	Validity: 05-01-2027 CE certificate: N/A Name of Manufacturer: ArjoHuntleigh AB Address: Hans Michelsensgatan 10 211 20 Malmo Sweden  LOA Type: Copy Notarization: Legalized Validity: 31-12-2025 • FSC Type: Copy	Brand Name: Sara Combilizer Generic Name: Standing and Raising Aid Class: A  Models/Code/sizes (as per FSC & application: APA1000xx Shelf Life: 10 years	Approved

		Issued By: Swedish Medical Products Agency		
		Legalization: Legalized Issued date: 12-07-2023		
		• ISO – Certificate: Type: Copy Notarization: Notarized		
		Validity: 05-01-2027 CE certificate: N/A		Na.
36.	M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore (ELI-0000150)  R&I Date:	Name of Manufacturer: ArjoHuntleigh AB Address: Hans Michelsensgatan 10 211 20 Malmo Sweden  LOA	Brand Name: Miranti Hygiene Lifters Generic Name: Standing and Raising Aid Class: A	Approved
	22-03-2021 Fee: 5,000/- Slip# 2078014	Type: Copy Notarization: Legalized Validity: 31-12-2025 • FSC Type: Copy Issued By: Swedish Medical Products Agency Legalization: Legalized Issued date: 12-07-2023 • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 05-01-2027 CE certificate: N/A	Models/Code/sizes (as per FSC & application: CEB8xxX-XX Shelf Life: 10 years	
37.	M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore (ELI-0000150)  R&I Date: 22-03-2021 Fee: 5,000/- Slip# 2078013	Name of Manufacturer: ArjoHuntleigh AB Address: Hans Michelsensgatan 10 211 20 Malmo Sweden  LOA Type: Copy Notarization: Legalized Validity: 31-12-2025 • FSC Type: Copy Issued By: Swedish Medical Products Agency Legalization: Legalized Issued date: 12-07-2023 • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 05-01-2027 CE certificate: N/A	Brand Name: Bolero Hygiene Lifters Generic Name: Standing and Raising Aid Class: A  Models/Code/sizes (as per FSC & application: CEB6xxx-Xx Shelf Life: 10 years	Approved

#### **DEFERRED CASES IMPORT (Ahsan Ul Haq Athar)**

S#	Importer Name	Manufacturer Details	Name of MD / Class / Codes / Shelf life / etc.	Decision
1.	Akash Traders, Flat No. 302, Office No. 07, Hina Palace, Housing Road, Civil Line Clifton, Karachi (ELI-00585)	Eyeol UK Ltd. 8 Apex Business Centre, Boscombe Road,Dunstable, UK LU5 4SB	EyeRhex (Trypan Blue Ophthalmic Solution)	Approved
2.	Noor International Noor House, 29-D, Block- 6, PECHS, Karachi -75400 (ELI-00061 Fee 62000/-	Top Corporation, 19-10 Senju-cho, Adachi-ku, Tokyo 120-0035, Japan  Meditop Corporation (M) SDN. BHD. (Plant 2), No. 3, Persiaran Usahawan, Taman IKS, Seksyen 9, 43650, Bandar Baru Bangi, Selangor Darul Ehsan, Malaysia Factory LOA valid till 31.12.2027  FSC Japan  Issue date 01.01.2025	TOP-5530  Syringe Pump 9018.1900  Class C Shelf life 6 years	Deferred for the following:  1. The LOA has been issued by Medicalnet International Singapore.  2. FSC states that the medical devices exported by TOP Corporation is manufactured under our supervision as stipulated in PMOT act of Japan. It does not clarify product marketing status in Japan. The availability status in the market of Japan is not clear.  3. copy of ISO is not notarized.  4. On FSC two manufacturing sites while as per Form 8A only one registrations site.
3.	Noor International Noor House, 29-D, Block- 6, PECHS, Karachi -75400 (ELI-00061 Fee 62000/-	Top Corporation, 19-10 Senju- Nakai-Cho, Adachi-Ku Tokyo 120- 0035, Japan  Inside Country of Origin: Top Corporation Koshigaya Factory, 40- 34 Noborito-cho, Koshigaya-shi Saitama, Japan  Meditop Corporation (M) SDN. BHD. (Plant 2), No. 3, Persiaran Usahawan, Taman IKS, Seksyen 9, 43650,	Infusion Pump MJ-210 Class C Shelf life 6 years	Deferred for the following:  1. The LOA has been issued by Medicalnet International Singapore.  2. FSC states that the medical devices exported by TOP Corporation is manufactured under our supervision as stipulated in PMOT act of Japan. It does not clarify product marketing status in Japan. The availability status in the market of Japan is not clear.  3. copy of ISO is not notarized.

	1	Dandar Dany Danai		4. On FSC two
		Bandar Baru Bangi,		
		Selangor Darul Ehsan,		manufacturing sites while
		Malaysia Factory		as per Form 8A only one
				registrations site.
		FSC issue date: 22-01-		
		2025		
4.	Applicant:	Legal Manufacturer	Brand name:	Approved
	M/s. Moody Global	Name: Shenzhen	Lifotronic	11
	Services	LifotronicTechnologyCo.,	Genericname:	OB.
	Address:OfficeNo.	Ltd	HBA1cReagentKits	
	14,2ndFloor,Mujahid	Address:UnitA4thfloor,	(IEC)	V.O
	plaza,JinnahAvenue,	Building15, YijingEstate,	Size/specification:	
	Bluearea,Islamabad,	No1008Songbairoad,		7
	44000,Pakistan.	NanshanDistrict,	100T/box	
	LicenseNo.	Shenzhencity, Guangdong	□ 200T/box	
	ELI-00926	province,518055,P.R	□ 400T/box	
	R&I date:	China.	Class:A	
	Not clear.	FSC	Shelflife:	
	Track ID:	Countryoforigin(China)	18months	
	7MP-68L-EWQ4	Validityperiod:24-09	Tomontino	
	Fee: PKR 5000/-	2022		
	Slip: 33438994	FSC		
	<b>Dated:</b> 08-12-2022	Referencecountry		
	Dated: 00-12-2022	(Germany)		
		Dateofissuance:		
		22-06-2021		
		LOAvalidity:		
		31-12-2027		
5.	M/s	Name: Shenzhen	Brand name:	Approved.
<i>J</i> .	Moody Global	Lifotronic Technology	Lifotronic	Approved.
	Services	Co., Ltd	Generic	
			name:	N 6
	Address: Office No		LUTEINIZING	
	14, 2nd Floor,	Address: Unit A, 4th	HORMONE	) *
	Mujahid Plaza,	Floor, Building 15,	(Electrochemil	
	Jinnah Avenue, Blue	Yijing Estate, No 1008	uminescence	
	Area, Islamabad	Songbai Road, Nanshan	Immunoassay)	
	44000, Pakistan	District, Shenzhen City,		
	2 2 7 2 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3	Guangdong Province, 518055, P.R China	Size/specifica	
	License No. ELI	J10033, F.K CIIIIIa	tion: 50T,	
	00926	FSC	100T, 2x100T	
	R&I detail:	Origin. China		
	26/10/2023	validity: 07/11/2022	Class: B	
	Fee Challan no.:	19,00		
	666882948276	LOA validity:	Shelf life:	
	25000	31/12/2027	12 months	
	dated 24/10/2023	13		
		10012407		
		<b>ISO13485</b> VALID until 25.4.24		
6.	M/s	Name: Shenzhen	Brand name:	Annroyad
0.	Moody Global	Lifotronic Technology	Lifotronic	Approved.
	Services	Co., Ltd	Generic	
	Del vices	Liu		
1			name:	
	Address: Office No		CHOLYGLYC	

	14, 2nd Floor,	Address: Unit A, 4th	INE -CG	
		Floor, Building 15,	(Electrochemil	
	Mujahid Plaza,	Yijing Estate, No 1008	`	
	Jinnah Avenue, Blue		uminescence	
	Area, Islamabad	Songbai Road, Nanshan	Immunoassay)	
	44000, Pakistan	District, Shenzhen City,		
		Guangdong Province,	Size/specifica	
	License No. ELI	518055, P.R China	tion: 50T,	
	00926	Fac	2x50T, 100T,	
	R&I detail:	FSC	2x100T	
	26/10/2023	Origin. China	2,11001	Old.
	Fee Challan no.:	validity: 07/11/2022	Class: B	
			Class. B	V.O
	0028351879	LOA validity:	a. 10110 S	
	25000	31/12/2027	Shelf life:	) *
	dated 24/10/2023		12 months	
		ISO13485	~(*) O\O;	
		VALID until 25.4.24	0, 42	
7.	M/s	Name: Shenzhen	Brand name:	Approved.
	Moody Global	Lifotronic Technology	Lifotronic	
	Services	Co., Ltd	Generic	
		1 × × × ×	name:	
	Address: Office No		ESTRADIOL	
	14, 2nd Floor,	Address: Unit A, 4th	(Electrochemil	
	Mujahid Plaza,	Floor, Building 15,	uminescence	
		Yijing Estate, No 1008		
	Jinnah Avenue, Blue	Songbai Road, Nanshan	Immunoassay)	
	Area, Islamabad	District, Shenzhen City,		
	44000, Pakistan	Guangdong Province,	Size/specifica	
	\ C	518055, P.R China	tion: 50T,	
	License No. ELI	-	100T, 2x100T	
	00926	FSC		_ ^
	R&I detail:	Origin. China	Class: B	
	26/10/2023	validity: 07/11/2022		
	Fee Challan no.:		Shelf life:	V.O
	01539320195	LOA validity:	6 months	
	25000	31/12/2027		) ~
	dated 24/10/2023		(18), 1, 1,	
	dated 24/10/2023			
		ISO13485	1'' 0'0'	
		VALID until 25.4.24	0, 2,	
8.	M/s	Name: Shenzhen	Brand name:	Approved
	Moody Global	Lifotronic Technology	Lifotronic	I F
	Services	Co., Ltd	Generic	
		1 1 1 10 10 10 10 10 10 10 10 10 10 10 1	name:	
	Address: Office No		TOTAL	
	14, 2nd Floor,	Address: Unit A, 4th	TRIIODOTHY	
		Floor, Building 15,		
	Mujahid Plaza,	Yijing Estate, No 1008	RONINE KIT	
	Jinnah Avenue, Blue	Songbai Road, Nanshan	(Electrochemil	
	Area, Islamabad	District, Shenzhen City,	uminescence	
	44000, Pakistan	Guangdong Province,	Immunoassay)	
	<b>\</b> 0	518055, P.R China		
	License No. ELI		Size/specifica	
	00926	FSC	tion: 100T,	
	R&I detail:	Origin. China	2x100T	
	26/10/2023	validity: 07/11/2022		
	Fee Challan no.:	_	Class: B	
	01539320195	LOA validity:	C10001 D	
	01337320173	<u> </u>		

	25000	31/12/2027	Shelf life:	
	dated 24/10/2023	31/12/2027	12 months	
	dated 24/10/2023		12 months	
		ISO13485		
		VALID until 25.4.24		
9.	M/s	Name: Shenzhen	Brand name:	Approved.
	Moody Global	Lifotronic Technology	Lifotronic	
	Services	Co., Ltd	Generic name:	
			PROCOLLAG EN III N	
	Address: Office No		TERMINAL PEPTIDE	Old.
	14, 2nd Floor,	Address: Unit A, 4th	(PIIINP) (Electrochemil	. 0
	Mujahid Plaza,	Floor, Building 15, Yijing Estate, No 1008	uminescence	V <sub>O</sub>
	Jinnah Avenue, Blue	Songbai Road, Nanshan	Immunoassay)	*
	Area, Islamabad	District, Shenzhen City,	Size/specification:	
	44000, Pakistan	Guangdong Province,	50T, 2X5O T , 100T,	
		518055, P.R China	2x100T Class: B	
	License No. ELI		Shelf life: 15 months	
	00926	FSC	· 0%	
	R&I detail:	Origin. China	4 A	
	26/10/2023	validity: 07/11/2022	3),	
	Fee Challan no.:			
	741065938	LOA validity: 31/12/2027		
	25000	31/12/2027		
	dated 24/10/2023	-613-10		
	1	ISO13485		
	V	VALID until 25.4.24		
10.	M/s	Name: Shenzhen	Brand name: Lifotronic	Approved.
•	Moody Global	Lifotronic Technology	Generic name:	rr
	Services	Co., Ltd	FOLLICLE	
			STIMULATING	
	Address: Office No		HORMONE	014
	14, 2nd Floor,	Address: Unit A, 4th	(Electrochemiluminescen	. 9.
	Mujahid Plaza,	Floor, Building 15,	ce Immunoassay)	70
	Jinnah Avenue, Blue	Yijing Estate, No 1008 Songbai Road, Nanshan	Size/specification: 50T,	<b>)</b>
	Area, Islamabad	District, Shenzhen City,	2X5O T, 100T, 2x100T	
	44000, Pakistan	Guangdong Province,	Class: B	
		518055, P.R China	Shelf life: 14 days	
	License No. ELI		0, 4/2	
	00926	FSC	, 42,	
	R&I detail:	Origin. China	- ( )	
	26/10/2023	validity: 07/11/2022	3, ,	
	Fee Challan no.:	TOA TITE		
	741065938	LOA validity:		
	25000	31/12/2027		
	dated 24/10/2023	651 MO		
	6	ISO13485		
	V	VALID until 25.4.24		
11.	M/s	Name: Shenzhen	Brand name:	Approved.
	Moody Global	Lifotronic Technology	Lifotronic	**
	Services	Co., Ltd	Generic	
			name:	
	Address: Office No		HYPERSENST	
	14, 2nd Floor,	Address: Unit A, 4th	IVITYC-	
	Mujahid Plaza,	Floor, Building 15,	REACTIVE	
	<u> </u>	Yijing Estate, No 1008		

	Jinnah Avenue, Blue Area, Islamabad	Songbai Road, Nanshan District, Shenzhen City,	PROTEIN (hs CRP ) Assay	
	44000, Pakistan	Guangdong Province, 518055, P.R China	kits(Lateral Flow	
	License No. ELI 00926	FSC	Immunoassay)	
	<b>R&amp;I detail:</b> 26/10/2023	Origin. China validity: 07/11/2022	Size/specifica tion: 1X 100T,	
	Fee Challan no.: 6876681318	LOA validity: 31/12/2027	2X 100T,	OF
	25000 dated 24/10/2023	31/12/2021	Class: B	18,
		<b>ISO13485</b> VALID until 25.4.24	Shelf life: 10 months	)*
12.	M/s	Name: Shenzhen	Brand name:	Approved.
	Moody Global	Lifotronic Technology	Lifotronic	
	Services	Co., Ltd	Generic	
		401, 200	name:	
	Address: Office No	Address: Unit A, 4th	FOLATE	
	14, 2nd Floor,	Floor, Building 15,	(Electrochemil	
	Mujahid Plaza,	Yijing Estate, No 1008	uminescence	
	Jinnah Avenue, Blue	Songbai Road, Nanshan	Immunoassay)	
	Area, Islamabad	District, Shenzhen City,		
	44000, Pakistan	Guangdong Province,	Size/specifica	
		518055, P.R China	tion: 50T,	
	License No. ELI		100T	
	00926	FSC	CI D	
	Receipt No.	Origin. China validity: 07/11/2022	Class: B Shelf life:	
	<b>R&amp;I detail:</b> 26/10/2023	LOA validity: 31/12/2027	12 months	48 PM
	Fee Challan no.: 15003630924	ISO13485 VALID until 25.4.24	1 (MIS) 5:5	
	25000	030	3/1 0/01	
	dated 24/10/2023	1 6	0, 4/2	
10	Continu	T 1 00 0 0 0		D 1
13.	Cardiac Care,	Legal Manufacturer:	Oxygen Mask and	5
	040 C Chadman 1 I ala	HSINER Co., Ltd	Accessories	MDB decision taken in its
	848-C, Shadman-1, Lahore-	312, Jhongshan Rd.,	Oxygen delivery mask	90 <sup>th</sup> meeting.
	54610, Pakistan.	Shengang Dist, Taichung	Class P	
	ELI-00070	City 426, Taiwan.	Class-B	
	ELI-000/0	FSC: Germany	Shelf Life: 3 Years	
		Date of Issuance: 14-11-	Shell Life. 3 Tears	
		2019.	Codes as per FSC	
14.	Cardiac Care,	Legal Manufacturer:	HME and HMEF	Rejected in the light of
14.	Cardiac Care,	HSINER Co., Ltd		.,
	848-C, Shadman-1, Lahore-	312, Jhongshan Rd.,	Moisture Exchange	MDB decision taken in its
	54610, Pakistan.	Shengang Dist, Taichung	iviolature Exchange	90 <sup>th</sup> meeting.
	ELI-00070	City 426, Taiwan.	Class-B	
	ELI-000/0	FSC: Germany	Shelf Life: 3 Years	
<u> </u>	l .	- Comming	2.1011 E110. 3 1 0a15	

		Date of Issuance: 14-11-		
		2019.	Codes as per FSC	
15.	Cardiac Care,	Legal Manufacturer:	CPAP/VPAP MASK	Rejected in the light of
		HSINER Co., Ltd	Positive airway pressure	MDB decision taken in its
	848-C, Shadman-1, Lahore-	312, Jhongshan Rd.,	mask.	90 <sup>th</sup> meeting.
	54610, Pakistan.	Shengang Dist, Taichung		
	EL 1 00070	City 426, Taiwan.	Class-B	
	ELI-00070	FSC: Germany	Shelf Life: 3 Years	
		Date of Issuance: 14-11-	Shell Life. 3 Tears	0
		2019.	Codes as per FSC	Yo
16.	Cardiac Care	Legal Manufacturer:	HORIZON AF PLUS	Deferred for the
10.	848-C Shadman-I Lahore.	EUROSETS S.r.l.	Oxygenator	followings:
		Strada Statale 12, n°143		1. clarification that firm
	ELI-00070	41036 Medolla (MO) Italy.	Class-B	claimed that original
	5984-P		0.00h	documents were
	31,000/-	FSC: Italy.	Shelf Life: 3.5 years	submitted with Kompass
		Date of Issuance: 12-07-		A. L. One vide R&I dated
		2024.	Model: AG5300	01.07.2024 while FSC
		LOA validity 31-12-2026 ISO 13485 validity 24-08-	AG3300	issuance date is
		2025		12.07.2024.
		CE certificate validity 26-		2. The Form 7A is
	6	05-2024 with extension		without undertaking and
	V	notification.		annexures.
		1		3. The name of device on
	×6			submitted Form 7A is
	450.			KOMPASS A.L. ONE
				oxygenator.
17.	Aston Medical Pakistan	Semikal Teknoloji Sanayi	Sectalon Intra-Articular	Deferred for:
	4-A 4th Floor 38c Bukhari	VE Ticaret Anonium	Gel	1. submission of FSC or
	Commercial, Lane 8, Phase 6,	Sirketi, AOSB 3, Kisim	1,51,6	FQA and Design
	Dha, Karachi	25, Cad. No: 14/11,	Sodium Hyaluronate	Examination Certificate
	(77.7.00-0-	Dosemealti,	30mg/2ml,	where strength and pack
	(ELI-00797	Antalya/Turkiye	Sodium Hyaluronate	size of the product is
	Date of R&I	LOA Validity: 25-03-2033	40mg/2ml, Sodium Hyaluronate	mentioned.
	30-04-2025	(notarized)	60mg/2.5ml,	2. Firm will apply
	30 OT 2023	(Hourizou)	Sodium Hyaluronate	separately for each
	Fee Details:	FSC Valid till: 30-01-2028	75mg/3ml,	strength.
	Paid Fee: 62030/-	(notarized)	Sodium Hyaluronate	3. Firm will provide the
	Fee Challan No:	(40, 10)	90mg/3ml,	stability data for each
	135864189	ISO Validity: 17-03-2026	Sodium Hyaluronate	product.
		(notarized)	Cross Linked %	•
	Y	FG (FGA)	2.4/2.5ml, Sodium Hyaluronate	
		EC (FQA) certificate 27-	Cross Linked %	
	10	05-2024 (notarized)	2.5/3ml,	
	,cO'	Design Examination	Sodium Hyaluronate	
		Certificate valid up to 27-	Cross Linked	
	N/Up	05-2024 (notarized)	% 3/3.0ml	
			~. ~	
			Class C	

18.	Applicant Name:  MBS Distributor Address: Flat 101,Shah Alam Arcade,Defence road Rawalpindi  (ELI-01287)  Date of R&I 15-04-2025	Name of Manufacturer:  M/s. Nanyang Major Medical Products Co. Ltd.  Address: No.16 County Road, Jinhua Town, Wancheng District, Nanyang City, Henan Province, China	Shelf Life: 5 years Applied as: Single  Models/ Specification; as above  Brand name:  Surgical Pack  Class-A  Shelf life: 03 Years  Models/ Specification: Spinal pack Craniotomy pack, Cardiovascular pack, Biopsy pack, Universal pack, Cesarean	Deferred for the following:  1. FSC issued by chamber of commerce instead of relevant regulatory authority.  2. Clarification that the name of device on FSC is Surgical Pack (Spinal Pack), name of the device on sample label is Spinal
19.	Fee Details: Paid Fee: 6,000/- Fee Challan No: 735163614509 Dated: 26-04-2025  Applicant Name: M/s Biocare Enterprises, Plot No. 64/2 St#17, FECHS (NPF) 0-9 PWD Road, Islamabad	LOA Validity: 31-12-2028  FSC: China Validity: 04-03-2027  ISO Validity: 14-08-2026  M/s Shenzhen Cornley Bio-Medical Co., Ltd., 6/F Building 10, Block 3, Yangbei Industrial Park, Huangtian Community,	Cornley Vitagas 5 Series Blood Gas and Electrolyte Analyser and their related reagent,	Drape Set and name of device on Form 6A is Spinal Pack.  Deferred for the following: 1. original documents not provided. 2. FSC of RRA or Ce
	(ELI-00220)  Date of R&I 11-04-2025  Fee Details: Paid Fee: 50000/- Slip No. 1165944563	Hangcheng Street, Bao'an 518128, China  LOA Validity: 16-01-2030  FSC: Germany Issue date: 28-02-2022  FSC: China Validity: 04-08-2026  ISO Validity: 08-12-2026	consumables, Accessories and Spare parts  Class-B  Shelf life: not mentioned  Models/ Specification: Not specified	marking Certificate no provided.  3. manufacturin credential not provided.  4. shelf life/ stability dat not provided.  5. clarification require that name of product o DOC is Blood Ga Electrolyte Analyzer.
20.	Hospital Supply corporation 42 Darul Aman Housing Society, Block 7&8, Karachi (ELI-00005	Medkonsult Medical technology s.r.o., Pasteurova 67/15, Klasterni Hradisko, 77900 Olomouc, Czech Republic	MMT Denflow Chord PC Class B	Deferred for the followings:  1. submitted LOA is not notarized.  2. FSC of RRA or CE marking certificate not attached.

21.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah- e-Faisal, Karachi ELI-00160 Date of R& I 10-01-2022 Fee: PKR 25,000/- Slip #610948064 Dated: 05-01-2022	Legal Manufacturer Fortress Diagnostic Limited, Unit 2C Antrim Technology Park, Belfast Road, Antrim BT41, 1QS, UK  Documents Submitted:  ISO 13485 certificate validity: 28-02-2022 LOA validity: 17-Jan- 2023	Brand name: HbA1c-Modified Enzymatic Reagent  Generic Name: HbA1c-Modified Enzymatic Reagent (IVD for HbA1c in human blood) (Reagent 01: 1x30ml) (Reagent 02: 1x10ml)  Models/ Specification (as per Free sale certificate): BXC0670A	3. Multiple codes has been applied in single medical device.  Deferred for the following.  1. Firm has not submitted the brand name.  2. The volume 30ml and 10ml not mentioned in FSC.  3. The address of manufacture on LOA and FSC is different from address provided on Form 7A.
	Thursda	sistant Ding	Class-B  Shelf life: At Optimum Temperature: 24 Months On board Stability: 06 months Storage Conditions: 2 - 8°C FSC country of origin validity: Date of Issue: 01-03- 2017 FSC RRA validity: N/A	18 PM
22.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah- e-Faisal, Karachi ELI-00160 Date of R& I 10-01-2022 Fee: PKR 25,000/- Slip #6429326603 Dated: 05-01-2022	Legal Manufacturer Fortress Diagnostic Limited, Unit 2C Antrim Technology Park, Belfast Road, Antrim BT41, 1QS, UK Documents Submitted:  ISO 13485 certificate validity: 28-02-2022 LOA validity: 17-Jan- 2023  FSC country of origin validity: Date of Issue: 01-03-2017	Brand name: HbA1c-Calibrator Set (2 levels)  Generic Name: HbA1c- Calibrator Set (Level 01: 2x0.5ml) (Level 02: 2x0.5ml)  Models/ Specification (as per Free sale certificate): BXC0678A  Class-B  Shelf life: 18 months  Storage Conditions: 2 - 8°C	Deferred for the followings:  1. Firm has not submitted the brand name.  2. The (Level 01: 2x0.5ml) (Level 02: 2x0.5ml) not mentioned in FSC.  3. The address of manufacture on LOA and FSC is different from address provided on Form 7A.

23.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah- e-Faisal, Karachi ELI-00160 Date of R& I 10-01-2022 Fee: PKR 25,000/- Slip #2813460301 Dated: 05-01-2022	Legal Manufacturer Fortress Diagnostic Limited, Unit 2C Antrim Technology Park, Belfast Road, Antrim BT41, 1QS, UK Documents Submitted:  ISO 13485 certificate validity: 28-02-2022 LOA validity: 17-Jan- 2023  FSC country of origin validity: Date of Issue: 01-03-2017	Brand name: HbA1c-Control Set (2 levels)  Generic Name: HbA1c- Control Set (Level 01: 1x0.5ml) (Level 02: 1x0.5ml)  Models/ Specification (as per Free sale certificate): BXC0669A  Class-B  Shelf life: 24 months  Storage Conditions: 2 - 8°C	Deferred for the followings:  1. Firm has not submitted the brand name.  2. The (Level 01: 1x0.5ml) (Level 02: 1x0.5ml) not mentioned in FSC.  3. The address of manufacture on LOA and FSC is different from address provided on Form 7A.
24.	Applicant Name:  M/s. Martin Dow Specialities Private Limited. Nice Trade Orbit Building 7th Floor, 44-A, Block 6, PECHS, Shahrah0-e-Karachi.  ELI:00160  Date of R&I: 25-02-2025  Fee details: Slip: 1968105377 Paid: PKR 6000/- Dated: 14-02-2025	Legal Manufacturer:  M/s Nova Biomedical Corporation, 200 Prospect Street, Waltham, MA 02454-9141, USA  FSC (USA): Validity: 21-01-2026  LOA Validity: 27-03-2025  ISO 13485 Validity: 24-10-2027	Brand name:  Prime CCS Comp Stat Profile Prime CCS Analyzer System  Class A  Shelf life: not applicable	Deferred for the following:  1. The name of the device Prime CCS Comp not mentioned in LOA.  2. Firm has not submitted the fee for the system.  3. Firm has not submitted the shelf life of the medical device.  4. Firm need to submit all documents that have the same name of the device.
25.	A.S Enterprises, 03- Mozang Lahore, Pakistan. ELI: 00190 Dossier# 3591 Submission date: 21/09/2022 Evaluator: DD-III	Legal Manufacturer: Acon laboraties Inc., 5850 Oberlin Drive, # 340, San Diego, CA, 92121, United States of America  Manufacturing site: Acon Biotech (Hangzhou) co, Ltd. No 210 Zhenzhong road west lake district Hangzhou P.R. China 310030  FSC: China Valit till: 2023/01/17	Acon Mission Plus Hemoglobin(Hb) Testing strips (Hemoglobin (Hb) Testing strips) Codes & Sizes: As per FSC Class-C Shelf Life: 24 Months	Deferred for the following:  1. Form 7A along with undertaking required.  2. The name of the device on FSC is Mission® Plus Hb Hemoglobin Test Strips while name on Form 7A is Acon Mission Plus Hemoglobin(Hb) Testing strips.  3. copy of ISO 13485 of manufacturing site valid

26.	A.S Enterprises, 03- Mozang Lahore, Pakistan. ELI: 00190 Dossier# 3592 Submission date: 21/09/2022 Evaluator: DD-III	Legal Manufacturer: Acon laboraties Inc., 5850 Oberlin Drive, # 340, San Diego, CA, 92121, United States of America  Manufacturing site: Acon Biotech (Hangzhou) co, Ltd. No 210 Zhenzhong road west lake district Hangzhou P.R. China 310030  FSC: China Valit till: 2023/01/17	Acon Mission Plus Hemoglobin (Hb) Testing Meter (Hemoglobin (Hb) Testing System) Codes & Sizes: As per FSC Class-C Shelf Life: 24 Months	till 14.07.2025 attached. ISO 13485 of legal manufacturer not attached.  4. The name Acon not mentioned in LOA.  5. Class of device not mentioned on DOC.  6. Firm has not submitted original documents.  Deferred for the following:  1. Form 7A along with undertaking required.  2. The name of the device on FSC is Mission® Plus Hb Hemoglobin Testing system while name on Form 7A is Acon Mission Plus Hemoglobin(Hb) Testing meter.  3. copy of ISO 13485 of manufacturing site valid till 14.07.2025 attached. ISO 13485 of legal manufacturer not attached.
27.	M/s UDL Distribution (Pvt)	M/s Karex Industries Sdn.	Pulse-Strawberry	<ul><li>4. The name Acon not mentioned in LOA.</li><li>5. Class of device not mentioned on DOC.</li><li>6. Firm has not submitted original documents.</li></ul>
	Ltd., 1-D-13, Sector 30, Korangi Industrial Area, Karachi	Bhd. Lot 2244, Batu 39 ½ Pontian Besar, 82000 Pontian, Johor, Malaysia.	Natural Rubber Latex Male Condoms Pulse – Strawberry	that address of manufacturer mentioned on FSC, CE QMS and ISO 13485 certificates is
	ELI-00073  Date of R& I 29.04.2025	LOA: Valid till: 21-04-2030 (Copy)	(Identifier: P53S-N1- 180-Red)	different from address given on Form 7A.
	Fee: Rs.`62000/ through slip no. 9182038880	FSC: Not provided  ISO 13485 - Validity Date: 02-07-2025 (Copy)	Applied as: Family Class C	
			Shelf Life: 5 Years	

EC Certificate (FQA) Valid till: 26-05-2024 (Copy)  28.  M/s UDL Distribution (Pvt) Ltd., 1-D-13, Sector 30, Korangi Industrial Area, Karachi  ELI-00073  Date of R& I 29.04.2025  Fee: Rs. 62000/ through slip no. 6379675693  UDL Distribution (pvt) Ltd.1- D-13, Sector 30, Korangi Industrial Area, Karachi.  (ELI-00073)  UDL Distribution (pvt) Ltd.1- D-13, Sector 30, Korangi Industrial Area, Karachi. (ELI-00073)  Date of R& I 29.04.2025  Foe: Rs. 62000/ through slip no. 6379675693  UDL Distribution (pvt) Ltd.1- D-13, Sector 30, Korangi Industrial Area, Karachi. (ELI-00073) Dossicr# 1046-c Date: 26-01-23 Submitted Fee: Date: 26-01-23 Submitted Fee: So.0000/-PKR Challan No.: 9691575380  EC Certificate (FQA) Valid till: 26-05-2024 (Copy)  Code/sizes:  Natural Rubber Latex Male Condoms Pulse Extra Sensitive  Natural Rubber Latex Male Condoms Pulse Class C  Class C  Class C  Shelf Life: 5 Years  Code/sizes:  Code/sizes:  United Paper Life-Chahat  (Natural Rubber Latex Male Condoms)  Deferred for clarificatic that address manufacturer mentione on FSC, CE QMS at ISO 13485 certificates different from addregiven on Form 7A.  Code/sizes:  Code/sizes:  Code/sizes:  United Paper Life-Chahat  (Natural Rubber Latex Male Condoms)  Deferred for submission on FSC, CE QMS at ISO 13485 certificates  (Natural Rubber Latex Male Condoms)  Deferred for submission of original and notarize for submission of orig
M/s UDL Distribution (Pvt) Ltd., 1-D-13, Sector 30, Korangi Industrial Area, Karachi   Bhd. Lot 2244, Batu 39 ½ Pontian Besar, 82000 Pontian, Johor, Malaysia.   Deferred for clarification that address manufacturer mentions on FSC, CE QMS at ISO 13485 certificates different from addre given on Form 7A.
Ltd., 1-D-13, Sector 30, Korangi Industrial Area, Karachi  ELI-00073  Date of R& I 29.04.2025  Fee: Rs. 62000/ through slip no. 6379675693  DUDL Distribution (pvt) Ltd.1-D-13, Sector 30, Korangi Industrial Area, Karachi  ELI-00073  UDL Distribution (pvt) Ltd.1-D-13, Sector 30, Korangi Industrial Area, Karachi (ELI-00073)  Date of R& I 29.04.2025  Fee: Rs. 62000/ through slip no. 6379675693  EC Certificate (FQA) Valid till: 26-05-2024 (Copy)  Legal Manufacturer: D-13, Sector 30, Korangi Industrial Area, Karachi (ELI-00073) Dossier# 1046-c Date: 26-01-23 Submitted Fee: 50,000/-PKR Challan No.: 9691575380  Bhd. Lot 2244, Batu 39 ½ Pontian Besar, 82000 Pontian Johor, Malaysia. Natural Rubber Latex Male Condoms Pulse – Extra Sensitive  Class C  Class C  Shelf Life: 5 Years  Code/sizes:  Code/sizes:  (Natural Rubber Latex Male Condoms)  Natural Rubber Latex Male Condoms Pulse – Extra Sensitive  that address manufacturer mention on FSC, CE QMS at ISO 13485 certificates different from addregiven on Form 7A.  Portian Java BT. 34 Jahn Pontian Jaya BT. 34 Jahn Pontian Johor, Darul Takzim, Malaysia Challan No.: 9691575380  Class-C  Class-C  Code: P53S Red  Class-C  Class-C
Korangi Industrial Area, Karachi  Pontian Besar, 82000 Pontian, Johor, Malaysia.  LOA:  LOA:  Valid till: 21-04-2030 (Copy)  Date of R& I 29.04.2025  Fee: Rs. 62000/ through slip no. 6379675693  Pontian Besar, 82000 Pontian, Johor, Malaysia.  FSC: Not provided  Fee: Rs. 62000/ through slip no. 6379675693  Pontian Besar, 82000 Pontian, Johor, Malaysia.  LOA:  Valid till: 21-04-2030 (Copy)  Applied as: Family  Class C  Shelf Life: 5 Years  EC Certificate (FQA) Valid till: 26-05-2024 (Copy)  Legal Manufacturer: D-13, Sector 30, Korangi Industrial Area, Karachi. (ELI-00073) Dossier# 1046-c Date: 26-01-23 Submitted Fee: 50,000/-PKR Challan No.: 9691575380  Pontian Besar, 82000 Pontian, Johor, Malaysia Male Condoms Pulse – Extra Sensitive  Male Condo
Rarachi   Pontian, Johor, Malaysia.   Male Condoms Pulse - Extra Sensitive   Extra Sensitive   Extra Sensitive   Extra Sensitive   Extra Sensitive   Solution   Sol
LOA: Valid till: 21-04-2030 (Copy)  Date of R& I 29.04.2025  Fee: Rs.`62000/ through slip no. 6379675693  ISO 13485 - Validity Date: 02-07-2025 (Copy)  EC Certificate (FQA) Valid till: 26-05-2024 (Copy)  D-13, Sector 30, Korangi Industrial Area, Karachi. (ELI-00073) Dossier# 1046-c Date: 26-01-23 Submitted Fee: 50,000/-PKR Challan No.: 9691575380  Challan No.: 9691575380  Extra Sensitive  Extra Sensitive  ISO 13485 certificates different from addre given on Form 7A.  Class C  Shelf Life: 5 Years  Code/sizes:  (Natural Rubber Latex Male Condoms)  Code: P53S Red  Class-C  Class-C  Extra Sensitive  ISO 13485 certificates different from addre given on Form 7A.  IsO 13485 certificates different from addre given on Form 7A.  Code/sizes:  Code/sizes:  (Natural Rubber Latex Male Condoms)  Code: P53S Red  Code: P53S Red  Class-C  Class-C
ELI-00073  Date of R& I 29.04.2025  Fee: Rs.`62000/ through slip no. 6379675693  UDL Distribution (pvt) Ltd.1-D-13, Sector 30, Korangi Industrial Area, Karachi. (ELI-00073) Dossier# 1046-c Date: 26-01-23 Submitted Fee: 50,000/-PKR Challan No.: 9691575380  Class C  Class C  Class C  Shelf Life: 5 Years  Code/sizes:  Code/sizes:  Happy Life- Chahat Of original and notarize for submission of original and n
Pate of R& I 29.04.2025  Fee: Rs.`62000/ through slip no. 6379675693  29. UDL Distribution (pvt) Ltd.1-D-13, Sector 30, Korangi Industrial Area, Karachi. (ELI-00073) Dossier# 1046-c Date: 26-01-23 Submitted Fee: 50,000/-PKR Challan No.: 9691575380  ECC ertificate (FQA) Valid till: 26-05-2024 (Copy)  Logal Manufacturer: Happy Life- Chahat (Natural Rubber Latex Male Condoms)  EC Certificate (FQA) Valid till: 26-05-2024 (Copy)  EC Code/sizes: Validity Date: (Natural Rubber Latex Male Condoms)  FSC: Not provided  Code/sizes: (Natural Rubber Latex Male Condoms)  FSC and valid QM certificate.  FSC and valid QM certificate.  Code: P53S Red  Takzim, Malaysia Manufacturing site: Lot 2244,Batu 39 ½  Class-C
Date of R& I 29.04.2025  Fee: Rs.`62000/ through slip no. 6379675693  ISO 13485 - Validity Date: 02-07-2025 (Copy)  EC Certificate (FQA) Valid till: 26-05-2024 (Copy)  29. UDL Distribution (pvt) Ltd.1- D-13, Sector 30, Korangi Industrial Area, Karachi. (ELI-00073) Dossier# 1046-c Date: 26-01-23 Submitted Fee: Pontian Jaya BT.34 Jalan Johor, R2000 Code: Submitted Fee: 50,000/-PKR Challan No.: Manufacturing site: 19691575380  Date of R& I 29.04.2025  FSC: Not provided Class C  Class C  Code/sizes:  Code/sizes:  Happy Life- Chahat Of original and notarize of original
Fee: Rs.`62000/ through slip no. 6379675693  FSC: Not provided  Class C  ISO 13485 - Validity Date: 02-07-2025 (Copy)  EC Certificate (FQA) Valid till: 26-05-2024 (Copy)  29. UDL Distribution (pvt) Ltd.1-D-13, Sector 30, Korangi Industrial Area, Karachi. (ELI-00073) Dossier# 1046-c Date:26-01-23 Submitted Fee: 50,000/-PKR Challan No.: 9691575380  FSC: Not provided  Class C  Shelf Life: 5 Years  Code/sizes:  Happy Life- Chahat (Natural Rubber Latex Male Condoms)  FSC: Not provided  Class C  Code/sizes:  FSC and valid QM/sertificate.  Code: P53S Red  Class-C  Class-C
Fee: Rs.`62000/ through slip no. 6379675693  ISO 13485 - Validity Date: 02-07-2025 (Copy)  EC Certificate (FQA) Valid till: 26-05-2024 (Copy)  29. UDL Distribution (pvt) Ltd.1- D-13, Sector 30, Korangi Industrial Area, Karachi. (ELI-00073) Dossier# 1046-c Date:26-01-23 Submitted Fee: 50,000/-PKR Challan No.: 9691575380  Fee: Rs.`62000/ through slip no. 6379675693  ISO 13485 - Validity Date: O2-07-2025 (Copy)  Shelf Life: 5 Years  Code/sizes:  Happy Life- Chahat (Natural Rubber Latex Male Condoms)  FSC and valid QM certificate.  Code: P53S Red  Class-C  Code: P53S Red  Class-C
slip no. 6379675693  ISO 13485 - Validity Date: 02-07-2025 (Copy)  EC Certificate (FQA) Valid till: 26-05-2024 (Copy)  29. UDL Distribution (pvt) Ltd.1- D-13, Sector 30, Korangi Industrial Area, Karachi. (ELI-00073) Dossier# 1046-c Date: 26-01-23 Johor, 82000 Submitted Fee: 50,000/-PKR Challan No.: 9691575380  ISO 13485 - Validity Date: 02-07-2025 (Copy)  Shelf Life: 5 Years  Code/sizes:  Happy Life- Chahat (Natural Rubber Latex Male Condoms)  FSC and valid QM certificate.  Code: P53S Red  Class-C  Class-C
Deferred for submission of original and notarized for submission of original a
EC Certificate (FQA) Valid till: 26-05-2024 (Copy)  29. UDL Distribution (pvt) Ltd.1- D-13, Sector 30, Korangi Industrial Area, Karachi. (ELI-00073) Dossier# 1046-c Date:26-01-23 Submitted Fee: 50,000/-PKR Challan No.: 9691575380  EC Certificate (FQA) Valid till: 26-05-2024 (Copy)  Happy Life- Chahat (Natural Rubber Latex Male Condoms)  Code: PSC and valid QM. certificate.  Code: P53S Red  Class-C  Class-C  Code/sizes:  Code/sizes:  Code/sizes:  Code/sizes:  Code/sizes:  Deferred for submission of original and notarize of original and notar
Valid till: 26-05-2024 (Copy)  29. UDL Distribution (pvt) Ltd.1- D-13, Sector 30, Korangi Industrial Area, Karachi. (ELI-00073) Dossier# 1046-c Date: 26-01-23 Submitted Fee: 50,000/-PKR Challan No.: 9691575380  Valid till: 26-05-2024 (Copy)  Happy Life- Chahat Of original and notarize (Natural Rubber Latex Male Condoms)  FSC and valid QM certificate.  Code: P53S Red Class-C  Class-C  Class-C
Valid till: 26-05-2024 (Copy)  29. UDL Distribution (pvt) Ltd.1- D-13, Sector 30, Korangi Industrial Area, Karachi. (ELI-00073) Dossier# 1046-c Date:26-01-23 Submitted Fee: Submitted Fee: 50,000/-PKR Challan No.: 9691575380  Valid till: 26-05-2024 (Copy)  Happy Life- Chahat (Natural Rubber Latex Male Condoms)  FSC and valid QM: certificate.  Code: P53S Red  Class-C  Class-C
29. UDL Distribution (pvt) Ltd.1- D-13, Sector 30, Korangi Industrial Area, Karachi. (ELI-00073) Dossier# 1046-c Date:26-01-23 Submitted Fee: 50,000/-PKR Challan No.: 9691575380  UDL Distribution (pvt) Ltd.1- Legal Manufacturer: Karex Industries Sdn. Bhd. PTD, 7906 & 7907 Taman Pontian Jaya BT.34 Jalan Johor,82000 Code: Pontian,Johor, Darul Takzim, Malaysia Challan No.: 9691575380  UDL Distribution (pvt) Ltd.1- Legal Manufacturer: Happy Life- Chahat (Natural Rubber Latex Male Condoms)  Code: P53S Red Class-C Class-C
D-13, Sector 30, Korangi Industrial Area, Karachi. (ELI-00073)
Industrial Area, Karachi. (ELI-00073) Dossier# 1046-c Date:26-01-23 Submitted Fee: 50,000/-PKR Challan No.: 9691575380  Karex Industries Sdn. Bhd. PTD, 7906 & 7907 Taman Pontian Jaya BT.34 Jalan Johor, 82000 Pontian, Johor, Darul Takzim, Malaysia Class-C  (Natural Rubber Latex Male Condoms)  Code: P53S Red  FSC and valid QM certificate.  FSC and valid QM certificate.
(ELI-00073)       PTD, 7906 & 7907 Taman Dossier# 1046-c       Male Condoms)       rsc and valid Qiv.         Date:26-01-23       Johor,82000       Code:         Submitted Fee:       Pontian,Johor, Darul       P53S Red         50,000/-PKR       Takzim, Malaysia       Class-C         9691575380       Lot 2244,Batu 39 ½
Dossier# 1046-c
Dossier# 1046-c
Submitted Fee: 50,000/-PKR Challan No.: 9691575380  Pontian, Johor, Darul Takzim, Malaysia Manufacturing site: Lot 2244, Batu 39 ½  P53S Red Class-C Class-C
50,000/-PKR Challan No.: 9691575380  Takzim, Malaysia Manufacturing site: Lot 2244,Batu 39 ½  Class-C
Challan No.:         Manufacturing site:         Class-C           9691575380         Lot 2244,Batu 39 ½
9691575380 Lot 2244,Batu 39 ½
Pontian Besar, 82000   Shelf Life: 05 years
Pontian, Johor, Darul
Takzim, Malaysia
FSC: Malaysia
Valid till: 16-01-2027
30. Treu-Dynamic Legal Manufacture Brand Name Rejected due
International(Pvt) Ltd Conmed Corporation Shoulder Arthroscopy following:
Office no.C-206,2 <sup>nd</sup> Floor, 525 French Road, Utica, System 1. Firm has not submitted
City Towers, Main New York 13502, USA fee for the codes.
Boulevard, Gulberg, $T_{+1404.855.4592}$ Class C 2. Firm has not submitted
Lahore. $F_{+1404.344.0283}$ the brand names.
171404.544.0203°
enneyures of Form 7
(0)
(Licence No.ELI-00175) Code not attached.
(Licence No.ELI-00175) Code not attached.
(Licence No.ELI-00175) File submitted on : LOA:  Description  A. Firm has not justified to the content of the c
(Licence No.ELI-00175) File submitted on : 19.02.2025  Validity 03-Year  Code Description H6100  H6100  not attached. 4. Firm has not justification the grouping of the groupi
(Licence No.ELI-00175) File submitted on : 19.02.2025 Fee challan No. (Sept-2023 to Dec-No.ELI-00175) Fee Challan No.ELI-00175
(Licence No.ELI-00175) File submitted on : 19.02.2025 Fee challan No. 121540329(13.02.25)  (LOA: Validity 03-Year (Sept-2023 to Declarity 12025).  (Sept-2023 to Declarity 12025)  (Code Description (Anchor Suture, CFK-475DT)  (Sept-2023 to Declarity 12025).  (Sept-2023 to Declarity 12025)  (Sept-2023 to Declarity 12025).
(Licence No.ELI-00175) File submitted on : 19.02.2025 Fee challan No. 121540329(13.02.25)  (LOA: Validity 03-Year (Sept-2023 to Declar) 121540329(13.02.25)  (Sept-2023 to Declar) 12025  (Sep
(Licence No.ELI-00175) File submitted on: 19.02.2025 Fee challan No. 121540329(13.02.25)  FSC:  Code Description H6100 Anchor Suture, CFK-475DT Anchor Suture CFK-55DT  Code Description H6100 Anchor Suture, CFK-475DT Anchor Suture CFK-55DT
(Licence No.ELI-00175) File submitted on : 19.02.2025 Fee challan No. 121540329(13.02.25)  FSC: Country of Origin USA  Code Description H6100 Anchor Suture, CFK-475DT Anchor Suture CFK-55DT Anchor Suture
(Licence No.ELI-00175) File submitted on : 19.02.2025 Fee challan No. 121540329(13.02.25)  FSC:  Code Description H6100 Anchor Suture, CFK-475DT Anchor Suture CFK-55DT  Code Description H6100 Anchor Suture, CFK-475DT Anchor Suture CFK-55DT

Validity 03-Years March 2024 —March 2027.  March 2024 —March 2027.  C7385 For anchor suture CKP-3500 Anchor suture CKP-4502 Anchor suture CF6140HB Anchor suture CF6140H Anchor suture C6140H Anchor suture GKP-3801 Anchor suture GKP-3801 Anchor suture GKP-3801 Anchor suture BKI_00M For Anchor suture BKI_00M For Anchor Suture BGU-00M For Anchor Suture T508 Anchor Suture SMI-02N For Anchor Suture C6005 Anchor Suture H5000 Anchor Suture H5000 Anchor Suture H5000 Anchor Suture BB23X30 Anchor Suture BB23X30 Anchor Suture BB23X30 Anchor Suture BB20X60 Anchor Suture BB30X60 Anchor Suture BB20X60 Anchor Suture BB20X60 Anchor Suture BB30X60 Anchor Suture BB30X60 Anchor Suture BB40X60 Anchor Suture	TGO 4240#	CE 1 CE
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For Anchor Suture T50S Anchor Suture SMI-02N For Anchor Suture C6005 Anchor Suture H5000 Anchor Suture		
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For Anchor Suture T50S Anchor Suture SMI-02N For Anchor Suture C6005 Anchor Suture H5000 Anchor Suture	651	For Anchor Suture
T50S Anchor Suture SMI-02N For Anchor Suture C6005 Anchor Suture H5000 Anchor Suture		BGU-00M
Anchor Suture SMI-02N For Anchor Suture C6005 Anchor Suture H5000 Anchor Suture		For Anchor Suture
SMI-02N For Anchor Suture C6005 Anchor Suture H5000 Anchor Suture	41	T50S
For Anchor Suture C6005 Anchor Suture H5000 Anchor Suture		Anchor Suture
C6005 Anchor Suture H5000 Anchor Suture	.50	SMI-02N
C6005 Anchor Suture H5000 Anchor Suture		For Anchor Suture
Anchor Suture H5000 Anchor Suture		
H5000 Anchor Suture		
Anchor Suture		
H5120 Anchor Suture C7480 For Anchor Suture BB23X30 Anchor Suture BB40X60 Anchor Suture PRO7450B Anchor Suture L3000 Advantage for Anchor Suture		
Anchor Suture C7480 For Anchor Suture BB23X30 Anchor Suture BB40X60 Anchor Suture PRO7450B Anchor Suture L3000 Advantage for Anchor Suture		H5120
C7480 For Anchor Suture BB23X30 Anchor Suture BB40X60 Anchor Suture PRO7450B Anchor Suture L3000 Advantage for Anchor Suture		Anchor Suture
For Anchor Suture BB23X30 Anchor Suture BB40X60 Anchor Suture PRO7450B Anchor Suture L3000 Advantage for Anchor Suture	, Gr	C7480
BB23X30 Anchor Suture BB40X60 Anchor Suture PRO7450B Anchor Suture L3000 Advantage for Anchor Suture	1111 CC	For Anchor Suture
Anchor Suture BB40X60 Anchor Suture PRO7450B Anchor Suture L3000 Advantage for Anchor Suture	20216	RR23Y30
BB40X60 Anchor Suture PRO7450B Anchor Suture L3000 Advantage for Anchor Suture	VA 0, ~	Anchor Suture
Anchor Suture PRO7450B Anchor Suture L3000 Advantage for Anchor Suture		RR40Y60
PRO7450B Anchor Suture L3000 Advantage for Anchor Suture	- 10 (c)	Anghor Suturo
Anchor Suture L3000 Advantage for Anchor Suture	36.00	DDO7450D
L3000 Advantage for Anchor Suture	65, M	Anghor Suturo
Advantage for Anchor Suture	1 3 1 3 1 3 1 3 1 3 1 3 1 3 1 3 1 3 1 3	Anchor Suture
Advantage for Anchor Suture		Advantage for Angles
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Advantage for Anchor		Advantage for Anchor
Suture		Suture
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Anchor Suture		Anchor Suture

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			PRO6125	
			Anchor Suture	
			MC5057	
			Universal Suture	
			PRO2043	
			For Anchor Suture	
			PRO203	<u> </u>
			For Anchor Suture	
			PRO2041	Ola.
			For Anchor Suture	0
			PRO6228	Yo
			For Anchor Suture	*
			PRO6240	
			For Anchor Suture	
			PRO3011	
		1 (32)		
			For Anchor Suture	
		MO Sile	PRO8500SB	
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			PRO6100	
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	450		E8030LSO	
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			E8130LSO	
			Anchor Suture	
			E8150LSO	
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		, G.,	E9011-2	
		1111 oC	Anchor Suture	
		1000-110	C8803	
		Dr. O.	Anchor Suture	
			D4240	
		401 (8)		
		Aladul Oirec	For Anchor Suture	
	_	ssistant Diric	D4000	
	7	3,0,	For Anchor Suture	
	\	13	9299A, 9263A, 9247A	
		41	For Anchor Suture	
		)-J	9599A, C9254, C9264	
	460		For Anchor Suture	
31.	Treu-Dynamic	Legal Manufacture	Brand Name	Rejected due to
	International(Pvt) Ltd	Conmed Corporation	Knee Arthroscopy	following:
	*	525 French Road, Utica,	System	1. Firm has not submitted
		New York 13502,USA		fee for the codes.
	•		•	-

	Office no.C-206,2 <sup>nd</sup> Floor,	T+1404.855.4592•	Class C	2. Firm has not submitted
	City Towers, Main	F+1404.344.0283•		the brand names.
	Boulevard, Gulberg, Lahore.	www.matrixsurgicalusa.co	Shelf life: 05 Years	3. The undertaking and
		<u>m</u>		annexures of Form 7A
			Code	not attached.
	(Licence No.ELI-00175)	LOA:	Description	
	File submitted on:	Validity 03-Year	10K	4. Firm has not justifies
	19.02.2025	(Sept-2023 to Dec-2025).	Arthroscopic for knee	the grouping of the
	Fee challan No.		10K150	applied codes.
	121540329(13.02.25)	FSC:	Arthroscopic for knee	
		Country of Origin USA	AES-1	8
		Validity: 31-12-2025	Arthroscopic for knee	
			KFL100	) *
		<u>ISO 13485</u> :	Arthroscopic for knee	
		March 2024 – March 2027.	8750	
		$Q_{\alpha}$	Arthroscopic for knee AES-FC	
		7111.18C	Arthroscopic for knee	
		Mo. Oll	AES-90SN, PS8834 Arthroscopic for knee	
		As Children	MR007C Arthroscopic for knee	
		de la companyante de	MR004C,	
		C2. M	Arthroscopic for knee	
		3	KTB014,KFB035	
			Arthroscopic for knee H5100, DMS70	
			Arthroscopic for knee	
		)- )	E9414, E9415A	
			Arthroscopic for knee	
			C8011, C8012, C8013,	
			ACL Screw for Knee	
			C8015, C8017, C8018,	70
			C8019 ACL Screw	
			for Knee	
			C8022, C8023, C8024,	
			C8025 ACL	
		, G.,	Screw for Knee	
			IA-2000-S, C7359,	
		1200-110	C7368 ACL	
		<b>DY</b> O''	Screw for Knee.	
32.	M/s Ear Technic Pvt. Ltd.,	Desu Medikal Urunler Ve	Brand Name:	Deferred for the
	Office No. 03, 2 <sup>nd</sup> Floor, G.8	Tibbi Cihazlar San. Ve Tic		followings:
	Square Plaza, G.8 Markaz	A.s. Universiteler mah.	Desu Medical Shunt	1. for submission of valid
	Islamabad	1596 Cad. Safir Bloklan E	Valves and Catheters	design examination
	6	Blok Ofis No. 02/03	with accessories	certificate.
	F1 1 00056	Zemin Kat Kapi No. 6		2. clarification of brand
	ELI-00956	Beytepe – Cankaya –	Generic:	name.
	Data of De I	Ankara Turkiye.	Total PSA (CLIA) and	3. Firm has applied
	<b>Date of R&amp; I</b> 25.04.2025		Total PSA (CLIA) controls	Ventriculoperitonial
	23.04.2023	LOA:	Controls	shunt, Peritoneal/ arterial
	Fee: Rs.`62000/ through	Valid till: 10-03-2026		I
	slip no. 241458572445	(Copy)	Applied as: Kit	1
	onp 110. 2+1+303/2443	(Сору)	Applica as. Kit	catheter and Cerebrosinal
L		<u> </u>	l	

_	ı	I	T	
		FSC: Turkiye issue date	Class D	External Drainage Kit etc
		25.01.2024.		in single application.
		Validity Date: 24-01-		4. Firm has not justified
		2027(Copy)	Shelf Life:	the grouping.
				5. Firm has attached
		ISO - Validity Date:	Code/sizes:	
		21-10-2027 (Copy)		multiple stability reports
		(313)		of multiple devices.
		EC Certificate Valid till:		Device wise stability
		Le certificate valid till.		report required.
				6. Justification for
			.616	applying multiple codes.
				7. submission of original
			( ( ( ) V. V. V.	documents.
		0		
		Go.	W. Wisi	
33.	LINK TRADERS	Dongguan TT Medical,	ORTUS	Deferred for the
	OFFICE NO 1 & 2	Inc. BID # 1, 1 Taoyuan	PTCA Balloon Catheter	followings:
	MEZZAINE FLOOR	Road, Songshan lake		1. The name on FSC is
	AHMAD TRADE	National Hi-Tec Industrial	0	
	CENTER, 2, B	Park, Dongguan,		Ortus Disposable PTCA
	COMMERCIAL AREA	Guangdong, PR China		Balloon Catheter. Further
	NAZIMABAD NO 2,	49		firm has mentioned on
	KARACHI	62, 470		Form 7A that fee of
		3.0		Rs.50000 deposited.
	(ELI-00727			2. Legalized copy of the
		. \ .		FSC China valid till
	\Q	81.		06.02.2025.
	609			
	113			The name of device on
				FSC is Coronary Dilation
				catheter.
	_			3. Firm has attached two
			.(6)	FCS (China) that have
				different product codes
			1 1/4 1/2	_
				and product name is
		. 0	9, 50,5,	Coronary Dilation
			~ 00r	catheter.
		90,100		4. FSC (Netherland) is
		70° VIII	120	neither original, nor
		L FA W	0	notarized. The name of
				product on FSC is
		40, 10,		Coronary Dilation
		15, 7		Catheter with names
		CD. M.		
		3,0		Vespentrator®,
	\	73		VesTraveler®,
		11		VexPander® and
	20	Abdul Oadi Sisiani Direct		EverFlow®.
	, cO			5. Tha name of device as
				per agreement is CTO
	-Wr.			PTCA Balloon catheter,
1				NC PTCA Balloon
				Catheter and Paclitexel

				coated PTCA Balloon Catheter.
				6. Firm has not submitted FQA and Design
				Examination Certificate.
34.	Tech Zone,	Legal Manufacturer:	Brand Name:	Approved subject to
31.	,			submission of fee for
	764 Askari 9, Zarar Shaheed	Adeor Medical AG	Perneczky Aneurysm	family and codes/sizes
	Road Cantt Lahore.	Address:	Clip 2	exceeding 20.
	ELI-00040	Martinshof 5, 83626	Aneurysm Clip	,
		Valley Germany		
	Date of R&I 28-04-2025	LOA Validity(Notarised):	Class D	
	20-04-2023	31-12-2027	Shelf Life: 10 years	
	Fee Details:	1200-1100		
	Paid Fee: 62030/-	FSC: Germany	Applied as: Single	
	Fee Challan No: 968000045229	Issuance date: 05-02-2025 (Original) expiry not	Models/ Specification	
	700000043227	mentioned	AS per FSC	
		190 M. I. I. 20 12		
		ISO Validity: 30-12- 2025( notarized)		
	,	2020(1100011200)		
	\ \( \)	EU QMS certificate		
	60	validity: 26-05-2024 (Original)		
		EU Design Examination		ON
		certificate validity: 26-05-		.03
	Y	2024 (Original)	6) 4	10
		Extension letter given		)*
35.	Roche Pakistan Limited.	Legal Manufacturer:	LumiraDx NT-	Approved
	1 <sup>st</sup> Floor, 37-B, Block 6,	LumiraDx UK Ltd.	proBNP	
	P.E.C.H.S, Karachi.	Dumyat Business Park,	Cl. Cl.	
	(ELI-00009)	Bond Street, Tullibody, Alloa, FK10 2PB,	Class: B	
		United Kingdom	<b>Product Name:</b>	
	R&I Date:		1. LumiraDx NT-	
	14-05-2025	<b>Manufacturing Site:</b>	proBNP	
	East 21 000/	LumiraDx UK Ltd.	Roche CAT #:	
	Fees: 31,000/- Challan No.	Dumyat Business Park, Bond Street, Tullibody,	10418320001 LumiraDx CAT #:	
	144385778263	Alloa, FK10 2PB,	L023000101012	
	Dated: 28-04-2025	United Kingdom	Pack size: 12 Tests	
	.0	&	Shelf life: 40 weeks at	
	11/5	Cliniqa Corporation.	2 - 8°C	
	V/Up	495 Enterprise Street,		
		San Marcos, CA 92078, USA		
		USA		

		<b>EU QMS Certificate:</b>		
		N/A		
		IVA		
		ISO 13485:		
		Lumira ISO Validity:		
		16-04-2026		
		Aalto ISO Validity:		
		30-05-2026		
37.	Roche Pakistan Limited.	Legal Manufacturer:	LumiraDx CRP Test	Approved
	1 <sup>st</sup> Floor, 37-B, Block 6,	LumiraDx UK Ltd.	Srips	10
	P.E.C.H.S, Karachi.	Dumyat Business Park,	.6) 6	
		Bond Street, Tullibody,	Class: B	
	(ELI-00009)	Alloa, FK10 2PB,	( ( ( ) V. V. V.	
		United Kingdom	Product Name:	
	R&I Date:	, Q. ,	1. LumiraDx CRP	
	14-05-2025	<b>Manufacturing Site:</b>	Roche CAT #:	
		LumiraDx UK Ltd.	10418044001	
	Fees: 31,000/-	Dumyat Business Park,	LumiraDx CAT #:	
	Challan No.	Bond Street, Tullibody,	L004000101024	
	0681274647	Alloa, FK10 2PB,	Pack size: 24 Test	
	Dated:	United Kingdom	Strips	
	28-04-25	651	Shelf life: 36 weeks at	
		FSC:	2 - 30°C	
	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	Validity: 15-12-2029		
		1		
		LOA		
	450	Validity: 16-03-2030		
		<b>EU QMS Certificate:</b>		
		N/A		70
			(5)	
		ISO 13485:		
		Lumira ISO Validity:		
		16-04-2026	300	
38.	Roche Pakistan Limited.	Legal Manufacturer:	LumiraDx	Approved
		LumiraDx UK Ltd.	Coagulation Markers	rr
	1 <sup>st</sup> Floor, 37-B, Block 6,	Dumyat Business Park,		
	P.E.C.H.S, Karachi.	Bond Street, Tullibody,	Class: B	
	(ELI-00009)	Alloa, FK10 2PB,		
	,	United Kingdom	Product Name:	
	R&I Date:		1. LumiraDx D-Dimer	
	14-05-2025	Manufacturing Site:	Test Strips	
	Y	LumiraDx UK Ltd.	Roche CAT #:	
	Fees: 50,000/- vide	Dumyat Business Park,	10418087001	
	Challan No	Bond Street, Tullibody,	LumiraDx CAT #:	
	068112877488 dated	Alloa, FK10 2PB,	L005000101012	
	28.04.2025.	United Kingdom	Pack size: 12 Test	
		&	Strips	
		Cliniqa Corporation.	Shelf life: 52 weeks at	
		Chinqu Corporation.	2 - 30°C	
			2 - 30 C	

		495 Enterprise Street,		
		San Marcos, CA 92078,	2. LumiraDx Multi	
		USA	Quality Controls	
		&	Roche CAT #:	
		Hart Biologicals Ltd.	10418281001	
		2 Rivergreen Business	LumiraDx CAT #:	
		Centre,	L020080101003	
		Queens Meadow,	Pack size: 3 sets/pack	
			_	
		Hartlepool, TS25 2DL,	Shelf life: 52 weeks at	
		United Kingdom	2 - 8°C	N 9
		FSC:	3. LumiraDx INR Test	*
		Validity: 15-12-2029	Strips	
		Validity: 13 12 202)	Roche CAT #:	
		104		
		LOA	10418010001	
		Validity: 16-03-2030	LumiraDx CAT #:	
		100-110	L003000101048	
		<b>EU QMS Certificate:</b>	Pack size: 48 Test	
		N/A	strips	
			Shelf life: 12 months	
		ISO 13485:	at 5 - 32°C	
			at 3 - 32 C	
		Lumira ISO Validity:		
		16-04-2026	4. LumiraDx INR	
	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	Cliniqa ISO Validity:	Quality Controls	
		04-06—2025	Roche CAT #:	
	29	Hart ISO Validity:	10418036001	
	460	10-01-2027	LumiraDx CAT #:	
		10-01-2027		
			L003080101003	
			Pack size: 3 sets/pack	. 9.
			Shelf life: 24 months	
			at 2 - 8°C	*
39.	Roche Pakistan Limited.	Legal Manufacturer:	LumiraDx SARS-	Approved
		LumiraDx UK Ltd.	CoV-2 Cluster	
	1 <sup>st</sup> Floor, 37-B, Block 6,	Dumyat Business Park,	Cov 2 Clubter	
	P.E.C.H.S, Karachi.		Class P	
	(EL L 00000)	Bond Street, Tullibody,	Class: B	
	(ELI-00009)	Alloa, FK10 2PB,	3/1,	
		United Kingdom	Product Name:	
	R&I Date:		1. LumiraDx SARS-	
	14-05-2025	<b>Manufacturing Site:</b>	CoV-2 Ag Test Strips	
		LumiraDx UK Ltd.	Roche CAT #:	
	Fees: 50,000/-	Dumyat Business Park,	10418141001	
	Challan No.		LumiraDx CAT #:	
		Bond Street, Tullibody,		
	05398418718	Alloa, FK10 2PB,	L016000101048	
	Dated:28-04-25	United Kingdom	Pack size: 48 Test	
	460	&	Strips	
		MRN Diagnostics	Shelf life: 18 months	
	*Wr	101 Constitution Blvd,	at 2 - 30°C	
		Suite G, Franklin, MA		
	The state of the s	Suite O, I Iulikilli, MA	1	İ

02038, United States of 2. LumiraDx SARS-America CoV-2 Ag Ultra Roche CAT #: FSC: 10418184001 Validity: 15-12-2029 LumiraDx CAT #: L016000401048 **LOA** Pack size: 48 Test Validity: 16-03-2030 Shelf life: 70 weeks at 2 - 30°C **EU QMS Certificate:** N/A 3. LumiraDx SARS-CoV-2 Ag Quality ISO 13485: Controls Lumira ISO Validity: Roche CAT #: 10418206001 16-04-2026 MRN ISO Validity: LumiraDx CAT #: 21-09-2025 L016080101002 Pack size: 2 sets/pack Shelf life: 25 months at 2 - 8°C 4. LumiraDx SARS-CoV-2 & Flu A/B Roche CAT #: 10418222001 LumiraDx CAT #: L019000101024 Pack size: 24 Tests Shelf life: 77 weeks at 2 - 30°C 5. LumiraDx SARS-CoV-2 & Flu A/B **Quality Controls** Roche CAT #: 10418265001 LumiraDx CAT #: L019080101002 Pack size: 2 sets/pack Shelf life: 24 months at 2 - 8°C 6. LumiraDx SARS-CoV-2 & RSV Roche CAT #: 10418303001 LumiraDx CAT #: L021000101024 Pack size: 24 Tests

Shelf life: 52 weeks at
2 - 30°C
7. LumiraDx SARS-
CoV-2 & RSV Quality
Controls
Roche CAT #:
10418311001
LumiraDx CAT #:
L021080101002
Pack size: 2 sets/pack
Shelf life: 25 months
at 2 - 8°C

		at 2 - 8°C	V			
DEFERRED CASES (LOCAL MANUFACTURING)						
	Manufacturer details	Medical device details				
40.	Blue Birds Enterprises, Plot No. 292,	Medi Plus BP Bulb	Approved subject to verification			
	Humak Industrial Estate, Kahuta Road,		of manufacturing facility.			
	Islamabad.	Class: A	The MDB constituted following			
	(ELM-0097)	Configuration code:	panel for verification of the			
	[1029-6L]	BB-5020	facility.			
	R & I. 15313 dated 29-05-2025	Shelf Life: 5 Years	1. Dr. Ayesha Ali, Department of			
	Approved Sections:	Fee: 6000	Pharmacy, Pakistan Institute of			
	i.Personal Protective Equipment (PPE)	Fee Slip No. 5846127042	Medical Sciences, Islamabad			
	Section		(Hospital Pharmacist).			
	ii.Ultrasound Gel Section		2. Mr. Luqman Ali, System			
	iii.Injection Molding Section (For		Analyst, Pakistan Institute of			
	components like nebulizer machine	.6	Medical Sciences, Islamabad.			
	Body oxygen mask cord clamp airways)		Wiedicar Sciences, Islamabad.			
	iv.Injection Molding Section (breast pump					
	steamer tourniquet urine bag	-20, 41, 61	*			
	parts and vacuum bottle. (Not for auto-	· 0. ~0/. ~0.				
	disable / disposable syringe)					
	v.EO (Ethylene Oxide) Sterilization Section	10.100				
	vi.Blistering / packing Section of IV Cannula / Cord Clamp	it Director, 5052				
	vii.Surgical Drapes Section					
	viii.Surgical Swab Section (Packing &	70,				
	Sterilization only)	0				
	ix.Surgical Gloves Section (Packing &					
	Sterilization only)					
	x.Orthopedic Soft Wears Section (soft					
	braces belts slings and binders					
	xi.					
41.	Blue Birds Enterprises, Plot No. 292, Humak	Medi Plus Nebulizer Machine	Approved subject to verification			
	Industrial Estate, Kahuta Road, Islamabad		of manufacturing facility.			
	(ELM-0097)	Class: B				
	[1000-7L]	Configurations Code:				

	D. No. 15350 dated 29-05-2025 Approved Sections:  (As stated above)	NM-9026 (Nebulizer machine) NM-9025 (Mini Nebulizer Machine) Shelf Life: 5 Years Fee: 25000 Fee Slip No. 337851399241	The MDB constituted following panel for verification of the facility.  1. Dr. Ayesha Ali, Department of Pharmacy, Pakistan Institute of Medical Sciences, Islamabad (Hospital Pharmacist).  2. Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad.
42.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [1027-6L] R & I. 15333 dated 29-05-2025 Approved Sections: As above	Medi Plus BP Cuff  Class: A Configuration code: CB-5021 (BP Cuff) CB-5020 (BP Cuff with Bladder) Sizes: S, M, L. Shelf Life: 5 Years Fee: 6000 Fee Slip No. 3533197159	Approved subject to verification of manufacturing facility. The MDB constituted following panel for verification of the facility.  1. Dr. Ayesha Ali, Department of Pharmacy, Pakistan Institute of Medical Sciences, Islamabad (Hospital Pharmacist).  2. Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad.
43.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [983-6L] D. No. 15354 dated 29-05-2025 Approved Sections: As above	Medi Plus Inhaler Spacer (Aerosol Holding Chamber)  Class: A Sizes: Small, Medium, Large Shelf Life: 5 Years Fee: 6000 Fee Slip No. 599636956917	Approved subject to verification of manufacturing facility. The MDB constituted following panel for verification of the facility.  1. Dr. Ayesha Ali, Department of Pharmacy, Pakistan Institute of Medical Sciences, Islamabad (Hospital Pharmacist).  2. Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad.
44.	Blue Birds Enterprises, Plot No. 292, Humak Industrial estate, Kahuta Road, Islamabad (ELM-0097) [943-6L] D. No. 13955 dated 20-05-2025 Approved Sections:  As Above	Medi Plus Nurse Cap  Class: A  Model: NC-1690  Shelf Life: 5 Years  Fee: 6000  Fee Slip No. 13005433061	Approved. The firm will submit samples of the device before issuance of Registration letter.
45.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [967-6L]	Medi Plus Air Mattress  (Medical Pressure Relief Air Mattress)	Approved subject to verification of manufacturing facility.  The MDB constituted following panel for verification of the facility.

	D. No. 15328 dated 29-05-2025 Approved Sections: As above	Class: A Code: AM-2510 Shelf Life: 5 Years Fee: 6000 Fee Slip No. 33136855935	<ol> <li>Dr. Ayesha Ali, Department of Pharmacy, Pakistan Institute of Medical Sciences, Islamabad (Hospital Pharmacist).</li> <li>Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad.</li> </ol>
46.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [980-7L] D. No. 15341 dated 29-05-2025 Approved Sections:  As above	Medi Plus Skin Traction Kit Configuration code: ST-1285 Sizes: Adult, Child, Infant Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 175996150588	Approved subject to verification of manufacturing facility. The MDB constituted following panel for verification of the facility.  1. Dr. Ayesha Ali, Department of Pharmacy, Pakistan Institute of Medical Sciences, Islamabad (Hospital Pharmacist).  2. Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad.
47.	Blue Birds Enterprises, Plot No. 292, Humak Industrial estate, Kahuta Road, Islamabad (ELM-0097) [955-7L] D. No. 13967 dated 20-05-2025 Approved Sections: As Above	Medi Plus Non-Woven Tape  Class: B Code: NWT-1800 Sizes: 1, 2, 3 & 4 inches Shelf Life: 5 Years Fee: 25000 Fee Slip No. 21469469	Approved subject to verification of manufacturing facility. The MDB constituted following panel for verification of the facility.  1. Dr. Ayesha Ali, Department of Pharmacy, Pakistan Institute of Medical Sciences, Islamabad (Hospital Pharmacist).  2. Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad.
48.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [984-7L] D. No. 15363 dated 29-05-2025 Approved Sections: As Above	Medi Plus Ear Syringe (Ear Irrigation Syringe)  Class: B Configuration Code: ES-1020 Sizes: 60ml, 90ml Shelf Life: 5 Years Fee: 25000 Fee Slip No. 6736115842	Approved subject to verification of manufacturing facility. The MDB constituted following panel for verification of the facility.  1. Dr. Ayesha Ali, Department of Pharmacy, Pakistan Institute of Medical Sciences, Islamabad (Hospital Pharmacist).  2. Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad.