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

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# DECISIONS OF 108<sup>TH</sup> MEETING OF THE MEDICAL DEVICE BOARD (MDB) HELD ON 12-11-2025 (MANUAL APPLICATIONS- PART-II)

108<sup>th</sup> 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 12<sup>th</sup> November, 2025. The meeting was chaired by Dr. Babar Khan, Chairman Medical Device Board, DRAP, Islamabad and attended by the following:

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

11.	Mr. Ayyaz Ahmed, Additional Director	Member-cum-Secretary
	(MD&MC), DRAP, Islamabad.	

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. Hanif Ullah	Deputy Director-XI

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

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

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

### FRESH ESTABLISHMENT LICENSE TO MANUFACTURE (ELM) CASES:

S.#	Name and Address of Establishment	Name of Production Incharge	Name of QC Incharge	Decision
1.	M/s Defence Science and Technology Organization Labs, Complex, Biological Research Centre, DESTO, 34-37 PNH, Lines, Karachi.	Dr. Shaukat Ali Bs Hons (Microbiology)  Experience as Deputy Chief Manager Desto from 01-09-2021 to 27- 1-2023	Ms. Misbah Khadim  MSc Biosciences  Experience: Incharge QC Desto 15 Years	The board considered the report of the firm and approved following sections for manufacturing of medical devices:  • Processing Kit Section • Microbiological Diagnostic Section • Immunodiagnostic Section • Sterile filling Section • Biomaterial Production Facility
		onday,		

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

### **FRESH CASES ELI**

S.#	Name of Establishment	Name of Qualified Technical Person	Decision
1.	M/s Accumed Supplies, B-16, Hina Palace, Hoshang Road, Civil Lines, Karachi South Saddar Town, Karachi	Engr. Nawab Suhail Imtiaz Bio Medical Engineer	Approved
2.	M/s MCG Healthcare (Private) Limited, Carim House, 6-Davis Road, Lahore	Ms. Qammer Saeed Pharm D	Approved
3.	M/s Universal Enterprises (Medcare), Office: 527-Janiper Block, Bahria Town, Lahore Godown: 1748 Pine Avenue Road Valencia Town, Lahore	Muhammad Tayyab  Bs (Hons) Medical Laboratory	Rejected. The board considered the findings of the inspector that the premises was used for residential purpose and no medical device storage facility was available. Therefore board decided to reject ELI application of the firm.
4.	M/s Mays Marketing Enterprises Office: 2 <sup>nd</sup> Floor, House No. 46/E/2, Block-6, PECHS, Karachi Godown: Room No. G02, Plot No. 42, Darulaman Housing Society Block 7 & 8, Karachi.	Muhammad Fareed Uddin BSC (Pass)	Deferred for appointment of technical staff as per requirement of Medical Devices Rules, 2017.

## <u>Deferred Cases for Grant of Establishment License to Import:</u>

Name of Establishment	Name of Person previuously	Remarks
	applied as Q.P.	
M/s Advance Medical Devices,	Mubashar Abbas	The board approved Establishment License
Apartment # 1 3rd floor Plaza 01		to Import medical devices as the firm has
linear commercial phase 8	CNIC37405-3758089-9	complied with the requirements of medical
Bahria town Rawalpindi.	1510 000	devices rules 2017 and appointed a qualified
	BS Computer Science	person Muhammad Nawaz Sultan, cnic
	030	1350491691851 Qualification Pharm D as
	1,00	per requirement law.

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

### **RENEWAL CASES ELI**

S.#	Name of Establishment	Name of Qualified Technical Person	Name of Management	Decision
1.	M/s Metro Commercial Enterprises,  Office/Godown: Suite No. 1, L.G.R., Abrar Business Centre, Wahdat Road, Lahore (ELI-00137)	Usama Bin Sabir Pharm D	Muhammad Jalil Tahir	Approved
2.	M/s Royal Enterprises, Shop No.5, Karimji Building, Opposite HBL, North Napier Road, Karachi. Godown 1: M-4, Asghar Ali Building, Campbell Street, Karachi. Godown 2: 201, Union Chambers, North Napier Road, Karachi	Syed Muhammad Sami Pharm D	Tausif Jamil	Approved
3.	M/s Sultan Sons, 133, Kutchi Gali No.1, Marriot Road, Karachi.  Godown 1: M-2, Mez floor, Asghar Ali Building, Karachi  Godown: 2nd Floor #29, Sadaf Centre, Serai Road, Karachi  Godown 3: 2nd floor 27/28 Sadaf centre, Serai Road, Karachi  Godown 4: 2-A Plot # 07/15 N.Napier Road, Karachi	Urooj Fatima Pharm-D	Mohammad Aslam Shakil Ahmed Jamil Sultan	Approved
4.	M/s Wasim Co, Kachi Gali No 1, Marriot Road, Karachi Godown: Sadaf Center SR3/22 Serial Road, 2nd Floor No.15 & 26, Karachi.	Humayun Khalid Pharm D	Khalil Ahmed	Approved
5.	M/s Princess Scientific Services,  Office/Godown: Office No. 11, 3 <sup>rd</sup> Floor, Zaraj Centre-II, Bakery Road, Opposite MAG Office Saddar, Rawalpindi (ELI-00215)	Ihsan Ullah MSc. Biochemistry	Abdul Hafeez	Approved
6.	M/s Hospital Supply Corporation,	Muhammad Sohail Arif	M Yahya Feroz Sohail Feroz	Approved

	Office: 42 Darul Aman Housing		M Yahya Feroz	
	Society, Block 7 & 8, Karachi	Pharm D		
	Godown 1: 42 Darul Aman Housing			
	Society, Block 7 & 8, Karachi			
	Godown 2: Room No. G01, Ground			
	Floor, Plot No. 167, Sector 23,			
	Korangi Industrail Area, Karachi.			
	ELI-00005		6	
7.	M/s 4A International,	Muhammad Ali	Sana Ullah Nasir	Approved
			(1)	
	Office/Godown:	Pharm D	(1, 0,	
	Plot 7, street No 11, lawyers Society,	0000	201	
	Chaklala, Rawalpindi (ELI-00099)	(G, *O,	KV	

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

### **Deferred Renewal Cases:**

S.#	Name of Establishment	Name of Qualified Technical Person	Name of Management	Decision
1.	M/s B.Braun Pakistan (Pvt) Ltd.,	Umair Saleem Khan	Sinon Esermann	Approved
	Office: The Forum, Suite no. 501, 5 <sup>th</sup> Floor			
	Khayaban-e-Jami, Clifton Block -9,	Pharm D	Muhammad Arqam	
	Karachi (ELI-00006)		5	
			Ali Jaleel	
	Godown:		Cristoph Hux	
	Ground Floor, Plot No. C-153, Sector 6F,		6	
	Mehran Town, Karachi	(G' (O) ~	J.S.,	

Item 1(E): Misc Cases

Subject: <u>CANCELLATION OF ESTABLISHMENT LICENSE TO IMPORT MEDICAL DEVICES OF</u>
M/S ADVANCE SYSTEMS, LAHORE (ELI-00616)

M/s Advance Systems, Lahore (ELI-00616) was granted Establishment license to Import (ELI) on 14-12-2020 for a period of 5 years. Ms. Zoha Khalid was appointed as qualified person of the firm at the time of grant of license. However, she left the company and the firm did not intimate medical devices board regarding this change. The qualified person Ms. Zoha Khalid has approached Wafaqi Mohtasib (Ombudsman) Secretariat, Lahore and requested for removal her name on the license of M/s Advance Systems, Lahore.

The firm has now submitted a letter in writing that they are going to close the import form their company and close the company due to financial constraints. The have further informed that they have not imported any shipment since long and company is almost closed.

Therefore, they have requested to withdraw the name of qualified person and cancel their license to import medical devices (ELI-00616).

Decision: The board observed that the firm had made a request to cancel ELI of the firm which was considered in 107 MDB meeting. To complete requirements of law, the firm was provided opportunity of personal hearing. However, the applicant did not appear before the board and submitted a written reply reiterating the previous stance for cancellation of license and that they have no objection to the immediate cancellation of license. The board considered this written statement of the firm and decided to cancel ELI-00616 granted to the applicant by MDB. The board further advised that the MIS division shall immediately remove the name of qualified person of the firm Ms. Zoha Khalid from the ELI - 00616 if it is appearing on DRAP website or any other DRAP IT system.

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

Dr. Hanif Ullah (Deputy Director-XI)

Sr. No.	Name of Applicant(s)	Name of Manufacturer	Medical Device	Decision
1.	Medifa Enterprises, TF-185, Deans Trade Center Peshawar Cantt. ELI-00756 R&I Date: 22.05.2025 Fee: 31000/- Slip #36376019	Name of Manufacturer: Shezan Biocare Bio- Medical Equipment Co. Ltd., Address: #16-1 Jinhui Road, Jinsha Community Kengzi Sub-District pingshan New District 518122 Shebzhen People's Republic of China LOA Type: Copy Notarization: No Issue date: 31.03.2023 Validity: Dec, 2026 FSC Type: Not submitted	Brand Name: Biocare Generic Name: Digital Electrocardiograph (ECG machine) Applied as: Single Class: B Models/Code/sizes (as per FSC & application: iE101, iE300 and iE6 Shelf Life: NIL	Deferred for:  Notarized LOA (mentioning the applied brand name) is required.  Legalized FSC in the country of origin issued by the Government of People's Republic of China is required.  Legalized FSC in reference country or CE certificate / EU QMS certificate is required.  Clarification / selection of the code is required.  Declaration of conformity is required.  Shelf life verification / stability studies report is required.  ISO – Certificate is required.

2.	Medifa	Issued By: NIL Legalization: NIL Validity: NIL ISO – Certificate: Type: NIL Notarization NIL Validity: NIL Name of Manufacturer:	Brand Name: Micomme	Deferred for:
2.	Enterprises, TF-185, Deans Trade Center Peshawar Cantt.  ELI-00756  R&I Date: 22.05.2025  Fee: 31000/- Slip #19257589534	Name of Manufacturer:  Shezan Biocare Bio- Medical Equipment Co. Ltd.,  Address: #16-1 Jinhui Road, Jinsha Community Kengzi Sub-District pingshan New District 518122 Shebzhen People's Republic of China LOA Type: Copy Notarization: No Issue date: 31.03.2023 Validity: Dec, 2026 FSC Type: Not submitted Issued By: NIL Legalization: NIL Validity: NIL ISO – Certificate: Type: NIL Notarization: NIL Validity: NIL Validity: NIL Validity: NIL	Brand Name: Micomme Medical  Generic Name: Heated humidified high flow nasal cannula therapy device (HNFC)  Applied as: Single  Class: B  Models/Code/sizes (as per FSC & application:  NIL  Shelf Life: NIL	Notarized LOA (mentioning the applied brand name) is required.  Legalized FSC in the country of origin issued by the Government of People's Republic of China is required.  Legalized FSC in reference country or CE marking document is required.  Clarification / selection of the code is required.  Declaration of conformity is required.  Shelf life verification / stability studies report is required.  ISO – Certificate is required.  Justification for applying as single, and not as a system.
3.	JF International,	Name of Manufacturer:	Brand Name: Bionet	Deferred for:
	4th Floor, 10C, 6th Sunset Commercial Lane, Phase 2	Bionet Co., Ltd., Address: 5F, 61, Digital-Ro 31-Gil, Guro-Gu, Seoul	Generic Name: Electrocardiographic Analyser Applied as: System	Stamp paper shall be issued in the name of the firm / signatory.

	Ext, DHA, Karachi  ELI-00246  R&I Date: 21.05.2025  Fee: 31000/-	Republic of Korea 08375 Sub Assembly unit: Bionet Co., Ltd., #401, 34LS-ro 91 beon-gil, Dongan-gu, Anyang-Si, Gyeonggi-do	Class: B  Models/Code/sizes (as per FSC & application: Cardio Touch 3000 Shelf Life: 10 years	Notarized LOA on the letter head of the manufacturer (mentioning the brand name) is required.  Legalized FSC in the country of origin with validity is required.  Shelf life verification / stability studies report is required.
	Fee: 31000/- Slip #7997027901	LOA Type: Original Notarization: yes Validity: 01.01.2030 FSC Type: Copy Issued by: National Institute of Medical Devices Safety Information, South Korea Legalization: Apostille Validity: NIL ISO – Certificate: Type: Copy Notarization: Yes Validity: 19.10.2026 CE certificate / EU QMS certificate (MDR) Type: Copy Notarization: Yes (apostilled the notarization) Validity: 26.05.2024 Extended till 31.12.2028 for class IIa devices.	Sul Cadif (M) Sul Director 202	Clarification regarding variation in the address of manufacturer in Form and FSC etc.
4.	La Vie Pvt. Ltd., 450 G/3, Gohar Town, Lahore ELI: 00113	Name of Manufacturer: Zhejiang haichuang Medical Device Co., Ltd. Address: #3 Building No. 146, East Chaofeng	Brand Name: Bi-fix Generic Name: Surgical incision closure set Applied as: Set Class: B	Deferred for:  The firm has mentioned new application as well as proposed changes in the Form-7A. Clarification is required.  Notarized LOA (both) on the letter head of the manufacturer mentioning the brand

R&I Date: Road, Linping District, Models/Code/sizes (as per name and complete address of 29.05.2025 Hangzhou China FSC & application: importer is required. Fee: 31000/-LOA1: (Zhejiang 5HWH-2, 5HWH-4, Shelf life verification / stability studies report is required. Merely, sterilization haichuang Medical 5HWH-6, 5HWH-8, Slip Device Co., Ltd.) has 5HWH-10, 5HWH-12, dose setting report does not serve the #77290818984 authorized Joy Beyond 5HWH-16, 5HWH-20, purpose. Health Limited, China) (5HWH-24 applied but Clarification regarding variation in the not mentioned in FSC) address of manufacturer in Form, LOA, Type: copy Shelf Life: 36 months QMS certificate and FSC etc. Notarization: No Legalized valid FSC in the country of Issue date: 13.09.2024 origin is required. Validity: 12.09.2027 The firm shall apply as family. LOA2: (Joy Beyond Models 5HWH-20 and 5HWH-24 applied Health Limited, China but not mentioned in CE certificate. has authorized La Vie Model 5HWH-24 applied but not Pvt. Ltd., 450 G/3, Gohar Town, Lahore mentioned in FSC. Type: copy Notarization: No Issue date:01.08.2024 Validity: 31.08.2027 **FSC** Type: Copy Issued By: Zhejiang Medical Product Administration Legalization: Notarized (China council for the Promotion of International Trade China Chamber of International Commerce) Apostilled the notarization. Validity: 20.09.2025 ISO – Certificate: Type: Copy Legalization: Notarized (China council for the Promotion of International Trade

China Chamber of

5.	Bay-G Pharma, House No. 103-A, A Block Satellite Town Rawalpindi  ELI-00016 R&I Date: 09.07.2025 Fee: 62000/- Slip #310027118	notarized FSC (China council for the Promotion of International Trade China Chamber of	Brand Name: Believia Oxygen Concentrator OXC-05 Generic Name: Believia Oxygen Concentrator OXC-05 Applied as: NIL Class: C Models/Code/sizes (as per FSC & application: NIL Shelf Life: 3 years	Deferred for: Original fee challan is required. Correction of the manufacturer's title and address in Form-7A is required. Specify the medical device grouping in Form-7A. Notarized LOA mentioning complete address (103A instead of 03A) of the importer and brand name is required. Legalized valid FSC in the country of origin is required. Clarification regarding variation in the address of manufacturer in Form, LOA, QMS certificate and FSC etc. Clarification / selection of the model is required. DOC on the letterhead of the firm is required. Copies of the legalized (apostilled) FSC and notarized ISO-certificate and CE certificate / EU QMS certificate is required.
		China Chamber of International Commerce) Validity: 13.07.2025 ISO – Certificate:		

		Type: copy of notarized certificate  Legalization: Notarized (China council for the Promotion of International Trade China Chamber of International Commerce)  Validity: 04.01.2027  CE certificate / EU QMS certificate (MDR):  Type: copy of notarized certificate Legalization: Notarized (China council for the Promotion of International Trade China Chamber of International Commerce)  Validity: 03.03.2029	aul Gadir 1000	5).35.6 AM
6.	Bay-G Pharma, House No. 103-A, A Block Satellite Town Rawalpindi  ELI-00016  R&I Date: 09.07.2025  Fee: 62000/- Slip #01523899	Name of Manufacturer: Jiangue Yuyue Medical Equipment and Supply Co., Ltd., Address: Baisheng Road No. 1, Yuwell Industrial Park, Dan Yang, Jiangsu Province P.R. China  LOA Type: copy of already notarized LOA Notarization: Issue date: 03.06.2025 Validity: five years FSC Type: copy of already notarized	Brand Name: Believia Oxygen Concentrator OXC-10 Generic Name: Believia Oxygen Concentrator OXC-10 Applied as: NIL Class: C Models/Code/sizes (as per FSC & application: NIL Shelf Life: 3 years	Deferred for: Original fee challan is required. Correction of the manufacturer's title and address in Form-7A is required. Specify the medical device grouping in Form-7A. Notarized LOA mentioning complete address (103A instead of 03A) of the importer and brand name is required. Legalized valid FSC in the country of origin is required. Clarification regarding variation in the address of manufacturer in Form, LOA, QMS certificate and FSC etc. Clarification / selection of the model is required. DOC on the letterhead of the firm is required. Copies of the legalized (apostilled) FSC and notarized ISO-certificate and CE certificate / EU QMS certificate is required.

		Issued By: Jiangsu Medical Product Administration Legalization: copy of notarized FSC (China council for the Promotion of International Trade China Chamber of International Commerce) Validity: 13.07.2025 ISO – Certificate: Type: copy of notarized certificate Legalization: Notarized (China council for the Promotion of International Trade China Chamber of International Trade China Chamber of International Commerce) Validity: 04.01.2027 CE certificate / EU QMS certificate (MDR): Type: copy of notarized certificate Legalization: Notarized (China council for the	Aul Cadif (M)  Ocernber 202	S).35.6 AM
		certificate Legalization:	dul Gadir 102	9.35.
	D C E'			
7.	Bay-G Pharma, House No. 103-A, A Block Satellite Town Rawalpindi	Name of Manufacturer: Jiangue Yuyue Medical Equipment and Supply Co., Ltd., Address: Baisheng Road No. 1, Yuwell	Brand Name: Believia Portable Phlegm Suction Unit SU-10 Generic Name: Portable Phlegm Suction Unit SU- 10	Deferred for: Original fee challan is required. Correction of the manufacturer's title and address in Form-7A is required. Specify the medical device grouping in Form-7A.
	ELI-00016 R&I Date: 09.07.2025	Industrial Park, Dan Yang, Jiangsu Province P.R. China	Applied as: NIL Class: B Models/Code/sizes (as per FSC & application:	Notarized LOA mentioning complete address (103A instead of 03A) of the importer and brand name is required.
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Fee: 31000/-	LOA	NIL	Legalized valid FSc in the country of
Slip	Type: Not attached	Shelf Life: 5 years	origin is required.
#76753680	Notarization: Issue date:		Clarification regarding variation in the address of manufacturer in Form, LOA,
			QMS certificate and FSC etc.
	Validity: FSC		Legalized valid FSC in the country of origin is required.
			Clarification / selection of the model is
	Type: copy of already notarized		required.
	Issued By: Jiangsu Medical Product	odir (M	DOC on the letterhead of the firm is required.
	Administration	0,401,01	Copies of the legalized (apostilled) FSC and notarized ISO-certificate and CE
	Legalization: copy of notarized FSC (China council for the	An Cite Cr. So.	certificate / EU QMS certificate is required.
	Promotion of International Trade	di mo	
	China Chamber of	i, coll	
	International Commerce)	000	
	Validity: 13.07.2025		
	ISO – Certificate:		
	Type: copy of notarized certificate		
	Legalization: Notarized (China council for the		C) GAM
	Promotion of International Trade		5) 25.
	China Chamber of		9:3
	International Commerce)	Qa ari	٥١
	Validity: 04.01.2027	All CCIO 201	
	CE certificate / EU	Oile et	
	QMS certificate (MDR):	ut Director 202	
	Type: copy of notarized certificate Legalization:	7800	
	Notarized (China		
	council for the Promotion of		
	International Trade		
	China Chamber of International		
	Commerce)		
	Validity: 03.03.2029		

8.	Bay-G Pharma, House No. 103-A, A Block Satellite Town Rawalpindi	Name of Manufacturer:  Cofoe Medical Technology Co., Ltd., Address: 816 Zhenhua Road, Yuhua District, 410000 Changsha, Hunan, China LOA	Brand Name: Believia Blood Glucose Test Strips BG-01 50T Generic Name: Believia Blood Glucose Test Strips BG-01 50T Applied as: NIL Class: C	Deferred for:  Specify the medical device grouping in Form-7A.  Clarification regarding variation in the address of manufacturer in Form-7A, LOA, QMS certificate and FSC etc.  Clarification / selection of the model is
	R&I Date: 11.07.2025	Type: Copy of notarized LOA	Models/Code/sizes (as per FSC & application:	required.  DOC on the letterhead of the firm is
	Fee: 62000/- Slip #69213969	Notarization: China council for the Promotion of International Trade	NIL Shelf Life: 5 years	required.  Clarification and proof are required about the claimed shelf life.  Valid CE certificate is required.
		China Chamber of International Commerce	Oirest, L	Specify the model as per FSC.
		Validity: 09.05.2030 FSC Type: copy of notarized FSC Issued By: Hunan Medical Product Administration	December	
		Legalization: Apostilled the notarization of China council for the Promotion of International Trade China Chamber of International Commerce		S):35:6 AM
		Validity: 26.02.2027 ISO – Certificate:	All Coto Jose	
		Type: copy of notarized certificate	ut Director 202	
		Legalization: Apostilled the notarization of China council for the Promotion of International Trade China Chamber of International Commerce	Decellin	
		Validity: 12.07.2028 CE certificate / EU QMS certificate (MDR):		

		Type: copy of notarized certificate  Legalization: Apostilled the notarization of China council for the Promotion of		
		International Trade China Chamber of International Commerce		S GAM
		Validity: 26.05.2025		3,00.
9.	Bay-G Pharma, House No. 103-A, A	Name of Manufacturer: Cofoe Medical Technology Co., Ltd.,	Brand Name: Believia Blood Glucose Test Strips BG-01 Foil Pack 50T	Deferred for:  Specify the medical device grouping in Form-7A.
	Block Satellite Town Rawalpindi	Address: 816 Zhenhua Road, Yuhua District, 410000 Changsha, Hunan, China	Generic Name: Believia Blood Glucose Test Strips BG-01 Foil Pack 50T Applied as: NIL	Clarification regarding variation in the address of manufacturer in Form-7A, LOA, QMS certificate and FSC etc.
	ELI-00016	LOA	Class: C	Clarification / selection of the model is required.
	R&I Date: 11.07.2025	Type: Copy of notarized LOA	Models/Code/sizes (as per FSC & application:	DOC on the letterhead of the firm is required.
	Fee: 62000/- Slip	Notarization: China council for the Promotion of	NIL Shelf Life: 5 years	Clarification and proof are required about the claimed shelf life.
	#726547825	International Trade China Chamber of		Clarification of the term Foil Pack is required.
		International Commerce Validity: 09.05.2030		Valid CE certificate is required.
		FSC		Specify the model as per FSC.
		True a compression of materials	Osdir I (M	9:3
		Issued By: Hunan Medical Product Administration	an Checko, 50%	
		Legalization: Apostilled the notarization of China council for the Promotion of International Trade China Chamber of International Commerce	December 302	
		Validity: 26.02.2027		
		ISO – Certificate		
		Type: copy of notarized certificate		

		Legalization: Apostilled the notarization of China council for the Promotion of International Trade China Chamber of International Commerce Validity: 12.07.2028  CE certificate / EU QMS certificate (MDR):  Type: copy of notarized certificate  Legalization: Apostilled the notarization of China council for the Promotion of International Trade China Chamber of International Commerce Validity: 26.05.2025	December 202	
10.	Nextawits Private Limited, Office No. 8, First Floor, Shaheen View, Block-6, P.E.C.H.S, Main Shahrah- e-Faisal, Karachi ELI-01171 R&I Date: 30.05.2025 Fee: 31000/- Slip #1851937536	Name of Manufacturer: Tianchang City Anrui Medical Equipment Co., Ltd., Address: Renhe Industrial District, TianChang City, Anhui Province China LOA Type: Original Notarization: China council for the Promotion of International Trade China Chamber of International Commerce Validity: 3 years from 15.08.2024 FSC Type: copy Issued By: NIL Legalization: Apostilled the notarization of China council for the	Brand Name: CuraPro Surgical Gloves Generic Name: Sterile Surgical Gloves for Single Use Applied as: Set Class: B Models/Code/sizes (as per FSC & application: 6, 6.5, 7, 7.5, 8, 8.5, 9 Shelf Life: 5 years	Deferred for:  Stamp paper shall be issued in the name of the firm / signatory.  The fee has been submitted for Curacare respiratory and Anesthesia Product. Clarification is required.  The firm shall apply as family.  English translation of the issuing authority of the FSC is required.  Clarification / selection of the model is required.

Inter Chin Inter	motion of crnational Trade na Chamber of crnational Commerce		
	idity: 15.01.2026		
	0 – Certificate		
	e: copy		DIA.
Note cour Proi Inte	galization: carization of China ncil for the motion of crnational Trade na Chamber of crnational Commerce	And Oracion 202	9.35.6 AM
Vali	idity: 19.07.2027		
QM	certificate / EU IS certificate DR):	nt cember	
Typi	e: copy of notarized ifficate	Des	
Note cour Prog Inte	galization: carization of China ncil for the motion of crnational Trade na Chamber of crnational Commerce		C) GAM
Vali	idity: 26.05.2024		5,02.
	ended till 12.2028 for Class IIa ices	"Osque Os	9.

### Item No. III DEFERRED APPLICATIONS FOR REGISTRATION /

### **EVALUATOR: RANA IHSAN UL HAQ ATHAR DEPUTY DIRECTOR**

### **DEFERRED CASES IMPORT**

S#	Importer Name	Manufacturer Details	Name of MD / Class / Codes / Shelf life / etc.	Decision
1.	Hoora Pharma(Pvt)	Fujifil Healthcare	whole body X-ray Ct	Deferred for (Final Opportunity)
	Ltd.	Corporation Medical Syste	System	for:
	WH-01-20-A7-A8,	Operatin Group, Kashiwa		
	Korangi Creek	1, Shintoyofuta, Kashiwa-		

	Industrial Park,	shi, Chiba, 277-0804 Japan		1. clarification that name of
	Karachi (ELI-00037	FSC Japan		device as per FSC is Whole Body X-ray CT system SCENARIA View.
				2. Submission of valid LOA.
				3. submission of Form 7A along with annexures and undertaking on stamp paer.
2.	M/s Moon Enterprises Address of Importer 324 Rewaz Garden, Lahore ELI-00356	(Legal Manufacturer) Atlas Medical Address: Ludwig-Erhard-Ring 3, D- 15827 Blankenfelde- Mahlow, Germany  Manufacturing Site: M/s Atlas Medical, King Abdullah the Second industrial Estate, Street 19, Sahab Free Zone Area,	Atlas Anti-Human Globulin kit	Deferred (Final Opportunity) for:  1. The submission of valid notarized LOA with device name mentioned in it.  2. clarification that device name as per FSC is Atlas Anti-Human Globulin Reagent 10ml/vial.
		P.O. Box 204, Amman		
3.	M/s Moon Enterprises Address of Importer 324 Rewaz Garden,	11512, Jordan  Legal Manufacturer) Atlas Medical Address: Ludwig-Erhard-Ring 3, D- 15827 Blankenfelde- Mahlow, Germany	Atlas CRP Latex Test Kit	Deferred (Final Opportunity) for:  1. The submission of valid notarized LOA with device name mentioned in it.
	Lahore	Manufacturing Site: M/s Atlas Medical, King Abdullah the Second industrial Estate, Street 19, Sahab Free Zone Area, P.O. Box 204, Amman 11512, Jordan	adir (MIS)	25:6 AM
4.	M/s Moon Enterprises Address of Importer	Legal Manufacturer) Atlas Medical Address: Ludwig-Erhard-Ring 3, D- 15827 Blankenfelde-	Atlas Bovine Albumin	Deferred (Final Opportunity) for:  1. The submission of valid notarized LOA with device name mentioned in it.
	324 Rewaz Garden, Lahore	Mahlow, Germany  Manufacturing Site: M/s Atlas Medical, King Abdullah the Second industrial Estate, Street 19, Sahab Free Zone Area, P.O. Box 204, Amman 11512, Jordan		2. clarification that device name as per FSC is Atlas Bovine Albumin Reagent (22%) 10ml/vial and LOA is Bovine Albumin 22% - 10ml.
5.	M/s Moon Enterprises	(Legal Manufacturer) Atlas Medical Address:	Atlas D-Dimer Latex Test Kit	Deferred (Final Opportunity) for:
	Address of	Ludwig-Erhard-Ring 3, D-		

6.	Importer 324 Rewaz Garden, Lahore  Anax Associates Pvt	15827 Blankenfelde-Mahlow, Germany  Manufacturing Site: M/s Atlas Medical, King Abdullah the Second industrial Estate, Street 19, Sahab Free Zone Area, P.O. Box 204, Amman 11512, Jordan  MedPro Flex Cystoscopy	A cystoscopy drape is a	The submission of valid notarized LOA with device name mentioned in it.  Deferred (last opportunity) the
	Ltd. Plot # 15, HDR Industrial Estate Next to Zaamin City Gajjumatah Lahore (ELM-0071) [883-6L] R & I Dy.No. 10712 dated 25-04-2025.	Drape Pack Class: A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 2765736166 Reference Code:  • 7012	specialized surgical drape designed to provide a sterile working surface and fluid control during cystoscopy procedures. Flex Cystoscopy Drape sheets made up of non-woven SMS/SMMS/SMMMS/PE fabric laminated with thin layer of PE film through adhesive lamination process.	case for submission of following:  1. Clarification whether the towels are manufactured by a medical device manufacturer. Submit ISO13485 and FSC as evidence.  2. Clarification that Surge Gauze will be procured from market or through out-sourcing.  3. submission of evidence from RRA that applied product is a medical device.  4. submission of size of each device included in set and its use.  5. Following panel is constituted for verification of manufacturing facility:  1. Prof. Dr. Mehmood Ahmad-Member MDB  2. Dr. Farid Khan-Member MDB  3. Area FID
		الال	Sc10, JOLE	Area FID will coordinate and submit the inspection report.
7.	Anax Associates Pvt Ltd. Plot # 15, HDR Industrial Estate Next to Zaamin City Gajjumatah Lahore (ELM-0071) [884-6L] R & I Dy.No. 10713 dated 25-04-2025.	MedPro Eye Drape Class: A Storage conditions: Temp: 25°C ± 5°C Humidity: NMT 60% Fee: 6000/- Fee Slip No. 066065472 Reference codes: • 2060 (60cm × 60cm) • 2100 (100cm ×100cm) • 2150 (100cm ×150cm)	Eye drapes are disposable sterile sheets that are used to separate and safeguard the eye or ocular area throughout medical tests and surgical operations. They are made up of non-woven SMS/SMMS/SMMMS/PE fabrics that are impervious to bacteria, fluids, and fragments, which make them	Deferred for the verification of the facility by the following panel  1. Prof. Dr. Mehmood Ahmad-Member MDB  2. Dr. Farid Khan-Member MDB  3. Area FID  Area FID will coordinate and submit the inspection report.

			perfect for preserving a sterile environment.	
8.	M/S Arsons Pharmaceutical	Belladerma Fast Plaster	Belladerma Fast Plaster	Rejected due to following reasons:
	Industries Pvt Ltd 2.5 km Defence Road, off Multan Road Lahore  [ELM No. 0051]  Approved Section: Adhesive Plaster/ Tape Section  Medicated Plaster Bandage Section  First Aid Bandage Section  Care Gauze Bandage Section  Arsotulle/Arsotin Section (Sterile)  Medi-Swab Section  Crepe Bandage	(Diclofenac Diethylamine2%) Class-B 5 years Sizes: 12cm x 14.5cm 12cm x 15.5cm 12cm x 16.5cm Pack Size 24 Plasters, (Patch) 20 Plasters Fee Challan No 4743893904 Rs. 20000/- Date 20-07-2023 08-08-2023	(Diclofenac Diethylamine2%) To treat muscle and joint pain due to sprains, bruises, etc. (including ligaments and tendons – structures that strengthen the joints) – for both pain at rest, pain on movement Swelling around the joints	<ol> <li>Firm has not provided any evidence that applied product is registered as medical device in any reference regulatory authorities.</li> <li>Firm has changed the name from Belladerma Fast Plaster to Voltrex Plaster but has not provided revised application Form.</li> <li>Firm stated that online application has been submitted to PE&amp;R and approval is awaited.</li> <li>Firm has submitted scientifically false statement that Diclofenac Diethylamine patch absorbs the pain only nor does it release any pharmacological drug into the skin.</li> </ol>
9.	Arsons Pharmaceuticals Industries (Pvt) Ltd, 2.5 KM, Defense Road, Off Multan Road, Lahore (ELM-0051) [727-L]	AR Cotton Roll 100% Absorbent Cotton Class A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 7690445907	100% Absorbent Cotton: Surgical Cotton Roll is also called cotton wool or absorbent cotton. It is essential in the medical field. It is made of 100% cotton, which provides softness and absorbency. The cotton rolls are highly used in wound cleaning, dressing, and cushioning.	Rejected as the MDB does not permit the manufacture of absorbent cotton under the First Aid Bandage section.
10.	Arsons Pharmaceuticals Industries (Pvt) Ltd, 2.5 KM, Defense Road, Off Multan Road, Lahore (ELM-0051) [728-L]	AR Wove Bandage 100% Cotton (BP Type 2) Class A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 503737508	A lightweight cotton bandage is used to hold a dressing in place, the Bandages is used to cover and protect wounds, to hold together the skin edges of a wound, to support an injured part of the	Deferred for the verification of the facility by the following panel 1. Prof. Dr. Mehmood Ahmad- Member MDB 2. Dr. Farid Khan-Member MDB 3. Area FID

			body, or to secure objects to the skin	Area FID will coordinate and submit the inspection report.
11.	Arsons Pharmaceuticals Industries (Pvt) Ltd, 2.5 KM, Defense Road, Off Multan Road, Lahore (ELM-0051) [878-7L]	Care Gauze Sterile X-Ray Detectable woven Gauze/cloth  Class: B Shelf Life: 5 years Fee: 25000 Fee Slip No. 9430238935  Sizes: (cm) 5x5, 7.5x7.5, 10x10, 15x15,	Sterile X-ray abdominal compresses are used in surgical procedures for the absorption of fluid. The dressing has an X-Ray thread which allows the product to be located using X-rays.  Intended Use  Used During Surgery to absorb blood & exudates. Clean wounds & prevent wounds from being infected.	Deferred for the verification of the facility by the following panel  1. Prof. Dr. Mehmood Ahmad-Member MDB  2. Dr. Farid Khan-Member MDB  3. Area FID  Area FID will coordinate and submit the inspection report.
12.	Arsons Pharmaceuticals Industries (Pvt) Ltd, 2.5 KM, Defense Road, Off Multan Road, Lahore (ELM-0051) [879-7L]	X-Ray Lap Sponges  X-Ray Detectable Open Wove Bandage Abdominal Cloth  Class: B Shelf Life: 3 years Fee: 25000 Fee Slip No. 2270953395 Sizes: (cm) 5x5, 7.5x7.5, 10x10, 15x15,	Sterile X-ray abdominal compresses are used in surgical procedures for the absorption of fluid. The dressing has an X-Ray thread which allows the product to be located using X-rays. Available in different sizes. The compresses have stitched edges and are available with and without loop.  Intended Use  Used During Surgery to absorb blood & exudates. Clean wounds & prevent wounds from being infected.	Deferred for the verification of the facility by the following panel  1. Prof. Dr. Mehmood Ahmad-Member MDB  2. Dr. Farid Khan-Member MDB  3. Area FID  Area FID will coordinate and submit the inspection report.
13.	Arsons Pharmaceuticals Industries (Pvt) Ltd, 2.5 KM, Defense Road, Off Multan Road, Lahore (ELM-0051) [880-7L]	ARSO-MAX Combine Dressing X-Ray Detectable Non-Woven Gauze Cloth  Class: B Shelf Life: 5 years Fee: 25000 Fee Slip No. 2751421858  Sizes: (cm) 10x10, 15x20,	Medical Arso-Max Combine Dressing Non- Woven is a sterile, absorbent, non-adherent dressing designed for use on wounds. It is composed of a non- woven pad, a polyurethane film, and a silicone adhesive intended use	Deferred for the verification of the facility by the following panel  1. Prof. Dr. Mehmood Ahmad-Member MDB  2. Dr. Farid Khan-Member MDB  3. Area FID  Area FID will coordinate and submit the inspection report.

			dressi	oned protection.	
			and p	ly over wound primarily for initia	ls
			injury contro	an olling blood loss	d
14.	Applicant Name:	Legal Manufacturer:	Bran	d Name:	Deferred with final opportunity to submit the following:
	M/s A.M. Distributors	M/s ANHUI TIANRUN MEDICAL PACKAGING		cal Sterilization ators	1. the brand name of the applied medical device.
	Address: 4th Floor, Plot 37-C,	MATERIALS CO., LTD Address:	Class Shelf	A life: 2 Years	2. the type of the medical device to be considered in this application as multiple products
	Bukhari Commercial Lane 8, Phase VI,	No. 29 of Chaoyang Road, Yixiu District 246003	S		has been applied in single application.
	D.H.A, Karachi, Pakistan 75500	Anqing City, Anqing Province - China	#	Codes Steam	
	ELI-00248	FSC (China)	1	Indicator Strips Class 4	
	Date of Receiving: 13-March-2025	Validity: 27-02-2027  LOA Validity:	2	Steam Indicator Strips Class 5	
	Fee: PKR 19,000/- + 6,000/-	20-June-2027	3	Steam Indicator Strips Class 6	E.G AM
	Slip: 63367766560 & 95417733		4	Formaldehyd e Indicator Strips Class 4	90.
		Abdul O	5	Plasma Chemical Indicator Strips	
		Assistant Dece	6	Plasma sterilization Biological Indicator	
		onday, and becar	7	Plasma sterilization Biological Indicator 0.5h	
		O.	8	Steam Sterilization Biological Indicator	

		Assistant Discontinues of the Control of the Contro	1 1 1 1 2 1 3 1 4	Biological Indicator 0.5h  ETO sterilization Biological Indicator 24h  Bowie & Dick Test Sheet  Plasma Tape 19mm x 50m  Autoclave Tape (Steam)  Bowie & Dick Test Pack  EO Tape  EO indicator	3	55.6 ANN
15.	M/s Moon Enterprises  Address of Importer 324 Rewaz Garden, Lahore	Legal Manufacturer) Guangzhou iCare Medical Technology Co., Ltd., Address: First Floor A No.8, Lianhua Port Industrial Zone, Lotus Mountain Bonded Area, China		ARE Blood Lance	t	Rejected the application due to following reasons:  1. the name of the device on LOA is iCare (ImuMed) Blood Safety Lancet.  2. FSC China valid till 27.06.2025 and device name in it is Alcohol Pads for Single Use.  3. copy of the FSC Germany issue date 08.01.2020. The name of device is safety lancet.  4. copy of the FSC Spain valid till 13.07.2020. The device name is iCare Twisted Safety Lancet.  5. Firm has not submitted the codes of the product.

16.	RMK Bio Private Ltd, 83A, BIII, Gulberg III, MM Alam Road, Near Hussain Chowk, Lahore.  ELI-01277 6022-P 31,000/-	Sonova AG Laubisrutistrasse 28, CH- 8712 Stafa, Switzerland.	Sonova Phonak Audeo I-Sphere Hearing Aid  Class-B  Shelf Life: 5 Years  Models: Phonak Audeo ISphere Trial (Atlantic green) Phonak Audeo ISphere Trial (Silver grey)	Deferred with final opportunity for the submission of:  1. original legalized FSC, EU QMS certificate.  2. Fee for the family.
17.	Perfect Medical System, D-442, D Block Satellite Town, Rawalpindi. ELI-00964 5705-P 62,000/-	Legal Manufacturer: Spinreact S.A.U CR Santa Coloma No. 7 SantEsteve, Spain.  FSC: Spain. Date of Issuance: 29-04-2022. LOA validity 02-03-2026 ISO 13485 validity 29-05-2025 CE certificate validity 27-05-2025	IVD (Coagulation Cluster)  Class-C Shelf Life: 2 Years	Deferred the application with final opportuity for the submission of:  1. that the firm will submit the type of the device to be considered in this application.  2. that the firm will apply remaining devices separately through online MDMC portal.
18.	Perfect Medical System, D-442, D	Legal Manufacturer: Spinreact S.A.U		Deferred (last opportunity) the application for:
	Block Satellite Town, Rawalpindi. ELI-00964 5704-P 62,000/-	CR Santa Coloma No. 7 SantEsteve, Spain.  FSC: Spain. Date of Issuance: 29-04-2022. LOA validity 02-03-2026 ISO 13485 validity 29-05-2025 CE certificate validity 27-05-2025	Serodiagnostic Cluster)  Class-C  Shelf Life: 1.5 Years  Codes as per FSC	1. that firm will submit the type of the device to be considered in this application. The name of the device should be as per FSC and LOA. Copies of FSC and LOA to be enclosed with reply.  2. that the firm will apply remaining device(s) separately through online MDMC portal.
19.	Noor International	Top Corporation, 19-10 Senju-cho, Adachi-ku, Tokyo 120-0035, Japan	TOP-5530	Deferred (Last opportunity) for submission of:

	Noor House, 29-D,		Syringe Pump	1. original legalized FSC
	Block-6, PECHS, Karachi -75400	Meditop Corporation (M) SDN. BHD. (Plant 2), No.	9018.1900	confirming the availability of the product in the market.
	(ELI-00061 Fee 62000/-	3, Persiaran Usahawan, Taman IKS, Seksyen 9, 43650, Bandar Baru Bangi,	Class C Shelf life 6 years	2. Notarized and valid LOA & ISO 13485.
		LOA valid till 31.12.2027	(8)	6.6 K
		FSC Japan	adif (MIS)	5
		Issue date 01.01.2025	cio 2023,	
20.	Hospital Supply corporation	technology s.r.o.,	MMT Denflow Chord PC	Deferred (Last opportunity) for submission of:
	42 Darul Aman Housing Society,	Pasteurova 67/15, Klasterni Hradisko, 77900 Olomouc,		1. valid, notarized LOA.
	Block 7&8, Karachi (ELI-00005	Czech Republic		2. Form 7A with annexures and undertaking on stamp paper.
21.	M/s Elite Traders Office 342-B 1st Floor,B-Block Satellite Town Rawalpindi. ELI-00193	Legal manufacturer: Beijing Chunlizhengda Medical Instruments Co., Ltd No.10 Xinmi West 2nd Road, South Area of Tongzhou Economic Development Zone, Beijing China.  Legalized FSC issued by China validity dated 20-03- 2024.	Hip Prosthesis System (Acetabular cup Mental cup)  Class-D  Shelf life: 5years  Sizes: 44, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70, 72	Deferred (Last opportunity) for submission of:  1. Design examination Certificate.  2. Brand name of the medical device.  3. the name of device as per FSC and ISO is Hip Joint Prosthesis (Acetabular Cup).
22.	M/s Safeway Systems Pakistan, Flat No. 4, 2nd Floor, Amna Shopping Centre, Misrial Road, Rawalpindi.  (ELI-00308)  Evaluator: AD-IV [2739-P]	Legal Manufacturer: M/s CPT Sutures Co., LTD, 83 Hai Ba Trung, Ben Nghe Ward, District 1, Ho Chi Minh City, 700000, Vietnam  FSC Vietnam issuance 25-09-2020 valid for 3 years (Original)	Carepace ® Temporary Cardiac Pacing Lead (Wire)  Class-D  Shelf life: 5 years  Codes & Sizes:	Rejected the application due to following reasons;  1. Firm has not submitted the FSC of any reference country.  2. Firm has submitted the certificate of compliance issued by QCC that is non-notified certification body.

23.	Applicant Name:	Name of Manufacturer:	Brand Name:	Approved Taqpath <sup>TM</sup> Menu Gene
	M/s. Briogene Pvt.	Gene Proof a.s	GeneProof <sup>TM</sup> Hepatitis	Proof Hepatitis C virus (HCV) Diagnostic PCR Kit Codes/Sizes A58427.
	Ltd	Manufacturing Site: Videnska 101/119, Dolni Herspice 619 00 Brno.	C Virus (HCV) Diagnostic PCR Kit	
	Address:	Czech Republic		- PI
	196-A, Sindhi Muslim, Cooperative Housing Society, Shahrah.e.Faisal, Karachi-74400	FSC: UK Validity- 31-12-2028 FSC: NA	(Generic name): Hepatitis C Virus (HCV) Diagnostic PCR Kit	35:6 AM
	(ELI-00015)	LOA Validity: 31-Dec -2025	Class: D	
	Date of R&I 07-01-2025	EC Certificate Validity: 17-01-2024 extension letter provided	Shelf Life: 23 months	
	Fee Details: Paid Fee: 62,000/-	ISO 13485 Validity: 26-11-2026	Codes/Sizes: A58427	
	·	20,000		
	Fee challan Number:	Ollie		
	0603703590 Dated: 08-01-2025			G AIN'
24.	Applicant Name:	Name of Manufacturer:	Brand Name:	Approved <b>Taqpath</b> <sup>TM</sup> <b>Menu</b>
21.	M/s. Briogene Pvt.	Legal Manufacturer:  Gene Proof a.s	GeneProof <sup>TM</sup> Hepatitis B Virus (HBV) PCR Kit	Gene Proof Hepatitis B virus (HBV) Diagnostic PCR Kit Codes/Sizes A58426.
		Manufacturing Site:		
	Address:	Videnska 101/119, Dolni	(Generic name):	
	196-A, Sindhi Muslim,	Herspice 619 00 Brno. Czech Republic	Hepatitis B Virus (HBV) PCR Kit	
	Cooperative Housing Society, Shahrah.e.Faisal, Karachi-74400	FSC: UK Validity- 31-12-2028	Class: D	
	Karaciii-74400	LOA Validity: 31-Dec -2025	Shelf Life: 23 months	
	(ELI-00015)	EC Certificate Validity: 17-01-2024		
	Date of R&I	extension letter provided	Codes/Sizes: A58426	
		ISO 13485		Dags 26 of 66

	24-01-2025	Validity: 26-11-2026		
	Fee Details:			
	Paid Fee: 62,000/-			
	Fee challan Number:			
	45051683			
	Dated: 15-01-2025			6
25.	M/S TRI-TECH INTERNATIONAL	Legal Manufacturer: M/S Jiangsu Yuyue Medical	Yuwell	Rejected due to the following reasons:
	10-C, 6TH Sunset Commercial Lane,	Equipment & Supply Co., Ltd No. 1 Baisheng Road, Development Zone,	Infrared Ear Thermometer	1. Firm has submitted copy of EU quality management System but product not mentioned in it.
	Phase 2 EXT, DHA, KARACHI,	Danyang, Jiangsu, 212300 China.	Class-B	2. copy of the ISO 13485 not
	PAKISTAN.	Manufacturing facilities:		notarized.
	ELI-00247	M/S Jiangsu Yuyue Medical Equipment & Supply Co.,	Shelf life: 5 years	3. copy of the FSC china is valid till 13.07.2025-expired.
	138-C	Ltd No. 1 Baisheng Road, Development Zone,	Model:	4. Firm has not submitted the original documents.
	Evaluator: AD-III	Danyang, Jiangsu, 212300 China.	YHT101	
	4	M/S Jiangsu Yuyue Medical Equipment & Supply Co., Ltd Yunyang Industrial Park, Danyang City, Jiangsu Province, CHINA	dir (MIS)	55:6 AM
		FSC China validity 09-02-2024	goto, 052,	
		FSC Germany issued 11- 08-2021	3081	
26.	M/S TRI-TECH INTERNATIONAL	Legal Manufacturer: M/S Jiangsu Yuyue Medical	Yuwell	Rejected due to the following reasons:
	10-C, 6TH Sunset Commercial Lane,	Equipment & Supply Co., Ltd No. 1 Baisheng Road,	Mesh Nebulizer	Firm has submitted copy of EU quality management System but
	Phase 2 EXT, DHA,	Development Zone, Danyang, Jiangsu, 212300	Class-B	product not mentioned in it.
	KARACHI,	China.		2. copy of the ISO 13485 not
	PAKISTAN.	Manufacturing facilities:	Shelf life: 5 years	notarized.
	ELI-00247	M/S Jiangsu Yuyue Medical Equipment & Supply Co.,	Model:	3. copy of the FSC china is valid till 13.07.2025. The device name not mentioned in it.
	139-C	Ltd No. 1 Baisheng Road, Development Zone,	M102	

	Evaluator: AD-III	Danyang, Jiangsu, 212300 China.		4. Firm has not submitted the original documents.
		M/S Jiangsu Yuyue Medical Equipment & Supply Co., Ltd Yunyang Industrial Park, Danyang City, Jiangsu Province, CHINA	adir (MIS)	GAM
		ECC China wali dita	1191	(a)
		FSC China validity	10 (M) The	
		09-02-2024	30, (1)	
		FSC Germany issued 11- 08-2021		
27.	M/S TRI-TECH INTERNATIONAL	Legal Manufacturer: M/S Jiangsu Yuyue Medical	Yuwell	Rejected due to the following reasons:
		Equipment & Supply Co.,	Electronic Blood	
	10-C, 6TH Sunset Commercial Lane,	Ltd No. 1 Baisheng Road, Development Zone,	Pressure Monitor	1. Firm has submitted copy of EU quality management System but
	Phase 2 EXT, DHA,	Danyang, Jiangsu, 212300	Class-B	product not mentioned in it.
	KARACHI, PAKISTAN.	China.  Manufacturing facilities:	Class-B	2. copy of the ISO 13485 not notarized.
			Shelf life: 5 years	3. copy of the FSC china is valid
	ELI-00247	M/S Jiangsu Yuyue Medical Equipment & Supply Co.,		till 13.07.2025. The device name
	142-C	Ltd No. 1 Baisheng Road,	Model:	is Yuwell Upper Arm Type Electronic Blood Pressure
	142-0	Development Zone,	YE660D	Monitor.
	Evaluator:	Danyang, Jiangsu, 212300 China.	TEOOOD	4. Firm has not submitted the
	AD-III	and		original documents.
		M/S Jiangsu Yuyue Medical Equipment & Supply Co., Ltd Yunyang Industrial Park, Danyang City, Jiangsu Province, CHINA	sciol Joss,	
			700.	
		FSC China validity		
		09-02-2024		
		FSC Germany issued 11- 08-2021		
28.	M/S TRI-TECH		Yuwell	Rejected due to the following
	INTERNATIONAL	M/S Jiangsu Yuyue Medical Equipment & Supply Co.,	Oxygen Concentrator	reasons:
	10-C, 6TH Sunset	Ltd No. 1 Baisheng Road,		1. As per submitted EU quality
	Commercial Lane,	Development Zone, Danyang, Jiangsu, 212300 China.	Class-B	management System, its class IIb medical device while firm has applied as Class B.
		MDD (12-11-2025.) (Manual )	<u> </u>	Do ao 20 of 66

	Phase 2 EXT, DHA,	Manufacturing facilities:	Shelf life: 3 years	2. copy of the ISO 13485 not
	KARACHI, PAKISTAN. ELI-00247 144-C	M/S Jiangsu Yuyue Medical Equipment & Supply Co., Ltd No. 1 Baisheng Road, Development Zone, Danyang, Jiangsu, 212300 China.	Model: 7F-B5	notarized.  3. copy of the FSC china is valid till 13.07.2025. The code 7F-B5 not mentioned in it.  4. Firm has not submitted the original documents.
	Evaluator: AD-III	M/S Jiangsu Yuyue Medical Equipment & Supply Co., Ltd Yunyang Industrial Park, Danyang City, Jiangsu Province, CHINA  FSC China validity 09-02-2024 FSC Germany issued 11- 08-2021	adir 1 (MIS)	35.6
29.	M/S TRI-TECH INTERNATIONAL  10-C, 6TH Sunset Commercial Lane, Phase 2 EXT, DHA, KARACHI, PAKISTAN.  ELI-00247  143-C  Evaluator: AD-III	M/S Jiangsu Yuyue Medical Equipment & Supply Co., Ltd No. 1 Baisheng Road, Development Zone, Danyang, Jiangsu, 212300 China.  Manufacturing facilities: M/S Jiangsu Yuyue Medical Equipment & Supply Co., Ltd No. 1 Baisheng Road		Rejected due to the following reasons:  1. ISO 13485 not notarized.  2. copy of the FSC China Valid till 13.07.2025.

20	N/G EDI EEGII	7 775 0 .	X 7 11	T
30.	M/S TRI-TECH INTERNATIONAL	M/S Jiangsu Yuyue Medical	Yuwell Portable Phlegm	Rejected due to the following reasons:
	10-C, 6TH Sunset Commercial Lane,	Equipment & Supply Co., Ltd No. 1 Baisheng Road, Development Zone,	Suction Unit	1. the device name not mentioned in EU QMS certificate.
	Phase 2 EXT, DHA, KARACHI,	Danyang, Jiangsu, 212300 China.	Class-B	2. copy of the ISO 13485 not notarized.
	PAKISTAN.	Manufacturing facilities: M/S Jiangsu Yuyue Medical	Shelf life: 5 years	3. copy of the FSC china is valid till 13.07.2025. The code 7E-B5
	ELI-00247	Equipment & Supply Co., Ltd No. 1 Baisheng Road,	1151	not mentioned in it.  4. Firm has not submitted the
	141-C	Development Zone, Danyang, Jiangsu, 212300	Model: 7E-B5	original documents.
	Evaluator: AD-III	China.	Sciol 5052	
		M/S Jiangsu Yuyue Medical Equipment & Supply Co., Ltd Yunyang Industrial Park, Danyang City, Jiangsu Province, CHINA FSC China validity 09-02-2024	uper,	
	d	FSC Germany issued 11-08-2021		. N
31.	M/S TRI-TECH INTERNATIONAL 10-C, 6TH Sunset Commercial Lane, Phase 2 EXT, DHA, KARACHI, PAKISTAN.	M/S Jiangsu Yuyue Medical Equipment & Supply Co., Ltd No. 1 Baisheng Road, Development Zone,	Yuwell Non-Contact Infrared Thermometer  Class-B  Shelf life: 5 years	Rejected due to the following reasons:  1. the name of device in LOA is Infrared Thermometer.  2. the name of device not mentioned in EU QMS certificate.  3. copy of the ISO 13485 not notarized.
	ELI-00247 140-C	Equipment & Supply Co., Ltd No. 1 Baisheng Road, Development Zone, Danyang, Jiangsu, 212300	Model: YT-2C	<ul><li>4. copy of the FSC china is valid till 13.07.2025. The code 7E-B5 not mentioned in it.</li><li>5. Firm has not submitted the</li></ul>
	Evaluator: AD-III	China.		original documents.
		M/S Jiangsu Yuyue Medical Equipment & Supply Co., Ltd Yunyang Industrial Park, Danyang City, Jiangsu Province, CHINA		

32.	Name National Enterprises Address of Importer	FSC China validity 09-02-2024 FSC Germany issued 11- 08-2021 Legal Manufacturer: Disa Medinotec (Pty) Ltd Manufacturing Site:	Brand Name Trachealator Rx Non- Occlusive Airway	Rejected the case due to the following reasons:
	409, 4th floor Al-Sehat Centre Annexe Reagent Plaza, Shahrah-e-Faisal Karachi  ELI- 00043  R & I 18-10-2024 & 04-12-2024	Stand 171,Northlands Business Park, Bush Telegraph Street, Northriding, Johannesburg, 2169, South Africa  FSC: Country of Origin Validity:06-02-2025  LOA Validity: 01-01-2027	Dilation Catheter (Generic name) Trachealator Rx Non- Occlusive Airway Dilation Catheter Class A Shelf Life: 03 years Codes/Sizes: TRD1-06030 TRD1- 07030 TRD1-08030 TRD1-09030 TRD1- 10030 TRD1-12040	<ol> <li>the generic name as per Form 6A is Bronchial Balloon or catheter.</li> <li>The FSC was not valid at the time of submission of reply.</li> <li>the applied codes are mentioned in the FSC.</li> <li>the firm has not submitted fee for the family as per MDB decision.</li> </ol>
		Assis Deco	TRD1-14540 TRD1- 16040 TRD1-18040	
33.	Quality Medical Services, H-49. Gordon College Road Rawalpindi ELI: 00123 1141-P	Legal Manufacturer:  M/s Zhangjiangang Xiehe Medical Apparatus & Instruments Co., Ltd, Zhashang Industrial Zone, Yangshe Town Zhangjiagang City, Jiangsu, China	Zhangjiangang Xiehe Medical Apparatus & Instruments Co., Ltd (Emergency Stretcher & Stretcher Accessories)	
	5,000/-	FSC Original China Valid till: 2025-02-24 LOA Validity: 30/04/2027	Shelf Life: 05 years  Codes & Sizes: as per FSC  STAIR STRETCHER  · YXH-5A · YXH-5B  · YXH-5E · YXH-5F  · YXH-5G · YXH-5H  · YXH-5L · YXH-5N  · YXH-5K · YXH-5M  TRANSFER BED  · YXH-4L · YXH-6L	4. firm has applied multiple products in single application.

		AMBULANCE STRETCHER	
		∘ YXH-3A ∘ YXH-3F	
		∘ YXH-3B ∘ YXH-3G	
		° YXH-3A2 ° YXH-2A	
		∘ YXH-3A3 ∘ YXH-2B	
		° YXH-3A5 ° YXH- 2C	
		° YXH-3B2 ° YXH-3B3	6.0
		° YXH-3C ° YXH-3E2	5
		° YXH-3D ° YXH-3K	
	, G	° YXH-3D2 ° YXH-3D3	
	1000 in	∘ YXH-3E ∘ YXH-4G	
	Vo. On	° YXH-3E3	
	Alou Di	TRANSFER BED	
	is to co	∘ YXH 2H ∘ YXH-3H	
	182, De	° YXH-2H1 ° YXH-4H	
	Assistant Dece	FOLDING STRETCHER	
		° 20170101	
	-00	· 20170191	
	onoc	SCOOP STRETCHER	
N	Onoc	SCOOP STRETCHER  • YXH-4A • YXH-4C	anh
N	Onoc	SCOOP STRETCHER	GAN
	onoc	SCOOP STRETCHER  • YXH-4A • YXH-4C	35:6 AM
	onoc	SCOOP STRETCHER  · YXH-4A · YXH-4C  · YXH-4B · YXH-4D  STRETCHER  · YXH-1A6A · YXH-	35:6 AM
	onoc . O	SCOOP STRETCHER  ∘ YXH-4A ∘ YXH-4C  ∘ YXH-4B ∘ YXH-4D  STRETCHER  ∘ YXH-1A6A ∘ YXH-6C	35:6 AM
	(O)	SCOOP STRETCHER  · YXH-4A · YXH-4C  · YXH-4B · YXH-4D  STRETCHER  · YXH-1A6A · YXH-6C  · YXH-1A6B · YXH-6D	5:6 AM
	(O)	SCOOP STRETCHER  · YXH-4A · YXH-4C  · YXH-4B · YXH-4D  STRETCHER  · YXH-1A6A · YXH-6C  · YXH-1A6B · YXH-	85:6 AM
	(O)	SCOOP STRETCHER  · YXH-4A · YXH-4C  · YXH-4B · YXH-4D  STRETCHER  · YXH-1A6A · YXH-6C  · YXH-1A6B · YXH-6D	35:6 AM
	(O)	SCOOP STRETCHER         ∘ YXH-4A ∘ YXH-4C         ∘ YXH-4B ∘ YXH-4D         STRETCHER         ∘ YXH-1A6A ∘ YXH-6C         ∘ YXH-1A6B ∘ YXH-6D         ∘ YXH-1A6C ∘ YXH-6E         ∘ YXH-1A6D ∘ YXH-	35.6 AM
	(O)	SCOOP STRETCHER  ∘ YXH-4A ∘ YXH-4C  ∘ YXH-4B ∘ YXH-4D  STRETCHER  ∘ YXH-1A6A ∘ YXH-6C  ∘ YXH-1A6B ∘ YXH-6D  ∘ YXH-1A6C ∘ YXH-6E  ∘ YXH-1A6D ∘ YXH-6F	35.6 AM
	(O)	SCOOP STRETCHER         ∘ YXH-4A ∘ YXH-4C         ∘ YXH-4B ∘ YXH-4D         STRETCHER         ∘ YXH-1A6A ∘ YXH-6C         ∘ YXH-1A6B ∘ YXH-6D         ∘ YXH-1A6C ∘ YXH-6E         ∘ YXH-1A6D ∘ YXH-6F         ∘ YXH-1A6E ∘ YXH-7A         ∘ YXH-1A6F ∘ YXH-	35.6 AM
	onday, and onday, onday	SCOOP STRETCHER  ∘ YXH-4A ∘ YXH-4C  ∘ YXH-4B ∘ YXH-4D  STRETCHER  ∘ YXH-1A6A ∘ YXH-6C  ∘ YXH-1A6B ∘ YXH-6D  ∘ YXH-1A6C ∘ YXH-6E  ∘ YXH-1A6C ∘ YXH-6F  ∘ YXH-1A6F ∘ YXH-7A  ∘ YXH-1A6F ∘ YXH-7B(A)  ∘ YXH-1A6G ∘ YXH-7B(A)	35.6 AM
	(O)	SCOOP STRETCHER  ∘ YXH-4A ∘ YXH-4C  ∘ YXH-4B ∘ YXH-4D  STRETCHER  ∘ YXH-1A6A ∘ YXH-6C  ∘ YXH-1A6B ∘ YXH-6D  ∘ YXH-1A6C ∘ YXH-6E  ∘ YXH-1A6C ∘ YXH-6F  ∘ YXH-1A6F ∘ YXH-7A  ∘ YXH-1A6F ∘ YXH-7B(A)  ∘ YXH-1A6G ∘ YXH-7B(B)  ∘ YXH-1A6K ∘ YXH-7B(B)	SS:6 ANN

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	○ YXH-1A6N ○ YXH- 8D
	∘ YXH-1A6H ∘ YXH- 6B
	° YXH-1A6L ° YXH- 1A6J
	∘ YXH-6A ∘ YXH-1A6P
	∘ YXH-6A ∘ YXH-1A6P ∘ YXH-1A6A-2
	MEDICAL EXTERNAL FIXATOR
	° YXH-7H(A) ° XH- 17(A)
Alogo Dir	° YXH- 7H(B) ° XH- 17(B)
	∘ XH-16(A) ∘ YXH- 7D
isla co	∘ XH-16(B) ∘ YXH-7N
Assistant Cel	∘ YXH- 8B(A) ∘ XH-15
4, 00	∘ YXH-8B(B) ∘ XH-18
194,	∘ YXH- 9 ∘ YXH-10
2000	EMERGENCY BED
*10,	∘ YXH-2L2 ∘ YXH-2T2
	∘ YXH-2L2 ∘ YXH-2T2 ∘ YXH-2R2 ∘ SAFETY BELTS ∘
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istor co	∘ XH-511 ∘ XH-512
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29.00	∘ ATHENA I
NOTIO	∘ YXH-2T2
	∘ YXH-4D
	∘ YXH-6D

• YXH-1A6L • YXH-1M • YXH-3A • YXH-5A • YXH-C1 • YXH-1A3 • YXH-1K • ATHENA II • YXH-3A2 • YXH-1A6A • YXH-5B • YXH-C2 • YXH-1L • YXH-3B • YXH-5C • YXH-1B2 • YXH-5C • YXH-1B3 • YXH-3B3 • YXH-3C • YXH-3B3 • YXH-3C • YXH-3C • YXH-3C • YXH-3C • YXH-3C • YXH-5C • YXH-5D		∘ YXH-1A2
• YXH-1M • YXH-3A • YXH-5A • YXH-C1 • YXH-1A3 • YXH-1K • ATHENA II • YXH-3A2 • YXH-1A6A • YXH-5B • YXH-C2 • YXH-IL • YXH-3B • YXH-5E • XXH-5C • YXH-1B2 • YXH-3B • YXH-5F • YXH-3B • YXH-3B • YXH-3B		
• YXH-5A • YXH-C1 • YXH-IA3 • YXH-IK • ATHENA II • YXH-3A2 • YXH-1A6A • YXH-5B • YXH-C2 • YXH-IL • YXH-3B • YXH-5E • XH-5C • YXH-1B2 • YXH-A2 • YXH-3B2 • YXH-5F • YXH-5F • YXH-1B3 • YXH-5F • YXH-1B3 • YXH-5K		
○ YXH-5A ○ YXH-IA3 ○ YXH-1K ○ ATHENA II ○ YXH-3A2 ○ YXH-1A6A ○ YXH-5B ○ YXH-C2 ○ YXH-1L ○ YXH-3B ○ YXH-5E ○ XH-5C ○ YXH-1B2 ○ YXH-A2 ○ YXH-3B2 ○ YXH-3B3 ○ YXH-5F ○ YXH-1B3 ○ YXH-1B3 ○ YXH-5K ○ YXH-1C		
∘ YXH-C1 ∘ YXH-1A3 ∘ YXH-1K ∘ ATHENA II ∘ YXH-3A2 ∘ YXH-1A6A ∘ YXH-5B ∘ YXH-C2 ∘ YXH-1L ∘ YXH-3B ∘ YXH-5E ∘ XH-5C ∘ YXH-1B2 ∘ YXH-A2 ∘ YXH-A2 ∘ YXH-B3 ∘ YXH-5F ∘ YXH-SF ∘ YXH-1B3 ∘ YXH-SK ∘ YXH-1C		
• ATHENATI • YXH-3A2 • YXH-1A6A • YXH-5B • YXH-C2 • YXH-1L • YXH-3B • YXH-5E • XH-5C • YXH-1B2 • YXH-A2 • YXH-3B2 • YXH-5F • YXH-1B3 • YXH-3B3 • YXH-5K • YXH-1C		• YXH-C1
• ATHENATI • YXH-3A2 • YXH-1A6A • YXH-5B • YXH-C2 • YXH-1L • YXH-3B • YXH-5E • XH-5C • YXH-1B2 • YXH-A2 • YXH-3B2 • YXH-5F • YXH-1B3 • YXH-3B3 • YXH-5K • YXH-1C		• YXH-1A3
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<ul> <li>YXH-3A2</li> <li>YXH-1B6A</li> <li>YXH-5B</li> <li>YXH-C2</li> <li>YXH-1L</li> <li>YXH-3B</li> <li>YXH-5E</li> <li>XH-5C</li> <li>YXH-1B2</li> <li>YXH-A2</li> <li>YXH-3B2</li> <li>YXH-5F</li> <li>YXH-1B3</li> <li>YXH-1B3</li> <li>YXH-5K</li> <li>YXH-1C</li> </ul>		• ATHENA II
<ul> <li>∘ YXH-1A6A</li> <li>∘ YXH-5B</li> <li>∘ YXH-C2</li> <li>∘ YXH-1L</li> <li>∘ YXH-3B</li> <li>∘ YXH-5E</li> <li>∘ XH-5C</li> <li>∘ YXH-1B2</li> <li>∘ YXH-A2</li> <li>∘ YXH-3B2</li> <li>∘ YXH-5F</li> <li>∘ YXH-1B3</li> <li>∘ YXH-1B3</li> <li>∘ YXH-5K</li> <li>∘ YXH-1C</li> </ul>		
• YXH-5B • YXH-C2 • YXH-1L • YXH-3B • YXH-5E • XH-5C • YXH-1B2 • YXH-A2 • YXH-3B2 • YXH-5F • YXH-1B3 • YXH-3B3 • YXH-5K • YXH-1C	100	*
∘ YXH-C2 ∘ YXH-1L ∘ YXH-3B ∘ YXH-5E ∘ XH-5C ∘ YXH-1B2 ∘ YXH-A2 ∘ YXH-3B2 ∘ YXH-3B3 ∘ YXH-3B3 ∘ YXH-5K ∘ YXH-1C	iodu,	
∘ YXH-3B ∘ YXH-5E ∘ XH-5C ∘ YXH-1B2 ∘ YXH-A2 ∘ YXH-3B2 ∘ YXH-5F ∘ YXH-1B3 ∘ YXH-3B3 ∘ YXH-5K ∘ YXH-1C	AU, D	
∘ YXH-3B ∘ YXH-5E ∘ XH-5C ∘ YXH-1B2 ∘ YXH-A2 ∘ YXH-3B2 ∘ YXH-5F ∘ YXH-1B3 ∘ YXH-3B3 ∘ YXH-5K ∘ YXH-1C	"all'i e	
∘ YXH-3B2 ∘ YXH-5F ∘ YXH-1B3 ∘ YXH-3B3 ∘ YXH-5K ∘ YXH-1C	isto co	
∘ YXH-3B2 ∘ YXH-5F ∘ YXH-1B3 ∘ YXH-3B3 ∘ YXH-5K ∘ YXH-1C	762.00	
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∘ YXH-3B2 ∘ YXH-5F ∘ YXH-1B3 ∘ YXH-3B3 ∘ YXH-5K ∘ YXH-1C	2000	∘ YXH-A2
∘ YXH-3B3 ∘ YXH-5K ∘ YXH-1C	9/0.	∘ YXH-3B2
∘ YXH-3B3 ∘ YXH-5K ∘ YXH-1C		∘ YXH-5F
∘ YXH-3B3 ∘ YXH-5K ∘ YXH-1C		∘ YXH-1B3
° YXH-1C		∘ YXH-3B3
<ul> <li>∘ YXH-1C</li> <li>∘ YXH-3C</li> <li>∘ YXH-5N</li> <li>∘ YXH-5C</li> <li>∘ YXH-1D</li> <li>∘ YXH-3D</li> </ul>		∘ YXH-5K
∘ YXH-3C ∘ YXH-5N ∘ YXH-5C ∘ YXH-1D ∘ YXH-3D		∘ YXH-1C
∘ YXH-5N ∘ YXH-5C ∘ YXH-1D ∘ YXH-3D	, hold air	∘ YXH-3C
• YXH-5C • YXH-1D • YXH-3D	AL V	∘ YXH-5N
• YXH-1D • YXH-3D	*2116	° YXH-5C
° YXH-3D	Sisterior	∘ YXH-1D
	ASSA	∘ YXH-3D
° YXH-1A6B	, 00	∘ YXH-1A6B
∘ YXH-1A5	707,	∘ YXH-1A5
° YXH-1N(A)		° YXH-1N(A)
	49	
° ATHENA III		
° YXH-1A6C		° YXH-1A6C

	° YXH-1N(C)
	∘ YXH-2R2
	∘ YXH-1A6
	∘ YXH-1N(B)
	∘ YXH-3A5
	∘ YXH-5D
	∘ HERMES I
	• YXH-5AS • YXH-5D • HERMES I • XH-4C
	∘ YXH-1A6N
	∘ YXH-1A6M
	• HEPHAESTUS II
1000 cil	∘ YXH-1B1
Aloc Di	• HESTIA III-B
1011-0	∘ YXH-1F4A
eis ec	∘ YXH-1A6A-2
AS-SS	• HERMES II
Assistant de la company de la	∘ VENUS II
707,	∘ YXH-1E
	° YXH-1A6D
	∘ VENUS III
	• VENUS III • YXH-1EF • YXH-1A6E
	∘ VENUS IV
C C	∘ YXH-1A6G
	• NEPTUNE
700 Oil	° YXH-1A6H
	° YXH-1F1B
	• YXH-1A6K
Sispe	0
P3 08	° VENUS I
	° YXH-1DL
Monday, and Digger	° YXH-C3
OUL	• HESTIA I
	• YXH-1F2
	° YXH-2L2
	° YXH-C4

			° YXH-1F3	
			• YXH-3K	
			• YXH-6A	
			° YXH-1F4	
			• YXH-4E	
			° YXH-3H	
			° YXH-6B	35:6 AM
			• YXH-7N	20.
			1201-00	
			• YXH-1G	
			° YXH-2A	
		100°01	° YXH-4A	
			• YXH-3D2	
			• YXH-5H	
		Sign	• YXH-3E	
			• YXH-5L	
		, 00	• YXH-3E2	
		ASSISTAIN CE	° YXH-5M	
			∘ YXH-50	
			° YXH-3F	
			∘ YXH-5P	E.G AM
			• HESTIA	(5)·
			• YXH-1EL	
			• YXH-3E3	
			• YXH-1F1	
		iodo in	• YXH-3GYXH-5G	
		Vo. O.	(O),	
34.	Mediland Pakistan	Legal Manufacturer:	RAPICIDE PA RTU	Rejected due to following
	Pvt Office No. b-09,	Medivators Inc. 14605 28th	High-Level Disinfectant	reasons:
	2nd Floor Masood Arcade IJP Road	Avenue North Minneapolis,	and Sterilant test strips	1. Firm has submitted
	near Saidpur Road,	MN 55447 USA	(Disinfectant for endoscopes)	manufacturer credentials of M/s Cantel Medical Instead of
	Rawalpindi.	Page Via	1 /	Medivators Inc. 14605 28th
		FSC: U.S.A	Class-C	Avenue North Minneapolis, MN 55447 USA.
	ELI: 00202	Valid Till: 04/03/2023		2. copy of LOA issued by Steris
	3314-P		Shelf Life: N/A	Corporation USA. While Steris
	18-08-2022		Shell Life, IVA	Corporation is not legal
	2.4.2.2.4.2.5.4.2.2.4	MDR (12-11-2025 ) (Manual )		Page <b>36</b> of <b>66</b>

			C 1	C / /1' / '1 :
			Codes: ML02-0117	manufacturer /distributor as per FSC.
			ML02-0116	3. The applied codes are not
			ML02-0115	mentioned in the FSC.
			ML02-0118 (Test strips)	4. End of Shelf life of Rapicide PA Sigle Dose issued by Cantel
			WILO2-0116 (Test surps)	Medical Italy while name of
				product in FSC and EU QMS is Rapicide PA High Level
			,(9)	Disinfectant.
		Alodul Oil	Sciol Josp 9	5. firm has not submitted proof of
			30 -1-1 05	separate applications for the rest of the types (PA RTU Test strips,
			Cio, 00,1	Rapicide OPA disinfectant, OPA
		, hold air	30	test strips and other types etc.
		Brit.	700,	
		431164		
35.	M/S Ghazali Brothers 1st Floor Azzainab	Ningbo Yingmed Medical Instruments Co., Ltd	Yingmed Non- Absorbable	Rejected because firm has not submitted:
	Court Campbell Street, Karachi, Pakistan	Address as per Form-7A:	Polypropylene Surgical	1. Valid legalized FSC of the
	Tanadan, Tunigan	Yingsheng Building, No.	Suture (with & without needles)	RRA or notarized copy of EC
		456 Tai'an Road, Southern	·	certificate (FQA).
	ELI-00240	Business Zone, 315199, Ningbo, China	Applied as : Single	<ul><li>2. valid notarized ISO 13485.</li><li>3. legalized FSC of the country of</li></ul>
	•	Address as per FSC		origin mentioning the address of
	Fees:	(MHRA) & DOC:	Class C	manufacture
	Rs 62,030 Paid on	Room 705, Yingsheng Building, No. 456 Tai'an	AIT (M" OF	4. requisite documents, hence correct address of the
	19/05/2025	Road, Southern Business	30 001	correct address of the manufacturer can't be verified.
	Challan # 66660494286	Zone, 315199, Ningbo, China.	Shelf Life: 5 years	5. Fee for the family.
		Address as per CE (FQA):		
	Date of R& I	Room 1201-9, No.456,	708.	
	14 <sup>th</sup> April 2025	Tai'an Middle RD, Yinzhou	Codes/Sizes: (as per	
		District, Ningbo, Zhejiang, China.	dossier but not mentioned in the FSC)	
		LOA:	mentioned in the 13C)	
		Agency Agreement (Notarized	PPL201, PPL202	
		copy): issued: 25-03-2025. (Validity	PPL203, PPL204	
	_	for ten years)	PPL205, PPL206	
			PPL207, PPL208	
		FSC:	PPL209, PPL210	
		100.		

		MHRA FSC	PPL211, PPL212	
		Valid Until: 09/07/2025	PPL213, PPL214	
		(copy)	PPL215, PPL216	
		FSC:	PPL217, PPL218	
		China FSC issued on 18-12-2023	PPL219, PPL220	
		Valid for two years	PPL221, PPL222	
		(Notarized copy)	PPL223	35:6 AM
		ISO:	1191	5
		ISO 13485:2016) Valid till: 23-11-2026 (Copy)	sqi, 1052, 0;	
		CE (FQA) valid up to 23- 11-2028.	upel,	
		(Notarized copy)		
36.	Name M/S GHAZALI	Legal Manufacturer:	ACCUMAX	Rejected because firm has not submitted:
	BROTHERS	M/S JIANGSU WEBEST MEDICAL PRODUCT CO.,	EXTENSION TUBE	Valid legalized FSC of the
	Address of Importer	LTD		RRA or notarized copy of EC
	1ST FLOOR AZZAINAB COURT	Manufacturing Sites	Class B	certificate (FQA).
	CAMPBELL	Manufacturing Site: NO. 5 YINGCHUN ROAD		2. valid notarized ISO 13485.
	STREET, KARACHI, PAKISTAN	INDUSTRIAL PARK,	Shelf Life: 5 Years	3. Fee for the family.
		XUYI, JIANGSU, CHINA. Tel: +86-517-88296001		4. The submitted FSC China is not valid (30.06.2025).
		WWW.CNWEBEST.COM	Codes/Sizes:	vanu (50.00.2025).
	ELI-00240	LOA:	SIZES: 150cm to 210cm, 300cm to 400cm	
		Sole Agency Agreement Valid till: 31-12-2029	210cm, 300cm to 400cm	
	Date of R& I	FSC:		
	14 <sup>th</sup> April 2025	CHINA FSC	70°	
		Validity: 30-06-2025		
	Fees:	ISO:		
	Challan # 19425068411 Rs	Production Quality		
	31,000.00 submitted on 27/04/2025	Management System Certificate (ISO 13485:2016) Valid till: 2026-05-31		
37.	Applicant:	(Legal Manufacturer)	Brand Name:	Deferred (final opportunity) for
	4S International,	Name:	Anntommed	following:
	Suite # 205, Al-Fiza Glass Tower, Rashid	M/s Anntom Medical, 5/F, Building A6, Yinlong	Balloon Inflation Devices	
Docisio	one of 109th Masting of	MDB (12-11-2025 ) (Manual A	Annliactions)	Page <b>38</b> of <b>66</b>

	Minhas Road, Karachi Block 10-A, Karachi (ELI- 00290)  Fee details: Amount paid: PKR 25,000/- Paid Slip / challan No.: 5696653243	Industrial Zone, 292, Shenshan Road, Longgang District, Shenzhen 518116, Guangdong, China	Generic: Models / Sizes: (17541) BID-20 20ml, 30bar BID-25 25ml, 30bar BID-30 30ml, 30ba Class-B Shelf life: 03 Years	<ol> <li>Both FSC and CE certificate are not apostille and notarized respectively.</li> <li>The manufacturer address in FSC and CE certificate is different from applied manufacturer address.</li> <li>justification required that as per NB confirmation letter, it is class I device placed on the market in sterile condition.</li> <li>fee for the family required.</li> </ol>
38.	Applicant:  4S International, Suite # 205, Al-Fiza Glass Tower, Rashid Minhas Road, Karachi Block 10-A, Karachi (ELI- 00290) Fee details: Amount paid: PKR 25,000/- Paid Slip / challan No.: 0973946316	(Legal Manufacturer)  Name: M/s Anntom Medical, 5/F, Building A6, Yinlong Industrial Zone, 292, Shenshan Road, Longgang District, Shenzhen 518116, Guangdong, China	Brand Name: Anntommed Manifolds Generic: Models / Sizes: (15587) 500PSI Right "ON" handle 500PSI Right "ON" handle with line 500PSI Right "OFF" handle 500PSI Right "OFF" handle S00PSI Right "OFF" handle S00PSI Right "OFF" handle S00PSI Right "OFF" handle with line	Deferred (final opportunity) for following:  1. Both FSC and CE certificate are not apostille and notarized respectively.  2. The manufacturer address in FSC and CE certificate is different from applied manufacturer address.  3. the codes in the FSC are different from the applied codes.  4. fee for the family required.
39.	Applicant: 4S International, Suite # 205, Al-Fiza Glass Tower, Rashid Minhas Road, Karachi Block 10-A, Karachi (ELI- 00290)  Fee details:	(Legal Manufacturer)  Name: M/s Anntom Medical, 5/F, Building A6, Yinlong Industrial Zone, 292, Shenshan Road, Longgang District, Shenzhen 518116, Guangdong, China	Brand Name: Anntommed Introducer Sets Generic: Models / Sizes: (10678) IS-04 4FX9CM	Deferred (Final Opportunity) for following:  1. Both FSC and CE certificate are not apostille and notarized respectively.  2. The manufacturer address in FSC and CE certificate is different from applied manufacturer address.  3. The codes IS-10, IS-11, IS-14, IS-18 are not mentioned in FSC.

	Amount paid: PKR 25,000/-		IS-05 5FX11CM IS-06 65X11CM	4. fee for the family required.
	Paid Slip / challan No.: 9442858643		IS-07 7FX11CM IS-08 8FX11CM	
			IS-09 9FX11CM IS-10 10FX11CM IS-11 11FX11CM IS-14 14FX14CM IS-18 18FX14CM Class-B Shelf life: As per	35:6 AM
			stability studies	
40.	Applicant:	(Legal Manufacturer)	Brand Name:	Deferred (Final opportunity) for following:
	4S International, Suite # 205, Al-Fiza Glass Tower, Rashid Minhas Road,	Name: M/s Anntom Medical, 5/F, Building A6, Yinlong Industrial Zone, 292,	Anntommed Hemostatic Valve Sets Generic:	1. Both FSC and CE certificate are not apostille and notarized respectively.
	Karachi Block 10-A, Karachi	Shenshan Road, Longgang	Models / Sizes:	2. The manufacturer address in
	(ELI- 00290)	District, Shenzhen 518116, Guangdong, China	(17578)	FSC and CE certificate is different from applied
		1,00	HV-02 <del>7Fr Puss/pull</del>	manufacturer address.
	Fee details: Amount paid: PKR 25,000/- Paid Slip / challan No.: 213944321136	ougsy,	HV02 7Fr Push/pull with line HV 01 8Fr Screw HV 01 8Fr Screw with line HV-03 8Fr Push/pull click HV- 03 8Fr Push/pull click with line	<ul><li>3. The codes mentioned in the FSC are HV-01, HV-02 and HV-03.</li><li>4. fee for the family required.</li></ul>
			Class-B	5
		dul	Shelf life: As per stability studies	
41.	M/s. TRI TECH	Legal Manufacturer:	Brand name:	Deferred (Final opportunity) for
	INTERNATIONAL 10/C 6 Sunset	M/s KLAROMED SP.ZO .O UL .SOBIESKIEGO 123	Diagnostic and Examination Lamp	following reasons:  1. LOA is not notarized.
	Comm Line Phase II Defence Housing	05 -70 SULEJOWEK	Model:	2. FSC is nor legalized/apostille.
	Authority Karachi.	POLAND.	PlusLED24 eco	3. The products PlusLED24 eco
	(ELI-00247)	FSC issuance date:	PlusLED7 eco	PlusLED7 eco
		30-01-2020		Not mentioned in the FSC.
	Date of R&I	Ollo	Class: A	
	07-05-2020		LOA Validity:	
	Fee: PKR 5000/-		10/01/2021	

	<b>Slip:</b> 2006260			
	<b>Dated:</b> 06-05-2020		Shelf life: 05 Years	
42.	ZYBIO MEDICAL PAKISTAN (SMC- PRIVATE)	LEGAL MANUFACTEURER Zybio Inc.	Direct Bilirubin (DBIL) Kit (Vanadate Oxidation Method)	Approved subject to submission of the fee for the family.
	Address of Importer	Company Address: No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China	Codes:  REF (as Specifica	95.0°
	House No 323, street No 66, Sector	Marketing Authorization	per tion (as per FSC)	
	I8/3, Islamabad	Letter (original): Validity Date: 23-11-2028	01.09.0 R1 30 0.20.EC mL × 3	
	Fee Amount & Fee Submission Date: Rs. 31,000/-	FSC: China (Original) Issuance Date: 03-	.01 R2 7.5 mL × 3	
	20/02/2025	11-2026  Production Quality Management System	01.09.0 R1 48 0.20.EC mL × 2 .02 R2 12 mL × 2	
	<b>Deposit Slip No:</b> 923394298	Certificate (ISO 13485) (Original) Validity Date: 29-11-2026	IIIL×2	
	4	Full Quality Assurance Certificate or Equivalent (Original):	Shelf Life: 18 months	GAM
		NA Submitted on basis of EU FSC	Class:B	35.0
43.	Merlin International, Office No. 341, 3rd	Legal Manufacturer: Chifeng Tianbo Medical	Well-Flow Infusion Set with Y-	Deferred (Last opportunity) for the following:
	Floor, Land Mark Plaza, Jail Road, Lahore	Device Co., Ltd Zhongjing Industrial Park Economic Development Area,	Port Class-B	1. The name of the device as per DOC and FSC is Sterile Infusion Sets for single Use with Needles.
	ELI: 00569 5953-P Fee 31,000/- slip no.	Ninhcheng District, Chifeng 024200, Inner Mongolia, P.R China.	Shelf life: Not mentioned	2. Complete stability study dully signed by authorized person is required.
	962491027856	LOA validity: Not clear	Codes/Specifications: As per FSC	3. fee for the family required, if device has the multiple codes/sizes.
		FSC validity 14-04-2025		
		ISP 13485 validity 17-02- 2025		

Corporation, 42 Darul Aman Housing Society Block 7 & 8, Karachi (ELI-00005)  Diary Dated: 25-06-2024 Fee Challan No.: 74862079 PKR: 50,000/-  PKR: 50,000/-  M/s. Hospital Supply Corporation, 42 Diary Dated: 28-11-2022  FOA validity: 27-04-2024 Extension letter attached Supply Corporation, 42 Diary Dated: 25-06-2024 Fee Challan No.: 74862079 PKR: 50,000/-  Nikkiso Belgium B.V. Housing Society Limited, Sirketi, Ledik O.S.B. Mah. Ari S.S. 1472. CadSK. No.120/. YENIMAHALLE ANKARA, TURKEY  Class C Class C Storage Condition: -10 to 50° C Codes & Sizes As per FSC  MD group: Set LOA Validity: 31-12-2025.  FSC (Turkey) (country of origin): Issuance date: 28-11-2022  FQA validity: 27-04-2024 Extension letter attached  ISO 13485 validity: 09-04-2026 (Kiwa)  Accusol K+0, Accusol K+2 and Accusol K +2 and Accusol K +2 and Accusol K +4  Thirmited, Sirketi, Loadis No.: 1. LOA is not in original. 2. The name of the LOA is LITHO! Intracorporeal Ultrasonic Pneumatic Kidney Stone Crushing Device  2. The name of the LOA is LITHO! Intracorporeal Ultrasonic Pneumatic Kidney Stone Crushing Device  2. The name of the LOA is LITHO! Intracorporeal Ultrasonic Pneumatic Kidney Stone Crushing Device  2. The name of the LOA is LITHO! Intracorporeal Ultrasonic Pneumatic Kidney Stone Crushing Device  2. The name of the LOA is LITHO! Intracorporeal Ultrasonic Pneumatic Kidney Stone Crushing Device  2. The name of the LOA is not in original. 2. The name of the LOA is LITHO! Intracorporeal Ultrasonic Pneumatic Kidney Stone Crushing Device  2. The name of the LOA is not in original.		T	<u> </u>	T
Corporation, 42 Darul Aman Housing Society Block 7 & 8, Karachi (ELI-00005)  Diary Dated: 25-06-2024 Fee Challan No.: 74862079 PKR: 50,000/-  M/s. Hospital Supply Corporation, 42, Darulaman Housing Society Block 7 & 8, Karachi (ELI-00005)  YENIMAHALLE ANKARA, TURKEY  Hizmetleri Sanayi Ticaret Limited, Sirketi, Lvedik O.S.B. Mah. Ari S.S. 1472. CadSK. No.120/. YENIMAHALLE ANKARA, TURKEY  Class C Shelf life: N/A  Storage Condition: -10 to 50° C Codes & Sizes As per FSC  MD group: Set LOA Validity: 31-12-2025.  FSC (Turkey) (country of origin): Issuance date: 28-11-2022  FQA validity: 27-04-2024 Extension letter attached  ISO 13485 validity: 09-04-2026 (Kiwa)  Accusol K+0, Accusol K + 2 and Accusol K + 2 and Accusol K - 1. The FSC Belgium - 1. LoA is not in original 2. The name of the LOA is LITHO! - Urasonic Pneum - 2. The name of the LOA is LITHO! - Urasonic Pneum - 2. The name of the LOA is LITHO! - Urasonic Pneum - 2. The name of the LOA is LITHO! - Urasonic Pneum - 2. The name of the LOA is LITHO! - Urasonic Pneum - 2. The name of the LOA is not in original 2. The name of the LOA is not in original 2. The name of the LOA is not in original 3. The primal documents of the LOA is LOA is not in original 2. The name of the LOA is not in original 3. The brand name - 4. Original documents of the LOA is LOA is not in original 4. LOA is not in original 4. LOA is not in transfer or in transfer	Technologies, A-21/2B-1, KDA Scheme 1 (Ext.) National Stadium Road Karachi. (ELI-00712) 4486	validity 17-02-2027  Legal Manufacturer: Urotronic, Inc. 2495 Xenium Lane N Minneapolis, MN 55441 USA  FSC: USA	Drug Coated Balloon catheter (Uretheral Drug Coated Balloon Catheter) Class-D Shelf life: 12 Months Codes are not provided.	
46. M/s. Hospital Supply Corporation. 42, Darulaman Housing Society 3300 Tiepen Belgium  Nikkiso Belgium B.V. Accusol K+0, Accusol K + 2 and Accusol K  + 4 1. The FSC Belgium	Corporation, 42 Darul Aman Housing Society Block 7 & 8, Karachi (ELI-00005)  Diary Dated: 25-06-2024 Fee Challan No.: 74862079	Hizmetleri Sanayi Ticaret Limited, Sirketi, Lvedik O.S.B. Mah. Ari S.S 1472. CadSK. No.120/, YENIMAHALLE ANKARA, TURKEY	LITHOBOX ZERO intracorporeal Combined Ultrasonic Pneumatic Kidney Stone Crushing Device  Class C  Shelf life: N/A  Storage Condition: -10 to 50° C Codes & Sizes As per FSC  MD group: Set  LOA Validity: 31-12-2025.  FSC (Turkey) (country of origin): Issuance date: 28-11-2022  FQA validity: 27-04-2024 Extension letter attached  ISO 13485 validity:	<ol> <li>LOA is not notarized and original.</li> <li>The name of the device as per LOA is <u>LITHOBOX ZERO-Intracorporeal</u> <u>Combined Ultrasonic Pneumatic Kidney Stone Crushing Device.</u></li> <li>The brand name not given in LOA or FSC.</li> <li>Original documents not</li> </ol>
	Supply Corporation. 42, Darulaman	Industriepark 6,	Accusol K+0, Accusol K + 2 and Accusol K	1. The FSC Belgium not valid
Block / and 8	Block 7 and 8 Karachi.	1	Class B,	(issue date 19 August 2019).  2. The device as per FSC is of class IIb.

	R&I Details:	<u>ISO 13485</u> :	Shelf life: 24 months.	
	14 May 2022	Validity: July.2026		
47.	Name Hospital Supply Corporation Address of Importer 42 Darul Aman Housing Society, Block 7& 8, Karachi, Pakistan	Name: Zhejiang Kindly Medical Devices Co. Ltd Address: No. 758 5th Binhai Road, Binhai Industrial Park, Longwan Distrit 325025, Wenzhou, Zhejiiang China	YMS disposable Infusion set with Burette	Deferred (last opportunity) for the following.  1. The FSC is neither original not legalized/ apostille.  2. clarification required that as per NB confirmation letter the device is of class IIb.
48.	M/s Ideal Distributor, House No.E-64, Block-E, Near Jamia Masjid Aqsa, Satellite Town, Rawalpindi  ELI-00944  R&I details 27/01/2025  Fee Challan No:7849801972	Legal Manufacturer: Legal Manufacturer: Ningbo Great Mountain Medical Instrument Co., Ltd.  Address: No. 309 Xigu Road, Xiangshan County, 315700 Ningbo City, Zhejiang Province, China.  FSC: China Date of Issuance: 11-10-2024. Validity 2 years.  LOA: Validity: 7/03/2027 EC Certificate: Validity: 26/05/2024 ISO 13485: Validity: 29/12/2025	Respiratory Filters Shelf Life: 5 Year Class: B	Deferred (last opportunity) for the following:  1. The name has been revised from Respiratory Filters to Heat and Moisture Exchange Filters but application has not been revised.  2. FSC not issued by the relevant Health Regulatory Authority.  3. clarification that Model on FSC is Adult, Child, Infant while as per Brochure is NGM-IM-008.  4. CE marking certificate or FSC of RRA required.
49.	Cardioline Systems (Pvt) Ltd, H. No. 168, Block-E, PIA Housing Society, Johar Town, Lahore.  ELI-01265 5980-P 62,000/-	Legal Manufacturer:  Dongguan TT Medical, Inc.  Bld-1, 1 Taoyuan Road,  Songshan Lake National  High-Tech Industrial Park,  Dongguan, Guangdong, PR  China.  FSC: Netherlands.  Validity: 31-12-2027.	EverFlow (Paclitaxel Coated PTCA Balloon Catheter)  Class-D  Shelf life: 2 years	The Board decided to call both the parties as per MDB decision taken in its 89 <sup>th</sup> meeting.

			Codes as per FSC	
			•	
50.	M. Yousaf & Co, 79 M Block Gulberg III Lahore. ELI-00302 1423-P 31,000/-	Legal Manufacturer: Sterilance Medicl (SUZHOU) Inc. No. 168, Putuoshan Road, New District 215153, SUZHOU, Jiangsu, Jiangsu, P.R. China. Original FSC: China. Validity: 07-06-2026. LOA validity 08-10-2029 ISO 13485 validity 01-12-2025 EU QMS certificate (MDR) validity 23-11-2027	SKYMAX Disposable Surgical Blade, carbon steel  Class-A Shelf Life: 5 years  Codes/sizes as per FSC: 9, 10, 10A, 11, 12, 12B, 12D, 13, 14, 15, 15C, 16, 17 18, 19, 20, 21, 22, 22A, 23, 24, 25, 26, 27, 34, 36, 60, 70, PM40	Approved subject to submission copy of legalized/apostille FSC and verification of fee for the family.
51.	Applicant Name:  Zam Zam Corporation, Suit No. 205, 206, Beaumont Plaza, 6- CL-10, Beaumont Road, Karachi  ELI-00412	30-11-2026 (Copy)  FSC: Spain Issue date: 14-05-	Brand name:  Inno-Ce Mesha Intense  Generic Name: 1 x 1.2ml/0.04 fl oz. Crosslinked Hyaluronic Acid 20mg/ml  Route of administration: Intradermal injections	Deferred (final opportunity) for the submission of:  1. submission of original, notarized LOA.  2. clarification that The name of the device as per FSC and LOA and DE certificate is Mesha® Intense while applied name is Inno-Ce Mesha Intense.  3. applied products Inno-Ce Mesha Essence, Inno-Ce Mesha Smile,
	Date of R&I 30-05-2025 Fee Details: Paid Fee: 62,000/- 1160861088	2024(Copy)  ISO Validity: 15-03-2027 (Copy)  EU QA/ EC Certificate  Validity:	Class-D Shelf life: 3 Years Models/ Specification	Inno-Ce Mesha Deepetc have the same formulations. 4. clarification of the difference b/w products having same formulation.
52.	Applicant Name:  Zam Zam Corporation, Suit No. 205, 206,	Laboratorio Innoaesthetics SL C/ Pont Reixat 3, 08960, Sant Just Desvern, Barcelona, Spain	Brand name: Inno-Ce Mesha Essence Generic Name:	Deferred (final opportunity) for the submission of: 1. submission of original, notarized LOA.

	Beaumont Plaza, 6-CL-10, Beaumont Road, Karachi  ELI-00412  Date of R&I 30-05-2025  Fee Details: Paid Fee: 62,000/-3180943871	LOA Validity: 30-11-2026 (Copy) FSC: Spain Issue date: 14-05- 2024(Copy)  ISO Validity: 15-03-2027 (Copy)  EU QA/ EC Certificate Validity:	1 x 1.2ml/0.04 fl oz. Crosslinked Hyaluronic Acid 20mg/ml  Route of administration: Intradermal injections  Class-D  Shelf life: 3 years  Models/ Specification	2. clarification that the name of the device as per FSC and LOA and DE certificate is Mesha® Essence while applied name is Inno-Ce Mesha Essence.  3. applied products Inno-Ce Mesha Intense, Inno-Ce Mesha Essence, Inno-Ce Mesha Smile, Inno-Ce Mesha Deepetc have the same formulations.  4. clarification of the difference b/w products having same formulation.
53.	Applicant Name:  Zam Zam Corporation, Suit No. 205, 206, Beaumont Plaza, 6- CL-10, Beaumont Road, Karachi  ELI-00412  Date of R&I 30-05-2025  Fee Details: Paid Fee: 62,000/- 040092056372	Laboratorio Innoaesthetics SL C/ Pont Reixat 3, 08960, Sant Just Desvern, Barcelona, Spain  LOA Validity: 30-11-2026 (Copy)  FSC: Spain Issue date: 14-05- 2024(Copy)  ISO Validity: 15-03-2027 (Copy)  EU QA/ EC Certificate Validity:	Brand name:  Inno-Ce Bi-Dens 2.5  Generic Name: 1 x 3ml/0.07 fl oz. Sodium Hyaluronate 2.5%  Route of administration: Intradermal injections  Class-D  Shelf life: 3 years  Models/ Specification	Deferred (final opportunity) for the submission of:  1. submission of original, notarized LOA.  2. clarification that The name of the device as per FSC and LOA and DE certificate is Bi-Dense 2.5 while applied name is Inno-Ce Bi-Dens 2.5.  3. The brand name not provided in FSC or LOA.
54.	Applicant Name:  Zam Zam Corporation, Suit No. 205, 206, Beaumont Plaza, 6- CL-10, Beaumont Road, Karachi	Laboratorio Innoaesthetics SL C/ Pont Reixat 3, 08960, Sant Just Desvern, Barcelona, Spain LOA Validity: 30-11-2026 (Copy) FSC: Spain	Brand name:  Brand name:  Inno-Ce Mesha Smile  Generic Name: 1 x 1.2ml/0.04 fl oz.  Crosslinked Hyaluronic Acid 20mg/ml	Deferred (final opportunity) for the submission of:  1. submission of original, notarized LOA.  2. clarification that the name of the device as per FSC and LOA and DE certificate is Mesha® Smile while applied name is Inno-Ce Mesha Smile.  3. applied products Inno-Ce

	ELI-00412  Date of R&I 30-05-2025  Fee Details: Paid Fee: 62,000/-42247277229	Issue date: 14-05-2024(Copy)  ISO Validity: 15-03-2027 (Copy)  EU QA/ EC Certificate  Validity:	Route of administration: Intradermal injections Class-D Shelf life: 3 years Models/ Specification	Mesha Intense, Inno-Ce Mesha Essence, Inno-Ce Mesha Smile, Inno-Ce Mesha Deepetc have the same formulations. 4. clarification of the difference b/w products having same formulation.
55.	Applicant Name:  Zam Zam Corporation, Suit No. 205, 206, Beaumont Plaza, 6- CL-10, Beaumont Road, Karachi  ELI-00412  Date of R&I 30-05-2025  Fee Details: Paid Fee: 62,000/- 8174193787	Laboratorio Innoaesthetics SL C/ Pont Reixat 3, 08960, Sant Just Desvern, Barcelona, Spain  LOA Validity: 30-11-2026 (Copy)  FSC: Spain Issue date: 14-05- 2024(Copy)  ISO Validity: 15-03-2027 (Copy)  EU QA/ EC Certificate Validity:	Brand name: Brand name: Inno-Ce Mesha Scars Generic Name: 1 x 1.2ml/0.04 fl oz. Crosslinked Hyaluronic Acid 20mg/ml  Route of administration: Intradermal injections Class-D Shelf life: 3 years  Models/ Specification	Deferred (final opportunity) for the submission of:  1. submission of original, notarized LOA.  2. clarification that the name of the device as per FSC and LOA and DE certificate is Mesha® Scars while applied name is Inno-Ce Mesha Scars.  3. applied products Inno-Ce Mesha Intense, Inno-Ce Mesha Essence, Inno-Ce Mesha Smile, Inno-Ce Mesha Deepetc have the same formulations.  4. clarification of the difference b/w products having same formulation.
56.	Applicant Name:  Zam Zam Corporation, Suit No. 205, 206, Beaumont Plaza, 6- CL-10, Beaumont Road, Karachi  ELI-00412  Date of R&I 30-05-2025	Laboratorio Innoaesthetics SL C/ Pont Reixat 3, 08960, Sant Just Desvern, Barcelona, Spain  LOA Validity: 30-11-2026 (Copy)  FSC: Spain Issue date: 14-05- 2024(Copy)	Brand name:  Inno-Ce Moist 1.5  Generic Name: 1 x 1.2ml/0.04 fl oz. Crosslinked Hyaluronic Acid 20mg/ml 15mg/ml  Route of administration: Intradermal injections  Class-D	Deferred (final opportunity) for the submission of:  1. submission of original, notarized LOA.  2. clarification that the name of the device as per FSC and LOA and DE certificate is Moist 1.5 while applied name is Inno-Ce Moist 1.5.

		ISO Validity:		
	E. D. G. H.	•	Shelf life: 3 years	
	Fee Details:	15-03-2027 (Copy)	·	
	Paid Fee: 62,000/-		Models/ Specification	
	5143040484	EU QA/ EC Certificate	wiodels/ Specification	
		Validity:		
57.	Applicant Name:	Laboratorio Innoaesthetics	Brand name:	Deferred (final opportunity) for
		SL C/ Pont Reixat 3, 08960, Sant Just Desvern,	Inna Ca Marka Dave	the submission of:
	Zam Zam	Barcelona, Spain	Inno-Ce Mesha Deep	1. submission of original,
	Corporation, Suit	, I	Generic Name:	notarized LOA.
	No. 205, 206,	LOA Validity:	1 x 1.2ml/0.04 fl oz.	2. clarification that the name of the device as per FSC and LOA
	Beaumont Plaza, 6- CL-10, Beaumont		Crosslinked Hyaluronic Acid 20mg/ml	and DE certificate is Mesha®
	Road, Karachi	30-11-2026 (Copy)	Acid 2011g/III	Deep while applied name is Inno-
		700 Oil		Ce Mesha Deep.
		FSC: Spain	Route of administration: Intradermal injections	3. applied products Inno-Ce
	ELI-00412	Issue date: 14-05-	miradermar injections	Mesha Intense, Inno-Ce Mesha Essence, Inno-Ce Mesha Smile,
		2024(Copy)	Class-D	Inno-Ce Mesha Deepetc have the
	Date of R&I	1200	Shelf life: 3 years	same formulations.
	30-05-2025	ISO Validity:	Shen me. 3 years	4. clarification of the difference
		15-03-2027 (Copy)	3.6 1.1 / G	b/w products having same formulation.
	Fee Details:	000	Models/ Specification	Tormuration.
		EU QA/ EC Certificate		-1
	Paid Fee: 62,000/-	Validity:		DIA.
	4082100844	,		~.6 ,
58.	Payal Madical	Dongguan TT Madical Inc	Restenix (Drug	Deformed (lest apportunity) for the
36.	Royal Medical, Office No. 26th, 3rd	Dongguan TT Medical, Inc. BID # 1, 1 Taoyuan Road,	(Paclitaxel) Coated	Deferred (last opportunity) for the following:
	Floor United Trader	Songshan lake National Hi-	Balloon Catheter)	1. The name of the device on FSC,
	Centre Plot No. 5,	Tec Industrial Park,	Shelf life 02 years	CE Certificate and DE certificate
	Block-6, Gulshan-e- Iqbal, Karachi	Dongguan, Guangdong, PR China	F (2000)	is EverFlow® paclitaxel Coated
	•	Notarized LOA valid	Fee 62000/-	Coronary Balloon Catheter while firm has applied as Restenix
	(ELI-00691)	till25.02.2030	Challlan no 303210117199	(Drug (Paclitaxel) Coated
	Date of application	ista aco	303210117199	Balloon Catheter).
	18.04.2025	Copy of Neterlands FSC	-	2. The fee for the family has not
	Fee Rs 62000	Valid till: 31.12.2031	Class D	been submitted by the firm.
				3. clarification that firm has
		ISO valid till 19.06.2027		submitted IPO trade mark registry while firm is not manufacturer or
	_	Copy of FOA valid till PCB2003	PCB20010, PCB20014,	researcher of the product.
		27.05.2024 and complete	PCB20018,	4. IPO trade mark registry issued
		extension letter having code		to Mrs Anum Ahmed instead of
		not provided		the firm.

	N	DCD20022 DCD20026	
	Notarized LOA valid till25.02.2030	PCB20022, PCB20026, PCB20030,	
	Copy of Design examination 27.05.2024	PCB20034, PCB20038, PCB22510,	
	FSC china Valid till: 08-04- 2026	PCB22514, PCB22518, PCB22522,	E.G AM
	. G	PCB22526, PCB22530, PCB22534,	5
	Abdul Dir	PCB22538, PCB25010, PCB25014,	
	ssistant Dece	PCB25018, PCB25022, PCB25026,	
	Vezig Den	PCB25030, PCB25034, PCB25038,	
4	one	PCB27510, PCB27514, PCB27518,	c.6 AM
		PCB27522, PCB27526, PCB27530,	35.0
	, bdul Oi	PCB27534, PCB27538, PCB30010,	
	istant of	PCB30014, PCB30018, PCB30022,	
	onday, and Dece	PCB30026, PCB30030, PCB30034,	
	ougas	PCB30038, PCB32510, PCB32514,	
•			

		Abdul Oil	PCB32518, PCB32522, PCB32526,  PCB32530, PCB32534, PCB32538,  PCB35010, PCB35014, PCB35018,  PCB35022, PCB35026, PCB35030,  PCB35034, PCB35038, PCB37510,  PCB37514, PCB37518, PCB37522,	35.6 ANN
		ougsy, 98 De	PCB37526, PCB37530, PCB37534,  PCB37538, PCB40010, PCB40014,	6.6 AM
		Alodul Oi	PCB40018, PCB40022, PCB40026,  PCB40030, PCB40034, PCB40038  Codes AS per FSC of Netherlands	
59.	Royal Medical, Office No. 26th, 3rd Floor United Trader Centre Plot No. 5, Block-6, Gulshan-e- Iqbal, Karachi (ELI-00691) Date of application 18.04.2025	Dongguan TT Medical, Inc. BID # 1, 1 Taoyuan Road, Songshan lake National Hi- Tec Industrial Park, Dongguan, Guangdong, PR China apostille china FSC Valid till: 08-04-2026 USFDA FSC Valid till: 03- 04-2026	Valvoflex (Valvuloplasty Balloon Catheter) Shelf life 03 years VBC1540, VBC1840 , VBC2140, VBC2340, VBC2640 , VBC2940:	Deferred for the following:  1. The registration is being issued on the basis of USFDA CFG, so the brand name in USFDA FSC required.  2. The fee for the family required.

			Class D	
		ISO valid till 19.06.2027		
		Notarized LOA valid		
		till25.02.2030		<u> </u>
				G Pil
60.	Royal Medical,	Dongguan TT Medical, Inc.	Angioflex (Semi	Deferred (last opportunity) for the
	Office No. 26th, 3rd Floor United Trader	BID # 1, 1 Taoyuan Road, Songshan lake National Hi-	Compliant Coronary Dilatation Balloon	following reasons:
	Centre Plot No. 5,	Tec Industrial Park,	Catheter)	1. Firm has not submitted FSC with correct name.
	Block-6, Gulshan-e-	Dongguan, Guangdong, PR China	Shelf life 2 years	with correct name.
	Iqbal, Karachi		Class D	2. Firm has also not submitted
	(ELI-00691)	Apostille China FSC Valid till: 08-08-2026	Codes	the CE FQA and DE certificate.
	Date of application		SD25010	
	18.04.2025	ISO valid till 19.06.2027	SD25014	3. The fee for the family required.
	Fee Rs 62000	FQA valid till 27.05.2024	SD25018	
		and having extension letter	SD25022	
		1	SD25030	
		Design examination	SD30010	
		27.05.2024	SD30014	
			SD30018	5:6 AM
			SD30022	6.6
			SD30026	59
			SD30030	
		, O	SD35010	
			SD35014	
		Plon Oil	SD35018	
			SD35022	
		· 6/10, - CO	SD35026	
		6515000	SD35030	
		onday, and becar	SD40010	
		212	SD40014	
		932	S040018	
		O	S040022	
	No.		SD25026	
			SD40026	

			SD40030	
61.	Applicant: M/s. REAGNCHEM scientific second floor A21- Block 13-D1 Rufi Cottages, Sehba Akhter Road, Gulshan-e-Iqbal, Karachi (ELI: 000345) Fee: Slip: Dated:	Legal Manufacturer: M/s Meizhou Cornley Hi-Tech CO LTD Cornley Hi-Tech Industrial Park, Jincheng Road, Fuda HiTechZone, Meixian, 514700 Meizhou, Guangdong PR China LOA Validity: 02-02-2026	MINI ISE ELECTROLYTE ANALYZER  Class A Shelf Life: 05 years Codes / Sizes (if any): K LITE 8A,K LITE 8B,K LITE 8D , KLITE 8E, K-LITE 8F, K-LITE 8G, K LITE 8H	Deferred (final opportunity) for the following:  1. Brand name with LOA is required.  2. FSC with model Mini ISE required.  3. The supporting document CE certificate and DOC required that support the claimed class of device.
62.	M/s. TRI TECH INTERNATIONAL 10/C 6 Sunset Comm Line Phase II Defence Housing Authority Karachi. (ELI-00247)  Date of R&I 07-05-2020	Legal Manufacturer:  M/s KLAROMED SP.ZO .O UL .SOBIESKIEGO 123 05 -70 SULEJOWEK POLAND.  FSC issuance date: 30-01-2020	Brand name: Surgical Light Model: PlusLED96 eco PlusLED56 eco Class: A LOA Validity: 10/01/2021	Deferred with final opportunity for submission of valid notarized LOA and legalized/ apostille FSC.
	Fee: PKR 5000/- Slip: 2006261 Dated: 06-05-2020	ondo	Shelf life: 05 Years	35:6 AM
63.	Applicant Name:  M/s. NI healthcare Products Pvt Ltd.  Address: Office No. A, Unit 10 Survey No. 263, Damlotte Road District Malir, Karachi  (ELI-01117)  Date of R&I	Jiangsu Hitec Medical Co. Ltd., Jiangxin Road North, Tongzhou Bay River Sea Joint Development Demonstration Zone, Jiangsu Province, China  FSC: Validity: 27-12-2026  LOA Validity: 17-12-2027	DYCO Suction Connecting Tube with Yankauer handle  Class B  Shelf Life:5 years  Codes/Sizes (If any) Sizes: with Yankauer handle 8.2mm	Deferred (final opportunity) for the following:  1. The brand name has resemblance to already approved name DYCO.  2. Notarized LOA with brand name required.  3. as per submitted brochure sizes 9.7mm and 10.7mm and Code: A060102 not mentioned.  4. FSC and complete brochure mentioning the sizes and codes required.  5. clarification that name of the firm is Hitec Medical Comentioned on brochure.
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	14-03-2025		9.0mm	6. Fee for the family required.
	Rs.31,000/-	CE Certificate	9.7mm	
	Slip# 07733267928	Validity: 08-04-2029	10.0mm	
			10.7mm	
		ISO 13485	11.2mm	
		Validity: 27-02-2027		CON.
			Code: A060102 Surgical Drainage Connection Medical tubes	35:6 AM
64.	NI healthcare Products Pvt Ltd Office No. A, Unit 10 Survey No. 263, Damlotte Road District Malir, Karachi (ELI-01117) Date of R&I 10-10-2024  Fee 62000/-	Medcaptain Medical Technology Co., Ltd., 12th Floor, Baiwang Research Building No. 5158 Shahe West Road, Xiii, Nanshan, 51 8055 Shenzhen, Guangdong, PEOPLE's REPUBLIC OF CHINA  Medcaptain Medical Technology Co., Ltd., Building C. Jiale Science and Technology Industrial Park, Matian Sreet, Guangming, PEOPLE'S REPUBLIC OF CHINA  Better Life Medical Technology Co., Ltd., Room 204, Building 15, No. 8 Jinfeng Road, Suzhou New District, 215163 Suzhou, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA  FSC not submitted  LOA Validity: 16-11s-2027  ISO 13485 Validity: 16-02-2026	Patient Monitor PMS 8310/ Vitavue 12 Patient Monitor 9018.1900 33586 Class: C Claimed Shelf Life:10- years	Approved the model/version PMS8310.
65.	NI healthcare	Medcaptain Medical Technology Co., Ltd., 12th Floor, Baiwang Research	Patient Monitor PMS 8300/ Vitavue 10	Approved the model/version PMS8300.

Office No. A, Unit 10 Survey No. 263, Damlotte Road District REPUBLIC OF CHINA Malir, Karachi (ELI-01117) Date of R&I 10-10-2024 Building C. Jiale Science and Technology Co., Ltd., Room 204, Building 15, No. 8 Jinfeng Road, Suzhou New District, 215163 Suzhou, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA  Better Life Medical Technology Co., Ltd., Room 204, Building 15, No. 8 Jinfeng Road, Suzhou New District, 215163 Suzhou, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA  FSC not submitted LOA Validity: 16-11s-2027  ISO 13485 Validity: 16-02-2026 FQA valid till 26.05.2024 extension letter submitted	_	1			
10 Survey No. 263, Damlotte Road District Malir, Karachi (ELI-01117) Date of R&I 10-10-2024  Medcaptain Medical Technology Co., Ltd., Building C. Jiale Science and Technology Industrial Park, Martian Street, Guangming, PEOPLE'S REPUBLIC OF CHINA  Better Life Medical Technology Co., Ltd., Room 204, Building L. Jian Street, Guangming, PEOPLE'S REPUBLIC OF CHINA  Better Life Medical Technology Co., Ltd., Room 204, Building L. Jo. Surbon, Jiangus Province, PEOPLE'S REPUBLIC OF CHINA  FSC not submitted LOA Validity: 16-11s-2027 ISO 13485 Validity: 16-02-2026 FQA valid till 26.05.2024 extension letter submitted LOA Validity: 16-02-2026 FQA valid till 26.05.2024 extension letter submitted LOA Validity: 16-11s-2027 ISO 13485 Validity: 16-02-2026 FQA valid till 26.05.2024 extension letter submitted  M's. NI healthcare Products Pvt Ltd.  MEDCAPTAIN LIFE SCIENCE CO., LTD. Manufacturing address: Room 103, 1st Floor, Room 601, 6th Floor, and Office No. A, Unit 10 Survey No. 263, Damlotte Road District Malir, Karachi Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA  FSC:  Date of R&I  FSC:  Place Manufacturing address: Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA  Shelf Life: 5 years  Shelf Life: 5 years		Products Pvt Ltd	Building No. 5158 Shahe	Patient Monitor	
263, Damlotte Road District Malir, Karachi (ELI-01117) Gate of R&I 10-10-2024  Medcaptain Medical Technology Co., Ltd., Building C. Jiale Science and Technology Cot, Ltd., Building C. Free 62000/-  Republic of CHINA  Better Life Medical Technology Co., Ltd., Building C. Jiale Science Guangming, PEOPLE'S REPUBLIC OF CHINA  Better Life Medical Technology Co., Ltd., Room 20.4 Building 15. No. 8. Jinfeng Road, Suzhou New District, 215163 Suzhou, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA  FSC not submitted LOA Validity: 16-11s-2027  ISO 13485 Validity: 16-02-2026 FQA valid till 26.05.2024 extension letter submitted  LOA Validity: 16-02-2026 FQA valid till 26.05.2024 extension letter submitted  M/s. NI healthcare Products Pvt Ltd.  Medcaptain Medical Technology Co., Ltd., Building C. Jiale Science Address: Room 103. 1st Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Block C. Jinweiyuan Generic Name: Video Laryngoscope Blade M1, M2, M3, M3D and M4 Class A Damlotte Road District Malir, Karachi  Date of R&I  FSC:  Date of R&I  FSC:  FSC:		Office No. A, Unit	West Road, Xiii, Nanshan,		
263, Damlotte Road District Malir, Karachi (ELI-01117) Gate of R&I 10-10-2024  Medcaptain Medical Technology Co., Ltd., Building C. Jiale Science and Technology Cot, Ltd., Building C. Free 62000/-  Republic of CHINA  Better Life Medical Technology Co., Ltd., Building C. Jiale Science Guangming, PEOPLE'S REPUBLIC OF CHINA  Better Life Medical Technology Co., Ltd., Room 20.4 Building 15. No. 8. Jinfeng Road, Suzhou New District, 215163 Suzhou, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA  FSC not submitted LOA Validity: 16-11s-2027  ISO 13485 Validity: 16-02-2026 FQA valid till 26.05.2024 extension letter submitted  LOA Validity: 16-02-2026 FQA valid till 26.05.2024 extension letter submitted  M/s. NI healthcare Products Pvt Ltd.  Medcaptain Medical Technology Co., Ltd., Building C. Jiale Science Address: Room 103. 1st Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Block C. Jinweiyuan Generic Name: Video Laryngoscope Blade M1, M2, M3, M3D and M4 Class A Damlotte Road District Malir, Karachi  Date of R&I  FSC:  Date of R&I  FSC:  FSC:		10 Survey No.	51 8055 Shenzhen,	9018.1900	
Road District Malir, Karachi Malir, Karachi Malir, Karachi Malir, Karachi Medicaptain Medical Technology Co., Ltd., Medcaptain Medical Technology To., Ltd., Date of R&I  Medcaptain Medical Technology Co., Ltd., Roma Sreet, Guangming, PEOPLE'S REPUBLIC OF CHINA  Better Life Medical Technology Co., Ltd., Room 204, Building 15, No. 8 Jinfeng Road, Suzhou New District, 215163 Suzhou, Jiangus Province, PEOPLE'S REPUBLIC OF CHINA FSC not submitted LOA Validity: 16-11s-2027 ISO 13485 Validity: 16-02-2026 FQA valid till 26.05.2024 extension letter submitted  LOA Validity: 16-11s-2027 ISO 13485 Validity: 16-02-2026 FQA valid till 26.05.2024 extension letter submitted  M/s. NI healthcare Products Pvt Ltd. Manufacturing address: Room 103, 1st Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Block C, Jinweiyuan Industrial Park, Julongshan Subdistrict, Pingshan Subdistrict, Pingshan District, 518118, Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA  FSC:  Date of R&I  Karachi  FSC:  Claimed Shelf Life: 10- years  Class: C Claimed Shelf Life: 10- years  Approved subject to submission of fee for the family.  Majo and Ma  Class A  Subdistrict, Fingshan District, 518118, Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA  Shenzhen, Cuangdong, PEOPLE'S REPUBLIC OF CHINA		_		33586	
Malir, Karachi (ELI-01117) Date of R&I 10-10-2024  Medcaptain Medical Technology Co., Ltd., Building C. Jiale Science and Technology Industrial Park, Matian Sreet, Guangming, PEOPLE'S REPUBLIC OF CHINA  Better Life Medical Technology Co., Ltd., Room 204, Building 15, No. 8 Jinfeng Road, Suzhou New District, 215163 Suzhou, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA  FSC not submitted LOA Validity: 16-11s-2027 ISO 13485 Validity: 16-02-2026 FQA valid till 26.05.2024 extension letter submitted  Logal Manufacturer:  MEDCAPTAIN LIFF SCIENCE CO., LTD. Manufacturing address: Room 103, 1st Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Block C. Jinweylouan Industrial Park, Julongshan Subfistrict, Pingshan District Malir, Karachi  Date of R&I  Medcaptain Medical Technology Co., Ltd., Building C. Jiale Science and Technology Industrial Park, Matian Street, Submitted Load, Room 701, 7th Floor, Block C. Jinweylouan Industrial Park, Julongshan Subfistrict, Pingshan District SISH 18, Shenzhen, Güangdong, PEOPLE'S REPUBLIC OF CHINA.  Class A Subfistrict, Pingshan District, SISH 18, Shenzhen, Güangdong, PEOPLE'S REPUBLIC OF CHINA.  Scheff Life: 10- years  Claimed Shelf Life: 10- years  Claimed Shelf Life: 10- years  Claimed Shelf Life: 10- years  Approved subject to submission of fee for the family.  Approved subject to submission of fee for the family.  Approved subject to submission Of fee for the family.  Scheff Life: 10- Yideo Laryngoscope Blade M1, M2, M3, M3D and M4  Class A Subfistrict, Pingshan District, SISH 18, Shenzhen, Güangdong, PEOPLE'S REPUBLIC OF CHINA.  FSC:					
CELI-01117   Date of R&I   Technology Co., Ltd., Building C. Jiale Science and Technology Industrial Park, Matian Street, Guangming, PEOPLE'S REPUBLIC OF CHINA   Better Life Medical Technology Co., Ltd., Rom 204, Building 15, No. 8 Jinfeng Road, Suzhou. New District, 215163 Suzhou, Jiangsus Province, PEOPLE'S REPUBLIC OF CHINA   FSC not submitted   LOA Validity: 16-11s-2027   ISO 13485 Validity: 16-02-2026 FQA valid till 26.05.2024 extension letter submitted   LOA validity: 16-02-2026 FQA valid till 26.05.024 extension letter submitted   Approved subject to submission of fee for the family.   Wideo Laryngoscope Blade MI, M2, M3, M3D and M4   M3, M3D and M4   M4, M3, M3D and M4   Class A Subdistrict, Pingshan District, SISI18, Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA.   FSC:   Date of R&I   FSC:   SCIENCE CO. FCHINA   Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA.   Shenzhen, Guangdong, PEOPLE'S REPUB			REFUBERCOT CHINAT	Class: C	
Suzhou, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA  FSC not submitted  LOA Validity: 16-01-2027  ISO 13485 Validity: 16-02-2026 FQA valid till 26.05.2024 extension letter submitted  Brand Name:  MEDCAPTAIN LIFE SCIENCE CO., LTD. Manufacturing address: Room 103, 1st Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Blade M1, M2, M3, M3D and M4  Class A  Shelf Life: 5 years  PEOPLE'S REPUBLIC OF CHINA.  FSC:  Date of R&I  FSC:		l '	Madaantain Madiaal		
Suzhou, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA  FSC not submitted  LOA Validity: 16-01-2027  ISO 13485 Validity: 16-02-2026 FQA valid till 26.05.2024 extension letter submitted  Brand Name:  MEDCAPTAIN LIFE SCIENCE CO., LTD. Manufacturing address: Room 103, 1st Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Blade M1, M2, M3, M3D and M4  Class A  Shelf Life: 5 years  PEOPLE'S REPUBLIC OF CHINA.  FSC:  Date of R&I  FSC:		1 1	Wiedcaptain Wiedcai	Claimed Shell Life:10-	
Suzhou, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA  FSC not submitted  LOA Validity: 16-01-2027  ISO 13485 Validity: 16-02-2026 FQA valid till 26.05.2024 extension letter submitted  Brand Name:  MEDCAPTAIN LIFE SCIENCE CO., LTD. Manufacturing address: Room 103, 1st Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Blade M1, M2, M3, M3D and M4  Class A  Shelf Life: 5 years  PEOPLE'S REPUBLIC OF CHINA.  FSC:  Date of R&I  FSC:			Technology Co., Ltd.,	years	
Suzhou, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA  FSC not submitted  LOA Validity: 16-01-2027  ISO 13485 Validity: 16-02-2026 FQA valid till 26.05.2024 extension letter submitted  Brand Name:  MEDCAPTAIN LIFE SCIENCE CO., LTD. Manufacturing address: Room 103, 1st Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Blade M1, M2, M3, M3D and M4  Class A  Shelf Life: 5 years  PEOPLE'S REPUBLIC OF CHINA.  FSC:  Date of R&I  FSC:		10-10-2024	Building C. Jiale Science		
Suzhou, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA  FSC not submitted  LOA Validity: 16-01-2027  ISO 13485 Validity: 16-02-2026 FQA valid till 26.05.2024 extension letter submitted  Brand Name:  MEDCAPTAIN LIFE SCIENCE CO., LTD. Manufacturing address: Room 103, 1st Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Blade M1, M2, M3, M3D and M4  Class A  Shelf Life: 5 years  PEOPLE'S REPUBLIC OF CHINA.  FSC:  Date of R&I  FSC:			and Technology Industrial		
Suzhou, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA  FSC not submitted  LOA Validity: 16-01-2027  ISO 13485 Validity: 16-02-2026 FQA valid till 26.05.2024 extension letter submitted  Brand Name:  MEDCAPTAIN LIFE SCIENCE CO., LTD. Manufacturing address: Room 103, 1st Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Blade M1, M2, M3, M3D and M4  Class A  Shelf Life: 5 years  PEOPLE'S REPUBLIC OF CHINA.  FSC:  Date of R&I  FSC:			Park, Matian Sreet,	191	6
Suzhou, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA  FSC not submitted  LOA Validity: 16-01-2027  ISO 13485 Validity: 16-02-2026 FQA valid till 26.05.2024 extension letter submitted  Brand Name:  MEDCAPTAIN LIFE SCIENCE CO., LTD. Manufacturing address: Room 103, 1st Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Blade M1, M2, M3, M3D and M4  Class A  Shelf Life: 5 years  PEOPLE'S REPUBLIC OF CHINA.  FSC:  Date of R&I  FSC:		Fee 62000/-	Guangming, PEOPLE'S		5
Suzhou, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA  FSC not submitted  LOA Validity: 16-01-2027  ISO 13485 Validity: 16-02-2026 FQA valid till 26.05.2024 extension letter submitted  Brand Name:  MEDCAPTAIN LIFE SCIENCE CO., LTD. Manufacturing address: Room 103, 1st Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Blade M1, M2, M3, M3D and M4  Class A  Shelf Life: 5 years  PEOPLE'S REPUBLIC OF CHINA.  FSC:  Date of R&I  FSC:			REPUBLIC OF CHINA	711 (112, 0)	
Suzhou, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA  FSC not submitted  LOA Validity: 16-01-2027  ISO 13485 Validity: 16-02-2026 FQA valid till 26.05.2024 extension letter submitted  Brand Name:  MEDCAPTAIN LIFE SCIENCE CO., LTD. Manufacturing address: Room 103, 1st Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Blade M1, M2, M3, M3D and M4  Class A  Shelf Life: 5 years  PEOPLE'S REPUBLIC OF CHINA.  FSC:  Date of R&I  FSC:			REPOBLIC OF CHEAT	20.	
Suzhou, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA  FSC not submitted  LOA Validity: 16-01-2027  ISO 13485 Validity: 16-02-2026 FQA valid till 26.05.2024 extension letter submitted  Brand Name:  MEDCAPTAIN LIFE SCIENCE CO., LTD. Manufacturing address: Room 103, 1st Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Blade M1, M2, M3, M3D and M4  Class A  Shelf Life: 5 years  PEOPLE'S REPUBLIC OF CHINA.  FSC:  Date of R&I  FSC:			Datter Life Medical	, V., U.D.	
Suzhou, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA  FSC not submitted  LOA Validity: 16-01-2027  ISO 13485 Validity: 16-02-2026 FQA valid till 26.05.2024 extension letter submitted  Brand Name:  MEDCAPTAIN LIFE SCIENCE CO., LTD. Manufacturing address: Room 103, 1st Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Blade M1, M2, M3, M3D and M4  Class A  Shelf Life: 5 years  PEOPLE'S REPUBLIC OF CHINA.  FSC:  Date of R&I  FSC:			Better Life Medical	40.00	
Suzhou, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA  FSC not submitted  LOA Validity: 16-01-2027  ISO 13485 Validity: 16-02-2026 FQA valid till 26.05.2024 extension letter submitted  Brand Name:  MEDCAPTAIN LIFE SCIENCE CO., LTD. Manufacturing address: Room 103, 1st Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Blade M1, M2, M3, M3D and M4  Class A  Shelf Life: 5 years  PEOPLE'S REPUBLIC OF CHINA.  FSC:  Date of R&I  FSC:			Technology Co., Ltd.,		
Suzhou, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA  FSC not submitted  LOA Validity: 16-01-2027  ISO 13485 Validity: 16-02-2026 FQA valid till 26.05.2024 extension letter submitted  Brand Name:  MEDCAPTAIN LIFE SCIENCE CO., LTD. Manufacturing address: Room 103, 1st Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Blade M1, M2, M3, M3D and M4  Class A  Shelf Life: 5 years  PEOPLE'S REPUBLIC OF CHINA.  FSC:  Date of R&I  FSC:			Room 204, Building 15, No.		
Suzhou, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA  FSC not submitted  LOA Validity: 16-01-2027  ISO 13485 Validity: 16-02-2026 FQA valid till 26.05.2024 extension letter submitted  Brand Name:  MEDCAPTAIN LIFE SCIENCE CO., LTD. Manufacturing address: Room 103, 1st Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Blade M1, M2, M3, M3D and M4  Class A  Shelf Life: 5 years  PEOPLE'S REPUBLIC OF CHINA.  FSC:  Date of R&I  FSC:			8 Jinfeng Road, Suzhou	.00	
PEOPLE'S REPUBLIC OF CHINA  FSC not submitted  LOA Validity: 16-11s-2027  ISO 13485 Validity: 16-02-2026 FQA valid till 26.05.2024 extension letter submitted  66. Applicant Name:  M/s. NI healthcare Products Pvt Ltd.  M/s. NI healthcare Products Pvt Ltd.  MEDCAPTAIN LIFE SCIENCE CO., L'TD. Manufacturing address: Room 103, 1st Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Blade M1, M2, M3, M3D and M4  Class A  Class A  Class A  Class A  Shelf Life: 5 years  PSC:  Date of R&I  PSC:			New District, 215163		
PEOPLE'S REPUBLIC OF CHINA  FSC not submitted  LOA Validity: 16-11s-2027  ISO 13485 Validity: 16-02-2026 FQA valid till 26.05.2024 extension letter submitted  66. Applicant Name:  M/s. NI healthcare Products Pvt Ltd.  M/s. NI healthcare Products Pvt Ltd.  MEDCAPTAIN LIFE SCIENCE CO., L'TD. Manufacturing address: Room 103, 1st Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Blade M1, M2, M3, M3D and M4  Class A  Class A  Class A  Class A  Shelf Life: 5 years  PSC:  Date of R&I  PSC:			Suzhou, Jiangsu Province,		
CHINA FSC not submitted LOA Validity: 16-11s-2027 ISO 13485 Validity: 16-02-2026 FQA valid till 26.05.2024 extension letter submitted  66. Applicant Name:  M/s. NI healthcare Products Pvt Ltd. M/s. NI healthcare Products Pvt Ltd. MEDCAPTAIN LIFE SCIENCE CO., LTD. Manufacturing address: Room 103, 1st Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Block C, Jinweiyuan Industrial Park, Julongshan District, 518118, Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA.  Brand Name: Video Laryngoscope Blade Generic Name: Video Laryngoscope Blade M1, M2, M3, M3D and M4 Class A  Class A  Shelf Life: 5 years  FSC:					
FSC not submitted LOA Validity: 16-01s-2027  ISO 13485 Validity: 16-02-2026 FQA valid till 26.05.2024 extension letter submitted  66. Applicant Name:  M/s. NI healthcare Products Pvt Ltd. M/s. NI healthcare Products Pvt Ltd.  MEDCAPTAIN LIFE SCIENCE CO., LTD. Manufacturing address: Room 103, 1st Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Block C, Jinweiyuan Industrial Park, Julongshan Subdistrict, Pingshan District Malir, Karachi  MEDCAPTAIN LIFE SCIENCE CO., LTD. Manufacturing address: Room 103, 1st Floor, Room 701, 7th Floor, Block C, Jinweiyuan Industrial Park, Julongshan Subdistrict, Pingshan District, 518118, Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA.  FSC:  Brand Name: Video Laryngoscope Blade N1, M2, M3, M3D and M4  Class A  Shelf Life: 5 years  Shelf Life: 5 years					
LOA Validity: 16-11s-2027  ISO 13485 Validity: 16-02-2026 FQA valid till 26.05.2024 extension letter submitted  66. Applicant Name:  M/s. NI healthcare Products Pvt Ltd.  MEDCAPTAIN LIFE SCIENCE CO., LTD. Manufacturing address: Room 103, 1st Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Block C, Jinweiyuan Industrial Park, Julongshan Subdistrict, Pingshan District Malir, Karachi  Date of R&I  Egal Manufacturer:  MEDCAPTAIN LIFE SCIENCE CO., LTD. Manufacturing address: Room 601, 6th Floor, and Room 701, 7th Floor, Block C, Jinweiyuan Industrial Park, Julongshan Subdistrict, Pingshan District, 518118, Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA.  FSC:  Date of R&I  FSC:			CIMVI		
LOA Validity: 16-11s-2027  ISO 13485 Validity: 16-02-2026 FQA valid till 26.05.2024 extension letter submitted  66. Applicant Name:  M/s. NI healthcare Products Pvt Ltd.  MEDCAPTAIN LIFE SCIENCE CO., LTD. Manufacturing address: Room 103, 1st Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Block C, Jinweiyuan Industrial Park, Julongshan Subdistrict, Pingshan District Malir, Karachi  Date of R&I  Egal Manufacturer:  MEDCAPTAIN LIFE SCIENCE CO., LTD. Manufacturing address: Room 601, 6th Floor, and Room 701, 7th Floor, Block C, Jinweiyuan Industrial Park, Julongshan Subdistrict, Pingshan District, 518118, Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA.  FSC:  Date of R&I  FSC:			ESC		
ISO 13485 Validity: 16-02-2026 FQA valid till 26.05.2024 extension letter submitted  66. Applicant Name:  M/s. NI healthcare Products Pvt Ltd.  MEDCAPTAIN LIFE SCIENCE CO., LTD. Manufacturing address: Room 103, 1st Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Block C, Jinweiyuan Industrial Park, Julongshan District Malir, Karachi  Date of R&I  FSC:  Brand Name:  Video Laryngoscope Blade Video Laryngoscope Blade M1, M2, M3, M3D and M4  Class A  Shelf Life: 5 years  FSC:			FSC not submitted		
ISO 13485 Validity: 16-02-2026 FQA valid till 26.05.2024 extension letter submitted  66. Applicant Name:  M/s. NI healthcare Products Pvt Ltd.  MEDCAPTAIN LIFE SCIENCE CO., LTD. Manufacturing address: Room 103, 1st Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Block C, Jinweiyuan Industrial Park, Julongshan District Malir, Karachi  Date of R&I  FSC:  Brand Name:  Video Laryngoscope Blade Video Laryngoscope Blade M1, M2, M3, M3D and M4  Class A  Shelf Life: 5 years  FSC:					
Validity: 16-02-2026 FQA valid till 26.05.2024 extension letter submitted  66. Applicant Name:  M/s. NI healthcare Products Pvt Ltd.  MEDCAPTAIN LIFE SCIENCE CO., LTD. Manufacturing address: Room 103, 1st Floor, Room 601, 6th Floor, and Office No. A, Unit 10 Survey No. 263, Damlotte Road District Malir, Karachi  District, 518118, Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA.  Brand Name:  Video Laryngoscope Blade Video Laryngoscope Blade Video Laryngoscope Blade M1, M2, M3, M3D and M4  Class A  Class A  Shelf Life: 5 years  FSC:			LOA Validity: 16-11s-2027		
Validity: 16-02-2026 FQA valid till 26.05.2024 extension letter submitted  66. Applicant Name:  M/s. NI healthcare Products Pvt Ltd.  MEDCAPTAIN LIFE SCIENCE CO., LTD. Manufacturing address: Room 103, 1st Floor, Room 601, 6th Floor, and Office No. A, Unit 10 Survey No. 263, Damlotte Road District Malir, Karachi  District, 518118, Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA.  Brand Name:  Video Laryngoscope Blade Video Laryngoscope Blade Video Laryngoscope Blade M1, M2, M3, M3D and M4  Class A  Class A  Shelf Life: 5 years  FSC:					
FQA valid till 26.05.2024 extension letter submitted  66. Applicant Name:    Legal Manufacturer:   Brand Name:   Approved subject to submission of fee for the family.					
extension letter submitted  66. Applicant Name:  M/s. NI healthcare Products Pvt Ltd.  Address:  Office No. A, Unit 10 Survey No. 263, Damlotte Road District Malir, Karachi  Date of R&I  Date of R&I  MEDCAPTAIN LIFE SCIENCE CO., LTD. Manufacturing address: Room 103, 1st Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Block C, Jinweiyuan Industrial Park, Julongshan Subdistrict, Pingshan District, 518118, Shenzhen, Guangdong, PEOPLE'S REPUBLIC  Date of R&I  MEDCAPTAIN LIFE SCIENCE CO., LTD. Generic Name: Video Laryngoscope Blade M1, M2, M3, M3D and M4  Class A  Class A  Shelf Life: 5 years  FSC:			Validity: 16-02-2026		
extension letter submitted  66. Applicant Name:  M/s. NI healthcare Products Pvt Ltd.  Address:  Office No. A, Unit 10 Survey No. 263, Damlotte Road District Malir, Karachi  Date of R&I  Date of R&I  MEDCAPTAIN LIFE SCIENCE CO., LTD. Manufacturing address: Room 103, 1st Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Block C, Jinweiyuan Industrial Park, Julongshan Subdistrict, Pingshan District, 518118, Shenzhen, Guangdong, PEOPLE'S REPUBLIC  Date of R&I  MEDCAPTAIN LIFE SCIENCE CO., LTD. Generic Name: Video Laryngoscope Blade M1, M2, M3, M3D and M4  Class A  Class A  Shelf Life: 5 years  FSC:			FO A1: 1 4:11 26 05 2024		
66. Applicant Name:  M/s. NI healthcare Products Pvt Ltd.  Address:  Office No. A, Unit 10 Survey No. 263, Damlotte Road District Malir, Karachi  Date of R&I  M/s. NI healthcare Products Pvt Ltd.  MEDCAPTAIN LIFE SCIENCE CO., LTD. Manufacturing address: Room 103, 1st Floor, and Room 701, 7th Floor, Block C, Jinweiyuan Industrial Park, Julongshan Subdistrict, Pingshan District, 518118, Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA.  Brand Name:  Video Laryngoscope Blade Video Laryngoscope Blade M1, M2, M3, M3D and M4  Class A  Class A  Shelf Life: 5 years  FSC:			-		6
M/s. NI healthcare Products Pvt Ltd.  MEDCAPTAIN LIFE SCIENCE CO., LTD. Manufacturing address: Room 103, 1st Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Block C, Jinweiyuan Industrial Park, Julongshan District Malir, Karachi  MEDCAPTAIN LIFE SCIENCE CO., LTD. Manufacturing address: Room 103, 1st Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Block C, Jinweiyuan Industrial Park, Julongshan Subdistrict, Pingshan District, 518118, Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA.  FSC:  Date of R&I  Video Laryngoscope Blade Video Laryngoscope Name: Video Laryngoscope Roam 103, 1st Floor, Room 103, 1st Floor, Room 701, 7th Floor, Blade M1, M2, M3, M3D and M4  Class A  Shelf Life: 5 years			extension letter submitted	191,	
M/s. NI healthcare Products Pvt Ltd.  MEDCAPTAIN LIFE SCIENCE CO., LTD. Manufacturing address: Room 103, 1st Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Block C, Jinweiyuan Industrial Park, Julongshan Subdistrict, Pingshan District Malir, Karachi  MEDCAPTAIN LIFE SCIENCE CO., LTD. Manufacturing address: Room 103, 1st Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Block C, Jinweiyuan Industrial Park, Julongshan Subdistrict, Pingshan District, 518118, Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA.  FSC:  Video Laryngoscope Blade  Generic Name: Video Laryngoscope Blade  Class A  Shelf Life: 5 years	66.	Applicant Name:	<b>Legal Manufacturer:</b>	Brand Name:	Approved subject to submission
M/s. NI healthcare Products Pvt Ltd.  MEDCAPTAIN LIFE SCIENCE CO., LTD. Manufacturing address: Room 103, 1st Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Block C, Jinweiyuan Industrial Park, Julongshan Subdistrict, Pingshan District, 518118, Shenzhen, Guangdong, PEOPLE'S REPUBLIC  (ELI-01117)  Blade Generic Name: Video Laryngoscope Blade M1, M2, M3, M3D and M4  Class A  Class A  Shelf Life: 5 years  FSC:				91, 16, 3,	of fee for the family.
M/s. NI healthcare Products Pvt Ltd.  MEDCAPTAIN LIFE SCIENCE CO., LTD. Manufacturing address: Room 103, 1st Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Block C, Jinweiyuan Industrial Park, Julongshan Subdistrict, Pingshan District, 518118, Shenzhen, Guangdong, PEOPLE'S REPUBLIC  (ELI-01117)  Blade Generic Name: Video Laryngoscope Blade M1, M2, M3, M3D and M4  Class A  Class A  Shelf Life: 5 years  FSC:				Video Laryngoscope	
Products Pvt Ltd.  SCIENCE CO., LTD.  Manufacturing address: Room 103, 1st Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Block C, Jinweiyuan Industrial Park, Julongshan Subdistrict, Pingshan District, 518118, Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA.  SCIENCE CO., LTD. Manufacturing address: Room 103, 1st Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Block C, Jinweiyuan Industrial Park, Julongshan Subdistrict, Pingshan District, 518118, Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA.  FSC:  Date of R&I  SCIENCE CO., LTD. Manufacturing address: Room 103, 1st Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Blade M1, M2, M3, M3D and M4  Class A  Shelf Life: 5 years		M/s. NI healthcare	MEDCAPTAIN LIFE	Blade	
Address:  Addres		Products Pvt Ltd.	SCIENCE CO., LTD.	-C/- U/O	
Address:  Office No. A, Unit 10 Survey No. 263, Damlotte Road District Malir, Karachi  Date of R&I  Room 103, 1st Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Blade M1, M2, M3, M3D and M4  Class A  Class A  Shelf Life: 5 years  FSC:  Room 103, 1st Floor, Room 601, 6th Floor, and Room 701, 7th Floor, Blade M1, M2, M3, M3D and M4  Class A  Shelf Life: 5 years  FSC:				Generic Name	
Address: Office No. A, Unit 10 Survey No. 263, Damlotte Road District Malir, Karachi  Date of R&I  Room 601, 6th Floor, and Room 701, 7th Floor, Block C, Jinweiyuan Industrial Park, Julongshan Subdistrict, Pingshan District, 518118, Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA.  Blade M1, M2, M3, M3D and M4  Class A  Shelf Life: 5 years  FSC:					
Office No. A, Unit 10 Survey No. 263, Damlotte Road District Malir, Karachi  Date of R&I  Room 701, 7th Floor, Block C, Jinweiyuan Industrial Park, Julongshan Subdistrict, Pingshan District, 518118, Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA.  Class A  Shelf Life: 5 years  FSC:		Address			
Block C, Jinweiyuan Industrial Park, Julongshan District Malir, Karachi  Block C, Jinweiyuan Industrial Park, Julongshan Subdistrict, Pingshan District, 518118, Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA.  FSC:  Date of R&I  Block C, Jinweiyuan Industrial Park, Julongshan Subdistrict, Pingshan District, 518118, Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA.  FSC:					
Damlotte Road District Malir, Karachi  Industrial Park, Julongshan Subdistrict, Pingshan District, 518118, Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA.  Shelf Life: 5 years  FSC:		*		MISD and M4	
Date of R&I  Subdistrict, Pingshan District, 518118, Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA.  Shelf Life: 5 years  Shelf Life: 5 years		10 Survey No. 263,		CI. A	
District Malir, Karachi  Subdistrict, Pingshan District, 518118, Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA.  Shelf Life: 5 years  FSC:		Damlotte Road		Class A	
Karachi  District, 518118, Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA.  Shelf Life: 5 years  FSC:					
(ELI-01117)  Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA.  Shelf Life: 5 years  FSC:		II			
PEOPLE'S REPUBLIC OF CHINA.  FSC:		1xuruciii	Shenzhen, Guangdong,	<b>Shelf Life</b> : 5 years	
(ELI-01117) OF CHINA.  FSC:			PEOPLE'S REPUBLIC		
Date of R&I FSC:		(EL L 01117)			
Date of R&I		(ELI-VIII/)			
Date of R&I					
Date of R&I			· *		
Date of R&I			FSC.		
		Date of R&I			
	1				

	28-03-2025	Validity: 08-09-2026		
	Rs. 6000			
	Slip# 953813925934	LOA		
		Validity: 10-01-2028		
		CE Certificate	adir 1 (MIS)	all
		Validity: 26-05-2024 with		6
		Extension letter Expiry 31-12-2028		20.
			911 (14, 3)	
		ISO 13485	, 01, 55,	
		Validity: 16-06-2025	Scr. Jo.	
67.	M/s Crown Traders, Flat No. G-01,	Name of Manufacturer:	Brand name: Xpert Lense 5.25 PMMA	Deferred (last opportunity) due to
	Flat No. G-01, Ground Floor,	Ophthalmic Experts Ltd., 50		following reasons:
	Seacon Arcade, Block-13, D/2	Ripplr Road, Barking, Essex, IG11 7PG, England.	Generic Name: PMMA IOL	1. The FSC is not legalized or apostille.
	Scheme-42, Gulshan-e-Iqbal,	DS & D	Applied as: Single	2. The name of device as per FSC is Xpert PMMA Single
	Karachi.	• LOA: Type: Copy of notarized	Class: C	Piece Intraocular Lens.
		Notarization: Notarized	Codoloizos (os non	3. ISO 13485 not notarized.
	ELI-01364	<b>Validity:</b> 29-08-2029	Code/sizes (as per DOC & Application):	4. applied code not mentioned in
		vanuity. 27-00-2027	PCC12052CRN	FSC.
	Date of R & I 02-06-2025	• FSC	Shelf Life: 5 Years	6
	Fee: <b>62,000</b> /-	Type: Copy		70.
	Slip # 838569842	Issued By: MHRA	YIL ' (W. O.	
		<b>Legalization:</b> Not Legalized	Sciol Josp.	
		<b>Issue Date:</b> 13-12-2023	Scr. 10.	
		Validity: Not mentioned.	10011	
		, analy, 1 to mentioned.	Up	
		• ISO – Certificate:		
		Type: Copy		
		<b>Notarization</b> : Not Notarized		
		Validity: 17-11-2027		
68.	M/s Crown Traders,	Name of Manufacturer:	Brand name:	Deferred (last opportunity) due to
	Flat No. G-01, Ground Floor,	Ophthalmic Experts Ltd., 50	Xpert Lense PMMA	following reasons:
	Seacon Arcade, Block-13, D/2	Ripplr Road, Barking, Essex, IG11 7PG, England.	Generic Name: PMMA IOL	1. The FSC is not legalized or apostille.
Danini	C 100th M C C	MDB (12-11-2025 ) (Manual A	A1:4:>	Page <b>54</b> of <b>66</b>

Scheme-42, Gulshan-e-Iqbal, Karachi.  ELI-01364  Date of R & I 02-06-2025  Fee: 62,000/- Slip # 52651769901	<ul> <li>LOA: Type: Copy of notarized Notarization: Notarized Validity: 29-08-2029</li> <li>FSC Type: Copy Issued By: MHRA Legalization: Not Legalized Issue Date: 13-12-2023 Validity: Not mentioned.</li> <li>ISO – Certificate: Type: Copy Notarization: Not Notarized</li> <li>Validity: 17-11-2027</li> </ul>	Applied as: Single Class: C Code/sizes Application): PJ313565CRO Shelf Life: 5 Years	<ol> <li>The name of device as per FSC is Xpert PMMA Single Piece Intraocular Lens.</li> <li>ISO 13485 not notarized.</li> <li>applied code not mentioned in FSC.</li> </ol>
69. M/s Crown Traders, Flat No. G-01, Ground Floor, Seacon Arcade, Block-13, D/2 Scheme-42, Gulshan-e-Iqbal, Karachi.  ELI-01364  Date of R & I 02-06-2025  Fee: 62,000/- Slip # 52651769901	Name of Manufacturer: Ophthalmic Experts Ltd., 50 Ripplr Road, Barking, Essex, IG11 7PG, England.  • LOA: Type: Copy of notarized Notarization: Notarized Validity: 29-08-2029  • FSC Type: Copy Issued By: MHRA Legalization: Not Legalized Issue Date: 13-12-2023 Validity: Not mentioned.  • ISO – Certificate: Type: Copy	Brand name: Mesto Hydrophobic Preloaded Lense  Generic Name: Hydrophobic Preloaded IOL  Applied as: Single  Class: C  Code/sizes (as per DOC & Application): FCL113060-CRA-PL  Shelf Life: 5 Years	Deferred (last opportunity) due to following reasons:  1. The FSC is not legalized or apostille.  2. The name of device as per FSC is Mestro, BIOL Hydrophobic Acrylic Foldable IOL  3. applied code not mentioned in FSC.  4. ISO 13485 not notarized.  5. the name of on LOA is Mestro Hydrophobic Intraocular Lens and code not mentioned.

70. M/s Crown Traders, Flat No. G-01, Ground Floor, Seacon Arcade, Block-13, D'2 Scheme-42, U23 Scheme-42, Gulshan-e-Iqbal, Karachi.  **ELI-01364**  **Date of R & 1 02-06-2025**  Fee: 62,0004- Slip # 3205927362**  **Iso Certificate: Type: Copy Notarized Issue Date: 13-12-2023 Validity: Not mentioned.  **ISO — Certificate: Type: Copy Notarized Notarized Supply Office No.204, 2 Floor, Makkah Tower, Namak Mandi, Peshawar  **Address: 1305-1, Konggang North Street Office Building, Shijiazhuang Comprehensive Bonded Zone, Zhengding District, Fee Challan No. 38080996**  **Notarized State of Makein Properties of State of Congress o			Notarization: Not		
70.   M/s Crown Traders, Flat No. G-01, Ground Floor, Seacon Arcade, Block-13, D/2 Scheme-42, Gulsham-e-Iqbal, Karachi.   Date of R & I 02-06-2025   Fcc. 62,000/- Slip # 3205927362   Issue Date: 13-12-2023 Validity: 17-11-2027   Floor, Makkah Tower, Namak Mandi, Peshawar   Address: 1305-1, Konggang North Street Office Building, Subject of Reliand No. 38080996   Slope Challeng No. 38080996   Sized Zone Challeng No. 38080996   Sized					
Flat No. G-01, Ground Floor, Seacon Arcade, Block-13, D/2 Scheme-42, Gulshan-e-Iqbal, Karachi.  ELI-01364  Date of R & 1 02-06-2025 Fee: 62,000/- Slip # 3205927362  Type: Copy Issued By: MHRA Legalization: Not Legalized Issue Date: 13-12-2023 Validity: Not mentioned.  PISO - Certificate: Type: Copy Notarization: Not Notarized Validity: 17-11-2027  T1. M/s Reliable Medical Supply Office No.204, 2 <sup>rol</sup> Floor, Makkah Tower, Namak Mandi, Peshawar  Mandi, Peshawar  Address: 1305-1, Konggang North Street Office Building. Shijiazhuang Comprehensive Bonded Zone, Zhengding District, China (Hebei) Pilot Free Trade Zone Shelf Life: 3 Years  Lasel Aspert IOI.  Generic Name: Hydrophilic Clear Foldable IOL Applied as: Single Class: C Code/sizes (as per FSC & Application):  Class: C Code/sizes (as per FSC & Application):  HFL1125606CRA Shelf Life: 5 Years  Shelf Life: 5 Years  Shelf Life: 5 Years  Single-use Container for Human Venous Blood Collection Specimen Collection Collection Specimen arriginal documents.  Class: A  Address: 1305-1, Konggang North Street Office Building. Shijiazhuang Comprehensive Bonded Zone, Zhengding District, China (Hebei) Pilot Free Trade Zone Shelf Life: 3 Years  Sized: As per FSC			<b>Validity:</b> 17-11-2027		
Ground Seacon Arcade, Block-13, D/2 Scheme-42, Gulshan-e-Iqbal, Karachi.  ELI-01364  ELI-01364  Date of R & I 02-05-2025 Fee: 62,000/- Slip # 3205927362  Sip # 3205927362  Type: Copy Notarization: Not Legalized Issue Date: 13-12-2023 Validity: 17-11-2027  M/s Reliable Medical Supply Office No.204, 2nd Floor, Markah Tower, Namak Mandi, Peshawar  ELI-00618  ELI-00618  Generic Name: Hydrophilic Clear Flokable IOL Applied as: Single Class: C Code/sizes (as per FSC & Application): HFLI125606CRA  Shelf Life: 5 Years  Generic Name: Hydrophilic Clear Flokable IOL Applied as: Single Class: C Code/sizes (as per FSC & Application): HFLI125606CRA  Shelf Life: 5 Years  Shelf Life: 5 Years  Shelf Life: 5 Years  Single-use Container for Human Venous Blood Collection Specimen Collection  Approved subject to submission of undertaking for every complication on stamp paper and original documents.  Address: 1305-1, Konggang North Street Offfice Building, Shijiazhuang Comprehensive Bonded Zone, Zhengding District, China (Hebel) Pilot Free Trade Zone  Sized: As per FSC	70.	· ·	Name of Manufacturer:		Deferred (last opportunity) due to
Seacon Arcade, Block-13, D/2   Scheme-42, Gulshane-elqbal, Karachi.   Foldable IOL   Applied as: Single   Applied as: Single   Class: C   Applied as: Single   Class: C   Code/sizes (as per FSC   Application):   FSC   Type: Copy   Copy   Slip # 3205927362   Issued By: MHRA   Legalization: Not motarized   Issue Date: 13-12-2023   Validity: Not mentioned.   Fig. 2   Validity: 17-11-2027   Floor, Makkah Tower, Namak Mandi, Peshawar   Address: 1305-1, Konggang North Street Office   ELI-00618   Subsequence   Subsequenc		,			
Scheme-42, Gulshan-e-lqbal, Karachi.  **LOA: Type: Copy of notarized Validity: 29-08-2029  Date of R & 1 02-06-2025 Fee: 62,0002- Slip # 3205927362  71.  M/S Reliable Medical Supply Office No.204, 2ml Floor, Makkah Tower, Namak Mandi, Peshawar  Mandi, Peshawar  Address: 1305-1, Konggang North Street Office ELI-00618  Building, Shijiazhuang Comprehensive Bonded, 38080996  **LOA: Type: Copy of notarized Notarization: Notarized Validity: 29-08-2029  Applied as: Single Class: C Code/sizes (as per FSC & Applieation: HFL1125606CRA Shelf Life: 5 Years  Shelf Life: 5 Years  Single-use Container for Human Venous Blood Collection Specimen Collectio		,		Hydrophilic Clear	apostille.
Type: Copy of notarized Notarization: Notarized Validity: 29-08-2029					
Notarization: Notarized Validity: 29-08-2029   Code/sizes (as per FSC & Application):				Applied as: Single	
ELI-01364  Date of R & I 02-06-2025 Fee: 62,000/- Slip # 3205927362  Fee: 62,000/- Slip # 3205927362  Type: Copy Issued By: MHRA Legalization: Not Legalized Issue Date: 13-12-2023 Validity: Not mentioned.  FISO — Certificate: Type: Copy Notarizzation: Not Notarized Validity: 17-11-2027  71. M/s Reliable Medical Supply Office No.204, 2nd Floor, Makkah Tower, Namak Mandi, Peshawar Mandi, Peshawar Mandi, Peshawar Mandi, Peshawar  Address: 1305-1, Konggang North Street Office ELI-00618  ELI-00618  ELI-00618  ELI-00618  Date of R & I O2-06-2025  Application: HFL112560CRA Shelf Life: 5 Years  Single-use Container for Human Venous Blood Collection Specimen Collection  Class: A Shelf Life: 3 Years  Single-use Container for Human Venous Blood Collection Specimen Collection  Class: A Shelf Life: 3 Years  Single-use Container for Human Venous Blood Collection Specimen Collection  Class: A Shelf Life: 3 Years  Single-use Container for Human Venous Blood Collection Specimen Collection  Class: A Shelf Life: 3 Years  Single-use Container for Human Venous Blood Collection Specimen Collection  Specimen Collection  Specimen Collection  Specimen Collection Specimen Collection Specimen Collection Specimen Collection Specimen Collection Specimen Collection Specimen Collection Specimen Collection Specimen Collection Specimen Collection Specimen Collection Specimen Collection Specimen Collection Specimen Specimen Collection Specimen Collection Specimen Collection Specimen Collection Specimen Specimen Collection Specimen Col			**	Class: C	3. applied code not mentioned in
Date of R & I 02-06-2025 Fee: 62,000/- Slip # 3205927362  Issued By: MHRA Legalization: Not Legalized Issue Date: 13-12-2023 Validity: Not mentioned.  ISO - Certificate: Type: Copy Notarization: Not Notarized Validity: 17-11-2027  71. M/s Reliable Medical Supply Office No.204, 2 <sup>nd</sup> Floor, Makkah Tower, Namak Mandi, Peshawar  Address: 1305-I, Konggang North Street Office Building, Shijiazhuang Comprehensive Bonded Zone, Zhengding District, Fee Challan No. 38080996  FSC Type: Copy Issued By: MHRA Legalization: Not Shelf Life: 5 Years  HFL1125606CRA Shelf Life: 5 Years  Single-use Container for Human Venous Blood Collection Specimen Collection Collection  Approved subject to submission Human Venous Blood Collection Specimen Collection  Class: A  Shelf Life: 3 Years  Single-use Container for Human Venous Blood Collection Collection  Approved subject to submission for undertaking for every application on stamp paper and original documents.  Class: A  Shelf Life: 3 Years  Sized: As per FSC  Sized: As per FSC		ELI-01364			
Fee: 62,000/- Slip # 3205927362  Type: Copy Legalization: Not Legalized Issue Date: 13-12-2023 Validity: Not mentioned.  • ISO – Certificate: Type: Copy Notarization: Not Notarized Validity: 17-11-2027  71. M/s Reliable Medical Supply Office No.204, 2 <sup>nd</sup> Floor, Makkah Tower, Namak Mandi, Peshawar  Address: 1305-1, Konggang North Street Office Building, Shijiazhuang Comprehensive Bonded Zone, Zhengding District, Fee Challan No. 38080996  Shelf Life: 5 Years  Shelf Life: 5 Years  Code not mentioned.  Shelf Life: 5 Years  Approved subject to submission of undertaking for every application on stamp paper and original documents.  Class: A  Shelf Life: 5 Years  Code not mentioned.  Approved subject to submission of undertaking for every application on stamp paper and original documents.  Class: A  Shelf Life: 5 Years  Shelf Life: 5 Years  Shelf Life: 5 Years  Approved subject to submission of undertaking for every application on stamp paper and original documents.  Class: A  Shelf Life: 5 Years  Shelf Life: 5 Years  Single-use Container for Collection Specimen Collection  Specimen Collecti			, hold air		5. the name of on LOA is X-pert
Issued By: MHRA Legalization: Not Legalized Issue Date: 13-12-2023 Validity: Not mentioned.  • ISO – Certificate: Type: Copy Notarization: Not Notarized Validity: 17-11-2027  71. M/s Reliable Medical Supply Office No.204, 2nd Floor, Makkah Tower, Namak Mandi, Peshawar  Address: 1305-1, Konggang North Street Office Building, Shijiazhuang Comprehensive Bonded Zone, Zhengding District, Fee Challan No. 38080996  Issued By: MHRA Legalization: Not Legalized Issue Date: 13-12-2023 Validity: Not mentioned.  • ISO – Certificate: Type: Copy Notarization: Not Notarization: Not Notarization: Not Notarized Validity: 17-11-2027  Single-use Container for Human Venous Blood Collection Specimen Collection  Class: A  Class: A  Class: A  Class: A  Shelf Life: 3 Years  Sized: As per FSC  Sized: As per FSC				Shelf Life: 5 Years	Hydrophobic Intraocular IOL and code not mentioned.
Legalized  Issue Date: 13-12-2023  Validity: Not mentioned.  • ISO – Certificate: Type: Copy  Notarization: Not Notarized  Validity: 17-11-2027  71. M/s Reliable Medical Supply Office No.204, 2nd Sploor, Makkah Tower, Namak Mandi, Peshawar  Address: 1305-1, Konggang North Street Office Building, Shijiazhuang Comprehensive Bonded Zone, Zhengding District, Fee Challan No. 38080996  Legal Manufacturer: M/s Hebei Free Trade Zone Shenghong Medical Devices Collection  Single-use Container for Human Venous Blood Collection Specimen Collection  Class: A  Class: A  Shelf Life: 3 Years  Sized: As per FSC  Sized: As per FSC			Issued By: MHRA		
Validity: Not mentioned.  • ISO – Certificate: Type: Copy  Notarization: Not Notarized  Validity: 17-11-2027  71. M/s Reliable Medical Supply Office No.204, 2nd Floor, Makkah Tower, Namak Mandi, Peshawar  Address: 1305-1, Konggang North Street Office ELI-00618  Building, Shijiazhuang Comprehensive Bonded Zone, Zhengding District, Fee Challan No. 38080996  Single-use Container for Human Venous Blood Collection Specimen Collection  Class: A  Shelf Life: 3 Years  Sized: As per FSC  Sized: As per FSC					
• ISO – Certificate: Type: Copy Notarization: Not Notarized Validity: 17-11-2027  71. M/s Reliable Medical Supply Office No.204, 2nd Floor, Makkah Tower, Namak Mandi, Peshawar  Address: 1305-1, Konggang North Street Office Building, Shijiazhuang Comprehensive Bonded Zone, Zhengding District, China (Hebei) Pilot Free Trade Zone  Single-use Container for Human Venous Blood Collection Specimen Collection  Class: A  Class: A  Shelf Life: 3 Years  Sized: As per FSC			<b>Issue Date:</b> 13-12-2023		
71. M/s Reliable Medical Supply Office No.204, 2nd Floor, Makkah Tower, Namak Mandi, Peshawar  ELI-00618    Validity: 17-11-2027    Legal Manufacturer: M/s Hebei Free Trade Zone Shenghong Medical Devices Co., Ltd.   Single-use Container for Human Venous Blood Collection Specimen Collection   Approved subject to submission of undertaking for every application on stamp paper and original documents.			Validity: Not mentioned.		
71. M/s Reliable Medical Supply Office No.204, 2nd Floor, Makkah Tower, Namak Mandi, Peshawar  ELI-00618    Validity: 17-11-2027    Legal Manufacturer: M/s Hebei Free Trade Zone Shenghong Medical Devices Co., Ltd.   Single-use Container for Human Venous Blood Collection Specimen Collection   Approved subject to submission of undertaking for every application on stamp paper and original documents.		4			GARM
71. M/s Reliable Medical Supply Office No.204, 2nd Floor, Makkah Tower, Namak Mandi, Peshawar  ELI-00618  M/s Hebei Free Trade Zone Shenghong Medical Devices Co., Ltd.  Single-use Container for Human Venous Blood Collection Specimen Collection  Collection  Class: A  Class: A  Class: A  Class: A  Class: A  Class: A  Single-use Container for Human Venous Blood Collection Specimen Collection  Shenghong Medical Devices Co., Ltd.  Class: A  Class: A  Single-use Container for Human Venous Blood Collection Specimen Collection  Shenghong Medical Devices Container for Human Venous Blood Collection Specimen Collection  Collection  Shenghong Medical Devices Container for Human Venous Blood Collection Specimen Collection  Shenghong Medical Devices Container for Human Venous Blood Collection Specimen Collection  Shenghong Medical Devices Container for Human Venous Blood Collection Specimen Collection  Shenghong Medical Devices Container for Human Venous Blood Collection Specimen Collection  Shenghong Medical Devices Collection Specimen Collection  Shenghong Medical Devices Container for Human Venous Blood Collection Specimen Collection  Shenghong Medical Devices Container for Human Venous Blood Collection Specimen Collection  Shenghong Medical Devices Container for Human Venous Blood Collection Specimen Collection  Shenghong Medical Devices Container for Human Venous Blood Collection Specimen Col				iii (MIS)	35
Medical Supply Office No.204, 2nd Floor, Makkah Tower, Namak Mandi, Peshawar  Address: 1305-1, Konggang North Street Office Building, Shijiazhuang Comprehensive Bonded Zone, Zhengding District, Fee Challan No. 38080996  M/s Hebei Free Trade Zone Shenghong Medical Devices Co., Ltd.  Human Venous Blood Collection Specimen Collection  Class: A  Class: A  Shelf Life: 3 Years  Sized: As per FSC  Sized: As per FSC			<b>Validity:</b> 17-11-2027	3011.11	
Office No.204, 2nd Floor, Makkah Tower, Namak Mandi, Peshawar  Address: 1305-1, Konggang North Street Office Building, Shijiazhuang Comprehensive Bonded Zone, Zhengding District, Fee Challan No. 38080996  M/s Hebel Free Trade Zone Specimen Collection Specimen Collection  Collection Specimen Collection  Collection Specimen Collection  Collection Specimen Collection  Specimen Collection  Collection Specimen Collection  Specimen Collection  Collection Specimen Collection  Specimen Collectio	71.		Legal Manufacturer:		11
Floor, Makkah Tower, Namak Mandi, Peshawar  Address: 1305-1, Konggang North Street Office Building, Shijiazhuang Comprehensive Bonded Zone, Zhengding District, Fee Challan No. 38080996  Collection  Class: A  Class: A  Shelf Life: 3 Years  Sized: As per FSC		113			
Mandi, Peshawar  Address: 1305-1, Konggang North Street Office Building, Shijiazhuang Comprehensive Bonded Zone, Zhengding District, China (Hebei) Pilot Free Trade Zone  Class: A  Shelf Life: 3 Years  Sized: As per FSC		· · · · · · · · · · · · · · · · · · ·		▶	
Address: 1305-1, Konggang North Street Office Building, Shijiazhuang Comprehensive Bonded Zone, Zhengding District, China (Hebei) Pilot Free Trade Zone  Class: A  Shelf Life: 3 Years  Sized: As per FSC		· ·	in The		
ELI-00618  Building, Shijiazhuang Comprehensive Bonded Zone, Zhengding District, China (Hebei) Pilot Free Trade Zone  Shelf Life: 3 Years  Sized: As per FSC		iviandi, Pesnawar		Class: A	
Comprehensive Bonded Zone, Zhengding District, China (Hebei) Pilot Free Trade Zone  Sized: As per FSC  Sized: As per FSC		ELI-00618			
Fee Challan No. 38080996 China (Hebei) Pilot Free Sized: As per FSC Trade Zone			Comprehensive Bonded	Shelf Life: 3 Years	
6 000/-			China (Hebei) Pilot Free	Sized: As per FSC	
0,000/-		6,000/-	0.		
6221-Kpk LOA Validity: 02/04/2030		6221-Kpk	LOA Validity: 02/04/2030		

	<u> </u>	EGG W-1: 1:4 02 00 2025		
		FSC Validity: 03-09-2026		
		ISO 13485 validity 16-03-		
		2026		
72.	MR Medical	SHENZHEN MINDRAY	DEHYDROEPIANDR	Deferred (last opportunity) for the
72.	Pakistan Pvt, Ltd.	BIO-MEDICAL	OSTERONE	submission of:
	Office in. 1101, 11th	ELECTRONICS CO.,	SULFATE (CLIA)	1. Form 7A with annexures and
	floor, ISE Tower,	LTD.MINDRAY	,(5),	undertaking on stamp paper.
	Jinnah Avenue, Blue	BUILDING, KEJI 12TH	10 101	2. FSC of RRA or WHO
	Area, Islamabad	ROAD SOUTH HIGH TECH INDUSTRIAL	301. 16. 3	prequalification or CE certificate.
	(ELI-01008	PARK NANSHAN,	Class B	^ ^
		SHENZHEN CHINA	Co OO	3. approval of storage condition 2-8°C.
		1000-11	Shelf life 18 Months	o C.
		Vo 'O'	(O),	
		, and		
		· C.	Storage condition 2-8 °C	
		cl <sup>3</sup> ~ 8 <sup>3</sup>	_	
73.	MR Medical	SHENZHEN MINDRAY	REVERSE	Deferred (last opportunity) for the
	Pakistan Pvt, Ltd. Office in. 1101, 11th	BIO-MEDICAL ELECTRONICS CO.,	TRIIODOTHYRONIN E RT3	submission of:
	floor, ISE Tower,	LTD.MINDRAY	L KIS	1. Form 7A with annexures and
	Jinnah Avenue, Blue	BUILDING , KEJI 12TH		undertaking on stamp paper.
	Area, Islamabad	ROAD SOUTH HIGH	Shelf life 18 Months	2. FSC of RRA or WHO
	(EV 1.01000	TECH INDUSTRIAL		prequalification or CE certificate.
	(ELI-01008	PARK NANSHAN , SHENZHEN CHINA	Storage condition 2-8	3. approval of storage condition 2-
		SHEWZHEN CHINA	°C	8°C
				50
74.	MR Medical	SHENZHEN MINDRAY	ANIT -	Deferred (last opportunity) for the
	Pakistan Pvt, Ltd.	BIO-MEDICAL	THYROTROPIN	submission of:
	Office in. 1101, 11th	ELECTRONICS CO.,	RECEPTOR	1. Form 7A with annexures and
	floor, ISE Tower,	LTD.MINDRAY	ANTIBODY (TRAB ) –	undertaking on stamp paper.
	Jinnah Avenue, Blue Area, Islamabad	BUILDING , KEJI 12TH ROAD SOUTH HIGH	CLIA	2. FSC of RRA or WHO
	1 11 cm, 15 imiliao au	TECH INDUSTRIAL	00	prequalification or CE certificate.
	(ELI-01008	PARK NANSHAN,		3. approval of storage condition 2-
		SHENZHEN CHINA		8°C.
		15° N	Shelf life 18 Months	
		1, 00	Shen me to Mulius	
		1,		
		707	Storage condition 2-8	
			°C	
75.	MR Medical	SHENZHEN MINDRAY	ALDOSTERONE	Deferred (last opportunity) for the
	Pakistan Pvt, Ltd.	BIO-MEDICAL	(CLIA)	submission of:
	Office in. 1101, 11th	ELECTRONICS CO.,		
	floor, ISE Tower,	LTD.MINDRAY		

	Jinnah Avenue, Blue Area, Islamabad (ELI-01008	BUILDING , KEJI 12TH ROAD SOUTH HIGH TECH INDUSTRIAL PARK NANSHAN , SHENZHEN CHINA	Shelf life 18 Months  Storage condition 2-8 °C	<ol> <li>Form 7A with annexures and undertaking on stamp paper.</li> <li>FSC of RRA or WHO prequalification or CE certificate.</li> <li>approval of storage condition 2-8°C.</li> </ol>
76.	M/s. Alam and Sons, 2 <sup>nd</sup> Floor, Asmat Chamber, 68-Mozang Road, Lahore.  (ELI- 01147)	Name of Manufacturer:  M/s. Anqing Kangmingna Packaging Co., Ltd., No. 8, Wuxiang Road, Daqiao Street, Yixiu District, 246000 Anqing City, China.  • LOA Type: Original Attested By: CCPIT	Brand name: KMN Gussted Reel  Generic Name: Sterillization Gussted Reel  Class: A	Deferred (final opportunity) for the submission of:  1. original, legalized FSC.  2. fee for the family.  3. clarification of the model applied.
	R&I detail 14-05-2025 Fee: 6,000/- Slip: 065731143238	• FSC Type: Original Issued By: CCCIEMHP Attested By: CCPIT	Codes/Sizes: Not mentioned  Applied as: Single	GAN
		<ul> <li>Legalization: Not legalized</li> <li>Validity: 06-04-2025</li> <li>ISO Certificate</li> <li>Type: Original</li> <li>Attested By: CCPIT</li> <li>Validity: 29-06-2026</li> </ul>	Shelf life: Not mentioned	55.6 K
77.	M/s. Alam and Sons, 2 <sup>nd</sup> Floor, Asmat Chamber, 68- Mozang Road, Lahore.	Name of Manufacturer:  M/s. Anqing Kangmingna Packaging Co., Ltd., No. 8, Wuxiang Road, Daqiao Street, Yixiu District, 246000 Anqing City, China.	Brand name:  KMN Sterilization Pouches  Generic Name:	Deferred (final opportunity) for the submission of:  1. original, legalized FSC.  2. fee for the family.  3. clarification of the model applied.
	(ELI- 01147) R&I detail	• LOA Type: Original Attested By: CCPIT Validity: March-2030	Sterilization Pouches  Class: A	

	14-05-2025		Codes/Sizes: Not	
	Fee: 6,000/-	• FSC	mentioned	
	<b>Slip:</b> 28496777	Type: Original		
	•	<b>Issued By:</b> CCCIEMHP	Applied as: Single	
		Attested By: CCPIT		
		Legalization: Not legalized		
		<b>Validity</b> : 06-04-2025	Shelf life: Not mentioned	5:6 AM
		• ISO Certificate Type: Original	3dir (ph. 9;	5
		Attested By: CCPIT	10, 050	
		<b>Validity:</b> 29-06-2026	Sc. 12.	
78.	M/s. Alam and Sons,	Name of Manufacturer:	Brand name:	Deferred (final opportunity) for
	2 <sup>nd</sup> Floor, Asmat Chamber, 68-	M/s. Anqing Kangmingna	KMN Flat Reel	the submission of:
	Mozang Road,	Packaging Co., Ltd., No. 8, Wuxiang Road, Daqiao		1. original, legalized FSC.
	Lahore.	Street, Yixiu District,	Generic Name:	2. fee for the family.
		246000 Anqing City, China.	Sterilization Flat Reel	3. clarification of the model applied.
	(ELI- 01147)	• LOA Type: Original	Class: A	арриса.
	<b>R&amp;I detail</b> 14-05-2025	Attested By: CCPIT Validity: March-2030	Codes/Sizes: Not mentioned	E-G AM
	Fee: 6,000/- Slip: 401295349	• FSC Type: Original	Applied as: Single	20.
		Issued By: CCCIEMHP	10, U.S.	
		Attested By: CCPIT	Shelf life: Not	
		<b>Legalization:</b> Not legalized	mentioned	
		<b>Validity</b> : 06-04-2025	Mo	
		• ISO Certificate Type: Original		
		Attested By: CCPIT		
		<b>Validity:</b> 29-06-2026		
79.	M/s. Alam and Sons,	Name of Manufacturer:	Brand name:	Deferred (final opportunity) for
	2 <sup>nd</sup> Floor, Asmat Chamber, 68-	M/s. Anqing Kangmingna	KMN Steam Indicator	the submission of:
	Mozang Road,	Packaging Co., Ltd., No. 8, Wuxiang Road, Daqiao	Strips	1. original, legalized FSC.
	Lahore.	Street, Yixiu District,		2. fee for the family.

	(ELI- 01147)  R&I detail 14-05-2025  Fee: 6,000/- Slip: 13361428962	<ul> <li>LOA Type: Original Attested By: CCPIT Validity: March-2030</li> <li>FSC Type: Original Issued By: CCCIEMHP Attested By: CCPIT Legalization: Not legalized Validity: 06-04-2025</li> <li>ISO Certificate Type: Original Attested By: CCPIT Validity: 29-06-2026</li> </ul>	Generic Name: Steam Indicator Strips  Class: A  Codes/Sizes: Not mentioned  Applied as: Single  Shelf life: Not mentioned	3. clarification of the model applied.  4. the name on FSC is Steam Indicator Label and on Covering letter is Steam Indicator Label/Strip Class 5.
80.	M/s. Alam and Sons, 2 <sup>nd</sup> Floor, Asmat Chamber, 68-Mozang Road, Lahore.  (ELI- 01147)  R&I detail 14-05-2025  Fee: 6,000/-Slip: 24181713696	Name of Manufacturer:  M/s. Anqing Kangmingna Packaging Co., Ltd., No. 8, Wuxiang Road, Daqiao Street, Yixiu District, 246000 Anqing City, China.  • LOA Type: Original Attested By: CCPIT Validity: March-2030  • FSC Type: Original Issued By: CCCIEMHP Attested By: CCPIT Legalization: Not legalized Validity: 06-04-2025  • ISO Certificate Type: Original	Brand name:  KMN Sterilization Crepe Paper  Generic Name: Sterilization Crepe Paper  Class: A  Codes/Sizes: Not mentioned  Applied as: Single  Shelf life: Not mentioned	Deferred (final opportunity) for the submission of:  1. original, legalized FSC.  2. fee for the family.  3. clarification of the model applied.

		Attested By: CCPIT		
		Validity: 29-06-2026		
81.	M/s. Alam and Sons,	Name of Manufacturer:	Brand name:	Deferred (final opportunity) for
	2 <sup>nd</sup> Floor, Asmat Chamber, 68- Mozang Road, Lahore.	M/s. Anqing Kangmingna Packaging Co., Ltd., No. 8, Wuxiang Road, Daqiao Street, Yixiu District, 246000 Anqing City, China.	KMN Tyvek Reel	the submission of: 1. original, legalized FSC. 2. fee for the family. 3. clarification of the model
			Generic Name:	
			Tyvek Sterilization Reel	applied.
	(ELI- 01147)	• LOA Type: Original	Class: A	50
	<b>R&amp;I detail</b> 14-05-2025	Attested By: CCPIT Validity: March-2030	Codes/Sizes: Not mentioned	
	Fee: 6,000/- Slip: 1435001130	• FSC Type: Original	Applied as: Single	
		Issued By: CCCIEMHP Attested By: CCPIT Legalization: Not legalized Validity: 06-04-2025	Shelf life: Not mentioned	
	N. A.	• ISO Certificate Type: Original Attested By: CCPIT Validity: 29-06-2026		55:6 AM
82.	Cardio Life, House		Delta Med	Deferred (last opportunity) for:
02.	No. 534, Ground Floor Lane 1, Main Khayaban e Tanveer,	Delta Med S.P.A, Via Guido Rossa 20, 46019 Viadana (MN) - Italy.	Arterial Cannula Class-D	1. clarification of the class of applied device.
	Scheme 3, Rawalpindi.	Original FSC: Italy. Date of Issuance: 12-08-2024.	Shelf Life: 5 Year Codes:	2. submission of real time shelf life study of the Delta Med Arterial Cannula.
	ELI-00984	12 00 2024.	393083103122 (3Fr x 8cm) 394103103222 (4Fr x	
	5465-P	DS-8	10cm)	
	62,000/-	, 00		
83.	M/s Reliable Medical Supply		Medical Tape	Deferred (last opportunity) for submission of:
	Office No.204, 2 <sup>nd</sup> Floor, Makkah Tower, Namak Mandi, Peshawar	M/s Zhejiang Bangli Medical Products Co., Ltd Address: No.118, Yuegui South Road, City West New District, 321300 Yongkang	Class: A	<ol> <li>Fee for the family.</li> <li>Brand name mentioned on LOA.</li> </ol>

		City, Zhejiang Province,	Shelf Life: 5 Years	
	ELI-00618	China		
			Sizes: As per FSC	
		LOA Validity: 16/03/2035		
	Fee Challan No.	FSC Validity: 10-03-2027		
	92530528	ISO 13485 validity 25-11-		-W
	6,000/-	2026		6 k
	6222-Kpk		,(6),	35:6 AM
			in Mila	
			30111	
84.	Zymotic Diagnostics	Legal Manufacturer:	NEPHSTAR	Rejected for the following
	International, 4th Floor Business	GOLDSITE DIAGNOSTICS INC.	Specific Protein Analyzer	reasons.:
	Center Regency		1 mary 201	1. FSC is not original.
	Road new Civil		Class-B	2. Stability study/Service life not submitted.
	Lines Faisalabad.	Rongtian Road, Kengzi, Pingshan District, Shenzhen,	Class-D	
	ELI-00880	China, 518122.	Shelf Life: 1 Year	3. Class of the device not corrected.
	7046-P	FSC: China.		4. firm has not submitted original
	31,000/-	Date of Validity: 02-01-2026.	Model:	documents and manufacturer credentials.
		LOA validity April, 2026	Nephstar	5. Firm has not applied separately
	12	ISO 13485 validity 15-10-		for all kits depending upon the
		2027		Class of kit.
85.	M/s	Legal Manufacturer:	AMS 700 Inflatable	Approved AMS 700 Inflatable
	Ferozsons	Boston Scientific	Penile Prosthesis and	Penile Prosthesis CX MS Pump
	Laboratories Limited, P. O.	Corporation 300	AMS 700 Accessory Kit	Inhibizone with following codes:
	Ferozsons,	Boston Scientific Way Marlborough MA 01752	40, 03,0	72404230
	Amangah, Nowshehra-KPK,	USA	Class D	72404231
	Pakistan	Manufacturer:		72404232
	(ELI-00120)	Boston Scientific	Shelf Life: <del>5 years</del> 2	72404232-10
	(ELI-00120)	Corporation 4100 Hamline Ave N	years	72404233
	Ess	Saint Paul, MN 55112	Codes & Sizes:	72404233-12
	Fee slip#7000318435	USA	72404010	72404234
	Dated: 22.04.2025		72404011	72404234-14
	Rs.1,95,000/-	FSC: US FDA	72404012 72404013	72404235
		Date of Issuance:	72404014	72404236
	R&I 05.05.2025	06.12.2023	72404300 72404301	72404237
	6231-KPK	Validity: 05.12.2025	72404301	72404238
	U431-KFK		72404303	

			72404305	72404239 subject to verification
				of the fee.
			72404306 72404307	of the fee.
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		0),	72404161	
			72404162	" Mi
			720182-01	G V
86.	M/s Maher Apparels,	Name Manufacturer:	Brand name:	Deferred with final opportunity
	Lahore.	Changzhou Major Madigal	Medelast Hydrocolloid	for submission of following:
		Changzhou Major Medical Products Co., Ltd.,No. 1,	Wound Dressing Ultra	1. LOA is not original. The date
		Beiyang Road, Hexi	Thin	of issuance not mentioned on
	ELI-01330	Village, Zouqu Town,	, "U, "U, D,	LOA, hence validity can't be
		Zhonglou District,	Generic Name:	assured.
	Date of R& I	Changzhou City, Jiangsu,	Hydrocolloid Wound	
	09-05-2025	China 213144.	Dressing	2. FSC not issued by the relevant
			70~	Health Regulatory Authority.
	Fee: PKR 31,000/-	"Oll of	Class: B	3. The device is of class IIb as per
	Slip # 5955313212	LOA:		EU QMS certificate while firm
		Not Submitted.	M - 1-1-/C'	has applied in class b.
		140t Subillitied.	Models/Sizes:	4. The fee for the family not
		1, 00	5x5cm, 10x10cm,	submitted.
		• FSC	15x15cm, 20x20cm	Submitted.
		Type: Copy of apostilled		
			<b>Shelf Life:</b> 3 Years	
		Issued By: CCCIEMHP		
	19	Legalization: Apostilled		
		<b>Validity</b> : 02-01-2027		
1				

	<ul> <li>ISO – Certificate: Type: Copy</li> <li>Notarization: By CCPIT</li> <li>Validity: 19-09-2026</li> <li>EU QMS Certificate: Type: Copy</li> <li>Notarization: By CCPIT</li> </ul>	.6)	E.G AM
	<b>Validity:</b> 14-07-2029	iii (M)	55
87. Sonoscape Medical Corporation Pakistan, Office No. FF-21, Ist Floor Hayat Arsallah Heights, Commercial Block, CBR Town Phase 1, Islamabad (ELI-01301)  R&I Date: 30-06-2025  Fee: 31,000/-Slip # 4879255436.	Name of Manufacturer:  Sonoscape Medical Corporation,  Address: Room 201 & 202, 12th Building, Shenzhen Software Park Phase II, 1 Keji Middle 2nd Road, Yuehai Sub district, Nanshan District, Shenzhen, 518057, Guangdong P.R. China  LOA:  Type: Copy  Notarization: No  Validity: 31-12-2027  FSC: Type: Copy	Brand Name: Digital Color Doppler Ultrasound Diagnostic Machine Generic Name: Model: P10 Applied as: System Class: B Models/Code/sizes (as per FSC & application P10 Shelf life:	Deferred (final opportunity) for the following reasons:  1. clarification that firm has submitted original documents were submitted 02.06.2025 while application was submitted on 30-06-2025.  2. The name of the device is Digital color Doppler Ultrasound System but fee for the system has not been submitted.  3. Firm has submitted same copy of apostille certificate No.12718950 for all the documents.  4. Firm is once again advised to submit original, notarized/apostille documents as per MDR 2017.

Abdul Gadir I (MIS):35:6 AM Assistant Director 2025. Monday, Ball Ose Services of The Worlds of the Country of the Coun

Abdul Gadir I (MIS):35:6 AM Assistant Director 2025. Monday, Ball Ose Services of The Worlds of the Country of the Coun