

DECISIONS OF 91ST MEETING OF MEDICAL DEVICE BOARD
HELD ON 17-06-2025

91st meeting of the Medical Device Board (MDB) was held in Headoffice of Drug Regulatory Authority of Pakistan (DRAP), Prime Minister Health Complex, Chak Shahzad, Islamabad on 17th June, 2025. The meeting was chaired by Dr. Muhammad Fakhr-ud-Din Amir, Chairman Medical Device Board, DRAP, Islamabad and attended by the following:

S.No.	Name and Designation/Department	Position in the MDB
1	Dr. Muhammad Fakhr-ud-Din Amir, Director, Medical Devices & Medicated Cosmetics, Drug Regulatory Authority of Pakistan, Islamabad.	Chairman
2	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)
3	Abdul Aleem Awan, Assistant Prof. Pharmacy Department, Abbottabad University of Science & Technology, Havelian.	Member
4	Dr. Farid Khan, Senior Consultant Neuro Surgery/Director Trauma & Emergency/Focal Person MSDS, Primary & Secondary Healthcare Department, Punjab.	Member
5	Prof. Brig. (Rtd). Nuzhat Mushahid (TI) Pathalogist, Riphah Health Care Services, Riphah University,	Member (attended meeting through videolink)
6	Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad.	Member (attended meeting through videolink)
7	Wajahat Ali, Biomedical Engineer, Liaquat College of Medicine and Dentistry & Darul Sehat Hospital, Karachi.	Member (attended meeting through videolink)
8	Miss. Tazeen S. Bukhari, Biomedical Engineer (co-opted expert), 192 Cavalry ground, street 4, shami road, Khalid Yaqoob chowk, Lahore.	co-opted expert (attended meeting through videolink)
9	Asif Jalil, Additional Director (MD&MC), DRAP, Islamabad.	Member-cum-Secretary (attended meeting through videolink)

The meeting commenced with the recitation of the Holy Quran. The Chairman, MDB welcomed all the participants. Mr. Saadat Ali Khan, Mr. Zia Ullah, Mst. Sadaf Ahmad, Dr. Ghayoor Ahmad and Mr. Waqar Ahmad presented the agenda before the Board.

REGISTRATION/ENLISTMENT OF MEDICAL DEVICES FOR IMPORT.

S#	Name of Applicant	Manufacturer/legal manufacturer	Name of Medical Device	Decision
1.	Siemens Healthcare (Pvt) Ltd, 4th Floor, State Life Building, 15-A, Sir Agha Khan Road, Lahore-54000, Pakistan. ELI-00146 5988-P 31,000/-	<u>Legal Manufacturer:</u> Siemens Shenzhen Magnetic Resonance Ltd Siemens MRI Center, Gaoxin C. Ave., 2nd Hi-Tech Industrial Park 518057 Shenzhen People's Republic of China. Original FSC: Germany. Date of Issuance: 18-07-2024. LOA issuance 20-02-2025 valid for 5 years ISO 13485 validity 05-07-2027 EU QMS certificate (MDR) validity 08-12-2025	MAGNETOM Flow (Ace + Plus) (Full-body MRI system, superconducting magnet) Class-B Service Life: 10 Years Article No: 11571248 (Ace) 11571313 (Plus)	Approved Ace. The firm shall submit fee as per revised SRO for System before the issuance of registration letter.
2.	Cardiac Care 848-C Shadman-I Lahore. ELI-00070 5984-P 31,000/-	<u>Legal Manufacturer:</u> EUROSETS S.r.l. Strada Statale 12, n°143 41036 Medolla (MO) Italy. FSC: Italy. Date of Issuance: 12-07-2024. LOA validity 31-12-2026 ISO 13485 validity 24-08-2025 CE certificate validity 26-05-2024 with extension notification.	HORIZON AF PLUS Oxygenator Class-B Shelf Life: 3.5 years Model: AG5300	Deferred for the provision of original documents as required in application Form.
3.	MED LAB SERVICES Office Address: KT 34, Main Khayaban e Tanvir Road, Chaklala scheme 3, Rawalpindi. ELI-00056	<u>Legal Manufacturer:</u> VIRCELL, S.L. Address: Parque Tecnológico de la Salud, Avicena 8, 18016 Granada (Spain) Telephone number: +34 958 441 264 Fax number: +34 958 510 712 E-mail address: info@vircell.com Official website: www.vircell.com Original FSC: Spain Validity date: 26/10/2028	VIRCELL HERPES SIMPLEX 1+2 ELISA IgG/IgM Class C Shelf life: 21 months Codes: G/M 1016 Fee Amount: Rs. 62,0000 Deposit Slip No: 303916120	Approved

		<p>Original LOA: Attached Validity date:31/12/2025</p> <p>Original ISO 13485: Attached Validity date:06/02/2027</p> <p>Declaration of conformity: Attached</p>	Submission date: 12-03-2025	
4.	<p>MED LAB SERVICES</p> <p>Office Address: KT 34, Main Khayaban e Tanvir Road, Chaklala scheme 3, Rawalpindi.</p> <p>ELI-00056</p>	<p><u>Legal Manufacturer:</u></p> <p>VIRCELL, S.L. Address: Parque Tecnológico de la Salud, Avicena 8, 18016 Granada (Spain) Telephone number: +34 958 441 264 Fax number: +34 958 510 712 E-mail address: info@vircell.com Official website: www.vircell.com</p> <p>FSC: Spain Validity date: 26/10/2028</p> <p>LOA: Attached Validity date:31/12/2025</p> <p>ISO 13485: Attached Validity date:06/02/2027</p> <p>Declaration of conformity: Attached</p>	<p>Vircell DENGUE ELISA IgM CAPTURE</p> <p>Class B</p> <p>Shelf life: 21 months</p> <p>Codes: M 1018</p> <p>Fee Amount: Rs. 31,000 Deposit Slip No: 4772965489</p> <p>Submission date: 12-03-2025</p>	Approved
5.	<p>MED LAB SERVICES</p> <p>Office Address: KT 34, Main Khayaban e Tanvir Road, Chaklala scheme 3, Rawalpindi.</p> <p>ELI-00056</p>	<p><u>Legal Manufacturer:</u></p> <p>VIRCELL, S.L. Address: Parque Tecnológico de la Salud, Avicena 8, 18016 Granada (Spain) Telephone number: +34 958 441 264 Fax number: +34 958 510 712 E-mail address: info@vircell.com Official website: www.vircell.com</p> <p>FSC: Spain Validity date: 26/10/2028</p> <p>LOA: Attached Validity date:31/12/2025</p>	<p>Vircell DENGUE ELISA IgG</p> <p>Class B</p> <p>Shelf life: 21 months</p> <p>Codes: G 1018</p> <p>Fee Amount: Rs. 31,000 Deposit Slip No: 2551279615</p> <p>Submission date: 12-03-2025</p>	Approved

		ISO 13485: Attached Validity date:06/02/2027 Declaration of conformity: Attached		
6.	MED LAB SERVICES Office Address: KT 34, Main Khayaban e Tanvir Road, Chaklala scheme 3, Rawalpindi. ELI-00056	<u>Legal Manufacturer:</u> VIRCELL, S.L. Address: Parque Tecnológico de la Salud, Avicena 8, 18016 Granada (Spain) Telephone number: +34 958 441 264 Fax number: +34 958 510 712 E-mail address: info@vircell.com Official website: www.vircell.com FSC: Spain Validity date: 26/10/2028 LOA: Attached Validity date:31/12/2025 ISO 13485: Attached Validity date:06/02/2027 Declaration of conformity: Attached	Vircell BRUCELLA ELISA IgG Class B Shelf life: 21 months Codes: G 1003 Fee Amount: Rs. 31,000 Deposit Slip No: 2077438049 Submission date: 12-03-2025	Approved
7.	MED LAB SERVICES Office Address: KT 34, Main Khayaban e Tanvir Road, Chaklala scheme 3, Rawalpindi. ELI-00056	<u>Legal Manufacturer:</u> VIRCELL, S.L. Address: Parque Tecnológico de la Salud, Avicena 8, 18016 Granada (Spain) Telephone number: +34 958 441 264 Fax number: +34 958 510 712 E-mail address: info@vircell.com Official website: www.vircell.com FSC: Spain Validity date: 26/10/2028 LOA: Attached Validity date:31/12/2025 ISO 13485: Attached Validity date:06/02/2027	Vircell BRUCELLA ELISA IgM Class B Shelf life: 21 months Codes: M 1006 Fee Amount: Rs. 31,000 Deposit Slip No: 93881714988 Submission date: 12-03-2025	Approved

		Declaration of conformity: Attached		
8.	MED LAB SERVICES Office Address: KT 34, Main Khayaban e Tanvir Road, Chaklala scheme 3, Rawalpindi. ELI-00056	<u>Legal Manufacturer:</u> VIRCELL, S.L. Address: Parque Tecnológico de la Salud, Avicena 8, 18016 Granada (Spain) Telephone number: +34 958 441 264 Fax number: +34 958 510 712 E-mail address: info@vircell.com Official website: www.vircell.com FSC: Spain Validity date: 26/10/2028 LOA: Attached Validity date: 31/12/2025 ISO 13485: Attached Validity date: 06/02/2027 Declaration of conformity: Attached	Vircell Helicobacter Pylori Elisa IgG Class B Shelf life: 21 months Codes: G 1022 Fee Amount: Rs. 31,000 Deposit Slip No: 1631606480 Submission date: 12-03-2025	Approved
9.	MED LAB SERVICES Office Address: KT 34, Main Khayaban e Tanvir Road, Chaklala scheme 3, Rawalpindi. ELI-00056	<u>Legal Manufacturer:</u> VIRCELL, S.L. Address: Parque Tecnológico de la Salud, Avicena 8, 18016 Granada (Spain) Telephone number: +34 958 441 264 Fax number: +34 958 510 712 E-mail address: info@vircell.com Official website: www.vircell.com FSC: Spain Validity date: 26/10/2028 LOA: Attached Validity date: 31/12/2025 ISO 13485: Attached Validity date: 06/02/2027 Declaration of conformity: Attached	Vircell Helicobacter Pylori Elisa IgA Class B Shelf life: 21 months Codes: A 1022 Fee Amount: Rs. 31,000 Deposit Slip No: 0271028779 Submission date: 12-03-2025	Approved

10.	MED LAB SERVICES Office Address: KT 34, Main Khayaban e Tanvir Road, Chaklala scheme 3, Rawalpindi. ELI-00056	<u>Legal Manufacturer:</u> VIRCELL, S.L. Address: Parque Tecnológico de la Salud, Avicena 8, 18016 Granada (Spain) Telephone number: +34 958 441 264 Fax number: +34 958 510 712 E-mail address: info@vircell.com Official website: www.vircell.com FSC: Spain Validity date: 26/10/2028 LOA: Attached Validity date:31/12/2025 ISO 13485: Attached Validity date:06/02/2027 Declaration of conformity: Attached	Vircell Hydatidosis ELISA IgG Class B Shelf life: 21 months Codes: G 1006 Fee Amount: Rs. 31,000 Deposit Slip No: 19149126339 Submission date: 12-03-2025	Approved
11.	MED LAB SERVICES Office Address: KT 34, Main Khayaban e Tanvir Road, Chaklala scheme 3, Rawalpindi. ELI-00056	<u>Legal Manufacturer:</u> VIRCELL, S.L. Address: Parque Tecnológico de la Salud, Avicena 8, 18016 Granada (Spain) Telephone number: +34 958 441 264 Fax number: +34 958 510 712 E-mail address: info@vircell.com Official website: www.vircell.com FSC: Spain Validity date: 26/10/2028 LOA: Attached Validity date:31/12/2025 ISO 13485: Attached Validity date:06/02/2027 Declaration of conformity: Attached	Vircell EPSTEIN-BARR VCA ELISA IgG Class B Shelf life: 21 months Codes: G 1005 Fee Amount: Rs. 31,000 Deposit Slip No: 3410756529 Submission date: 12-03-2025	Approved
12.	MED LAB SERVICES	<u>Legal Manufacturer:</u> VIRCELL, S.L.	Vircell EPSTEIN-BARR VCA ELISA IgM	Approved

	Office Address: KT 34, Main Khayaban e Tanvir Road, Chaklala scheme 3, Rawalpindi. ELI-00056	Address: Parque Tecnológico de la Salud, Avicena 8, 18016 Granada (Spain) Telephone number: +34 958 441 264 Fax number: +34 958 510 712 E-mail address: info@vircell.com Official website: www.vircell.com FSC: Spain Validity date: 26/10/2028 LOA: Attached Validity date:31/12/2025 ISO 13485: Attached Validity date:06/02/2027 Declaration of conformity: Attached	Class B Shelf life: 21 months Codes: M 1005 Fee Amount: Rs. 31,000 Deposit Slip No: 836989108427 Submission date: 12-03-2025	
13.	MED LAB SERVICES Office Address: KT 34, Main Khayaban e Tanvir Road, Chaklala scheme 3, Rawalpindi. ELI-00056	<u>Legal Manufacturer:</u> VIRCELL, S.L. Address: Parque Tecnológico de la Salud, Avicena 8, 18016 Granada (Spain) Telephone number: +34 958 441 264 Fax number: +34 958 510 712 E-mail address: info@vircell.com Official website: www.vircell.com FSC: Spain Validity date: 26/10/2028 LOA: Attached Validity date:31/12/2025 ISO 13485: Attached Validity date:06/02/2027 Declaration of conformity: Attached	Vircell LEPTOSPIRA ELISA IgM Class B Shelf life: 21 months Codes: M 1003 Fee Amount: Rs. 31,000 Deposit Slip No: 297919067 Submission date: 12-03-2025	Approved
14.	Cabbot Surgicals, 09 Rose Lane 1 Gulberg Avenue New Lalazar Rawalpindi 46000.	<u>Legal Manufacturer:</u> Bonree Medical Co., Ltd 1st Floor of Building No. 2, Building No. 4, Longzhu Village Economic Estate, Longzhu Avenue, Nanlang,	VISTA BONREE YANKAUER SUCTION SETS Class-B	Approved

	ELI-00415 31,000/-	528451 Zhongshan, Guangdong, People's Republic of China. FSC: China Validity: 24-10-2025 LOA validity 30-12-2028 ISO 13485 Validity 31-07- 2025 CE certificate with extension notification letter.	Shelf Life: 5 Years Size: 9/32", 1/4", 3/16"	
15.	Cabbot Surgicals, 09 Rose Lane 1 Gulberg Avenue New Lalazar Rawalpindi 46000. ELI-00415 31,000/-	<u>Legal Manufacturer:</u> Bonree Medical Co., Ltd 1st Floor of Building No. 2, Building No. 4, Longzhu Village Economic Estate, Longzhu Avenue, Nanlang, 528451 Zhongshan, Guangdong, People's Republic of China. FSC: China Validity: 24-10-2025 LOA validity 30-12-2028 ISO 13485 Validity 31-07- 2025 CE certificate with extension notification letter.	VISTA BONREE ENDOTRACHEAL TUBES Class-B Shelf Life: 5 Years Type: Oral/Nasal Endotracheal Tube, Oral Endotracheal Tube, Nasal Endotracheal Tube Sub-type: Cuffed, Uncuffed Size: I.D. 2.0 I.D. 2.5 I.D. 3.0 I.D. 3.5 I.D. 4.0 I.D. 4.5 I.D. 5.0 I.D. 5.5 I.D. 6.0 I.D. 6.5 I.D. 7.0 I.D. 7.5 I.D. 8.0 I.D. 8.5 I.D. 9.0 I.D. 9.5 I.D. 10.0	Approved Oral endotracheal tube, cuffed type.
16.	Cabbot Surgicals, 09 Rose Lane 1 Gulberg Avenue New Lalazar Rawalpindi 46000.	<u>Legal Manufacturer:</u> Bonree Medical Co., Ltd 1st Floor of Building No. 2, Building No. 4, Longzhu Village Economic Estate, Longzhu Avenue, Nanlang,	VISTA BONREE ENDOBONCHIAL TUBES Class-B	Approved

	ELI-00415 31,000/-	528451 Zhongshan, Guangdong, People's Republic of China. FSC: China Validity: 24-10-2025 LOA validity 30-12-2028 ISO 13485 Validity 31-07- 2025 CE certificate with extension notification letter.	Shelf Life: 5 Years Type or size: Fr28, Fr32, Fr35, Fr37, Fr39, Fr41, (including "left" and "right") Endobronchial Tubes	
17.	Cabbot Surgicals, 09 Rose Lane 1 Gulberg Avenue New Lalazar Rawalpindi 46000. ELI-00415 31,000/-	Legal Manufacturer: Bonree Medical Co., Ltd 1st Floor of Building No. 2, Building No. 4, Longzhu Village Economic Estate, Longzhu Avenue, Nanlang, 528451 Zhongshan, Guangdong, People's Republic of China. FSC: China Validity: 24-10-2025 LOA validity 30-12-2028 ISO 13485 Validity 31-07- 2025 CE certificate with extension notification letter.	VISTA BONREE NASOPHARYNGEAL AIRWAYS Class-B Shelf Life: 5 Years Type or size: I.D.3.0, I.D.3.5, I.D.4.0, I.D.4.5, I.D.5.0, I.D.5.5, I.D.6.0, I.D.6.5, I.D.7.0, I.D.7.5, I.D.8.0, I.D.8.5, I.D.9.0	Approved
18.	Cabbot Surgicals, 09 Rose Lane 1 Gulberg Avenue New Lalazar Rawalpindi 46000. ELI-00415 31,000/-	Legal Manufacturer: Bonree Medical Co., Ltd 1st Floor of Building No. 2, Building No. 4, Longzhu Village Economic Estate, Longzhu Avenue, Nanlang, 528451 Zhongshan, Guangdong, People's Republic of China. FSC: China Validity: 24-10-2025 LOA validity 30-12-2028 ISO 13485 Validity 31-07- 2025 CE certificate with extension	VISTA BONREE GUIDEWIRES Class-B Shelf Life: 5 Years Type: PTFE Guidewire, Hydrophilic Guidewire, Zebra Guidewire Size: 0.018, 0.025, 0.028,	Approved PTFE type.

		notification letter.	0.032, 0.035, 0.038,	
19.	Cabbot Surgicals, 09 Rose Lane 1 Gulberg Avenue New Lalazar Rawalpindi 46000. ELI-00415 31,000/-	<u>Legal Manufacturer:</u> Bonree Medical Co., Ltd 1st Floor of Building No. 2, Building No. 4, Longzhu Village Economic Estate, Longzhu Avenue, Nanlang, 528451 Zhongshan, Guangdong, People's Republic of China. FSC: China Validity: 24-10-2025 LOA validity 30-12-2028 ISO 13485 Validity 31-07- 2025 CE certificate with extension notification letter.	VISTA BONREE SUCTION CATHETERS Class-B Shelf Life: 5 Years Type or Size: Fr5, Fr6, Fr8, Fr10, Fr12, Fr14, Fr16, Fr18, Fr20, Fr22,	Approved
20.	Cabbot Surgicals, 09 Rose Lane 1 Gulberg Avenue New Lalazar Rawalpindi 46000. ELI-00415 31,000/-	<u>Legal Manufacturer:</u> Bonree Medical Co., Ltd 1st Floor of Building No. 2, Building No. 4, Longzhu Village Economic Estate, Longzhu Avenue, Nanlang, 528451 Zhongshan, Guangdong, People's Republic of China. FSC: China Validity: 24-10-2025 LOA validity 30-12-2028 ISO 13485 Validity 31-07- 2025 CE certificate with extension notification letter.	VISTA BONREE TRACHEOSTOMY TUBES Class-B Shelf Life: 5 Years Type or Size: I.D.3.0, I.D.3.5, I.D.4.0, I.D.4.5, I.D.5.0, I.D.5.5, I.D.6.0, I.D.6.5, I.D.7.0, I.D.7.5, I.D.8.0, I.D.8.5, I.D.9.0, I.D.9.5, I.D.10.0.	Approved
21.	Cabbot Surgicals, 09 Rose Lane 1 Gulberg Avenue	<u>Legal Manufacturer:</u> Bonree Medical Co., Ltd 1st Floor of Building No. 2,	VISTA BONREE STOMACH TUBES	Approved

	New Lalazar Rawalpindi 46000. ELI-00415 31,000/-	Building No. 4, Longzhu Village Economic Estate, Longzhu Avenue, Nanlang, 528451 Zhongshan, Guangdong, People's Republic of China. FSC: China Validity: 24-10-2025 LOA validity 30-12-2028 ISO 13485 Validity 31-07- 2025 CE certificate with extension notification letter.	Class-B Shelf Life: 5 Years Type or Size: Fr6, Fr8, Fr10, Fr12, Fr14, Fr16, Fr18, Fr20, Fr22,	
22.	Cabbot Surgicals, 09 Rose Lane 1 Gulberg Avenue New Lalazar Rawalpindi 46000. ELI-00415 31,000/-	<u>Legal Manufacturer:</u> Bonree Medical Co., Ltd 1st Floor of Building No. 2, Building No. 4, Longzhu Village Economic Estate, Longzhu Avenue, Nanlang, 528451 Zhongshan, Guangdong, People's Republic of China. FSC: China Validity: 24-10-2025 LOA validity 30-12-2028 ISO 13485 Validity 31-07- 2025 CE certificate with extension notification letter.	Bonree Feeding Tubes Class-B Shelf Life: 5 Years <u>Type or Size:</u> Fr4, Fr5, Fr6, Fr8, Fr10, Fr12, Fr14, Fr16, Fr18, Fr20,	Deferred for the clarification of Brand name since Brand already applied by Meher traders, Karachi
23.	Cabbot Surgicals, 09 Rose Lane 1 Gulberg Avenue New Lalazar Rawalpindi 46000. ELI-00415 31,000/-	<u>Legal Manufacturer:</u> Bonree Medical Co., Ltd 1st Floor of Building No. 2, Building No. 4, Longzhu Village Economic Estate, Longzhu Avenue, Nanlang, 528451 Zhongshan, Guangdong, People's Republic of China. FSC: China Validity: 24-10-2025 LOA validity 30-12-2028 ISO 13485 Validity 31-07- 2025 CE certificate with extension notification letter.	Bonree Ureteral Catheters Class-B Shelf Life: 5 Years <u>Type</u> Straight Tip Closed Straight Tip Open <u>Size</u> Straight Tip Closed:4.0FR, 5.0FR, 6.0FR, 7.0FR Straight Tip Open:4.0FR, 5.0FR, 6.0FR, 7.0FR	Deferred for the clarification of Brand name since Brand already applied by Meher traders, Karachi

24.	Cabbot Surgicals, 09 Rose Lane 1 Gulberg Avenue New Lalazar Rawalpindi 46000. ELI-00415 31,000/-	Legal Manufacturer: Bonree Medical Co., Ltd 1st Floor of Building No. 2, Building No. 4, Longzhu Village Economic Estate, Longzhu Avenue, Nanlang, 528451 Zhongshan, Guangdong, People's Republic of China. FSC: China Validity: 24-10-2025 LOA validity 30-12-2028 ISO 13485 Validity 31-07- 2025 CE certificate with extension notification letter.	Bonree Reinforced Endotracheal Tubes Class-B Shelf Life: 5 Years Type Size: I.D.3.0, I.D.3.5, I.D.4.0, I.D.4.5, I.D.5.0, I.D.5.5, I.D.6.0, I.D.6.5, I.D.7.0, I.D.7.5, I.D.8.0, I.D.8.5, I.D.9.0, I.D.9.5, I.D.10.0,	Deferred for the clarification of Brand name since Brand already applied by Meher traders, Karachi
25.	Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi, Pakistan. ELI-00109 6029-P 31,000/-	Legal Manufacturer: BioMerieux S.A. 376 Chemin de l'Orme 69280 Marcy-l'Etoile-France. Original FSC: France. Date of Issuance: 17-01- 2024. LOA validity 31-03-2025 ISO 13485 validity 07-11- 2027	RAPIDEC® CARBA NP (10) test Class-B Shelf Life: 24 Months Code: 415418	Deferred for the provision of original, valid and notarized LOA.
26.	Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi, Pakistan. ELI-00109 6028-P 31,000/-	Legal Manufacturer: BioMerieux S.A. 376 Chemin de l'Orme 69280 Marcy-l'Etoile-France. Original FSC: France. Date of Issuance: 17-01- 2024. LOA validity 31-03-2025 ISO 13485 validity 07-11- 2027	FB (FAST BLUE BB) 2AMP Class-B Shelf Life: 12 Months Code: 70562	Deferred for the provision of original, valid and notarized LOA.
27.	Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi, Pakistan. ELI-00109	Legal Manufacturer: BioMerieux S.A. 376 Chemin de l'Orme 69280 Marcy-l'Etoile-France. Original FSC: France. Date of Issuance: 09-10- 2024.	VIDAS® Vitamin B12 TOTAL Class-B Shelf Life: 12 Months Code:	Deferred for the provision of original, valid and notarized LOA.

	6027-P 31,000/-	LOA validity 31-03-2025 ISO 13485 validity 07-11-2027	424106	
28.	Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi, Pakistan. ELI-00109 7030-P 31,000/-	Legal Manufacturer: Hologic, Inc. 10210 Genetic Center Drive San Diego, CA 92121 USA. FSC: USA. Date of Validity: 04-12-2026. LOA issuance 17-05-2024 ISO 13485 validity 13-05-2027 EU QMS certificate (IVDR) validity 06-12-2027	Panther Fusion Flu A/B/RSV Assay (A multiplex real time PCR (RT-PCR) kit Class-B Shelf Life: 27 Months Codes: Panther Fusion Flu A/B/RSV Assay PRD-04325 Panther Fusion Flu A/B/RSV Assay Controls PRD-04336	Approved.
29.	Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi, Pakistan. ELI-00109 7029-P 31,000/-	Legal Manufacturer: Hologic, Inc. 10210 Genetic Center Drive San Diego, CA 92121 USA. FSC: USA. Date of Validity: 04-12-2026. LOA issuance 17-05-2024 ISO 13485 validity 13-05-2027 EU QMS certificate (IVDR) validity 06-12-2027	Panther Fusion ParaFlu Assay A multiplex real time PCR (RT-PCR) kit Class-B Shelf Life: 27 Months Codes:	Deferred for the provision of original and embassy attested FSC mentioning the subject device.
30.	Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi, Pakistan. ELI-00109 7028-P 62,000/-	Legal Manufacturer: Abbott Medical (known as St. Jude Medical) 15900 Valley View Court Sylmar, CA 91342, USA. FSC: USA. Date of Validity: 05-09-2026. LOA validity 31-12-2026 ISO 13485 validity 31-03-2025 EU QMS certificate (MDR) validity 14-08-2027	CPS AIM UNIVERSAL II (Slittable Inner Catheter) Class-D Shelf Life: 2 Years Codes: CPS Universal II (DS2A006) Slittable inner Catheter DS2N100-59 DS2N100-65 DS2N101-59 DS2N1101-65 DS2N102-59 DS2N1102-65 DS2N1103-65 DS2N1104-65	Approved. The firm shall submit fee as per revised SRO for Family.
31.	Global Marketing Services, 111,	Legal Manufacturer: Hologic, Inc.	Aptima SARS-Co V-2/Flu Assay	Deferred for the provision of Original

	Hali Road 1, Westridge Rawalpindi, Pakistan. ELI-00109 7120-P 62,000/-	10210 Genetic Center Drive San Diego, CA 92121 USA. FSC missing LOA issuance 17-05-2024 ISO 13485 validity 13-05-2027 EU QMS certificate (IVDR) validity 06-12-2027	(IVD Test kit) Class-C Shelf Life: 14 Months Codes: FSC is missing	and embassy attested FSC mentioning the subject device.
32.	Bio Indus, B-526, B Satellite Town, Rawalpindi. ELI-00979 5989-P 31,000/-	<u>Legal Manufacturer:</u> Labnovation Technologies, Inc 102, 602, 702, 802, Sheng Hui Hongxing Chuangzhi Square, Tongren Road, Tianliao Community, Yutang Street, Guangming District, 518107 Shenzhen, Guangdong, People's Republic of China. Original FSC: China. Validity: 14-11-2024. LOA validity 23-05-2026 ISO 13485 validity 06-08-2026	POCT HbA1c Analyzer System (POCT HbA1c Analyzer & Hemoglobin A1c Test Kit (Boronate Affinity) Class-B Shelf Life: Analyzer 5 Years Kit 9 Months Control 12 Months Models: Analyzer: LD-100 LD-120, LD-160 Hemoglobin A1c Test Kit (Boronate Affinity) (25 tests/box, 50 tests/box HbA1c Control kit: Level 1: 0.1mLx3, Level 2: 0.1mLx3	Deferred for the provision of following: Valid and notarized ISO 13485. Original embassy attested FSC of reference country or notarized CE certificate. Fee as per the SRO for System Clarification of applied sysem or kit
33.	Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi, Pakistan. ELI-00109 1542-P 6,000/-	<u>Legal Manufacturer:</u> BioMerieux S.A. 376 Chemin de l'Orme 96280 Marcy-l'Etoile -France. <u>Manufacturing Site:</u> Biomerieux, Inc. 595 Anglum Road, Hazelwood, Missouri 63042, USA Biomerieux Inc. 100 Radolphe Street, Durham, North Carolina 27712, USA. Original FSC: France. Date of Issuance: 15-10-2024. LOA validity 31-03-2025 ISO 13485 validity 17-12-2027	VITEK® MI-TUBE Class-A Shelf Life: 20 Months Code: 424179	Deferred for the provision of original, valid and notarized LOA.
34.	Global Marketing Services, 111, Hali Road	<u>Legal Manufacturer:</u> BioMerieux S.A. 376 Chemin de l'Orme 96280	VITEK® COMPACT PRO	Deferred for the provision of original, valid and notarized

	Westridge 1, Rawalpindi, Pakistan. ELI-00109 1543-P 6,000/-	<p>Marcy-l'Etoile -France. <u>Manufacturing Sites:</u> Biomerieux, Inc. 595 Anglum Road, Hazelwood, Missouri 63042, USA</p> <p>Biomerieux Inc. 100 Radolphe Street, Durham, North Carolina 27712, USA.</p> <p>Original FSC: France. Date of Issuance: 15-10- 2024. LOA validity 31-03-2025 ISO 13485 validity 17-12- 2027</p>	<p>Class-A</p> <p>Shelf Life: N/A</p> <p>Model/code: 423465 (Instrument) 423737 (Software)</p>	LOA and fee as per revised SRO for System.
35.	Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi, Pakistan. ELI-00109 1566-P 6,000/-	<p><u>Legal Manufacturer:</u> BioMerieux S.A. 376 Chemin de l'Orme 96280 Marcy-l'Etoile -France. <u>Manufacturing Site:</u> Biomerieux S.A. 5 rue des Aqueducs-69290 CRAPONNE, France</p> <p>Original FSC: France. Date of Issuance: 06-06-2024 LOA validity 31-03-2025 ISO 13485 validity 17-12- 2027</p>	<p>Trypcase Soy Agar</p> <p>Class-A</p> <p>Shelf Life: 21 weeks</p> <p>Code: 43011</p>	Deferred for the provision of original, valid and notarized LOA
36.	Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi, Pakistan. ELI-00109 1567-P 6,000/-	<p><u>Legal Manufacturer:</u> BioMerieux S.A. 376 Chemin de l'Orme 69280 Marcy- l'Etoile - France. <u>Manufacturing Site:</u> BIOMERIEUX S.A 5 rue des Aqueducs-69290 Craponne, France.</p> <p>FSC: France. Date of Issuance: 06-06- 2024. LOA validity 31-03-2025 ISO 13485 validity 17-12- 2027</p>	<p>KOVACS Reagent</p> <p>Class-A</p> <p>Shelf Life: 2 years</p> <p>Code: 55631</p>	Deferred for the provision of original, valid and notarized LOA
37.	Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi, Pakistan. ELI-00109	<p><u>Legal Manufacturer:</u> BioMerieux S.A. 376 Chemin de l'Orme 69280 Marcy- l'Etoile - France. <u>Manufacturing Site:</u> BIOMERIEUX S.A 5 rue des Aqueducs-69290 Craponne, France.</p>	<p>ID INDOLE TDA</p> <p>Class-A</p> <p>Shelf Life: 1 Year</p> <p>Code: 56541</p>	Deferred for the provision of original, valid and notarized LOA

	1568-P 6,000/-	FSC: France. Date of Issuance: 06-06-2024. LOA validity 31-03-2025 ISO 13485 validity 17-12-2027		
38.	Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi, Pakistan. ELI-00109 1569-P 6,000/-	<u>Legal Manufacturer:</u> BioMerieux S.A. 376 Chemin de l'Orme 69280 Marcy-l'Etoile - France. <u>Manufacturing Site:</u> Biomerieux, Inc. 595 Anglum Road, Hazelwood, Missouri 63042, USA. Biomerieux Inc. 100 Radolphe Street, Durham, North Carolina 27712, USA. FSC: France. Date of Issuance: 02-07-2024. LOA validity 31-03-2025 ISO 13485 validity 17-12-2027	VITEK® 2 Pipetter/Diluter Accessory Kit Class-A Shelf Life: N/A Code:b21219	Deferred for the provision of original, valid and notarized LOA
39.	Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi, Pakistan. ELI-00109 1569-P 6,000/-	<u>Legal Manufacturer:</u> BioMerieux S.A. 376 Chemin de l'Orme 69280 Marcy-l'Etoile - France. <u>Manufacturing Site:</u> 3 route de Port Michaud-38390 LA BALME LES GROTTEs, France. Original FSC: France. Date of Issuance: 05-06-2024. LOA validity 31-03-2025 ISO 13485 validity 17-12-2027	VITEK® MS SMARTCALIBRANT Class-A Shelf Life: 11 Months Code: 423710	Deferred for the provision of original, valid and notarized LOA
40.	Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi, Pakistan. ELI-00109 1571-P	<u>Legal Manufacturer:</u> BioMerieux S.A. 376 Chemin de l'Orme 69280 Marcy-l'Etoile - France. <u>Manufacturing Site:</u> PiSA Farmaceutica, Calle 2676, Colon Industrial-44930 Guadalajara, Jaalisco, Mexico.	BTL, 0.45% SALINE SOLUTION Class-A Shelf Life: 24 Months Codes: 423718 (1 L x 12)	Deferred for the provision of original, valid and notarized LOA

	6,000/-	FSC: France. Date of Issuance: 03-07-2024. LOA validity 31-03-2025 ISO 13485 validity 17-12-2027	423719 (0.5 L x 18)	
41.	Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi, Pakistan. ELI-00109 1572-P 6,000/-	Legal Manufacturer: BIOMERIEUX Inc. 100 Radolphe Street, Durham, North Carolina 27712, USA. Manufacturing Site: Biomerieux, Inc. 595 Anglum Road, Hazelwood, Missouri 63042, USA. FSC: France. Date of Issuance: 02-07-2024. LOA validity 31-03-2025 ISO 13485 validity 17-12-2027	SCS UNIVERSAL 100/240V Class-A Shelf Life: N/A Code: 27209	Deferred for the provision of original, valid and notarized LOA and shelf life.
42.	RMK Bio Private Ltd, 83A, BIII, Gulberg III, MM Alam Road, Near Hussain Chowk, Lahore. ELI-01277 6022-P 31,000/-	Legal Manufacturer: Sonova AG Laubisrutistrasse 28, CH-8712 Stafa, Switzerland. FSC: Switzerland Validity: 09-09-2027. LOA validity issuance 04-02-2024 ISO 13485 validity 28-02-2028 EU QMS certificate (MDR) validity 21-04-2027	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 for the provision of original and attested documents as per application Form..
43.	Imtiaz Brothers, Suite No. 7B, 2nd Floor, Abrar Business Center, 25 Main Wahdat Road, Lahore - 54600, Pakistan. ELI-00133 6019-P 31,000/-	Legal Manufacturer: Shenzhen JCR Medical Technology Limited Company 101, Building 1, Plant B, No. 1, Tianfu Road, Tianliao Community, Yutang Street, Guangming District, 518132 Shenzhen, Guangdong, People's Republic of China. Original FSC: Netherland. Validity: 31-01-2028. LOA validity 10-03-2027 ISO 13485 validity 01-05-	JCR Disposable Pressure Transducer Class-B Shelf Life: 3 Years Codes: JIBPT-01-YP, JIBPT-01-UT, JIBPT-01-BD, JIBPT-01-EDW, JIBPT-01-MD, JIBPT-01-BL,	Approved in Class-c. The firm shall submit fee as per the revised SRO for Family in Class-C

		2027 FQA certificate validity	JIBPT-01-PVB, JIBPT-01-USB, JIBPT-01-MR; JIBPT-E-01-YP, JIBPT-E-01-UT, JIBPT-E-01-BD, JIBPT-E-01-EDW, JIBPT-E-01-MD, JIBPT-E-01-BL, JIBPT-E-01-PVB, JIBPT-E-01-USB, JIBPT-E-01-MR;	
44.	<u>M/S. TEK Enterprises</u> Office No. MZ-9 Al-Hafeez Heights Sir Syed Road, Gulberg, Lahore. ELI-00189 DOI.17.10.2018 DOE.17.10.2023 Renewal Applied FEE Challan: 3324148739, PKR: 31000/- Date: 30.1.2025 49340040 PKR:31000/- Date: 6.3.2025	<u>Legal Manufacturer:</u> M/s ASAHI Intecc co., ltd., 1).3-100 Akatsuki-cho, Seto, Aichi 489-0071 Japan. Manufacturing sites: 1. ASAHI INTECC (THAILAND) CO., LTD., 158/1 Moo 5 Bangkadi Industrial Park, Tiwanon Road, Tambol Bangkadi, Amphur Muang, Pathumthani 12000, Thailand. 2) ASAHI INTECC HANOI CO. LTD. G03 Thang Long Industrial Park, Dong Anh Dist., Hanoi, Ha Noi, Thanh Pho, 001, Vietnam. Tel. no.: +81-561-48-5551 Fax no.: +81-561-48-5551 Website: www.asahi-intecc.com FSC: JAPAN Validity: 31/10/2025 LOA Validity: 30/06/2025 ISO 13485 Valid 24.3.2026 Reference Country Japan Valid	ASAHI Gladius MG 14 PV ES ASAHI Peripheral Guide Wire Class-D Shelf Life: 3 Years Codes: PP14R004S ASAHI GLADIUS MG 14 PV ES 190CM STRAIGHT PP14R004P ASAHI GLADIUS MG 14 PV ES 190CM PRE SHAPED PP14R204S ASAHI GLADIUS MG 14 PV ES 235CM STARIGHT PP14R204P ASAHI GLADIUS MG 14 PV ES 235CM PRESHAPED PP14R304S ASAHI GLADIUS MG 14 PV ES 300CM STARIGHT PP14R304P ASAHI GLADIUS MG 14 PV ES 300CM PRESHAPED	Approved. The firm shall submit fee as per revised SRO for Family.
45.	<u>M/S. TEK Enterprises</u> Office No. MZ-9	<u>Legal Manufacturer:</u> M/s ASAHI Intecc co., ltd., 1).3-100 Akatsuki-cho, Seto, Aichi 489-0071 Japan.	ASAHI Gladius MG 18 PV ES ASAHI Peripheral Guide Wire	Approved. The firm shall submit fee as per revised SRO

	<p>Al-Hafeez Heights Sir Syed Road, Gulberg, Lahore.</p> <p>ELI-00189 DOI.17.10.2018 DOE.17.10.2023 Renewal Applied</p> <p>FEE Challan: 03609006304, PKR: 31000/- Date: 30.1.2025</p> <p>4621046629 PKR:31000/- Date: 6.3.2025</p>	<p>Manufacturing sites:</p> <p>1) ASAHI INTECC (THAILAND) CO., LTD., 158/1 Moo 5 Bangkadi Industrial Park, Tiwanon Road, Tambol Bangkadi, Amphur Muang, Pathumthani 12000, Thailand.</p> <p>2) ASAHI INTECC HANOI CO. LTD. G03 Thang Long Industrial Park, Dong Anh Dist., Hanoi, Ha Noi, Thanh Pho, 001, Vietnam. Tel. no.: +81-561-48-5551 Fax no.: +81-561-48-5551</p> <p>Website: www.asahi-intecc.com FSC: JAPAN</p> <p>Validity: 31/10/2025 (Justification Letter attached)</p> <p>LOA Validity: 30/06/2025 FSC: JAPAN Validity: 31/10/2025 ISO 13485 Valid 24.3.2026 Reference Country Japan Valid</p>	<p>Class D</p> <p>Shelf Life: 3 Years</p> <p>Storage: Store in cool and dry place</p> <p>Codes / Sizes PP18R004S ASAHI GLADIUS MG 18 PV ES 190CM STRAIGHT PP18R004P ASAHI GLADIUS MG 18 PV ES 190CM PRE SHAPED PP18R204S ASAHI GLADIUS MG 18 PV ES 235CM STARIGHT PP18R204P ASAHI GLADIUS MG 18 PV ES 235CM PRESHAPED PP18R304S ASAHI GLADIUS MG 18 PV ES 300CM STARIGHT PP18R304P ASAHI GLADIUS MG 18 PV ES 300CM PRESHAPED</p>	for Family.
46.	<p>The Lab House GF-34 Pak Medical Center Khyber Bazar Peshawar.</p> <p>6194-Kp 6,030/-</p>	<p>Legal Manufacturer: Contec Medical Systems Co.,Ltd Address: No 112 Qinhuang West, Str; E&T Development Zone, Qinhuagdao; Hebei Province, China.</p> <p>LOA issuance 06-12-2024 valid for 5 years FSC China validity 18-02-2025 ISO 13485 validity 10-12-2027</p>	<p>CONTEC Semi-auto Biochemistry analyzer</p> <p>Class-A</p> <p>Shelf life: 5 years</p> <p>Model: BC 300</p>	Deferred for the provision of original FSC.
47.	<p>M/s Tahir Scientific</p>	<p>Legal Manufacturer: M/s Shenzhen Comen</p>	<p>Comen Automatic Hematology</p>	Approved in Class-A. firm will submit

	Supplies. 13-Karachi Market, Khyber Bazar, Peshawar. 6209-Kp 31,000/-	Medical Instruments Co. Ltd. Floor 10-12, Section C of Building 1A Floor 1A & Floor 1-5 of Building 2, Fiyta Timepiece Building, Nanhuan Avenue, Matian Sub District, Guanaming District Shenzhen, Guangdong 518106, P.R. China. LOA validity 22-07-2025 FSC validity 19-09-2024 ISO 13485 validity 23-07- 2026	Analyzer Class-B Shelf life: 05 Years Model: CH8300	original valid FSC of country of origin.
48.	M/s Al Qazi Marketing Group. 10-11-E, Karachi Market, Khyber Bazar, Peshawar. ELI-00540 6199-Kp 6,000/-	<u>Legal Manufacturer:</u> M/s Centronic GmbH. Am Kleinfeld 11, 85456 Wartenberg, Germany. LOA validity 31-05-2027 FSC Germany issuance 28- 06-2023 ISO 13485 validity 31-10- 2025	Clinical Chemistry- Substrates System Reagents Class-A Shelf life: Bilirubin total/direct Jendrassik Fluid = 24 months Cholesterol CHOD/PAP Monoreagent = 24 months LDL-Cholesterol Fluid (Heparin) = 24 months HDL Cholesterol Fluid (Phosphotuncsticacid) = 24 months Triglycerides fluid Mono = 24 months LDH-P Fluid 4+1 = 18 months Creatinine Jaffé kin. fluid (1+1) = 24 months Urea UV Fluid 4+1 = 24 months Uric acid PAP fluid Mono = 18 months	Deferred for the provision of following: Correct class. Clarification of grouping. Brand name. Prescribed form.

			<p>Albumin fluid Mono = 24 months</p> <p>Glucose GOD/PAP Fluid Monoreagent = 24 months 18 Months (2)</p> <p>Article No: UF0800400 = Urea UV Fluid 4+1</p> <p>UF10000050 = Uric acid PAP fluid Mono</p> <p>UF10000050-4 = Uric acid PAP fluid Mono</p> <p>UF10000050-8 = Uric acid PAP fluid Mono</p> <p>AF01000050 = Albumin fluid Mono</p> <p>AF01000100 = Albumin fluid Mono</p> <p>AF01000500 = Albumin fluid Mono</p> <p>GF03000100 = Glucose GOD/PAP Fluid Monoreagent</p> <p>GF03000100-2 = Glucose GOD/PAP Fluid Monoreagent</p> <p>GF03000500 = Glucose GOD/PAP Fluid Monoreagent</p> <p>GF03001000 = Glucose GOD/PAP Fluid Monoreagent</p>	
49.	<p>M/s Al Qazi Marketing Group. 10-11-E, Karachi Market, Khyber Bazar, Peshawar.</p> <p>ELI-00540 6200-Kp 6,000/-</p>	<p><u>Legal Manufacturer:</u> M/s Centronic GmbH. Am Kleinfeld 11, 85456 Wartenberg, Germany.</p> <p>LOA validity 31-05-2027 FSC Germany issuance 28-06-2023 ISO 13485 validity 31-10-</p>	<p>Clinical-Chemistry Electrolyte Reagents</p> <p>Class-A</p> <p>shelf life: 24 Months</p> <p>Article No: MF01000050 =</p>	<p>Deferred for the provision of following:</p> <p>Correct class. Clarification of grouping.</p> <p>Brand name.</p>

		2025	<p>Magnesium Fluid Mono MF01000100-2 = Magnesium Fluid Mono CF02000050 = Calcium OCP Fluid 1+1 CF02000050-2 = Calcium OCP Fluid 1+1 SF01000050 = Sodium Fluid 1+1 SF01000060 = Sodium Fluid enzymatic PF01000050 = Phosphorus UV Fluid Mono PF01000100-2 = Phosphorus UV Fluid Mono CF07000050 = Chloride Fluid Mono</p>	Prescribed form.
50.	<p>M/s Al Qazi Marketing Group. 10-11-E, Karachi Market, Khyber Bazar, Peshawar.</p> <p>ELI-00540 6201-Kp 6,000/-</p>	<p><u>Legal Manufacturer:</u> M/s Centronic GmbH. Am Kleinfeld 11, 85456 Wartenberg, Germany.</p> <p>LOA validity 31-05-2027 FSC Germany issuance 28- 06-2023 ISO 13485 validity 31-10- 2025</p>	<p>Immuno-Cytology Reagent System Reagents</p> <p>Class-A</p> <p>Shelf life: 24 Months</p> <p>Article no. GPT(ALAT)IFCC Fluid (4+1) GF10000100 GF10000200 GF10000400</p>	<p>Deferred for the provision of following:</p> <p>Correct class. Clarification of grouping.</p> <p>Brand name. Prescribed form.</p>
51.	<p>M/s Al Qazi Marketing Group. 10-11-E, Karachi Market, Khyber Bazar, Peshawar.</p> <p>ELI-00540 6202-Kp 6,000/-</p>	<p><u>Legal Manufacturer:</u> M/s Centronic GmbH. Am Kleinfeld 11, 85456 Wartenberg, Germany.</p> <p>LOA validity 31-05-2027 FSC Germany issuance 28- 06-2023 ISO 13485 validity 31-10- 2025</p>	<p>Immuno-Chemistry- Liver Function System Reagents</p> <p>Class-A</p> <p>Shelf life: 24 Months</p> <p>Article no. GOT(ASAT)IFCC Fluid (4+1) GF09000100</p>	<p>Deferred for the provision of following:</p> <p>Correct class. Clarification of grouping. Brand name. Prescribed form.</p>
52.	<p>M/s Al Qazi Marketing Group. 10-11-E, Karachi Market, Khyber Bazar, Peshawar.</p> <p>ELI-00540 6203-Kp</p>	<p><u>Legal Manufacturer:</u> M/s Centronic GmbH. Am Kleinfeld 11, 85456 Wartenberg, Germany.</p> <p>LOA validity 31-05-2027 FSC Germany issuance 28- 06-2023</p>	<p>Immuno-Chemistry Bone and Mineral Metabolism Assays System Reagents</p> <p>Class-A</p> <p>Shelf life: 24 Months</p>	<p>Deferred for the provision of following:</p> <p>Correct class. Clarification of grouping.</p>

	6,000/-	ISO 13485 validity 31-10-2025	Article no. Alkaline Phosphatase Fluid (4+1) DGKC AF21000100 AF21000200	Brand name. Prescribed form.
53.	M/s Al Qazi Marketing Group. 10-11-E, Karachi Market, Khyber Bazar, Peshawar. ELI-00540 6204-Kp 6,000/-	<u>Legal Manufacturer:</u> M/s Centronic GmbH. Am Kleinfeld 11, 85456 Wartenberg, Germany. LOA validity 31-05-2027 FSC Germany issuance 28-06-2023 ISO 13485 validity 31-10-2025	Immuno-Chemistry- Cardiac Markers System Reagents Class-A Shelf life: 24 Months Article no. CF28000050 = CK-MB Fluid 4+1 CF28000050-1-CK-MB Fluid 4+1 CF27000050 CK-NAC Fluid 4+1 CF27000050-1 = CK- NAC Fluid 4+1	Deferred for the provision of following: Correct class. Clarification of grouping. Brand name. Prescribed form.
54.	M/s Al Qazi Marketing Group. 10-11-E, Karachi Market, Khyber Bazar, Peshawar. ELI-00540 6205-Kp 6,000/-	<u>Legal Manufacturer:</u> M/s Centronic GmbH. Am Kleinfeld 11, 85456 Wartenberg, Germany. LOA validity 31-05-2027 FSC Germany issuance 28-06-2023 ISO 13485 validity 31-10-2025	Immuno-Chemistry- Anemia System Reagents Class-A Shelf life: 24 Months Article no. Iron Nitro PAPS Fluid Mono IF02000050	Deferred for the provision of following: Correct class. Clarification of grouping. Brand name. Prescribed form.
55.	M/s Al Qazi Marketing Group. 10-11-E, Karachi Market, Khyber Bazar, Peshawar. ELI-00540 6206-Kp 6,000/-	<u>Legal Manufacturer:</u> M/s Centronic GmbH. Am Kleinfeld 11, 85456 Wartenberg, Germany. LOA validity 31-05-2027 FSC Germany issuance 28-06-2023 ISO 13485 validity 31-10-2025	Immuno-Chemistry Electrolyte Electrodes System Reagents Class-A Shelf life: 24 Months Article no. Potassium fluid Mono PF05000050 PF05000100	Deferred for the provision of following: Correct class. Clarification of grouping. Brand name. Prescribed form.
56.	M/s Al Qazi Marketing Group. 10-11-E, Karachi Market, Khyber Bazar, Peshawar. ELI-00540	<u>Legal Manufacturer:</u> M/s Centronic GmbH. Am Kleinfeld 11, 85456 Wartenberg, Germany. LOA validity 31-05-2027 FSC Germany issuance 28-	Clinical-Chemistry Enzymes System Reagents Class-A Shelf life:	Deferred for the provision of following: Correct class. Clarification of grouping.

	6207-Kp 6,000/-	06-2023 ISO 13485 validity 31-10-2025	Lipase = 24 months alpha Amylase CNPG3 = 20 months Gamma-GT-3-Carboxy Fluid 4+1 = 24 months Article no. LF09000027 = Lipase LF09000060 = Lipase LF09000060-1 = Lipase AF23000010 = alpha Amylase CNPG3 AF23000010-3 = alpha Amylase CNPG3 AF23000010-6 = alpha Amylase CNPG3 GF11000050 = Gamma-GT-3-Carboxy Fluid 4+1	Brand name. Prescribed form.
57.	M/s Al Qazi Marketing Group. 10-11-E, Karachi Market, Khyber Bazar, Peshawar	<u>Legal Manufacturer:</u> M/s Centronic GmbH. Am Kleinfeld 11, 85456 Wartenberg, Germany. LOA validity 31-05-2027 FSC Germany issuance 28-06-2023 ISO 13485 validity 31-10-2025	Hemostasis (Coagulation) System Reagents Class-A Shelf life: Protein CSF Fluid Mono: 18 Months Protein Total Fluid Mono 24 Months Article No. Protein CSF Fluid Mono PF3000050 PF03000100 Protein Total Fluid Mono PF04000050 PF04000100	Deferred for the provision of the following: Correct class. of Clarification of grouping. Brand name. Prescribed form.
58.	M/s Ferozsos Laboratories Limited, P.O Ferozsos, Amangarh, Nowshera (KPK)-Pakistan. ELI-00120 6230-Kp 62,000/-	<u>Legal Manufacturer:</u> M/s Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA <u>Manufacturing Site:</u> M/s Boston Scientific Corporation 302 Parkway, Global Park, Heredia, Costa Rica. LOA validity 31-12-2025 FSC is missing ISO 13485 validity 01-09-	Rotawire™ Drive and WireClip™ Torquer Guidewire and Guidewire Manipulation Device Catheter Guidewire Class-D shelf life: 24 Months	Deferred for the provision of original and embassy attested FSC and product types applied

		2025 EU QMS certificate 27-10-2027 EU Technical Documentation Assessment Certificate 14-12-2027		
59.	Alfa Scientific Store, 24-Maclogen Road, Lahore. ELI-00148 6068-P 31,000/-	Legal Manufacturer: Zhejiang Orient Gene Biotech Co, Ltd 3787#, East Yangguang Avenue, Dipu Street, Anji, 313300 Zhejiang, China. Original FSC: Germany. Date of Issuance: 31-08-2022. FSC: China. Date of Validity: 30-10-2025. LOA validity 25-02-2030 ISO 13485 validity 16-03-2026	Bio Check H. Pylori Ab Rapid Test Strip (Serum / Plasma) Class-B Shelf Life: 24 Months Codes as per FSC GCHP-401a	Approved
60.	Alfa Scientific Store, 24-Maclogen Road, Lahore. ELI-00148 6068-P 31,000/-	Legal Manufacturer: Zhejiang Orient Gene Biotech Co, Ltd 3787#, East Yangguang Avenue, Dipu Street, Anji, 313300 Zhejiang, China. Original FSC: Germany. Date of Issuance: 31-08-2022. FSC: China. Date of Validity: 30-10-2025. LOA validity 25-02-2030 ISO 13485 validity 16-03-2026	Bio Check H. Pylori Ag Rapid Test Cassette (Feces) Class-B Shelf Life: 24 Months Code: GCHP-602a	Approved
61.	Alfa Scientific Store, 24-Maclogen Road, Lahore. ELI-00148 6070-P 31,000/-	Legal Manufacturer: Zhejiang Orient Gene Biotech Co, Ltd 3787#, East Yangguang Avenue, Dipu Street, Anji, 313300 Zhejiang, China. Original FSC: Germany. Date of Issuance: 31-08-2022.	Bio Check Dengue NSI Antigen Rapid Test Cassette Class-B Shelf Life: 24 Months Code: GCDEN(NS)-402c	Approved

		<p>FSC: China. Date of Validity: 30-10-2025.</p> <p>LOA validity 25-02-2030 ISO 13485 validity 16-03-2026</p>		
62.	<p>Alfa Scientific Store, 24-Maclogen Road, Lahore.</p> <p>ELI-00148 6071-P 31,000/-</p>	<p>Legal Manufacturer: Zhejiang Orient Gene Biotech Co, Ltd 3787#, East Yangguang Avenue, Dipu Street, Anji, 313300 Zhejiang, China.</p> <p>Original FSC: Germany. Date of Issuance: 31-08-2022.</p> <p>FSC: China. Date of Validity: 30-10-2025.</p> <p>LOA validity 25-02-2030 ISO 13485 validity 16-03-2026</p>	<p>Bio Check Dengue NS1+IgG Combo Rapid Test Cassette</p> <p>Class-B</p> <p>Shelf Life: 24 Months</p> <p>Code: GCDEN-425a</p>	Approved
63.	<p>Alfa Scientific Store, 24-Maclogen Road, Lahore.</p> <p>ELI-00148 6072-P 31,000/-</p>	<p>Legal Manufacturer: Zhejiang Orient Gene Biotech Co, Ltd 3787#, East Yangguang Avenue, Dipu Street, Anji, 313300 Zhejiang, China.</p> <p>Original FSC: Germany. Date of Issuance: 31-08-2022.</p> <p>FSC: China. Date of Validity: 30-10-2025.</p> <p>LOA validity 25-02-2030 ISO 13485 validity 16-03-2026</p>	<p>Bio Check Dengue IgM / IgG Rapid Test Cassette</p> <p>Class-B</p> <p>Shelf Life: 24 Months</p> <p>Code: GCDEN(ab)-402c</p>	Approved
64.	<p>Alfa Scientific Store, 24-Maclogen Road, Lahore.</p> <p>ELI-00148 6075-P 31,000/-</p>	<p>Legal Manufacturer: Zhejiang Orient Gene Biotech Co, Ltd 3787#, East Yangguang Avenue, Dipu Street, Anji, 313300 Zhejiang, China.</p> <p>Original FSC: Belgium. Date of Issuance: 13-05-2022.</p>	<p>Orient Gene HCG Pregnancy Rapid Test-Midstream</p> <p>Class-B</p> <p>Shelf Life: 24 Months</p> <p>Code: GAHCG-103a-1T GAHCG-103a-2T</p>	Deferred for the clarification of Brand name and fee as per revised SRO for Family.

		<p>FSC: Germany. Date of Issuance: 31-08-2022.</p> <p>FSC: China. Date of Validity: 30-10-2025.</p> <p>LOA validity 25-02-2030</p> <p>ISO 13485 validity 16-03-2026</p> <p>FQA validity 07-04-2025</p>	<p>GAHCG-103b-1T GAHCG-103b-2T GAHCG-103d-1T GAHCG-103d-2T</p>	
65.	<p>Alfa Scientific Store, 24-Maclogen Road, Lahore.</p> <p>ELI-00148 6076-P 31,000/-</p>	<p><u>Legal Manufacturer:</u> Zhejiang Orient Gene Biotech Co, Ltd 3787#, East Yangguang Avenue, Dipu Street, Anji, 313300 Zhejiang, China.</p> <p>Original FSC: Belgium. Date of Issuance: 13-05-2022.</p> <p>FSC: Germany. Date of Issuance: 31-08-2022.</p> <p>FSC: China. Date of Validity: 30-10-2025.</p> <p>LOA validity 25-02-2030</p> <p>ISO 13485 validity 16-03-2026</p> <p>FQA validity 07-04-2025</p>	<p>Malaria P.f./Pan Ag Rapid Test Cassette (Whole Blood) Class-B Shelf Life: 24 Months Codes: GCMAL(pf/pan)-402a</p>	<p>Approved.</p> <p>The firm shall submit Brand name before the issuance of registration letter.</p>
66.	<p>Alfa Scientific Store, 24-Maclogen Road, Lahore.</p> <p>ELI-00148 6077-P 31,000/-</p>	<p><u>Legal Manufacturer:</u> Zhejiang Orient Gene Biotech Co, Ltd 3787#, East Yangguang Avenue, Dipu Street, Anji, 313300 Zhejiang, China.</p> <p>Original FSC: Belgium. Date of Issuance: 13-05-2022.</p> <p>FSC: Germany. Date of Issuance: 31-08-</p>	<p>Malaria P.f./Pv Ag Rapid Test Cassette (Whole Blood) Class-B Shelf Life: 24 Months Codes: GCMAL(pf/pv)-402a</p>	<p>Approved.</p> <p>The firm shall submit Brand name before the issuance of registration letter.</p>

		2022. FSC: China. Date of Validity: 30-10-2025. LOA validity 25-02-2030 ISO 13485 validity 16-03-2026 FQA validity 07-04-2025		
67.	Alfa Scientific Store, 24-Maclogen Road, Lahore. ELI-00148 6079-P 31,000/-	Legal Manufacturer: Zhejiang Orient Gene Biotech Co, Ltd 3787#, East Yangguang Avenue, Dipu Street, Anji, 313300 Zhejiang, China. Original FSC: Belgium. Date of Issuance: 13-05-2022. FSC: Germany. Date of Issuance: 31-08-2022. FSC: China. Date of Validity: 30-10-2025. LOA validity 25-02-2030 ISO 13485 validity 16-03-2026 FQA validity 07-04-2025	Typhoid IgG/IgM Rapid Test Cassette (Serum/Plasma) Class-B Shelf Life: 24 Months Codes: GCTYP-302a	Approved. The firm shall submit Brand name before the issuance of registration letter.
68.	Alfa Scientific Store, 24-Maclogen Road, Lahore. ELI-00148 6080-P 31,000/-	Legal Manufacturer: Zhejiang Orient Gene Biotech Co, Ltd 3787#, East Yangguang Avenue, Dipu Street, Anji, 313300 Zhejiang, China. Original FSC: Belgium. Date of Issuance: 13-05-2022. FSC: Germany. Date of Issuance: 31-08-2022. FSC: China.	Tuberculosis IgG/IgM Rapid Test Cassette (Serum/Plasma) Class-B Shelf Life: 24 Months Codes: GCTB-302a GCTB-402a	Approved. The firm shall submit Brand name before the issuance of registration letter.

		<p>Date of Validity: 30-10-2025.</p> <p>LOA validity 25-02-2030</p> <p>ISO 13485 validity 16-03-2026</p> <p>FQA validity 07-04-2025</p>		
69.	<p>Alfa Scientific Store, 24-Maclogen Road, Lahore.</p> <p>ELI-00148 6083-P 31,000/-</p>	<p><u>Legal Manufacturer:</u> Arena BioScien Block 5, Street 9, Ismailia Free Zone, Ismailia - Egypt.</p> <p>FSC: Spain. Date of Issuance: 30-12-2024. LOA validity 31-12-2028</p>	<p>Serology ASOT (ASOT Latex with controls, ASOT Latex only)</p> <p>Class-B</p> <p>Shelf life: 24 Months</p>	<p>Deferred for the provision of following:</p> <p>Credentials. Original notarized LOA. Original legalized FSC mentioning the subject device. Notarized ISO 13485. CE certificate Brand name.</p>
70.	<p>Alfa Scientific Store, 24-Maclogen Road, Lahore.</p> <p>ELI-00148 6084-P 31,000/-</p>	<p><u>Legal Manufacturer:</u> Arena BioScien Block 5, Street 9, Ismailia Free Zone, Ismailia - Egypt.</p> <p>FSC: Spain. Date of Issuance: 30-12-2024. LOA validity 31-12-2028</p>	<p>Coagulation Reagents and controls (Thromboplastin (PT) ISI=1.5, Thromboplastin (PT) ISI=1.05, Thrombocelin (APTT)+Calcium Chloride, Fibrinogen, FDP, Plasmatrol I, Plasmatrol II, Plasmatrol III)</p> <p>Class-B</p> <p>Shelf life: 24 Months</p>	<p>Deferred for the provision of following:</p> <p>Credentials. Original notarized LOA. Original legalized FSC mentioning the subject device. Notarized ISO 13485. CE certificate Brand name.</p>
71.	<p>Alfa Scientific Store, 24-Maclogen Road, Lahore.</p> <p>ELI-00148 6088-P 31,000/-</p>	<p><u>Legal Manufacturer:</u> Arena BioScien Block 5, Street 9, Ismailia Free Zone, Ismailia - Egypt.</p> <p>FSC: Spain. Date of Issuance: 30-12-2024. LOA validity 31-12-2028</p>	<p>Vitamin D (Turbi Latex)</p> <p>Class-B</p> <p>Shelf life: 24 Months</p>	<p>Deferred for the provision of following:</p> <p>Credentials. Original notarized LOA. Original legalized FSC mentioning the subject device. Notarized ISO 13485. CE certificate Brand name.</p>

72.	Alfa Scientific Store, 24-Maclogen Road, Lahore. ELI-00148 6089-P 31,000/-	Legal Manufacturer: Arena BioScien Block 5, Street 9, Ismailia Free Zone, Ismailia - Egypt. FSC: Spain. Date of Issuance: 30-12-2024. LOA validity 31-12-2028	Electrolytes (Calcium OCP, Calcium (Arsenazo), Chloride, Magnesium, Phosphorus, Potassium, Sodium, Zinc, Copper, Total Iron, TIBC) Class-B Shelf life: 24 Months	Deferred for the provision of following: Credentials. Original notarized LOA. Original legalized FSC mentioning the subject device. Notarized ISO 13485. CE certificate Brand name. Clarification of grouping of Cluster and fee as per revised SRO for Cluster
73.	Alfa Scientific Store, 24-Maclogen Road, Lahore. ELI-00148 6090-P 31,000/-	Legal Manufacturer: Arena BioScien Block 5, Street 9, Ismailia Free Zone, Ismailia - Egypt. FSC: Spain. Date of Issuance: 30-12-2024. LOA validity 31-12-2028	Febrile Antigens (Brucella A, Brucella M, Brucella Roase Bengal, Brucella A + M + Control, WIDAL with control, WIDAL typhi (O&H) with control, WIDAL typhi (O&H), WIDAL Single, Proteus OX19, Proteus OX2, Proteus OXK, Proteus (3X5ml) + Control.) Class-B Shelf life: 24 Months	Deferred for the provision of following: Credentials. Original notarized LOA. Original legalized FSC mentioning the subject device. Notarized ISO 13485. CE certificate Brand name. Clarification of grouping of Cluster and fee as per revised SRO for Cluster
74.	Alfa Scientific Store, 24-Maclogen Road, Lahore. ELI-00148 6095-P 31,000/-	Legal Manufacturer: Arena BioScien Block 5, Street 9, Ismailia Free Zone, Ismailia - Egypt. FSC: Spain. Date of Issuance: 30-12-2024. LOA validity 31-12-2028	Substrates (Albumin. Bilirubin Jendrassik (Total + Direct), Bilirubin DMSO (Total + Direct), Cholesterol CHOD-PAP, HDL Cholesterol, HDL Direct (3+1) with calibrator, LDL Cholesterol (3+1) with calibrator, Creatinine Jaffe (Fixed Rate). Creatinine End Point Method, Glucose GOD-PAP, Haemoglobin Conc, Haemoglobin	Deferred for the provision of following: Credentials. Original notarized LOA. Original legalized FSC mentioning the subject device. Notarized ISO 13485. CE certificate Brand name. Clarification of grouping of Cluster and fee as per revised

			Ready to use, Lactate, Lipase, Total Protein, Triglycerides, Urea/BUN End Point Method, Urea/BUN-UV Method, Uric acid) Class-B Shelf life: 24 Months	SRO for Cluster
75.	Alfa Scientific Store, 24-Maclogen Road, Lahore. ELI-00148 6099-P 31,000/-	<u>Legal Manufacturer:</u> Arena BioScien Block 5, Street 9, Ismailia Free Zone, Ismailia - Egypt. FSC: Spain. Date of Issuance: 30-12-2024. LOA validity 31-12-2028	Enzymes (Amylase - Total, Alkaline Phosphatase (9+1) Kinetic Method, Alanine Aminotransferase (ALT/GPT) Kinetic Method, Alanine Aminotransferase (ALT/GPT) End Point Method, Aspartate Aminotransferase (AST/GOT) Kinetic Method, Aspartate Aminotransferase (AST/GOT) End Point Method, CK-Nac, y-Glutamyltransferase (GGT) (9+1), LDH) Class-B Shelf life: 24 Months	Deferred for the provision of following: Credentials. Original notarized LOA. Original legalized FSC mentioning the subject device. Notarized ISO 13485. CE certificate Brand name. Clarification of grouping of Cluster and fee as per revised SRO for Cluster
76.	Alfa Scientific Store, 24-Maclogen Road, Lahore. ELI-00148 6073-P 62,000/-	<u>Legal Manufacturer:</u> Zhejiang Orient Gene Biotech Co, Ltd 3787#, East Yangguang Avenue, Dipu Street, Anji, 313300 Zhejiang, China. Original FSC: Germany. Date of Issuance: 31-08-2022. FSC: China. Date of Validity: 30-10-2025. LOA validity 25-02-2030 ISO 13485 validity 16-03-2026	Troponin I Rapid Test Cassette (Serum / Plasma) Class-C Shelf Life: 24 Months Code: GDTRO-302a	Approved. The firm shall submit Brand name before the issuance of registration letter.
77.	Alfa Scientific Store, 24-	<u>Legal Manufacturer:</u> Zhejiang Orient Gene Biotech	Toxoplasma gondii (Toxo) IgG/IgM Rapid	Approved.

	Maclogen Road, Lahore. ELI-00148 6074-P 62,000/-	Co, Ltd 3787#, East Yangguang Avenue, Dipu Street, Anji, 313300 Zhejiang, China. FSC: China. FSC: China. Date of Validity: 30-10-2025. LOA validity 25-02-2030 ISO 13485 validity 16-03-2026 Original FSC: Belgium. Date of Issuance: 13-05-2022.	Test Class-C Shelf Life: 24 Months Code: GCTOX(IgG/IgM)-302a	The firm shall submit Brand name before the issuance of registration letter.
78.	Alfa Scientific Store, 24-Maclogen Road, Lahore. ELI-00148 6078-P 62,000/-	<u>Legal Manufacturer:</u> Zhejiang Orient Gene Biotech Co, Ltd 3787#, East Yangguang Avenue, Dipu Street, Anji, 313300 Zhejiang, China. FSC: China. FSC: China. Date of Validity: 30-10-2025. LOA validity 25-02-2030 ISO 13485 validity 16-03-2026 Original FSC: Belgium. Date of Issuance: 13-05-2022.	Syphilis Ab Rapid Test Cassette (Serum/Plasma) Class-C Shelf Life: 24 Months Code: GCSYP-302a	Approved. The firm shall submit Brand name before the issuance of registration letter.
79.	Alfa Scientific Store, 24-Maclogen Road, Lahore. ELI-00148 6081-P 62,000/-	<u>Legal Manufacturer:</u> Arena BioScien Block 5, Street 9, Ismailia Free Zone, Ismailia - Egypt. FSC: Spain. Date of Issuance: 30-12-2024. LOA validity 31-12-2028	D-Dimer latex with (P+N) control Class-C Shelf Life: 24 Months	Deferred for the provision of following: Credentials. Original notarized LOA. Original legalized FSC mentioning the subject device. Notrized ISO 13485and CE certificate. Brand name.
80.	Alfa Scientific Store, 24-Maclogen Road, Lahore.	<u>Legal Manufacturer:</u> Arena BioScien Block 5, Street 9, Ismailia Free Zone, Ismailia - Egypt.	RF Latex (RF Latex with controls) Class-C	Deferred for the provision of following:

	ELI-00148 6082-P 62,000/-	FSC: Spain. Date of Issuance: 30-12-2024. LOA validity 31-12-2028	Shelf Life: 24 Months	Credentials. Original notarized LOA. Original legalized FSC mentioning the subject device. Notrized ISO 13485and CE certificate. Brand name.
81.	Alfa Scientific Store, 24-Maclogen Road, Lahore. ELI-00148 6085-P 62,000/-	<u>Legal Manufacturer:</u> Arena BioScien Block 5, Street 9, Ismailia Free Zone, Ismailia - Egypt. FSC: Spain. Date of Issuance: 30-12-2024. LOA validity 31-12-2028	Rheumatoid Factor (RF) Turbi-Latex Class-C Shelf Life: 24 Months	Deferred for the provision of following: Credentials. Original notarized LOA. Original legalized FSC mentioning the subject device. Notrized ISO 13485and CE certificate. Brand name.
82.	Alfa Scientific Store, 24-Maclogen Road, Lahore. ELI-00148 6086-P 62,000/-	<u>Legal Manufacturer:</u> Arena BioScien Block 5, Street 9, Ismailia Free Zone, Ismailia - Egypt. FSC: Spain. Date of Issuance: 30-12-2024. LOA validity 31-12-2028	SLE Latex Test SLE Latex Class-C Shelf Life: 24 Months	Deferred for the provision of following: Credentials. Original notarized LOA. Original legalized FSC mentioning the subject device. Notrized ISO 13485and CE certificate. Brand name.
83.	Alfa Scientific Store, 24-Maclogen Road, Lahore. ELI-00148 6087-P 31,000/-	<u>Legal Manufacturer:</u> Arena BioScien Block 5, Street 9, Ismailia Free Zone, Ismailia - Egypt. FSC: Spain. Date of Issuance: 30-12-2024. LOA validity 31-12-2028	Hemoglobin A1c (HbA1c) (Turbi-Latex with controls+calibrator set), C3 Turbi-Latex, C4 Turbi-Latex Class-B Shelf Life: 24 Months	Deferred for the provision of following: Credentials. Original notarized LOA. Original legalized FSC mentioning the subject device. Notrized ISO 13485and CE certificate.

				Brand name.
84.	Alfa Scientific Store, 24-Maclogen Road, Lahore. ELI-00148 6091-P 62,000/-	Legal Manufacturer: Arena BioScien Block 5, Street 9, Ismailia Free Zone, Ismailia - Egypt. FSC: Spain. Date of Issuance: 30-12-2024. LOA validity 31-12-2028	Serology CRP Latex (CRP Latex with controls, CRP Latex only) Class-C Shelf Life: 24 Months	Deferred for the provision of following: Credentials, Original notarized LOA. Original legalized FSC mentioning the subject device. Notrized ISO 13485and CE certificate. Brand name.
85.	Alfa Scientific Store, 24-Maclogen Road, Lahore. ELI-00148 6092-P 62,000/-	Legal Manufacturer: Arena BioScien Block 5, Street 9, Ismailia Free Zone, Ismailia - Egypt. FSC: Spain. Date of Issuance: 30-12-2024. LOA validity 31-12-2028	CK-MB CK-MB Class-C Shelf Life: 24 Months	Deferred for the provision of following: Credentials, Original notarized LOA. Original legalized FSC mentioning the subject device. Notrized ISO 13485and CE certificate. Brand name.
86.	Alfa Scientific Store, 24-Maclogen Road, Lahore. ELI-00148 6094-P 62,000/-	Legal Manufacturer: Arena BioScien Block 5, Street 9, Ismailia Free Zone, Ismailia - Egypt. FSC: Spain. Date of Issuance: 30-12-2024. LOA validity 31-12-2028	C REACTIVE PROTEIN (CRP) Turbi-Latex Class-C Shelf Life: 24 Months	Deferred for the provision of following: Credentials, Original notarized LOA. Original legalized FSC mentioning the subject device. Notrized ISO 13485and CE certificate. Brand name.Product description.
87.	Alfa Scientific Store, 24-Maclogen Road, Lahore. ELI-00148 6096-P 62,000/-	Legal Manufacturer: Arena BioScien Block 5, Street 9, Ismailia Free Zone, Ismailia - Egypt. FSC: Spain. Date of Issuance: 30-12-2024.	RPR Latex Test RPR Latex test Class-C Shelf Life: 24 Months	Deferred for the provision of following: Credentials, Original notarized LOA. Original legalized

		LOA validity 31-12-2028		FSC mentioning the subject device. Notrized ISO 13485and CE certificate. Brand name.. Product description.
88.	Alfa Scientific Store, 24-Maclogen Road, Lahore. ELI-00148 6097-P 62,000/-	<u>Legal Manufacturer:</u> Arena BioScien Block 5, Street 9, Ismailia Free Zone, Ismailia - Egypt. FSC: Spain. Date of Issuance: 30-12-2024. LOA validity 31-12-2028	Bovine Albumin 22%, Bovine Albumin 30% Class-C Shelf Life: 24 Months	Deferred for the provision of following: Credentials, Original notarized LOA. Original legalized FSC mentioning the subject device. Notrized ISO 13485and CE certificate. Brand name. Product description.
89.	Alfa Scientific Store, 24-Maclogen Road, Lahore. ELI-00148 6098-P 62,000/-	<u>Legal Manufacturer:</u> Arena BioScien Block 5, Street 9, Ismailia Free Zone, Ismailia - Egypt. FSC: Spain. Date of Issuance: 30-12-2024. LOA validity 31-12-2028	Toxoplasma Latex Toxoplasma Latex Class-C Shelf Life: 24 Months	Deferred for the provision of following: Credentials, Original notarized LOA. Original legalized FSC mentioning the subject device. Notrized ISO 13485and CE certificate. Brand name. Product description.
90.	Alfa Scientific Store, 24-Maclogen Road, Lahore. ELI-00148 6065-P 62,000/-	<u>Legal Manufacturer:</u> Zhejiang Orient Gene Biotech Co, Ltd 3787#, East Yangguang Avenue, Dipu Street, Anji, 313300 Zhejiang, China. Original FSC: China. Date of Validity: 30-10-2025. LOA validity 25-02-2030 ISO 13485 validity 16-03-2027 CE certificate validity 26-05-	HCV Rapid Test (Serum / Plasma) (Cassette) Class-D Shelf Life: 24 Months Size: 40 tests/lit GCHCV-302a (Serum / Plasma) GCHCV-402a (whole blood/ Serum /	Approved. The firm shall submit Brand name, valid notarized CE and Design examination certificate before the issuance of registration letter.

		2025 DE certificate validity 26-05-2025	Plasma)	
91.	Alfa Scientific Store, 24-Maclogen Road, Lahore. ELI-00148 6066-P 62,000/-	Legal Manufacturer: Zhejiang Orient Gene Biotech Co, Ltd 3787#, East Yangguang Avenue, Dipu Street, Anji, 313300 Zhejiang, China. Original FSC: China. Date of Validity: 30-10-2025. LOA validity 25-02-2030 ISO 13485 validity 16-03-2027 CE certificate validity 26-05-2025 DE certificate validity 26-05-2025	HBsAg Rapid Test (Serum / Plasma) (Cassette) Class-D Shelf Life: 24 Months	Deferred for the provision of Original and legalized FSC mentioning subject product and notarized CE and Design examination certificate and Brand name.
92.	Alfa Scientific Store, 24-Maclogen Road, Lahore. ELI-00148 6067-P 62,000/-	Legal Manufacturer: Zhejiang Orient Gene Biotech Co, Ltd 3787#, East Yangguang Avenue, Dipu Street, Anji, 313300 Zhejiang, China. Original FSC: China. Date of Validity: 30-10-2025. LOA validity 25-02-2030 ISO 13485 validity 16-03-2027 CE certificate validity 26-05-2025 DE certificate validity 26-05-2025	HIV 1/2 Human Immunodeficiency Virus Rapid Test Class-D Shelf Life: 24 Months Size: 40 tests/lit GCHIV-302a (Serum / Plasma) GCHIV-402a (whole blood/ Serum / Plasma)	Deferred for the provision of Original and legalized FSC mentioning subject product and notarized CE and Design examination certificate and Brand name.
93.	Alfa Scientific Store, 24-Maclogen Road, Lahore. ELI-00148 6093-P 62,000/-	Legal Manufacturer: Arena BioScien Block 5, Street 9, Ismailia Free Zone, Ismailia - Egypt. FSC: Spain. Date of Issuance: 30-12-2024. LOA validity 31-12-2028	Blood Grouping Reagents (Anti-A, Anti-B, Anti-D (IgG & IgM), Anti-D (IgG), Anti-AB, Anti-Human Globulin, Anti-A+B+D, Anti-CDE) Class-D Shelf Life: 24 Months	Deferred for the provision of following: Credentials. Original notarized LOA. Original legalized FSC of Spain mentioning the subject device. Notarized ISO 13485 and CE/FQA and Design examination

				certificate. Brand name. Clarification of grouping of blood reagents in single application. Product description.
94.	Medico International, B-235, Block B, Satellite Town, Rawalpindi. ELI-01038 7002-P 31,000/-	<u>Legal Manufacturer:</u> JOYTECH Healthcare Co., Ltd No. 365, Wuzhou Road, Yuhang Economic Development Zone, Hangzhou City, 311100 Zhejiang, P.R. China. FSC: China. Date of Validity: 09-05-2026. FSC Germany issuance 18- 06-2024 LOA validity 08-07-2029 ISO 13485 validity 27-04- 2025 EU QMS certificate (MDR) validity 27-04-2027	Medico Electric Breast Pump Class-B Shelf Life: 3 years Model: BR-105	Approved
95.	Medico International, B-235, Block B, Satellite Town, Rawalpindi. ELI-01038 7003-P 31,000/-	<u>Legal Manufacturer:</u> JOYTECH Healthcare Co., Ltd No. 365, Wuzhou Road, Yuhang Economic Development Zone, Hangzhou City, 311100 Zhejiang, P.R. China. FSC: China. Date of Validity: 09-05-2026. FSC Germany issuance 18- 06-2024 LOA validity 08-07-2029 ISO 13485 validity 27-04- 2025 EU QMS certificate (MDR) validity 27-04-2027	Medico Forehead Thermometer Class-B Shelf Life: 3 years Model: FT-15	Approved, Firm will submit copy of valid ISO 13485.
96.	Medico International, B-235, Block B, Satellite Town, Rawalpindi. ELI-01038	<u>Legal Manufacturer:</u> JOYTECH Healthcare Co., Ltd No. 365, Wuzhou Road, Yuhang Economic Development Zone, Hangzhou City, 311100	Medico Digital Thermometer Class-B Shelf Life: 3 years	Approved Firm will submit copy of valid ISO 13485.

	7004-P 31,000/-	Zhejiang, P.R. China. FSC: China. Date of Validity: 09-05-2026. FSC Germany issuance 18-06-2024 LOA validity 08-07-2029 ISO 13485 validity 27-04-2025 EU QMS certificate (MDR) validity 27-04-2027	Model: DT-40	
97.	Medico International, B-235, Block B, Satellite Town, Rawalpindi. ELI-01038 7005-P 31,000/-	<u>Legal Manufacturer:</u> JOYTECH Healthcare Co., Ltd No. 365, Wuzhou Road, Yuhang Economic Development Zone, Hangzhou City, 311100 Zhejiang, P.R. China. FSC: China. Date of Validity: 09-05-2026. FSC Germany issuance 18-06-2024 LOA validity 08-07-2029 ISO 13485 validity 27-04-2025 EU QMS certificate (MDR) validity 27-04-2027	Medico Digital Flexible Thermometer Class-B Shelf Life: 3 years Model: FT-33	Approved Firm will submit copy of valid ISO 13485.
98.	Medico International, B-235, Block B, Satellite Town, Rawalpindi. ELI-01038 7006-P 31,000/-	<u>Legal Manufacturer:</u> JOYTECH Healthcare Co., Ltd No. 365, Wuzhou Road, Yuhang Economic Development Zone, Hangzhou City, 311100 Zhejiang, P.R. China. FSC: China. Date of Validity: 09-05-2026. LOA validity 08-07-2029 ISO 13485 validity 27-04-2025 EU QMS certificate (MDR) validity 27-04-2027	Medico Fingertip Pulse Oximeter Class-B Shelf Life: 3 years Model: FPO-109	Approved Firm will submit copy of valid ISO 13485.
99.	Medico International, B-235, Block B, Satellite Town, Rawalpindi. ELI-01038 7007-P	<u>Legal Manufacturer:</u> JOYTECH Healthcare Co., Ltd No. 365, Wuzhou Road, Yuhang Economic Development Zone, Hangzhou City, 311100 Zhejiang, P.R. China.	Medico Digital Blood Pressure Monitor, Upper Arm-type Class-B Shelf Life: 3 years	Approved Firm will submit copy of valid ISO 13485.

	31,000/-	FSC: China. Date of Validity: 09-05-2026. FSC Germany issuance 18-06-2024 LOA validity 08-07-2029 ISO 13485 validity 27-04-2025 EU QMS certificate (MDR) validity 27-04-2027	Model: BPM-55	
100.	Medico International, B-235, Block B, Satellite Town, Rawalpindi. ELI-01038 7008-P 31,000/-	<u>Legal Manufacturer:</u> JOYTECH Healthcare Co., Ltd No. 365, Wuzhou Road, Yuhang Economic Development Zone, Hangzhou City, 311100 Zhejiang, P.R. China. FSC: China. Date of Validity: 09-05-2026. FSC Germany issuance 18-06-2024 LOA validity 08-07-2029 ISO 13485 validity 27-04-2025 EU QMS certificate (MDR) validity 27-04-2027	Medico Digital Blood Pressure Monitor, Wrist-type Class-B Shelf Life: 3 years Model: BPM-42	Approved Firm will submit copy of valid ISO 13485.
101.	Medico International, B-235, Block B, Satellite Town, Rawalpindi. ELI-01038 7009-P 31,000/-	<u>Legal Manufacturer:</u> JOYTECH Healthcare Co., Ltd No. 365, Wuzhou Road, Yuhang Economic Development Zone, Hangzhou City, 311100 Zhejiang, P.R. China. FSC: China. Date of Validity: 09-05-2026. FSC Germany issuance 18-06-2024 LOA validity 08-07-2029 ISO 13485 validity 27-04-2025 EU QMS certificate (MDR) validity 27-04-2027	Medico Digital Blood Pressure Monitor, Upper Arm-type Class-B Shelf Life: 3 years Model: BPM-35	Approved Firm will submit copy of valid ISO 13485.
102.	Amir Traders, 43-A, Infantry Road, Lahore Cantt, Lahore.	<u>Legal Manufacturer:</u> Osstem Implant Co., Ltd 66-16, Bansong-ro 513 Beon-gil, Haeundae-gu, Busan, 48002,	TS III BA Implant System Dental implant, Fixture	Approved. The firm shall submit fee as per revised SRO

	ELI-01136 6064-P 62,000/-	Republic of Korea. Original FSC: Korea. Date of Issuance: 07-10-2024. FSC Australia issuance 03-12-2024, ARTG 225382 LOA issuance 03-08-2023 ISO 13485 validity 14-12-2025 FQA certificate 27-05-2024	Class-C Shelf Life: 5 Years Codes: BTS3M3008B, BTS3M3010B BTS3M3011B, BTS3M3013B BTS3M3507B, BTS3M3508B BTS3M3510B, BTS3M3511B BTS3M3513B, BTS3M3515B BTS3M3518B, BTS3M3520B BTS3S4007B, BTS3S4008B BTS3S4010B, BTS3S4011B BTS3S4013B, BTS3S4015B BTS3S4018B, BTS3S4020B BTS3S4506B, BTS3S4507B BTS3S4508B, BTS3S4510B BTS3S4511B, BTS3S4513B BTS3S4515B, BTS3S4518B BTS3S4520B, BTS3S5004B BTS3S5005B, BTS3S5006B BTS3S5007B, BTS3S5008B BTS3S5010B, BTS3S5011B BTS3S5013B, BTS3S5015B BTS3S5018B, BTS3S5020B BTS3S5506B, BTS3S5507B BTS3S5508B, BTS3S5510B BTS3S5511B, BTS3S5513B BTS3S5515B	for System.
103.	MOD Scientific	<u>Legal</u> <u>Manufacturer:</u>	Accufast	Approved.

	Traders, 3-Syed Mouj Darya Road Lahore. ELI-00655 6062-P 62,000/-	Hubei Meibao Biotechnology Co., Ltd No. 5 Hongfu Road, Shayang Economic Development Zone 448200, Jingmen City, P.R. China. Original FSC: China. Validity: 20-07-2025. LOA validity 05-02-2030 ISO 13485 validity 23-01- 2027 CE certificate validity 10-10- 2023 with extension notification letter	HCG Pregnancy Test Strip Class-C Shelf Life: 3 Years Models: GTT01	The firm shall submit Credentials before the issuance of registration letter.
104.	Cardiac Care, 848-C, Shadman- 1 Lahore - 54610, Pakistan. ELI-00070 7045-P 62,000/-	<u>Legal Manufacturer:</u> HEMONART Medikal Sistemler San. Tic. A.S. Alacaatli Mah., Sehit Hayrettin Eren Cad., No: 24/AF, 06810 CankayaAnkara Turkey. FSC: Turkey. Date of Issuance: 27-07-2023 valid for 3 years. LOA validity 31-12-2028	Blac T ACT Test Tube Activated Clotting Test Tube Class-C Shelf Life: 3 Years Model: ACT3017	Deferred for the provision of following: Clarification of Class of medical device. Notrized ISO 13485. Legalized original valid FSC of Reference country or notarized CE certificate/ WHO PQ. Stability studies Clarification of the brand name as same device is already addressed in 79 th meeting for M/s Flowtronix system having Brand name hemonart.
105.	Defence Resource Group, 309, 3rd Floor, Divine Mega II, New Airport Road, Lahore. ELI-01319 1544-P 6,000/-	<u>Legal Manufacturer:</u> A1 Globe SDN. BHD. A1-2, Block A, Jalan Haruan 5/9, Psurat Komersial Oakland, 70300 Seremban, Negeri Sembilan, Malaysia. FSC: Malaysia. Validity: 19-06-2027. LOA validity 15-07-2029	HANDEX Latex Powder Free Examination Gloves Class-A Shelf Life: 3 Year	Deferred for the provision of original legalized/ notarized documents as required in application form. clarification since the same brand is already applied by Delta Plus, Islamabad from the same manufacturer
106.	M/s Anwar & Sons Apartment No 10, Safari Villas-2	<u>Legal Manufacturer:</u> M/s MBK Group Tekstil Sanayi Ic Ve Dis Tic. Ltd. Sti	Midikal - Anti Embolism Stockings (Knee High Anti Embolism Stockings)	Approved

	Commercial Complex, Bahria Town Phase-7 Rawalpindi Pakistan. ELI-00017 1588-P 6,000/-	Ikitelli OSB Mah. ISDOK SOSYAL TESIS 2 Sok. A Block No:9 KAT:2, Basaksehir/Istanbul, 34490, Turkey TEL: +90 545 472 1602 Email: info@mbkgroup.com.tr Website: www.mbkgroup.com.tr LOA Issuance: 13.03.24 FSC Validity: 22.07.2029 ISO 13485 Validity: 12.04.2025	Class A Shelf life: N/A Codes as per FSC KHMA31S, KHMA31M KHMA31L, KHMA31XL	
107.	Medequips SMC Pvt Ltd, 30-Shahrah E Quaid E Azam, Lahore, 54000, Pakistan. ELI-00362 7023-P	<u>Legal Manufacturer:</u> MEDISONO LLC. 3016 NW 82nd Avenue, Doral, FL 33122, USA. FSC: USA. Date of Validity: 23-10-2026. LOA issuance 05-12-2024 ISO 13485 missing. 510k No. K231659 for P11 Plus	MS12 Digital Color Doppler Ultrasound System and P11 Plus Digital Color Doppler Ultrasound System (Digital Color Doppler Ultrasound System) Class-B Service life: 7 years Model as per FSC	Deferred for the provision of following: Original legalized/notrized documents as per application form. Nortized ISO 13485 is Fee slip is missing. Clarification and justification for applying Two systems in single application.
108.	Best Way Enterprises, Flat # 314, 3rd Floor, Empress Tower, 46 Empress Road, Lahore. ELI-01270 7024-P 62,000/-	<u>Legal Manufacturer:</u> Huaian Pingan Medical Instrument Co., Ltd. No. 128 West Meigao Road, Huaian, Jiangsu, China. FSC: China. Date of Validity: 15-01-2026. FSC: Spain. Date of Issuance: 02-08-2024. LOA issuance 20-01-2025 ISO 13485 validity 26-04-2027 CE and DE certificates validity 3-05-2024 with extension notification letter.	BESTPDO Sterile Absorbable Polydioxanone PDO Sutures Class-D Shelf Life: 3 Years Codes as per FSC	Approved with codes as per FSC.
109.	Best Way Enterprises, Flat #	<u>Legal Manufacturer:</u> Huaian Pingan Medical	BESTCRYL Sterile Absorbable	Approved with codes as per FSA.

	314, 3rd Floor, Empress Tower, 46 Empress Road, Lahore. ELI-01270 7025-P 62,000/-	Instrument Co., Ltd. No. 128 West Meigao Road, Huaian, Jiangsu, China. FSC: China. Date of Validity: 15-01-2026. FSC: Spain. Date of Issuance: 02-08-2024. LOA issuance 20-01-2025 ISO 13485 validity 26-04-2027 CE n DE certificates validity 3-05-2024 with extension notification letter.	Polyglycolic Acid Sutures Class-D Shelf Life: 3 Years Codes as per FSC	
110.	Best Way Enterprises, Flat # 314, 3rd Floor, Empress Tower, 46 Empress Road, Lahore. ELI-01270 7026-P 62,000/-	<u>Legal Manufacturer:</u> Huaian Pingan Medical Instrument Co., Ltd. No. 128 West Meigao Road, Huaian, Jiangsu, China. FSC: China. Date of Validity: 15-01-2026. FSC: Spain. Date of Issuance: 02-08-2024. LOA issuance 20-01-2025 ISO 13485 validity 26-04-2027 CE certificate validity 3-05-2024 with extension notification letter.	BESTSILK Sterile Non-Absorbable Silk Braided Sutures Class-D Shelf Life: 3 Years Codes as per FSC	Approved in Class-C with codes as per FSC
111.	Best Way Enterprises, Flat # 314, 3rd Floor, Empress Tower, 46 Empress Road, Lahore. ELI-01270 7027-P 62,000/-	<u>Legal Manufacturer:</u> Huaian Pingan Medical Instrument Co., Ltd. No. 128 West Meigao Road, Huaian, Jiangsu, China. FSC: China. Date of Validity: 15-01-2026. FSC: Spain. Date of Issuance: 02-08-2024.	BESTROLIN Sterile Non-Absorbable Polypropylene Monofilament Sutures Class-D Shelf Life: 3 Years Codes as per FSC	Approved in Class-C with codes as per FSC

		LOA issuance 20-01-2025 ISO 13485 validity 26-04-2027 CE certificate validity 3-05-2024 with extension notification letter.		
112.	MR Medical Pakistan Pvt Ltd, Office No. 1101, 11th Floor, ISE Tower, Jinnah Avenue, Blue Area Islamabad. ELI-01008 7286-IBD 62,000/-	<u>Legal Manufacturer:</u> Shenzhen Mindray Bio-Medical Electronics Co., Ltd Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057 Shenzhen, People Republic of China. FSC: China. Date of Validity: 12-03-2026. FSC: Germany. Date of Issuance: 12-08-2023. LOA validity 14-04-2027 EU QMS certificate (MDR) validity 20-11-2029 ISO 13485 validity 31-08-2026	Mindray Patient Monitor Class-C Service life: 10 Years Model: ePM 15M	Deferred for the provision of original legalized FSC of china and Germany. Notrized iso 13485 and CE. fee as per revised SRO for System.
113.	J&W Pharma (Pvt) Ltd, 36-C/1, Block C, Satellite Town Chandni Chowk, Rawalpindi. ELI-01379	<u>Legal Manufacturer:</u> MORTAN.INC Main Site: 329 East Pine, Missoula, Montana 59802, United States. FSC: USA. Date of Validity: 01-02-2026. LOA issuance 28-02-2025	The Morgan mor-Flex lens Class-B Shelf Life: 5 Years Model: MT202	Deferred for the provision of following: Original and legalized FSC, legalized LOA, ISO 13485. Generic name. Intended use.
114.	SOS Technologies (Pvt) Ltd, House 951-B, Mumtazabad Multan. ELI-01005 7047-P 31,000/-	<u>Legal Manufacturer:</u> Yingcheng U-Phten Import & Export Co A2-1, 2 (First Floor), Haishan Yingzhicheng, Yingcheng Economic and Technological Development Zone, Xiaogan City, Hubei Province. FSC: China. Date of Validity: 24-11-2023.	Ab Gauze Pad Non-woven gauze Pad Class-B Shelf Life: 5 years Sizes: 2in x 2in 4in x 4in	Deferred for the provision of following: Credentials. Original valid notarized LOA Original legalized FSC.

				<p>ISO 13485 is copy without notarization.</p> <p>No ref country FSC/CE certificate is provided.</p> <p>No stability data is provided.</p>
115.	<p>Chemical House, 6-C Sikandar Malhi Road, Canal Park, Gulberg II, Lahore, Pakistan.</p> <p>ELI-00156 7048-P 31,000/-</p>	<p><u>Legal Manufacturer:</u> Bio-Rad Laboratories 9500 Jeronimo rd, Irvine, CA, USA.</p> <p>FSC: USA. Date of Validity: 12-05-2026. LOA validity 31-12-2025 ISO 3485 validity 17-05-2025</p>	<p>Liquichek Ethanol / Ammonia Control</p> <p>Class-B</p> <p>Shelf Life: 720 Days</p> <p>Catalogue No. 544, 545, 546, 545X</p>	<p>Approved.</p> <p>The firm shall submit valid ISO 13485 certificate before the issuance of registration letter.</p>
116.	<p>Zymotic Diagnostics International, 4th Floor Business Center Regency Road new Civil Lines Faisalabad.</p> <p>ELI-00880 7046-P 31,000/-</p>	<p><u>Legal Manufacturer:</u> GOLDSITE DIAGNOSTICS INC. Goldsite Mansion, No. 9 Rongtian Road, Kengzi, Rongtian Road, Kengzi, Pingshan District, Shenzhen, China, 518122.</p> <p>FSC: China. Date of Validity: 02-01-2026. LOA validity April, 2026 ISO 13485 validity 15-10-2027</p>	<p>NEPHSTAR Specific Protein Analyzer</p> <p>Class-B</p> <p>Shelf Life: 1 Year</p> <p>Model: Nephstar</p>	<p>Deferred for the provision of following:</p> <p>Original legalized /norried documents as per application form.</p> <p>Correct Class.</p> <p>Ref country FSC or CE certificate is not provided.</p> <p>Stability studies data is not provided.</p> <p>Credentials.</p> <p>The firm is required to apply separately for all kits depending upon the Class of kit.</p>
117.	<p>Total Care (Pvt) Ltd, 1st Floor, 870-B, Faisal Town, Lahore, 54770 Pakistan.</p> <p>ELI-01240 1667-P</p>	<p><u>Legal Manufacturer:</u> Ottobock SE & Co., KGaA Max-Nader-Str. 15 D-37115 Duderstadt Germany.</p> <p>FSC: Germany. Date of Issuance: 16-03-2023.</p>	<p>Upper Limbs / Arms (Set)</p> <p>Class-A</p> <p>Shelf Life:</p>	<p>Deferred for the provision of following:</p> <p>Application form with all relevant documents.</p>

	6,000/-			Original Fee challan.
118.	Total Care (Pvt) Ltd, 1st Floor, 870-B, Faisal Town, Lahore, 54770 Pakistan. ELI-01240 1668-P 6,000/-	Legal Manufacturer: Wagner Polymertechnik GmbH Neuer Weg 4, D-37345 Sonnenstein / Silkerode, Germany. FSC: N/A Date of Issuance: N/A	Lower Limb / Leg (Set) Class-A Shelf Life:	Deferred for the provision of following: Application form with all relevant documents. Original Fee challan.
119.	Total Care (Pvt) Ltd, 1st Floor, 870-B, Faisal Town, Lahore, 54770 Pakistan. ELI-01240 1669-P 6,000/-	Legal Manufacturer: Ottobock SE & CO. KGaA Max-Nader-Str. 15 D-37115 Duderstadt Germany. FSC: Germany Date of Issuance: 16-03-2023.	Lower Limbs / Leg (Set) Class-A Shelf Life:	Deferred for the provision of following: Application form with all relevant documents. Original Fee challan.
120.	Total Care (Pvt) Ltd, 1st Floor, 870-B, Faisal Town, Lahore, 54770 Pakistan. ELI-01240 1670-P 6,000/-	Legal Manufacturer: IB-ER Makina A.S Selvilitepe OSB Mah. OSB 2006 Cad. No. 12/1 Turgutlu, Manisa, Turkey. FSC: Turkey. Date of Issuance: 07-04-2022.	Lower Limb / Leg (Set) Class-A Shelf Life:	Deferred for the provision of following: Application form with all relevant documents. Original Fee challan.
121.	Kaumedex, E-144/2, New Super Town Link-2, Defence Road, Lahore. ELI-00162 1582-P 6,000/-	Legal Manufacturer: Supermax Glove Manufacturing SDN. BHD, Lot 38 & 42, Putra Industrial Park, Bukit Rahman Putra, 40160 Sungai Buloh, Selangor Darul Ehsan, Malaysia. FSC: Malaysia. Date of Validity: 30-03-2025. LOA issuance 26-01-2024 ISO 13485 validity 21-07-2025	High-Max Non-Sterile Latex Examination Gloves, Powdered Class-A Shelf Life: 5 Years Sizes: XS, S, M, L, XL	Deferred for the provision of following: Original legalized/notrized and valid documents as per application form.
122.	Kaumedex, E-144/2, New Super Town Link-2, Defence Road, Lahore. ELI-00162 1582-P 6,000/-	Legal Manufacturer: Supermax Glove Manufacturing SDN. BHD, Lot 38 & 42, Putra Industrial Park, Bukit Rahman Putra, 40160 Sungai Buloh, Selangor Darul Ehsan, Malaysia. FSC: Malaysia.	High-Max Non-Sterile Latex Examination Gloves, Powdered Free Class-A Shelf Life: 5 Years Sizes:	Original legalized/notrized and valid documents as per application form.

		Date of Validity: 30-03-2025. LOA issuance 26-01-2024 ISO 13485 validity 21-07-2025	XS, S, M, L,	
123.	Care Scientific, 13-14, C/A 1st Floor Chuburgi, Center, Multan Road, Lahore. ELI-00487 1553-P 6,000/-	Legal Manufacturer: Atlas Medical GmbH Ludwig-Erhard-Ring 3 15827 Blankenfelde-Mahlow, Berlin, Germany. FSC: Germany Date of Issuance: 09-01-2023. LOA issuance 04-04-2024 valid for 2 years. ISO 13485 validity 08-10-2026	ATLAS IM Latex Kit Class-A Shelf Life: 24 Months Codes: 00170415 (50 tests/kit n 100 tests/kit)	Deferred for the provision of following: The subject device falls in Class-B so form-7A and fee as per revised SRO. Original and legalized FSC. Notarized CE.
124.	Care Scientific, 13-14, C/A 1st Floor Chuburgi, Center, Multan Road, Lahore. ELI-00487 1554-P 6,000/-	Legal Manufacturer: Atlas Medical GmbH Ludwig-Erhard-Ring 3 15827 Blankenfelde-Mahlow, Berlin, Germany. FSC: Germany Date of Issuance: 09-01-2023. LOA issuance 04-04-2024 valid for 2 years. ISO 13485 validity 08-10-2026	ATLAS TOXO Latex Kit Class-A Shelf Life: 24 Months	Deferred for the provision of following: The subject device falls in Class-C so form-7A and fee as per revised SRO. Original and legalized FSC mentioning the subject device. Notrized CE.
125.	Care Scientific, 13-14, C/A 1st Floor Chuburgi, Center, Multan Road, Lahore. ELI-00487 1555-P 6,000/-	Legal Manufacturer: Atlas Medical GmbH Ludwig-Erhard-Ring 3 15827 Blankenfelde-Mahlow, Berlin, Germany. FSC: Germany Date of Issuance: 09-01-2023. LOA issuance 04-04-2024 valid for 2 years. ISO 13485 validity 08-10-2026	ATLAS RPR Carbon Antigen Kit Class-A Shelf Life: 27 Months	Deferred for the provision of following: The subject device falls in Class-C so form-7A and fee as per revised SRO. Original and legalized FSC mentioning the subject device. Notrized CE.
126.	Care Scientific, 13-14, C/A 1st Floor Chuburgi, Center, Multan Road, Lahore. ELI-00487 1556-P 6,000/-	Legal Manufacturer: Atlas Medical GmbH Ludwig-Erhard-Ring 3 15827 Blankenfelde-Mahlow, Berlin, Germany. FSC: Germany Date of Issuance: 09-01-2023. LOA issuance 04-04-2024	ATLAS SLE Latex Kit Class-A Shelf Life: 24 Months Codes: 00170413 (50 tests/kit, 100 tests/kit	Deferred for the provision of following: The subject device falls in Class-B so form-7A and fee as per revised SRO. Original and legalized

		valid for 2 years. ISO 13485 validity 08-10-2026		FSC Notrized CE.
127.	Care Scientific, 13-14, C/A 1st Floor Chuburgi, Center, Multan Road, Lahore. ELI-00487 1557-P 6,000/-	Legal Manufacturer: Atlas Medical GmbH Ludwig-Erhard-Ring 3 15827 Blankenfelde-Mahlow, Berlin, Germany. FSC: Germany Date of Issuance: 09-01-2023. LOA issuance 04-04-2024 valid for 2 years. ISO 13485 validity 08-10-2026	ATLAS BRUCELLA ROSE BENGAL KIT Class-A Shelf Life: 24 Months Codes: 00171783 (50 tests/kit, 100 tests/kit)	Deferred for the provision of following: The subject device falls in Class-C so form-7A and fee as per revised SRO. Original and legalized FSC Notrized CE.
128.	Care Scientific, 13-14, C/A 1st Floor Chuburgi, Center, Multan Road, Lahore. ELI-00487 1558-P 6,000/-	Legal Manufacturer: Atlas Medical GmbH Ludwig-Erhard-Ring 3 15827 Blankenfelde-Mahlow, Berlin, Germany. FSC: Germany Date of Issuance: 09-01-2023. LOA issuance 04-04-2024 valid for 2 years. ISO 13485 validity 08-10-2026	ATLAS HCG Latex Kit Class-A Shelf Life: 24 Months Code: 00170416 (50 tests/kit, 100 tests/kit)	Deferred for the provision of following: The subject device falls in Class-B so form-7A and fee as per revised SRO. Original and legalized FSC Notrized CE.
129.	Care Scientific, 13-14, C/A 1st Floor Chuburgi, Center, Multan Road, Lahore. ELI-00487 1559-P 6,000/-	Legal Manufacturer: Atlas Medical GmbH Ludwig-Erhard-Ring 3 15827 Blankenfelde-Mahlow, Berlin, Germany. FSC: Germany Date of Issuance: 09-01-2023. LOA issuance 04-04-2024 valid for 2 years. ISO 13485 validity 08-10-2026	ATLAS Staphylococcus Latex Kit Class-A Shelf Life: 24 Months Code: 00171610 (50 tests/kit, 100 tests/kit)	Deferred for the provision of following: The subject device falls in Class-B so form-7A and fee as per revised SRO. Original and legalized FSC Notrized CE.
130.	Care Scientific, 13-14, C/A 1st Floor Chuburgi, Center, Multan Road, Lahore. ELI-00487 1560-P	Legal Manufacturer: Atlas Medical GmbH Ludwig-Erhard-Ring 3 15827 Blankenfelde-Mahlow, Berlin, Germany. FSC: Germany Date of Issuance: 09-01-	ATLAS TPHA Kit Class-A Shelf Life: 24 Months Code:	Deferred for the provision of following: The subject device falls in Class-C so form-7A and fee as per revised SRO.

	6,000/-	2023. LOA issuance 04-04-2024 valid for 2 years. ISO 13485 validity 08-10-2026	00171686 (100 tests/kit, 200 tests/kit)	Original and legalized FSC Notrized CE.
131.	Care Scientific, 13-14, C/A 1st Floor Chuburgi, Center, Multan Road, Lahore. ELI-00487 1561-P 6,000/-	Legal Manufacturer: Atlas Medical GmbH Ludwig-Erhard-Ring 3 15827 Blankenfelde-Mahlow, Berlin, Germany. FSC: Germany Date of Issuance: 09-01-2023. LOA issuance 04-04-2024 valid for 2 years. ISO 13485 validity 08-10-2026	ATLAS STREPTOCOCCUS LATEX KIT, 6 GROUPS Class-A Shelf Life: 24 Months Code: 00171673 (6x 50 tests)	Deferred for the provision of following: The subject device falls in Class-B so form-7A and fee as per revised SRO. Original and legalized FSC Notrized CE.
132.	Bio-Tech Services, 746- Shadman-1, Lahore, Pakistan. ELI-00715 7010-P 62,000/-	Legal Manufacturer: Edan Instruments, Inc. No. 15 Jinhui Rd., Jinsha Community, Kengzi Subdistrict, Pingshan District Shenzhen, 518122 P.R. China. Original FSC: China. Date of Validity: 07-01-2026. LOA validity 30-06-2027 ISO 13485 validity 30-11-2025 EU QMS certificate (MDR)17-02-2026	EDAN Patient Monitor Class-C Shelf Life: N/A Models: elite V5, elite V6, elite V8	Approved elite V5. The firm shall submit fee as per revised SRO for system and shelf life.
133.	Bio-Tech Services, 746- Shadman-1, Lahore, Pakistan. ELI-00715 7012-P 62,000/-	Legal Manufacturer: Edan Instruments, Inc. No. 15 Jinhui Rd., Jinsha Community, Kengzi Subdistrict, Pingshan District Shenzhen, 518122 P.R. China. Original FSC: China. Date of Validity: 07-01-2026. LOA validity 30-06-2027 ISO 13485 validity 30-11-2025 EU QMS certificate (MDR)17-02-2026	EDAN Fetal & Maternal Monitor Class-C Shelf Life: N/A Models: EHG, EHG Plus, EHG Pro, EHG C, EHGA, EHGB, FECGI FECG , FECG Plus, FECG Pro, FECG Net, FECG C, FECG A, FECG B	Deffered for : Justification for applying different types and models in single application. Type and model to be considered for instant application. Shelf life
134.	Bio-Tech Services, 746- Shadman-1,	Legal Manufacturer: Edan Instruments, Inc. No. 15 Jinhui Rd., Jinsha	EDAN Vital Signs Monitor	Deffered for : Justification for applying different

	Lahore, Pakistan. ELI-00715 7013-P 62,000/-	Community, Kengzi Subdistrict, Pingshan District Shenzhen, 518122 P.R. China. Original FSC: China. Date of Validity: 07-01-2026. LOA validity 30-06-2027 ISO 13485 validity 30-11-2025 EU QMS certificate (MDR)17-02-2026	Class-C Shelf Life: N/A Models: iM3s, iHM3s, iM3As 、 iM3Bs	types and models in single application. Type and model to be considered for instant application. Shelf life
135.	Bio-Tech Services, 746-Shadman-1, Lahore, Pakistan. ELI-00715 7011-P 31,000/-	Legal Manufacturer: Edan Instruments, Inc. No. 15 Jinhui Rd., Jinsha Community, Kengzi Subdistrict, Pingshan District Shenzhen, 518122 P.R. China. Original FSC: China. Date of Validity: 07-01-2026. LOA validity 30-06-2027 ISO 13485 validity 30-11-2025 EU QMS certificate (MDR)17-02-2026	EDAN Electrocardiography (ECGs) Class-B Shelf Life: N/A Models: SE-15, SE-16	Approved SE-15 The firm shall submit shelf life before issuance of letter.
136.	Pakistan Hospital and Industrial Laboratory Co 36-Abkari Road, New Anarkali, Lahore (ELI-00817) Rs. 6,000 Slip # 900808258	Legal Manufacturer Zhuhai DL Biotech Co.Ltd No.59, Ding Wan 10th Road, Jinwan District, Zhuhai Gong Dong Province, China, 519040 FSC: China Validity: 18-01-2026 LOA validity 01-03-2026 DoC Certificate Validity :19-11-2033 ISO: 13485 Validity :07-11-2026	DL Automated Blood Culture Bottles Aerobic Colorimetric Model: (I-1) Class: A Shelf Life : 12 Months	Approved
137.	Pakistan Hospital and Industrial Laboratory Co 36-Abkari Road, New Anarkali, Lahore (ELI-00817) Rs. 6,000	Legal Manufacturer Zhuhai DL Biotech Co.Ltd No.59, Ding Wan 10th Road, Jinwan District, Zhuhai Gong Dong Province, China, 519040 FSC: China Validity: 18-01-2026	DL Automated Blood Culture Bottles Anaerobic Colorimetric Model: (II-1) Class: A	Approved

	Slip # 146786946794	LOA validity 01-03-2026 DoC Certificate Validity :19-11-2033 ISO: 13485 Validity :07-11-2026	Shelf Life : 12 Months	
138.	Pakistan Hospital and Industrial Laboratory Co 36-Abkari Road, New Anarkali, Lahore (ELI-00817) Rs. 6,000 Slip # 52433547996	<u>Legal Manufacturer</u> Zhuhai DL Biotech Co.Ltd No.59, Ding Wan 10th Road, Jinwan District, Zhuhai Gong Dong Province, China, 519040 FSC: China Validity: 18-01-2026 LOA validity 01-03-2026 DoC Certificate Validity :19-11-2033 ISO: 13485 Validity :07-11-2026	DL Automated Blood Culture Bottles Children's (Pediatric) Colorimetric Model: (III-1) Class: A Shelf Life : 12 Months	Approved
139.	Pakistan Hospital and Industrial Laboratory Co 36-Abkari Road, New Anarkali, Lahore (ELI-00817) Rs. 6,000 Slip # 33096867268	<u>Legal Manufacturer</u> Zhuhai DL Biotech Co.Ltd No.59, Ding Wan 10th Road, Jinwan District, Zhuhai Gong Dong Province, China, 519040 FSC: China Validity: 18-01-2026 LOA validity 01-03-2026 DoC Certificate Validity :19-11-2033 ISO: 13485 Validity :07-11-2026	DL Automated Blood Culture System Model: BT24, BT48, BT60, BT120, BT240 Class: A Shelf Life : 10 Years	Approved BT24. The firm shall submit differential fee for sytem before issuance of letter.
140.	Orbit.AR Private Limited, A-1 Block, Plot No. 43, Haji Park, Ferozpur Road Kasur. ELI-00830 7000-P 31,000/-	<u>Legal Manufacturer:</u> Cofee Medical Technology Co., Ltd 816 Zhenhua Road, Yuhua District, Changsha City, Hunan Province, P.R. China. Original FSC: China. Date of Validity: 15-04-2026. LOA validity 30-09-2029 ISO 13485 validity 12-07-	Orbit Blood Glucose Monitoring System Class-B Shelf Life: 5 Years Model: Meter KF-A10-C/ KF-A10	Deferred for the clarification since the firm applied as system but in FSC the meter and strips are mentioned separately. Correct class as The System falls in class-C.

		2025 FQA/CE certificate validity 26-05-2025	Strips KF-A01-C/ KF-A01	
141.	Orbit.AR Private Limited, A-1 Block, Plot No. 43, Haji Park, Ferozpur Road Kasur. ELI-00830 7000-P 31,000/-	Legal Manufacturer: Cofee Medical Technology Co., Ltd 816 Zhenhua Road, Yuhua District, Changsha City, Hunan Province, P.R. China. Original FSC: China. Date of Validity: 15-04-2026. LOA validity 30-09-2029 ISO 13485 validity 12-07-2025 FQA/CE certificate validity 26-05-2025	Orbit Blood Glucose Test Strips Class-B Shelf Life: 2 Years Model: Strips KF-A01-C/ KF-A01	Approved KF-A01-C
142.	Orbit.AR Private Limited, A-1 Block, Plot No. 43, Haji Park, Ferozpur Road Kasur. ELI-00830 1578-P-P 6,000/-	Legal Manufacturer: Cofee Medical Technology Co., Ltd 816 Zhenhua Road, Yuhua District, Changsha City, Hunan Province, P.R. China. Original FSC: China. Date of Validity: 15-04-2026. LOA validity 30-09-2029 ISO 13485 validity 12-07-2025 FQA/CE certificate validity 26-05-2025	ORBIT HCG Pregnancy Test Strip Class-A Shelf Life: 2 years Specifications: 1 test/box, 2 test/box, 5 test/box, 10 test/box, 100test/box,	Deferrd for the provision of revised Form and fee since the device falls in Class-B
143.	Khan Muhammad Enterprises, Street No. 1, Near Dera Saleem Ladhar, Niaz Town Multan. ELI-00879 1573-P 6,000/-	Legal Manufacturer: Guangdong Dayang Medical Technology Co., Ltd Xingxian Development Zone, Changhongling Industrial Park (2nd Phase) Shishan, Nanhai Distric, Foshan, Guangdong, China. FSC: China. Date of Issuance: 17-07-2024 valid for 2 years LOA validity 08-01-2030 ISO 13485 validity 24-06-2025	Walking Stick Class-A Shelf Life: 5 Years Models/codes as per FSC	Approved. The firm shall submit Brand name and fee as per revised SRO for Family i.e 25,000/ up to 20 codes and addition of 5000 as per the code addition.
144.	Khan Muhammad Enterprises, Street No. 1, Near Dera Saleem Ladhar, Niaz Town Multan.	Legal Manufacturer: Guangdong Dayang Medical Technology Co., Ltd Xingxian Development Zone, Changhongling Industrial Park (2nd Phase) Shishan, Nanhai Distric, Foshan,	Commode Chair Class-A Shelf Life: 5 Years	Approved. The firm shall submit Brand name and fee as per revised SRO for Family i.e 25,000/ up to 20 codes and

	ELI-00879 1574-P 6,000/-	Guangdong, China. FSC: China. Date of Issuance: 17-07-2024 valid for 2 years LOA validity 08-01-2030 ISO 13485 validity 24-06-2025	Models as per FSC	addition of 5000 as per the code addition.
145.	Khan Muhammad Enterprises, Street No. 1, Near Dera Saleem Ladhar, Niaz Town Multan. ELI-00879 1575-P 6,000/-	<u>Legal Manufacturer:</u> Guangdong Dayang Medical Technology Co., Ltd Xingxian Development Zone, Changhongling Industrial Park (2nd Phase) Shishan, Nanhai Distric, Foshan, Guangdong, China. FSC: China. Date of Issuance: 17-07-2024 valid for 2 years LOA validity 08-01-2030 ISO 13485 validity 24-06-2025	Walker Class-A Shelf Life: 5 Years Models as per FSC	Approved. The firm shall submit Brand name and fee as per revised SRO for Family i.e 25,000/ up to 20 codes and addition of 5000 as per the code addition.
146.	Khan Muhammad Enterprises, Street No. 1, Near Dera Saleem Ladhar, Niaz Town Multan. ELI-00879 1576-P 6,000/-	<u>Legal Manufacturer:</u> Guangdong Dayang Medical Technology Co., Ltd Xingxian Development Zone, Changhongling Industrial Park (2nd Phase) Shishan, Nanhai Distric, Foshan, Guangdong, China. FSC: China. Date of Issuance: 17-07-2024 valid for 2 years LOA validity 08-01-2030 ISO 13485 validity 24-06-2025	Manual Wheelchair Class-A Shelf Life: 5 Years Models as per FSC	Approved. The firm shall submit Brand name and fee as per revised SRO for Family i.e 25,000/ up to 20 codes and addition of 5k as per the code addition.
147.	Medical Equipment & Systems, 60/61 F.C.C Syed Maratib Ali Road Gulberg IV, Lahore, 54000, Pakistan. ELI-00554 7021-P	<u>Legal Manufacturer:</u> APELEM 9 Avenue du canal Philippe Lamour - 30660 - Gallargues-le-Montueux-France. <u>Manufacturing site:</u> Technix S.p.A. located at Via E. Fermi, 45-24050, Grassobbio BG - Italy FSC: Italy. Date of Issuance: 02-04-2024 LOA validity 31-12-2025 ISO 13485 validity 04-05-	EVO+, EVO R+ Mobile fluoroscopic / radiographic unit Class-C Shelf Life: 10 Years	Deferred for the provision of following: Original and valid legalized/notrized documents. The provided FSC mentioned only the manufacturing site not the legal manufacture. document showing link b/w the legal

		2027 FQA certificate validity 04-05-2023		<p>manufacturer and the manufacturing site located at Italy.</p> <p>Justification for applying two system in a Family EVO+ and EVO R+.</p> <p>Valid FQA certificate</p> <p>Fee Challan is missing.</p> <p>ISO 13485 of manufacturing site is missing.</p>
148.	<p>Medical Equipment & Systems, 60/61 F.C.C Syed Maratib Ali Road Gulberg IV, Lahore, 54000, Pakistan.</p> <p>ELI-00554 7022-P</p>	<p><u>Legal Manufacturer:</u> APELEM 9 Avenue du canal Philippe Lamour - 30660 - Gallargues-le-Montueux-France.</p> <p>FSC: France. Date of Issuance: 20-03-2023. LOA validity 31-12-2025 ISO 13485 validity 04-05-2027 FQA certificate validity 04-05-2023</p>	<p>MEDIX DR X-ray bone densitometer</p> <p>Class-C</p> <p>Shelf Life: N/A</p> <p>Model: MEDIX DR</p>	<p>Deferred for the provision of following:</p> <p>Original legalized/notrized documents as per application form.</p> <p>Valid FQA certificate</p> <p>Fee Challan.</p>
149.	<p>Raffay Associates, Office No. 04, 2nd Floor Ahmed Plaza Range Road, Rawalpindi.</p> <p>ELI-00021 7049-P 62,000/-</p>	<p><u>Legal Manufacturer:</u> S&G Biotech Inc. 82 Bugok-ro, Pogok-eup, Cheoin-gu, Yongin-Si, Gyeonggi-do, Korea (PO) 17023</p> <p>Original FSC: Korea. Date of Issuance: 06-03-2024. LOA issuance 16-01-2024 ISO 13485 validity 19-12-2026</p>	<p>Seal Bifurcated Stent Graft Extension</p> <p>Class-C</p> <p>Shelf Life: 3 Years</p> <p>Codes as per FSC</p>	<p>Deferred for the provision of original lregalized FSC of reference country or nortized CE marked document.</p> <p>Applied as Family total 54 codes, fee as per revised SRO.</p>
150.	<p>Raffay Associates, Office No. 04, 2nd Floor Ahmed Plaza Range Road,</p>	<p><u>Legal Manufacturer:</u> S&G Biotech Inc. 82 Bugok-ro, Pogok-eup, Cheoin-gu, Yongin-Si, Gyeonggi-do, Korea (PO) 17023</p>	<p>Seal e-PTFE Partial Covered Stent</p> <p>Class-C</p>	<p>Deferred for the provision of original lregalized FSC of reference country or nortized CE marked document</p>

	Rawalpindi. ELI-00021 7050-P 62,000/-	Original FSC: Korea. Date of Issuance: 06-03-2024. LOA issuance 16-01-2024 ISO 13485 validity 19-12-2026	Shelf Life: 3 Years Codes as per FSC	Applied as Family total 48 codes, fee as per revised SRO.
151.	Audi-Med Pakistan, 63/3A, Block D-1, Gulberg-III, Sir Syed Road, Opposite Hijaz Hospital, Lahore, Pakistan. ELI-00596 7016-P 31,000/-	<u>Legal Manufacturer:</u> Interacoustics A/S Audiometer Alle 1 Middelfart, Denmark. Original FSC: Denmark Date of Validity: 03-04-2025. LOA validity 31-12-2025 ISO 13485 validity 28-11-2025 EU QMS (MDR) validity 09-09-2026	Interacoustics PA5 Screening Audiometer Class-B Shelf Life: N/A Model: PA5	Approved. The firm shall submit valid original FSC and shelf life.
152.	Audi-Med Pakistan, 63/3A, Block D-1, Gulberg-III, Sir Syed Road, Opposite Hijaz Hospital, Lahore, Pakistan. ELI-00596 7017-P 31,000/-	<u>Legal Manufacturer:</u> Interacoustics A/S Audiometer Alle 1 Middelfart, Denmark. Original FSC: Denmark Date of Validity: 03-04-2025. LOA validity 31-12-2025 ISO 13485 validity 28-11-2025 EU QMS (MDR) validity 09-09-2026	Interacoustics Titan Auditory Analysis Platform Class-B Shelf Life: N/A Model: TITAN	Approved. The firm shall submit valid original FSC and shelf life
153.	Audi-Med Pakistan, 63/3A, Block D-1, Gulberg-III, Sir Syed Road, Opposite Hijaz Hospital, Lahore, Pakistan. ELI-00596 7018-P 31,000/-	<u>Legal Manufacturer:</u> Interacoustics A/S Audiometer Alle 1 Middelfart, Denmark. Original FSC: Denmark Date of Validity: 03-04-2025. LOA validity 31-12-2025 ISO 13485 validity 28-11-2025 EU QMS (MDR) validity 09-09-2026	Interacoustics Eclipse Medical PC Platform Class-B Shelf Life: N/A Model: Eclipse	Approved. The firm shall submit valid original FSC and shelf life
154.	Audi-Med Pakistan, 63/3A, Block D-1, Gulberg-III, Sir Syed Road, Opposite Hijaz Hospital, Lahore, Pakistan. ELI-00596	<u>Legal Manufacturer:</u> Interacoustics A/S Audiometer Alle 1 Middelfart, Denmark. Original FSC: Denmark Date of Validity: 03-04-2025. LOA validity 31-12-2025 ISO 13485 validity 28-11-2025	Interacoustics AD226 Diagnostic Audiometer Class-B Shelf Life: N/A Model: AD226	Approved. The firm shall submit valid original FSC and shelf life

	7019-P 31,000/-	EU QMS (MDR) validity 09-09-2026		
155.	Audi-Med Pakistan, 63/3A, Block D-1, Gulberg-III, Sir Syed Road, Opposite Hijaz Hospital, Lahore, Pakistan. ELI-00596 7020-P 31,000/-	Legal Manufacturer: Interacoustics A/S Audiometer Alle 1 Middelfart, Denmark. Original FSC: Denmark Date of Validity: 03-04-2025. LOA validity 31-12-2025 ISO 13485 validity 28-11-2025 EU QMS (MDR) validity 09-09-2026	Interacoustics Affinity Compact Universal Audio Analyzer Platform Class-B Shelf Life: N/A Model: Affinity Compact	Approved. The firm shall submit valid original FSC and shelf life
156.	Cabbot Surgicals, 09 Rose Lane 1 Gulberg Avenue New Lalazar Rawalpindi 46000. ELI-00415 6039-P 62,000/-	Legal Manufacturer: Suzhou Kangli Orthopedics Instrument Co., Ltd Nanyuan East Road, Tangqiao Town, Zhangjiagang City, Jiangsu Province. FSC: China Validity: 08-04-2025. LOA validity 20-05-2027 ISO 13485 validity 28-11-2025 CE with extension letter 26-05-2024	Kangli Non-Sterile Bone Screws Class-C Shelf Life: 5 Years Codes/model as per FSC: JD (Metal bone screw, non-anodized, non-sterile with Shallow thread, Spherical and taper head type.	Approved The firm shall submit Original and valid FSC and differential fee as per new SRO before the issuance of registration letter.
157.	Cabbot Surgicals, 09 Rose Lane 1 Gulberg Avenue New Lalazar Rawalpindi 46000. ELI-00415 6040-P 62,000/-	Legal Manufacturer: Suzhou Kangli Orthopedics Instrument Co., Ltd Nanyuan East Road, Tangqiao Town, Zhangjiagang City, Jiangsu Province. FSC: China Validity: 08-04-2025. LOA validity 20-05-2027 ISO 13485 validity 28-11-2025 CE with extension letter 26-05-2024	Kangli Non-Sterile Spinal System Class-C Shelf Life: 5 Years Codes/model as per FSC: JZ/P-I Type Spinal fixation, common type, non-anodized, non-sterile I type	Approved JZ/P-I Type Spinal fixation, common type, non- anodized, non-sterile I type. The firm shall submit Original and valid FSC and differential fee as per new SRO before the issuance of registration letter.
158.	Cabbot Surgicals, 09 Rose Lane 1 Gulberg Avenue New Lalazar Rawalpindi 46000. ELI-00415 6041-P	Legal Manufacturer: Suzhou Kangli Orthopedics Instrument Co., Ltd Nanyuan East Road, Tangqiao Town, Zhangjiagang City, Jiangsu Province. FSC: China	Kangli Non-Sterile Intramedullary Nailing Systems Class-C Shelf Life: 5 Years Codes/model as per FSC:	Approved SJDS(K) Angle Intramedullary Nail (Angle intramedullary nail, solid, non- anodized, non-sterile. The firm shall submit Original and valid

	62,000/-	Validity: 08-04-2025. LOA validity 20-05-2027 ISO 13485 validity 28-11-2025 CE with extension letter 26-05-2024	SJDS(K) Angle Intramedullary Nail (Angle intramedullary nail, solid, non-anodized, non-sterile.	FSC and differential fee as per new SRO before the issuance of registration letter.
159.	Cabbot Surgicals, 09 Rose Lane 1 Gulberg Avenue New Lalazar Rawalpindi 46000. ELI-00415 6042-P 62,000/-	<u>Legal Manufacturer:</u> Suzhou Kangli Orthopedics Instrument Co., Ltd Nanyuan East Road, Tangqiao Town, Zhangjiagang City, Jiangsu Province. FSC: China Validity: 08-04-2025. LOA validity 20-05-2027 ISO 13485 validity 28-11-2025 CE with extension letter 26-05-2024	Kangli Non-Sterile, Metal Straight Bone Plate Class-C Shelf Life: 5 Years Codes/model as per FSC: ZB, Stainless steel type.	Approved. The firm shall submit Original and valid FSC and differential fee as per new SRO before the issuance of registration letter.
160.	Cabbot Surgicals, 09 Rose Lane 1 Gulberg Avenue New Lalazar Rawalpindi 46000. ELI-00415 6030-P 62,000/-	<u>Legal Manufacturer:</u> Tian Xin Fu (Beijing) Medical Appliance Co. Ltd No. 30 Huoju Street, Science Park, Changping District, Beijing, China. Original FSC: China. Validity: 01-07-2025. LOA validity 31-12-2029 ISO 13485 validity 05-08-2027	DuraFrame Biological Membrane (Artificial Dura / Artificial Spinal Dura) Class-C Shelf Life: 3 Years Codes/sizes as per FSC	Deferred for the provision of following: Originl legalized FSC of reference country or notarized CE certificate. The Brand mentioned on LOA is Tech Thinkful but firm applied DuraFrame, clarification is required. Justification for applying Duraframe with both dura artificial and Spinal Dura applied in single application.
161.	Cabbot Surgicals, 09 Rose Lane 1 Gulberg Avenue New Lalazar Rawalpindi 46000. ELI-00415 6040-P 62,000/-	<u>Legal Manufacturer:</u> Changzhou Haida Medical Equipment Co., Ltd Sanhekou Industrial Zone, Zhenglu Town, Tianning Dist., Changzhou City, Jiangsu Province, China. FSC: Germany Date of Issuance: 11-03-	Disposable Skin Stapler Class-C Shelf Life: 5 Years Product Codes: HPF-15A, HPF-15B, HPF-25A, HPF-25B,	Deferred for the provision of following: Original legalized/notrized documents a sper application form Original Fee challan.

		2024. FSC: China. Date of Validity: 06-08-2024. LOA validity 01-03-2030 ISO 13485 validity 28-02-2025 FQA certificate validity 26-05-2024	HPF-35A, HPF-35B, HPF-45A, HPF-45B; Stapler Remover: HPF-C	ISO 13485 is expired. Fee is not as per the revised SRO for Family. Brand name.
162.	Cabbot Surgicals, 09 Rose Lane 1 Gulberg Avenue New Lalazar Rawalpindi 46000. ELI-00415 6041-P 62,000/-	Legal Manufacturer: Changzhou Haida Medical Equipment Co., Ltd Sanhekou Industrial Zone, Zhenglu Town, Tianning Dist., Changzhou City, Jiangsu Province, China. FSC: Germany Date of Issuance: 11-03-2024. FSC: China. Date of Validity: 06-08-2024. LOA validity 01-03-2030 ISO 13485 validity 28-02-2025 FQA certificate validity 26-05-2024	Disposable Linear Cutter Stapler Disposable Linear Cutter Stapler Class-C Shelf Life: 5 Years Product Code: HQ-60L/M/H, HQ-80L/M/H, HQ-100L/M/H; HQZ-60L/M/H, HQZ-80L/M/H, HQZ-100L/M/H, HDQ-60L, HDQ-60M, HDQ-60H, HDQ-80L, HDQ-/80M, HDQ-80H, HDQ-100L, HDQ-100M, HDQ-100H, HDQZ-60L, HDQZ-60M, HDQZ-60H, HDQZ-80L, HDQZ-80M, HDQZ-80H, HDQZ-100L, HDQZ-100M, HDQZ-100H.	Deferred for the provision of following: Original legalized/notrized documents a sper application form Original Fee challan. ISO 13485 is expired. Fee is not as per the revised SRO for Family. Brand name.
163.	Bio Indus, B-526, B Satellite Town, Rawalpindi. ELI-00979	(Legal Manufacturer) Name: M/s Zhejiang CuraWay Medical Technology Co. Ltd. located at Room 106, Building 1, No. 600, 21st Avenue, Baiyang Sub-district, Qiantang New	CuraWay Bone Marrow Biopsy Needle Models / Sizes: BNMAB-1-1.2(18G)/25 、BNMAB-1-	Deferred for the provision of following: Valid and notarized QMS certificate

		<p>District, 310018 Hangzhou City, Zhejiang Province, China</p> <p>Free Sale Certificate Validity: (21-07-2026)</p> <p>ISO 13485 certificate validity: (missing)</p> <p>EC certificate Validity: (not provided)</p> <p>Letter of authorization: Validity: 31-12-2026</p> <p>510(K) Number: K242322</p>	<p>1.2(18G)/40、BNMAB-1-1.2(18G)/55、BNMAB-1-1.6(16G)/25、BNMAB-1-1.6(16G)/40、BNMAB-1-1.6(16G)/55、BNMAB-1-1.8(15G)/25、BNMAB-1-1.8(15G)/40、BNMAB-1-1.8(15G)/55、BNMAB-1-2.1(14G)/25、BNMAB-1-2.1(14G)/40、BNMAB-1-2.1(14G)/55、BNMA/CB-1-3.5(9G)/70 BNMA/CB-1-3.5(9G)/100 BNMA/CB-1-3.5(9G)/150 BNMA/CB-1-3.0(11G)/70 BNMA/CB-13.0(11G)/100 BNMA/CB-13.0(11G)/150 BNMA/CB-1-2.4(13G)/70 BNMA/CB-12.4(13G)/100 BNMA/CB-12.4(13G)/150 BNMAB-1F-1.2(18G)/25 BNMAB-1F-1.2(18G)/40 BNMAB-1F-1.2(18G)/55 BNMAB-1F-1.6(16G)/25 BNMAB-1F-1.6(16G)/40 BNMAB-1F-1.6(16G)/55 BNMAB-1F-1.8(15G)/25 BNMAB-1F-1.8(15G)/40 BNMAB-1F-1.8(15G)/55 BNMAB-1F-2.1(14G)/25</p>	<p>Valid and notarized FQA certificate/legalized FSC Of SRA.</p> <p>The subject device falls in Class-C, so revised form and fee is required.</p>
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			BNMA-B-1F- 2.1(14G)/40 BNMA-B-1F- 2.1(14G)/55 BNMA/CB-1F- 3.5(9G)/70 BNMA/CB- 1F3.5(9G)/100 BNMA/CB- 1F3.5(9G)/150 BNMA/CB- 1F3.0(11G)/70 BNMA/CB1F3.0(11G)/1 00 BNMA/CB1F3.0(11G)/1 50 BNMA/CB- 1F2.4(13G)/70 BNMA/CB1F2.4(13G)/1 00 BNMA/CB1F2.4(13G)/1 50 BNMDB-1F- 1.2(18G)/25-3.5(9G)/70 、 BNMDB-1F- 1.2(18G)/25-3.5(9G)/100 、 BNMDB-1F- 1.2(18G)/25-3.5(9G)/150 、 BNMDB-1F- 1.2(18G)/25-3.0(11G)/70 、 BNMDB-1F- 1.2(18G)/25- 3.0(11G)/100、 BNMDB-1F- 1.2(18G)/25- 3.0(11G)/150、 BNMDB-1F- 1.2(18G)/25-2.4(13G)/70 、 BNMDB-1F- 1.2(18G)/25- 2.4(13G)/100、 BNMDB-1F- 1.2(18G)/25- 2.4(13G)/150、 BNMDB-1F- 1.2(18G)/40-3.5(9G)/70 、	
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			BNMDB-1F- 1.2(18G)/40-3.5(9G)/100 、 BNMDB-1F- 1.2(18G)/40-3.5(9G)/150 、 BNMDB-1F- 1.2(18G)/40-3.0(11G)/70 、 BNMDB-1F- 1.2(18G)/40- 3.0(11G)/100、 BNMDB-1F- 1.2(18G)/40- 3.0(11G)/150、 BNMDB-1F- 1.2(18G)/40-2.4(13G)/70 、 BNMDB-1F- 1.2(18G)/40- 2.4(13G)/100、 BNMDB-1F- 1.2(18G)/40- 2.4(13G)/150、 BNMDB-1F- 1.2(18G)/55-3.5(9G)/70 、 BNMDB-1F- 1.2(18G)/55-3.5(9G)/100 、 BNMDB-1F- 1.2(18G)/55-3.5(9G)/150 、 BNMDB-1F- 1.2(18G)/55-3.0(11G)/70 、 BNMDB-1F- 1.2(18G)/55- 3.0(11G)/100、 BNMDB-1F- 1.2(18G)/55- 3.0(11G)/150、 BNMDB-1F- 1.2(18G)/55-2.4(13G)/70 、 BNMDB-1F- 1.2(18G)/55- 2.4(13G)/100、 BNMDB-1F- 1.2(18G)/55- 2.4(13G)/150	
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			BNMDB-1F- 1.6(16G)/25-3.5(9G)/70 、 BNMDB-1F- 1.6(16G)/25-3.5(9G)/100 、 BNMDB-1F- 1.6(16G)/25-3.5(9G)/150 、 BNMDB-1F- 1.6(16G)/25-3.0(11G)/70 、 BNMDB-1F- 1.6(16G)/25- 3.0(11G)/100、 BNMDB-1F- 1.6(16G)/25- 3.0(11G)/150、 BNMDB-1F- 1.6(16G)/25-2.4(13G)/70 、 BNMDB-1F- 1.6(16G)/25- 2.4(13G)/100、 BNMDB-1F- 1.6(16G)/25- 2.4(13G)/150、 BNMDB-1F- 1.6(16G)/40-3.5(9G)/70 、 BNMDB-1F- 1.6(16G)/40-3.5(9G)/100 、 BNMDB-1F- 1.6(16G)/40-3.5(9G)/150 、 BNMDB-1F- 1.6(16G)/40-3.0(11G)/70 、 BNMDB-1F- 1.6(16G)/40- 3.0(11G)/100、 BNMDB-1F- 1.6(16G)/40- 3.0(11G)/150、 BNMDB-1F- 1.6(16G)/40-2.4(13G)/70 、 BNMDB-1F- 1.6(16G)/40- 2.4(13G)/100、	
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			BNMDB-1F- 1.6(16G)/40- 2.4(13G)/150、 BNMDB-1F- 1.6(16G)/55-3.5(9G)/70 、 BNMDB-1F- 1.6(16G)/55-3.5(9G)/100 、 BNMDB-1F- 1.6(16G)/55-3.5(9G)/150 、 BNMDB-1F- 1.6(16G)/55-3.0(11G)/70 、 BNMDB-1F- 1.6(16G)/55- 3.0(11G)/100、 BNMDB-1F- 1.6(16G)/55- 3.0(11G)/150、 BNMDB-1F- 1.6(16G)/55-2.4(13G)/70 、 BNMDB-1F- 1.6(16G)/55- 2.4(13G)/100、 BNMDB-1F- 1.6(16G)/55- 2.4(13G)/150、 BNMDB-1F- 1.8(15G)/25-3.5(9G)/70 、 BNMDB-1F- 1.8(15G)/25-3.5(9G)/100 、 BNMDB-1F- 1.8(15G)/25-3.5(9G)/150 、 BNMDB-1F- 1.8(15G)/25-3.0(11G)/70 、 BNMDB-1F- 1.8(15G)/25- 3.0(11G)/100、 BNMDB-1F- 1.8(15G)/25- 3.0(11G)/150、 BNMDB-1F- 1.8(15G)/25-2.4(13G)/70 、	
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			BNMDB-1F- 1.8(15G)/25- 2.4(13G)/100、 BNMDB-1F- 1.8(15G)/25- 2.4(13G)/150、 BNMDB-1F- 1.8(15G)/40-3.5(9G)/70 、 BNMDB-1F- 1.8(15G)/40-3.5(9G)/100 、 BNMDB-1F- 1.8(15G)/40-3.5(9G)/150 、 BNMDB-1F- 1.8(15G)/40-3.0(11G)/70 、 BNMDB-1F- 1.8(15G)/40- 3.0(11G)/100、 BNMDB-1F- 1.8(15G)/40- 3.0(11G)/150、 BNMDB-1F- 1.8(15G)/40-2.4(13G)/70 、 BNMDB-1F- 1.8(15G)/40- 2.4(13G)/100、 BNMDB-1F- 1.8(15G)/40- 2.4(13G)/150、 BNMDB-1F- 1.8(15G)/55-3.5(9G)/70 、 BNMDB-1F- 1.8(15G)/55-3.5(9G)/100 、 BNMDB-1F- 1.8(15G)/55-3.5(9G)/150 、 BNMDB-1F- 1.8(15G)/55-3.0(11G)/70 、 BNMDB-1F- 1.8(15G)/55- 3.0(11G)/100、 BNMDB-1F- 1.8(15G)/55- 3.0(11G)/150、	
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			BNMDB-1F- 1.8(15G)/55-2.4(13G)/70 、 BNMDB-1F- 1.8(15G)/55- 2.4(13G)/100、 BNMDB-1F- 1.8(15G)/55- 2.4(13G)/150、 BNMDB-1F- 2.1(14G)/25-3.5(9G)/70 、 BNMDB-1F- 2.1(14G)/25-3.5(9G)/100 、 BNMDB-1F- 2.1(14G)/25-3.5(9G)/150 、 BNMDB-1F- 2.1(14G)/25-3.0(11G)/70 、 BNMDB-1F- 2.1(14G)/25- 3.0(11G)/100、 BNMDB-1F- 2.1(14G)/25- 3.0(11G)/150、 BNMDB-1F- 2.1(14G)/25-2.4(13G)/70 、 BNMDB-1F- 2.1(14G)/25- 2.4(13G)/100、 BNMDB-1F- 2.1(14G)/25- 2.4(13G)/150、 BNMDB-1F- 2.1(14G)/40-3.5(9G)/70 、 BNMDB-1F- 2.1(14G)/40-3.5(9G)/100 、 BNMDB-1F- 2.1(14G)/40-3.5(9G)/150 、 BNMDB-1F- 2.1(14G)/40-3.0(11G)/70 、 BNMDB-1F- 2.1(14G)/40- 3.0(11G)/100、	
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			BNMDB-1F-2.1(14G)/40-3.0(11G)/150、 BNMDB-1F-2.1(14G)/40-2.4(13G)/70 、 BNMDB-1F-2.1(14G)/40-2.4(13G)/100、 BNMDB-1F-2.1(14G)/40-2.4(13G)/150、 BNMDB-1F-2.1(14G)/55-3.5(9G)/70 、 BNMDB-1F-2.1(14G)/55-3.5(9G)/100 BNMDB-1F-2.1(14G)/55-3.5(9G)/150 、 BNMDB-1F-2.1(14G)/55-3.0(11G)/70 、 BNMDB-1F-2.1(14G)/55-3.0(11G)/100、 BNMDB-1F-2.1(14G)/55-3.0(11G)/150、 BNMDB-1F-2.1(14G)/55-2.4(13G)/70 、 BNMDB-1F-2.1(14G)/55-2.4(13G)/100、 BNMDB-1F-2.1(14G)/55-2.4(13G)/150、 Class-B Shelf life: 3 Years	
164.	Medi Hope Enterprises, House # 38/1, Rose Line # 4 New Lalazar	Legal Manufacturer: Zhejiang Ekang Medical Technology Co., Ltd South Village, Hongqiao Town, Yueqing City,	Medi-Fine Non-Woven Adhesive Tapes Class-A	Approved

	Morgha, Rawalpindi. ELI-00707 1562-P 6,000/-	Zhejiang Province, China. Original FSC: China. Validity: 09-03-2026. LOA validity 09-12-2025 ISO 13485 validity 25-05-2026	Shelf Life: 5 Years Sizes as per FSC	
165.	Medi Hope Enterprises, House # 38/1, Rose Line # 4 New Lalazar Morgha, Rawalpindi. ELI-00707 1562-P 6,000/-	Legal Manufacturer: Zhejiang Ekang Medical Technology Co., Ltd South Village, Hongqiao Town, Yueqing City, Zhejiang Province, China. Original FSC: China. Validity: 09-03-2026. LOA validity 09-12-2025 ISO 13485 validity 25-05-2026	Medi-Fine Band-Aid (Wound Plaster) First-Aid Plaster Class-A Shelf Life: 5 Years Sizes as per FSC	Approved
166.	Medi Hope Enterprises, House # 38/1, Rose Line # 4 New Lalazar Morgha, Rawalpindi. ELI-00707 1562-P 6,000/-	Legal Manufacturer: Zhejiang Ekang Medical Technology Co., Ltd South Village, Hongqiao Town, Yueqing City, Zhejiang Province, China. Original FSC: China. Validity: 09-03-2026. LOA validity 09-12-2025 ISO 13485 validity 25-05-2026	Medi-Fine Polyethylene Film Tape (PE Tapes) Class-A Shelf Life: 5 Years Sizes as per FSC	Approved
167.	Medi Hope Enterprises, House # 38/1, Rose Line # 4 New Lalazar Morgha, Rawalpindi. ELI-00707 1562-P 6,000/-	Legal Manufacturer: Zhejiang Ekang Medical Technology Co., Ltd South Village, Hongqiao Town, Yueqing City, Zhejiang Province, China. Original FSC: China. Validity: 09-03-2026. LOA validity 09-12-2025 ISO 13485 validity 25-05-2026	Medi-Fine Zinc Oxide Adhesive Plaster Class-A Shelf Life: 5 Years Sizes as per FSC	Approved
168.	M/S Rehabilitation Center For Hearing Impaired (Pvt.) Ltd. Ghafoor Plaza, 289-Ferozpur Road, 12-L Gulberg Lahore. (ELI-01209)	(Legal Manufacturer) Name: "WSAUD A/S" Nymollevvej 6 DK-3540 Lyng Denmark MANUFACTURING SITES: 1. Widex A/S, Nymollevvej 6 DK-3540 Lyng Denmark	Brand Name: Widex Generic: Hearing Aid Accessories & Components, Ear Impression & Ear Mould Materials Models / Sizes: 1) EVOKE 2) MOMENT	Deferred for the clarification of applied models and Hearing Aid Accessories & Components, Ear Impression & Ear Mould Materials. Also specify your priority regarding any

	<p>R& I Date: (12/06/2024)</p> <p>Fee details: Amount paid: PKR 25,030/- Paid Slip / challan No.: 323810697 Dated: (05/04/2024)</p>	<p>2. Sivantos Pte.Ltd. 18 Tai Seng Street, #08-08 Singapore 539775</p> <p>Free Sale Certificate Validity: (Evoke, Magnify, Moment: 27-05-2026 and Impact: 17-12-2026)</p> <p>ISO 13485 certificate validity: (30-11-2025)</p> <p>EC certificate Validity: (31-12-2028)</p> <p>Letter of authorization: Validity: (30-09-2029)</p>	<p>3) MAGNIFY 4) IMPACT</p> <p>Class-B</p> <p>Shelf life: 5 years</p>	<p>one model.</p>
169.	<p>Cardioline Systems (Pvt) Ltd, H. No. 168, Block-E PIA Housing Society, Johar Town Lahore.</p> <p>ELI-01265 6025-P Fee 31,000/-</p>	<p>Legal Manufacturer: Anntommed Medical Ltd. 5/F, Building A6, Yinlong Industrial Zone, 292, Shenshan Road, Longgang District, Shenzhen 518116, Guangdong, China.</p> <p>FSC: China. Date of Issuance: 12-01-2023. FSC of Germany issuance 21-02-2020 ISO 13485 validity 13-11-2027 CE with notification.</p>	<p>Balloon Inflation Device Inflation Device</p> <p>Class-B</p> <p>Shelf Life: 3 Years</p>	<p>Deferred for the provision of following:</p> <p>Original, valid and notarized LOA.</p> <p>Credentials of manufacturer abroad.</p> <p>Original legalized FSC.</p> <p>ISO 13485 and CE are without notarization.</p> <p>Declaration of conformity.</p> <p>Stability studies for the claimed shelf life.</p> <p>Clarification regarding the address of manufacturer as per FSC</p>
170.	<p>Cardioline Systems (Pvt) Ltd, H. No. 168, Block-E PIA Housing Society, Johar Town Lahore.</p>	<p>Legal Manufacturer: Princeton Medical Scientific Co., Ltd RM503, Building C, No. 8 Fukang West Street, Yushu Industrial Park, Guangzhou Science City, Luogang District, Guangzhou, 510663,</p>	<p>URETERAL ACCESS SHEATH URETERAL ACCESS SHEATH</p> <p>Class-D</p> <p>Shelf Life: 3 Year</p>	<p>Deferred for the provision of following:</p> <p>Original, valid and notarized/legalized documents as per application form.</p>

	<p>ELI-01265 6026-P Fee 31,000/-</p>	<p>China.</p> <p>FSC: China. Validity: 01-11-2025. LOA validity 31-12-2026 ISO 13485 validity 23-11-2027 CE certificate validity 26-05-2024</p>		<p>Credentials of manufacturer abroad.</p> <p>Original legalized FSC of country of origin.</p> <p>Notrized ISO 13485. Notarized CE/ FSC of SRA country.</p> <p>Stability studies for the claimed shelf life.</p> <p>Brand name of the device.</p> <p>Address clarification of legal manufacturer, in agreement only Room 503 is mentioned whereas in FSC room 501 is also mentioned in addition to 503.</p>
171.	<p>M/s JAWAD SURGICAL Address: Office 13 Naz Medicine Market Namak Mandi Peshawar ELI-00913</p> <p>R&I details 26 SEP 2024</p> <p>Fee Rs. 6,000/ through slip no. 99748062, dated 09-09-2024</p>	<p>(Legal Manufacturer) Jiangsu TaiMedical Technology Co.,Ltd Building1,56 Youshan Road,Gaochun Economic Development Zone,Nanjing City,Jiangsu Province 211300</p> <p>LOA: Validity: 28-Aug-2029</p> <p>FSC: Validity: 02-08-2026</p> <p>ISO-13485: Validity: 16-08-2026</p>	<p>NEO MEDICAL Surgical Paper Tape)</p> <p>Class-A</p> <p>Shelf Life :3 years</p> <p>Code/ Sizes: (10-10000mm) *(10-300mm)</p>	<p>Approved</p>
172.	<p>Diamond Star International, F-115 First Floor Glass Tower Adjacent PSO Head Office Clifton Karachi</p>	<p>O-TWO Medical Technologies Inc., 45A Armthorpe Road, Brampton, Ontario, Canada L6T 5M</p> <p>Copy of LOA issu date 2.19.2022 valid till 2.19.2026</p>	<p>Breathing Circuit</p> <p>Class B 02 years</p> <p>Fee 310000/-</p>	<p>Deferred for following:</p> <p>Provide Legalized and valid FSC as the firm has provided E-manufacturer certificaite to export</p>

	(ELI-00629) Application 21.02.2025	FSC digitally signed issued on 20.02.2025 ISO valid till 19.09.2027 CE provided		licensed medical device from Canada signed by regulatory manager. The name in the FSC is O-Two ventilation circuit for E series electronic transport ventilators Stability studies not provided
173.	Jasani Scientifics, SC-45, Marium Square, Chadni Chowk, Stadium Road, Karachi. (ELI-00416 Application Submitted: 10.02.2025	Huvitz Co., LTD. (1F, 4F-section, 5F-section) 38 Burim-ro 170beon-gil, Dongan-gu, Anyang-si, Gyeonggi-do, Korea Rep Notarized FSC issue date: : 31-07-2024 LOA issue date 01.01.2024 valid till 01.01.2029 ISO13485 16.08.2026 FQA valid till 26.05.2024 and extension letter provided	Ophthalmic Refractometer Auto Ref/Keratometer (HRK- 8100A) Class B Shelf life 07 years	Deferred for the provision of following: Stability studies. the product is not mentioned in LOA. The code not reflected in FSC and CE certificate clarify and submit evidence.
174.	Roche Pakistan Limited. 1st Floor, 37- B, Block 6, P.E.C.H.S, Karachi. (ELI- 00009) R&I: 19/02/2025	Legal Manufacturer: Roche Diabetes Care GmbH, Sandhofer Str.116, 68305 Mannheim, Germany Manufacturing Site: Flextronics Romania S.R.L Calea Torontalului DN6, km 5.7, RO-300000 Timisoara Romania FSC: Germany issue date 27.01.2025 LOA Validity: 17-01-2028 EU QMS Certificate: Validity: 12-09-2025	Accu-Chek Smart Guide Device Class: C Fees: 62,000/- Product Name: 1. Accu-Chek Smart Guide Device CAT #: 09907050343 Pack size: One Unit Shelf life: 12 months at 2-27°C	Approved. Firm shall sub,it stability sata of 12 months.

		ISO 13485: Validity of Legal Mfg: 31-10-2027 Validity of Phy. Mfg: 18-03-2026		
175.	Roche Pakistan Limited. 1st Floor, 37- B, Block 6, P.E.C.H.S, Karachi. (ELI-00009) R&I: 12/03/2025	Legal Manufacturer: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany Manufacturing Site: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany Embassy attested FSC: Germany Issuance Date: 27-08-2024 LOA Issu date 2.10.2023 Validity: 17-01-2028 EU QMS Certificate: Validity: 14-12-2025 ISO 13485: Validity: 29-06-2027	HSCR P Class: C Fees: 62,000/- Product Name: 1. HSCR P CAT #: 09188266190 Pack size: 250 Tests Shelf life: 25 months at 2-8°C 2. HSCR P CAT #: 09188240190 Pack size: 300 Tests Shelf life: 25 months at 2-8°C 3. HSCR P CAT #: 09188231190 Pack size: 500 Tests Shelf life: 25 months at 2-8°C	Approved
176.	Roche Pakistan Limited. 1st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009) R&I: 27/03/2025	Legal Manufacturer: Ventana Medical Systems, Inc. 1910 E. Innovation Park Dr. Tucson, AZ 85711 USA Manufacturing Site: Ventana Medical Systems, Inc. 1910 E. Innovation Park Dr. Tucson, AZ 85711 USA Apostille FSC: CFG, USA. Validity: 20-08-2026 Copy LOA Validity: 17-01-2028 ISO 13485:	SSR Solution Class: A Fees: 6,000/- 1. SSR Solution CAT # 06890059001 Pack size: 2 L Shelf life: 24 months at 15 - 30°C	Approved

		Validity: 19-08-2027		
177.	Roche Pakistan Limited. 1st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009) R&I: 12/03/2025	Legal Manufacturer: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany Manufacturing Site: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany & Roche Diagnostics (Suzhou) Ltd. No.259 Zhongyuan Road 215028 Suzhou, Jiangsu China FSC: Germany Issuance Date: 06-11-2024 01-04-2025 LOA Validity: 17-01-2028 EU QMS Certificate: Validity: 14-12-2025 ISO 13485: Validity: 29-06-2027 Validity: 20-10-2025	Elecsys CEA Class: C Fees: 62,000/- Product Name: 1. Elecsys CEA CAT #: 09755616190 Pack size: 100 Tests Shelf life: 18 months at 2 - 8°C 2. Elecsys CEA CAT #: 04491777190 Pack size: 200 Tests Shelf life: 18 months at 2 - 8°C 3. Elecsys CEA CAT #: 07027079214 Pack size: 300 Tests Shelf life: 18 months at 2 - 8°C	Approved
178.	Roche Pakistan Limited. 1st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009) R&I: 12/03/2025	Legal Manufacturer: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany Manufacturing Site: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany & Roche Diagnostics (Suzhou) Ltd. No.259 Zhongyuan Road 215028 Suzhou, Jiangsu China FSC: Germany 06-11-2024	Elecsys Ferritin Class: B Fees: 31,000/- Product Name: 1. Elecsys Ferritin CAT #: 09755667190 Pack size: 100 Tests Shelf life: 18 months at 2 - 8°C 2. Elecsys Ferritin CAT #: 03737551214 Pack size: 100 Tests Shelf life: 18 months at 2 - 8°C 3. Elecsys Ferritin	Approved

		LOA Validity: 17-01-2028 EU QMS Certificate: Validity: 14-12-2025 ISO 13485: Validity: 29-06-2027 Validity: 20-10-2025	CAT #: 07027273214 Pack size: 300 Tests Shelf life: 18 months at 2 - 8°C	
179.	Roche Pakistan Limited. 1st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009) R&I: 27/03/2025	Legal Manufacturer: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany Manufacturing Site: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany FSC: Germany Issuance Date: 06-11-2024 LOA Validity: 17-01-2028 EU QMS Certificate: Validity: 14-12-2025 ISO 13485: Validity: 29-06-2027	Elecsys PIVKA-II Class: C Fees: 62,000/- Product Name: 1.Elecsys PIVKA-II CAT #: 09652043190 Pack size: 100 Tests Shelf life: 24 months at 2 - 8°C	Approved
180.	Roche Pakistan Limited. 1st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009) R&I: 27/03/2025	Legal Manufacturer: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany Manufacturing Site: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany. FSC: Germany Issuance Date: 06-11-2024	Elecsys Rubella IgM Class: C Fees: 62,000/- Product Name: 1. Elecsys Rubella IgM CAT #: 09755837190 Pack size: 100 Tests Shelf life: 12 months at 2 - 8°C	Approved

		LOA Validity: 17-01-2028 EU QMS Certificate: Validity: 14-12-2025 ISO 13485: Validity: 29-06-2027		
181.	Roche Pakistan Limited. 1st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009) R&I: 12/03/2025	Legal Manufacturer: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany Manufacturing Site: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany FSC: Germany Issuance Date: 06-11-2024 LOA Validity: 17-01-2028 EU QMS Certificate: Validity: 14-12-2025 ISO 13485: Validity: 29-06-2027	Elecsys SHBG Class: B Fees: 31,000/- Product Name: 1. Elecsys SHBG CAT #: 09744495190 Pack size: 100 Tests Shelf life: 18 months at 2 - 8°C	Approved
182.	Roche Pakistan Limited. 1st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009) R&I: 12/03/2025	Legal Manufacturer: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany Manufacturing Site: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany FSC: Germany Issuance Date: 06-11-2024 LOA Validity: 17-01-2028	Elecsys Toxo IgM Class: C Fees: 62,000/- Product Name: 1. Elecsys Toxo IgM CAT #: 09755861190 Pack size: 100 Tests Shelf life: 14 months at 2 - 8°C	Approved

		EU QMS Certificate: Validity: 14-12-2025 ISO 13485: Validity: 29-06-2027		
183.	Roche Pakistan Limited. 1st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009) R&I: 12/03/2025	Legal Manufacturer: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany Manufacturing Site: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany & Roche Diagnostics (Suzhou) Ltd. No.259 Zhongyuan Road 215028 Suzhou, Jiangsu China FSC: Germany Issuance date 06-11-2024 LOA Validity: 17-01-2028 EU QMS Certificate: Validity: 14-12-2025 ISO 13485: Validity: 29-06-2027 Validity: 20-10-2025	Elecsys Vitamin B12 II Class: B Fees: 31,000/- Product Name: 1. Elecsys Vitamin B12 II CAT #: 09755896190 Pack size: 100 Tests Shelf life: 24 months at 2 - 8°C 2. Elecsys Vitamin B12 II CAT #: 07028121214 Pack size: 300 Tests Shelf life: 24 months at 2 - 8°C	Approved
184.	Roche Pakistan Limited. 1st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009) R&I: 12/03/2025	Legal Manufacturer: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany Manufacturing Site: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany & Roche Diagnostics (Suzhou) Ltd. No.259 Zhongyuan Road 215028 Suzhou, Jiangsu China	Elecsys free PSA Class: C Fees: 62,000/- Product Name: 1. Elecsys free PSA CAT #: 09744908190 Pack size: 100 Tests Shelf life: 18 months at 2 - 8°C 2. Elecsys free PSA CAT #: 08828610214 Pack size: 300 Tests	Approved

		FSC: Germany 06-11-2024 LOA Validity: 17-01-2028 EU QMS Certificate: Validity: 14-12-2025 ISO 13485: Validity: 29-06-2027 Validity: 20-10-2025	Shelf life: 18 months at 2 - 8°C	
185.	Ghazali Brothers, 1st Floor, Azzainab Court, Campbell Street Karachi (ELI- 00240) R&I Date 10-03-2025 Fee Rs. 5,000/ Dated 12/10/2023 Challan No. Slip no. 2809985668	Hospital & HomeCare Imp. & EXP, Co., Ltd, Room no. 608-611 No.5 Zhonghtai International Plzaz No. 311, Jiangdong Road, Nanjing China (as per FSC issued by MHRA) Documents submitted: Copy of Sole Agency Agreement validity: 10-02-2028 (attached in file of the product DispoPlus 3way Stopcock) Copy of FSC (MHRA) Valid till: 26-05-2025 EC Certificate: Not provided ISO-13485 Validity: 2025-05-31	ATC Tape (AutoClave Tape) Apply as Single Class: A Shelf life: 5 Years Codes/Sizes: MW231d 12.5mm*50m, 19mm*50m, 25mm*50m	Deferred for the provision of following: Fee of Rs. 5000/- has been submitted instead of Rs. 6000/- LOA not provided. All the original documents (FSC, LOA, ISO etc.) are photocopy without attestation/notarizatio n. FSC of the country of origin (China) is not provided However, the copy of FSC of RRA (MHRA) has been provided. FSC expired. ISO 13485 expired on 26-05-2025 DOC not provided. Difference in the Address of manufacturer as per the application Form & provided Sole Agency Agreement (Room no. 618-611) &

				the FSC issued by MHRA (Room no. 608-611).
186.	<p>Ghazali Brothers, 1st Floor, Azzainab Court, Campbell Street Karachi (ELI- 00240)</p> <p>R&I Date 12th March 2025</p> <p>Fee Rs. 31,000/ Dated 10/03/2025</p> <p>Challan No. Slip no. 2622643894</p>	<p>Hospital & HomeCare Imp. & EXP, Co., Ltd, Room no. 608-611 No.5 Zhongtai International Plzaz No. 311, Jiangdong Road, Nanjing China (as per FSC issued by MHRA)</p> <p>Documents submitted:</p> <p>Copy of Sole Agency Agreement validity: 10-02-2028</p> <p>Copy of FSC (MHRA) Valid till: 26-05-2025</p> <p>EC Certificate: Not provided</p> <p>Copy of ISO-13485 Validity 2025-05-31</p>	<p>DispoPlus 3way Stopcock (with and without Tube)</p> <p>Apply as Single</p> <p>Class: B</p> <p>Shelf life: 5 Years</p> <p>Codes/Sizes N/A</p>	<p>Deferred for the provision of following:</p> <p>The firm applied two different products 3-way stopcock & 3-way stopcock with extension tube in a single application.</p> <p>All the original documents (FSC, LOA, ISO etc.) are photocopy without attestation/notarization.</p> <p>The applied product is not mentioned the provided copy of Sole Agency Agreement.</p> <p>Stability study data not provided.</p> <p>FSC of the country of origin (China) is not provided but the copy of FSC of RRA (MHRA) has been provided, However the applied product is not mentioned the provided FSC.</p> <p>ISO 13485 expired on 26-05-2025</p> <p>Difference in the Address of manufacturer as per the application Form & provided Sole Agency Agreement (Room no. 618-611) & the FSC issued by MHRA (Room no. 608-611)</p>
187.	Ghazali Brothers,	Hospital & HomeCare Imp.	Care Cooling Patch	Deferred for the

	19-SR-7, Azzainab Court Campbell Street, 1st Floor Karachi (ELI-00240) R&I Date 06/03/2025 Fee Rs. 6,000/ Dated 17/02/2025 Challan No. Slip no. 132054343	& EXP, Co., Ltd, Room no. 608-611 No.5 Zhongtai International Plzaz No. 311, Jiangdong Road, Nanjing China (as per FSC issued by MHRA) Documents submitted: Copy of Sole Agency Agreement validity: 10-02-2028 (attached in file of the product DispoPlus 3way Stopcock) Copy of FSC (MHRA) Valid till: 26-05-2025 EC Certificate: Not provided Copy of ISO-13485 Validity 2025-05-31	(Softgel Sheets) Apply as Single Class: A Shelf life: 5 Years Codes/Sizes: MC 10141 5*12, 5*11, 4*11	provision of following: All the original documents (FSC, LOA, ISO etc.) are photocopy without attestation/notarizatio n. FSC of the country of origin (China) is not provided but the copy of FSC of RRA (MHRA) has been provided. FSC expired. ISO 13485 expired on 26-05-2025. Demanded Shelf life is 5 years while the Stability study data shows 3 years shelf life. Difference in the Address of manufacturer as per the application Form & provided Sole Agency Agreement (Room no. 618-611) & the FSC issued by MHRA (Room no. 608-611)
188.	Ghazali Brothers, 19-SR-7, Azzainab Court Campbell Street, 1st Floor Karachi (ELI-00240) R&I Date 06/03/2025 Fee Rs. 5,000 Dated 12/10/2023	Hospital & HomeCare Imp. & EXP, Co., Ltd, Room no. 608-611 No.5 Zhongtai International Plzaz No. 311, Jiangdong Road, Nanjing China (as per FSC issued by MHRA) Documents submitted: Copy of Sole Agency Agreement validity: 10-02-2028 (attached in file of the	Hospital & Homecare Night Drainage Urine Bag Apply as Single Class: A Shelf life: 5 Years Codes/Sizes: MW38B PEDIATRIC 100ML/200ML; ADULT	Deferred for the provision of following: Fee of Rs. 5000/- has been submitted instead of Rs. 6000/- LOA not provided. The firm applied different products like Adult, Pediatric in a single application.

	Challan No. Slip no. 53201856635	product DispoPlus 3way Stopcock) Copy of FSC (MHRA) Valid till: 26-05-2025 EC Certificate: Not provided Copy of ISO-13485 Validity 2025-05-31	2000ML/2500ML	All the original documents (FSC, LOA, ISO etc.) are photocopy without attestation/notarizatio n. FSC of the country of origin (China) is not provided but the copy of FSC of RRA (MHRA) has been provided. FSC expired. ISO 13485 expired on 26-05-2025. Stability study data not provided. Difference in the Address of manufacturer as per the application Form & provided Sole Agency Agreement (Room no. 618-611) & the FSC issued by MHRA (Room no. 608-611)
189.	Ghazali Brothers, 19-SR-7, Azzainab Court Campbell Street, 1st Floor Karachi (ELI-00240) R&I Date 06/03/2025 Fee Rs. 6,000/ Dated 17/02/2025 Challan No. Slip no. 52530833069	Hospital & HomeCare Imp. & EXP, Co., Ltd, Room no. 608-611 No.5 Zhonghtai International Plzaz No. 311, Jiangdong Road, Nanjing China (as per FSC issued by MHRA) Documents submitted: Copy of Sole Agency Agreement validity: 10-02-2028 (attached in file of the product DispoPlus 3way Stopcock) Copy of FSC (MHRA) Valid till:	Hospital & Homecare Wooden Tongue Depressor Apply as Single Class A Shelf Life: 5 Years Codes/Sizes: MC241a	Deferred for the provision of following: All the original documents (FSC, LOA, ISO etc.) are photocopy without attestation/notarizatio n. FSC of the country of origin (China) is not provided but the copy of FSC of RRA (MHRA) has been provided.

		<p>26-05-2025</p> <p>EC Certificate: Not provided</p> <p>Copy of ISO-13485 Validity 2025-05-31</p>		<p>FSC expired.</p> <p>ISO 13485 expired on 26-05-2025.</p> <p>Stability study data not provided.</p> <p>Difference in the Address of manufacturer as per the application Form & provided Sole Agency Agreement (Room no. 618-611) & the FSC issued by MHRA (Room no. 608-611)</p>
190.	<p>Ghazali Brothers, 19-SR-7, Azzainab Court Campbell Street, 1st Floor Karachi (ELI-00240)</p> <p>R&I Date 06/03/2025</p> <p>Fee Rs. 6,000/ Dated 17/02/2025</p> <p>Challan No. Slip no. 706766625765</p>	<p>Hospital & HomeCare Imp. & EXP, Co., Ltd, Room no. 608-611 No.5 Zhonghtai International Plzaz No. 311, Jiangdong Road, Nanjing China (as per FSC issued by MHRA)</p> <p>Documents submitted:</p> <p>Copy of Sole Agency Agreement validity: 10-02-2028 (attached in file of the product DispoPlus 3way Stopcock)</p> <p>Copy of FSC (MHRA) Valid till: 26-05-2025</p> <p>EC Certificate: Not provided</p> <p>Copy of ISO-13485 Validity 2025-05-31</p>	<p>Hospital & Homecare Aneroid Sphygmomanometer (B.P Aneroid)</p> <p>Apply as Single Class A</p> <p>Shelf Life: 5 Years</p> <p>Codes/Sizes: MA2</p>	<p>Deferred for the provision of following:</p> <p>All the original documents (FSC, LOA, ISO etc.) are photocopy without attestation/notarization.</p> <p>FSC of the country of origin (China) is not provided but the copy of FSC of RRA (MHRA) has been provided.</p> <p>FSC expired.</p> <p>ISO 13485 expired on 26-05-2025.</p> <p>Stability study data not provided.</p> <p>Difference in the Address of manufacturer as per the application Form & provided Sole Agency Agreement (Room no. 618-611) & the FSC issued by MHRA (Room no. 608-611)</p>

191.	<p>Ghazali Brothers, 19-SR-7, Azzainab Court Campbell Street, 1st Floor Karachi</p> <p>(ELI-00240)</p> <p>R&I Date 10th March 2025</p> <p>Fee Rs. 6,000 Dated 06/03/2025</p> <p>Challan No. Slip no. 87023649015</p>	<p>Ningbo Yingmed Medical Instruments Co., Ltd Room No. 705 Yingsheng Building, No. 456 Tai, an Road, Southern Business Zone, 315199, Ningbo, China.</p> <p>Documents submitted:</p> <p>LOA issued on 27-02-2019 validity: Valid until both parties are satisfied with the cooperation (as mentioned in the LOA)</p> <p>FSC (MHRA) issued on 09-02-2018</p> <p>EC Certificate Validity: 18-07-2022</p> <p>ISO-13485 Validity 2020-07-18</p>	<p>AIROCARE (Air Cushion with Cover & Pump)</p> <p>Apply as Single</p> <p>Class: A</p> <p>Shelf life: 5 Years</p> <p>Codes/Sizes</p> <table><tr><td>Size</td><td>38x38cm</td></tr></table>	Size	38x38cm	<p>Deferred for the provision of following:</p> <p>FSC of the country of origin (China) is not provided but the copy of FSC of RRA (MHRA) has been provided.</p> <table><tr><td>FSC expired.</td></tr></table> <p>ISO 13485 & EC expired. All the original documents (FSC, LOA, ISO etc.) are photocopy without attestation/notarization.</p> <p>In LOA products are not mentioned.</p>	FSC expired.
Size	38x38cm						
FSC expired.							
192.	<p>Intra Health, 56A, Unit No. 1, Justice Inamullah Road, Block 7/8, KCHS - Karachi</p> <p>ELI-00416</p> <p>R&I Date: 27-03-2025</p> <p>Fee Rs 6000/- vide Challan no. 731758587596</p>	<p>M/s Weifang Kawa Medical Products Co.,Ltd., No. 2, Xingan Road, Shouguang Beiluo Industrial Park, 262700, Weifang, Shandong</p> <p>Copy of LOA validity: 20-10-2026</p> <p>FSC Valid till: 28-02-2030</p> <p>EC Certificate Validity:26-05-2024 (Copy) with extension letter</p> <p>ISO-13485 Validity: 30-11-2026 (Copy)</p>	<p>KAWA Urine Bag 2600ml + Urine Meter 500ml</p> <p>Generic Name : Urine Bag with Urine Meter</p> <p>Applied as : Not Mentioned</p> <p>Class: A</p> <p>Shelf life: 5 Years</p> <p>Codes/Sizes Urine Bag: 2600ml Urine Meter: 500ml</p>	<p>Deferred for the provision of original legalized/notrized documents as required in application form.</p>			
193.	<p>M/s Jasani Scientifics, SC-45, Marium Square, Chandni Chowk, Stadium Road, Karachi</p> <p>ELI-00416</p> <p>R&I Date: 11-3-</p>	<p>M/s FE-Groups S.r.l., Via IV Novembre 118, 21058 Solbiate Olona (VA) Italy. (As per Form-7A)</p> <p>M/s F.I.S.O S.r.l, 21058 Solbiate Olona, Varese, Italy, Via IV Novembre 118, Fiscal Code and Vat. No, 02251040123</p>	<p>Panvisus Moon Lens FE-Group Ophthalmic Refraction Unit</p> <p>Applied as : Not Mentioned</p> <p>Class: A</p>	<p>Deferred for the provision of following:</p> <p>The firm applied multiple products, codes and accessories in one application with single fee without mentioning the</p>			

	2025 Fee Rs 6000/- vide Challan no. 44682491	(As per FSC) LOA validity: 31-12-2028 (copy of LOA) FSC (Italy) Issue date: 29-01-2009(Copy of FSC) EC Certificate Validity: Not Provided ISO-13485 Validity: Not Provided	Shelf life: 15 years Codes/Sizes: 65L	family/system. Codes/accessories are not mentioned in the FSC. Name of manufacturer are different in Form- 7A & in the provided FSC. ISO 13485 not provided. All the original documents (FSC, LOA, ISO etc.) are photocopy without attestation/notarizatio n.
194.	M/s Jasani Scientifics, SC- 45, Marium Square, Chandni Chowk, Stadium Road, Karachi ELI-00416 R&I Date: 11-3- 2025 Fee Rs 6000/- vide Challan no. 4990847771	M/s FE-Groups S.r.l., Via IV Novembre 118, 21058 Solbiate Olona (VA) Italy. (As per Form-7A) M/s F.I.S.O S.r.l, 21058 Solbiate Olona, Varese, Italy, Via IV Novembre 118, Fiscal Code and Vat. No, 02251040123 (As per FSC) LOA validity: 31-12-2028 (copy of LOA) FSC (Italy) Issue date: 29-01-2009(Copy of FSC) EC Certificate Validity: Not Provided ISO-13485 Validity: Not Provided	Panvisus Doublette FE- Group Generic Name : Ophthalmic Refraction Unit Applied as : Not Mentioned Class: A Shelf life: 15 Years Codes/Sizes: 68	Deferred for the provision of following: The firm applied multiple products, codes and accessories in one application with single fee without mentioning the family/system. Codes/accessories are not mentioned in the FSC. Name of manufacturer are different in Form- 7A & in the provided FSC. ISO 13485 not provided. All the original documents (FSC, LOA, ISO etc.) are photocopy without attestation/notarizatio n.

195.	<p>M/s Jasani Scientifics, SC-45, Marium Square, Chandni Chowk, Stadium Road, Karachi</p> <p>ELI-00416</p> <p>R&I Date: 11-3-2025</p> <p>Fee Rs 6000/- vide Challan no. 62669618445</p>	<p>M/s FE-Groups S.r.l., Via IV Novembre 118, 21058 Solbiate Olona (VA) Italy. (As per Form-7A)</p> <p>M/s F.I.S.O S.r.l, 21058 Solbiate Olona, Varese, Italy, Via IV Novembre 118, Fiscal Code and Vat. No, 02251040123 (As per FSC)</p> <p>LOA validity: 31-12-2028 (copy of LOA)</p> <p>FSC (Italy) Issue date: 29-01-2009(Copy of FSC)</p> <p>EC Certificate Validity: Not Provided</p> <p>ISO-13485 Validity: Not Provided</p>	<p>Panvisus Trio FE-Group</p> <p>Generic Name : Ophthalmic Refraction Unit</p> <p>Applied as : Not Mentioned</p> <p>Class: A</p> <p>Shelf life: 15 years</p> <p>Codes/Sizes:69</p>	<p>Deferred for the provision of following:</p> <p>The firm applied multiple products, codes and accessories in one application with single fee without mentioning the family/system.</p> <p>Codes/accessories are not mentioned in the FSC.</p> <p>Name of manufacturer are different in Form-7A & in the provided FSC.</p> <p>ISO 13485 not provided.</p> <p>All the original documents (FSC, LOA, ISO etc.) are photocopy without attestation/notarization.</p>
196.	<p>M/s Jasani Scientifics, SC-45, Marium Square, Chandni Chowk, Stadium Road, Karachi</p> <p>ELI-00416</p> <p>R&I Date: 11-3-2025</p> <p>Fee Rs 6000/- vide Challan no.</p>	<p>M/s FE-Groups S.r.l., Via IV Novembre 118, 21058 Solbiate Olona (VA) Italy. (As per Form-7A)</p> <p>M/s F.I.S.O S.r.l, 21058 Solbiate Olona, Varese, Italy, Via IV Novembre 118, Fiscal Code and Vat. No, 02251040123 (As per FSC)</p>	<p>Panvisus Rondo FE-Group</p> <p>Ophthalmic Refraction Unit</p> <p>Applied as : Not Mentioned</p> <p>Class: A</p> <p>Shelf life: 15 years</p> <p>Codes/Sizes: 62A, 62B, 62C, 62EA, 62EB, 62EC</p>	<p>Deferred for the provision of following:</p> <p>The firm applied multiple products, codes and accessories in one application with single fee without mentioning the family/system.</p> <p>Codes/accessories are not mentioned in the</p>

	556650162	<p>LOA validity: 31-12-2028 (copy of LOA)</p> <p>FSC (Italy) Issue date: 29-01-2009(Copy of FSC)</p> <p>EC Certificate Validity: Not Provided</p> <p>ISO-13485 Validity: Not Provided</p>		<p>FSC.</p> <p>Name of manufacturer are different in Form-7A & in the provided FSC.</p> <p>ISO 13485 not provided.</p> <p>All the original documents (FSC, LOA, ISO etc.) are photocopy without attestation/notarization.</p>
197.	<p>M/s Jasani Scientifics, SC-45, Marium Square, Chandni Chowk, Stadium Road, Karachi</p> <p>ELI-00416</p> <p>R&I Date: 07-03-2025</p> <p>Fee Rs 31000/- vide Challan no. 60783694</p>	<p>M/s Avimed Medical Optics, Borsigstr.34, 65205 Wiesbaden, Germany. (As per Form-7A & LOA)</p> <p>M/s Medio-Haus-Medizinprodukte GmbH, Brunswiker StraBe 51, 24105 Kiel, Deutschland. (Asper ISO 13485)</p> <p>LOA validity: July 2024 (copy of LOA)</p> <p>FSC Issue date: Not provided.</p> <p>EC Certificate Not provided.</p> <p>ISO-13485 Validity: (Copy submitted in German Language) wherein the manufacturer name is also different.</p>	<p>Medio-Clear HPMC 2.4 Medio-Clear 24 OVD HPMC</p> <p>Applied as : Not Mentioned</p> <p>Class: B</p> <p>Shelf life: 4 Years</p> <p>Codes/Sizes: 2mL Disposable glass syringe with needle 23G</p>	<p>Deferred for the provision of following:</p> <p>Copy ISO 13485 submitted in German Language) wherein the manufacturer name is also different from that mentioned in Form-7A & in the provided ISO13485.</p> <p>FSC not provided.</p> <p>CE not provided.</p> <p>LOA expired.</p> <p>All the documents (FSC, LOA, ISO etc.) are photocopy without legalization/notarization</p>
198.	<p>M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi.</p>	<p>Zhejiang Xinke Medical Technology Co., Ltd. No.133, Lengshui Road, Jinpan Development Zone, Jinhua City, Zhejiang Province, China</p>	<p>AF Lyse (Hematology Analytic agent)</p> <p>(Active ingredient: Quaternary ammonium</p>	<p>Deferred for the provision of following:</p> <p>All the documents (FSC, LOA, ISO etc.)</p>

	(ELI- 00619) R&I detail 20/03/2025 Fee: 6000 Slip: 55749115 Dated: 11/03/2025	LOA Validity: 25-03-2029 (copy) FSC Validity (China): 30-10-2025 (Copy) ISO 13485 Validity: 20-11-2026 (Copy) EC Certificate or FSC of RRA: Not provided	salt, buffer) Applied as : Single Class: A Codes/Sizes: 1L 20L Shelf life: 1L – 02 years 20L - 02 years	are photocopy without attestation/notarizatio n. Stability study data is not complete & no conclusion has been provided as well.
199.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e- Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 20/03/2025 Fee: 6000 Slip: 96074000762Date d: 11/03/2025	Legal Manufacturer Zhejiang Xinke Medical Technology Co., Ltd. No.133, Lengshui Road, Jinpan Development Zone, Jinhua City, Zhejiang Province, China LOA Validity: 25-03-2029 (copy) FSC Validity: 30-10-2025(copy) ISO 13485 Validity: 20-11-2026(copy) EC Certificate issue date: 25-11-2022(copy)	CT Diluent (Hematology Analyzer Diluent) Applied as: Single Class: A Codes/Sizes: 20L Shelf life: 20L – 02 years	Deferred for the provision of following: All the documents (FSC, LOA, ISO etc.) are photocopy without attestation/notarizatio n. Stability study data is not complete & no conclusion has been provided as well.
200.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e- Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 20/03/2025 Fee: 6000 Slip: 269862474522 Dated: 11/03/2025	Zhejiang Xinke Medical Technology Co., Ltd. No.133, Lengshui Road, Jinpan Development Zone, Jinhua City, Zhejiang Province, China LOA Validity: 25-03-2029 (copy) FSC Validity (China): 30-10-2025 (Copy) ISO 13485 Validity: 20-11-2026 (Copy) EC Certificate or FSC of RRA: Not provided	EZ Cleaning Solution (Hematology Analyzer cleaning solution) Applied as : Single Class: A Codes/Sizes: 5L Shelf life: 02 years	Deffered for: Original legalized FSC, notrized LOA and ISO 13485 data of stability studies
201.	M/s. Nextek Healthcare Plot	Zhejiang Xinke Medical Technology Co., Ltd.	XCY Wash Concentrate Buffer	Deferred for the provision of original

	No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) R&I detail 20/03/2025 Fee: 6000 Slip: 527374045 Dated: 11/03/2025	No.133, Lengshui Road, Jinpan Development Zone, Jinhua City, Zhejiang Province, China LOA Validity: 25-03-2029 (copy) FSC Validity (China): 30-10-2025 (Copy) ISO 13485 Validity: 20-11-2026 (Copy) EC Certificate or FSC of RRA: Not provided	(Buffer) Applied as: Single Class: A Codes/Sizes: 10L 714ml Shelf life: 10L - 02 years 714ml - 02 years	legalized/notrized documents as required in application form.
202.	Medzntech Pvt.Ltd., D-21 Sector 16-A Govt. Teachers CO- operative Housing Society, KDA Scheme 33, Karachi (ELI-00657) R&I date: 06-03- 2025 Fee Rs 31000/- vide Challan no. 1601051333	M/s Alcon Laboratories, Inc. 6201 South Freeway Fort Worth, TX, USA 76134 LOA/sole agency :11-11- 2029(Notarized copy of LOA) FSC USFDA Valid till: 10-10-2025 EC Certificate 24-04-2025 (copy) ISO-13485 Validity: 20-02-2027(Copy)	NGenuity 3D Visualization System 1.5 (Model: 8065000399) Generic Name : NGenuity 3D Visualization System Applied as : Not Mentioned Class: B Shelf life: N/a Codes/Sizes	Deferred for the provision of original legalized/notrized documents as required in application form.
203.	M/s Meher Enterprises, 1st Floor Az-Zainab Court, Campbell Street, Karachi (ELI-00241) R&I date: 17-03- 2025 Fee Rs 31000/- vide Challan no. 3534092557	Shandong Wuzhou Medical Equipment CO., Ltd, Dingtao (YanTai) Industrial Area, Heze, 274100 Shandong, P.R. China Exporter: M/s Ningbo Greatcare Trading Co., Ltd., Unit 93, Building 12, NO. 818, Qiming Road, Ningbo, China LOA/sole agency valid till :04-08-2029(Notarized LOA) FSC Issue date: 07-01-2026(Notarized FSC)	Greatcare Intravenous Infusion Sets with Burette Intravenous Infusion Sets with Burette Applied as : Not Mentioned Class: B Shelf life: 5 Years Codes/Sizes : 100ml without Check- Valve, Normal PVC 100ml with Check Valve, Normal PVC	Deferred for the clarification regarding multiple codes on single application without mentioning family etc.

		<p>EC Certificate valid till: 26-05-2024(Notarized EC Certificate)</p> <p>ISO-13485 Validity: 04-09-2025(Notarized ISO Certificate)</p>	<p>100 with Check Valve, PVC DEHP Free 100ml without Check Valve, PVC DEHP Free 120ml without Check Valve, Normal PVC</p> <p>120ml with check Valve, Normal PVC 120ml with Check Valve, PVC DEHP Free 120ml without Check valve, PVC DEHP Free 150 without Check Valve, Normal PVC 150ml with Check Valve, Normal PVC 150ml with Check Valve, PVC DEHP Free 150ml without Check Valve, PVC DEHP Free</p>	
204.	<p>M/s Meher Enterprises, 1st Floor Az-Zainab Court, Campbell Street, Karachi</p> <p>(ELI-00241)</p> <p>R&I date: 17-03-2025</p> <p>Fee Rs 31000/- vide Challan no. 975382923085</p>	<p>Shandong Wuzhou Medical Equipment CO., Ltd, Dingtao (YanTai) Industrial Area, Heze, 274100 Shandong, P.R. China</p> <p>Exporter: M/s Ningbo Greatcare Trading Co., Ltd., Unit 93, Building 12, NO. 818, Qiming Road, Ningbo, China</p> <p>LOA/sole agency valid till :04-08-2029(Notarized LOA)</p> <p>FSC Issue date: 07-01-2026(Notarized FSC)</p> <p>EC Certificate valid till: 26-05-2024(Notarized EC Certificate)</p> <p>ISO-13485 Validity: 04-09-2025(Notarized ISO Certificate)</p>	<p>Greatcare Disposable Sterile Infusion Set Infusion Set</p> <p>Class: B</p> <p>Shelf life: 5 Years</p> <p>Codes/Sizes : With needle, without needle</p>	<p>Approved.</p> <p>The firm shall submit fee as per revised SRO for Family.</p>
205.	<p>M/s Meher Enterprises, 1st Floor Az-Zainab Court, Campbell Street, Karachi</p> <p>(ELI-00241)</p>	<p>M/s Legal Manufacturer: Shandong Wuzhou Medical Equipment CO., Ltd, Dingtao (YanTai) Industrial Area, Heze, 274100 Shandong, P.R. China</p>	<p>Greatcare Disposable Sterile Blood Transfusion Set</p> <p>Blood Transfusion set</p> <p>Class: B</p>	<p>Approved.</p> <p>The firm shall submit fee as per revised SRO for Family.</p>

	<p>R&I date: 17-03-2025</p> <p>Fee Rs 31000/- vide Challan no. 066027854229</p>	<p>Exporter: M/s Ningbo Greatcare Trading Co., Ltd., Unit 93, Building 12, NO. 818, Qiming Road, Ningbo, China</p> <p>LOA/sole agency valid till :04-08-2029(Notarized LOA)</p> <p>FSC Issue date: 07-01-2026(Notarized FSC)</p> <p>EC Certificate (Production QA) valid till: 26-05-2024(Notarized EC Certificate) with extension letter</p> <p>ISO-13485 Validity: 04-09-2025(Notarized ISO Certificate)</p>	<p>Shelf life: 5 Years</p> <p>Codes/Sizes : With needle, without needle</p>	
206.	<p>M/s Global Biotech Medical Devices Private Limited First Floor of Plot No: 35-N/3, PECHS Block 6, Near ROHAIL KHUND SOCIETY KARACHI (ELI-01292)</p> <p>R&I date: 26-03-2025</p> <p>Fee Rs 31000/- vide Challan no. 8947697815</p>	<p>M/s AndraTec GmbH, Simmerner Str. 70, 56075 Koblenz Germany</p> <p>LOA/sole agency :09-06-2027 (copy of LOA)</p> <p>FSC (Germany) Issue date: 17-03-2024 (Notarized FSC)</p> <p>EC Certificate 28-10-2028 (Notarized EC certificate)</p> <p>ISO-13485 Validity: 13-10-2027(Notarized ISO Certificate)</p>	<p>Lokum L-Quest Guidewire</p> <p>Guide Wire</p> <p>Applied as : Single</p> <p>Class: B</p> <p>Shelf life: 5 Years</p> <p>Codes/Sizes:</p>	<p>Deferred for the provision of following:</p> <p>Stability Study data is not complete.</p> <p>Sizes not demanded/mentioned in the Form-7A.</p> <p>All the documents (FSC, LOA, ISO etc.) are photocopy without attestation/notarization</p>
207.	<p>M/s Global Biotech Medical Devices Private Limited First Floor of Plot No: 35-N/3, PECHS Block 6, Near ROHAIL</p>	<p>M/s AndraTec GmbH, Simmerner Str. 70, 56075 Koblenz Germany</p> <p>LOA/sole agency :09-06-2027 (copy of LOA)</p>	<p>Lokum L-Quest MINI Guidewire</p> <p>Generic Name : Guidewire</p> <p>Applied as : Single</p>	<p>Deferred for the provision of following:</p> <p>Stability Study data is not complete.</p> <p>Sizes not</p>

	<p>KHUND SOCIETY KARACHI (ELI-01292)</p> <p>R&I date: 26-03-2025</p> <p>Fee Rs 31000/- vide Challan no. 4746366812</p>	<p>FSC (Germany) Issue date: 17-03-2024 (Notarized FSC)</p> <p>EC Certificate 28-10-2028 (Notarized EC certificate)</p> <p>ISO-13485 Validity: 13-10-2027(Notarized ISO Certificate)</p>	<p>Class: B</p> <p>Shelf life: 5 Years</p> <p>Codes/Sizes</p>	<p>demanded/mentioned in the Form-7A.</p> <p>All the documents (FSC, LOA, ISO etc.) are photocopy without attestation/notarization</p>
208.	<p>Applicant Name:</p> <p>M/s. A.Feroz & Co. Address: Medicine Street No.1, Marriot Road, Karachi (ELI-00066)</p> <p>Date of R&I 28-03-2025</p> <p>Fee Details: Paid Fee: 31,000/- Fee Challan No: 7705412635 Dated: 22-03-2025</p>	<p>Name of Manufacturer:</p> <p>M/s. Zibo Eastmed Healthcare Products Co., Ltd.</p> <p>Address: No. 118 Huaguang Road, Zhangdian District, Zibo 255000 Shandong, China</p> <p>LOA Validity: 02-03-2030</p> <p>FSC: CHINA Validity: 02-03-2027</p> <p>CE Validity: 31-12-2028</p> <p>ISO Validity: 16-08-2026</p>	<p>Brand name:</p> <p>Star AF Blood Transfusion Set</p> <p>Generic Name: Blood Transfusion Set</p> <p>Class-B</p> <p>Shelf life: 05 years</p> <p>Models/ Specification DMYX-02, DMYX-03, DMYX-04, DMYX-05, DMYX-01</p>	Approved.
209.	<p>Applicant Name:</p> <p>M/s. A.Feroz & Co. Address: Medicine Street No.1, Marriot Road, Karachi (ELI-00066)</p> <p>Date of R&I 28-03-2025</p> <p>Fee Details: Paid Fee: 31,000/-</p>	<p>Name of Manufacturer:</p> <p>M/s. Zibo Eastmed Healthcare Products Co., Ltd.</p> <p>Address: No. 118 Huaguang Road, Zhangdian District, Zibo 255000 Shandong, China</p> <p>LOA Validity: 02-03-2030</p> <p>FSC: CHINA Validity: 02-03-2027</p> <p>CE Validity:</p>	<p>Brand name:</p> <p>Star AF Latex Examination Gloves, Powdered</p> <p>Generic Name: Latex Examination Gloves, Powdered</p> <p>Class-A</p> <p>Shelf life: 05 years</p> <p>Models/ Specification S, M, L, XL</p>	Approved

	Fee Challan No: 9354031412 Dated: 22-03-2025	31-12-2028 ISO Validity: 16-08-2026		
210.	Applicant Name: M/s. A.Feroz & Co. Address: Medicine Street No.1, Marriot Road, Karachi (ELI-00066) Date of R&I 28-03-2025 Fee Details: Paid Fee: 31,000/- Fee Challan No: 549757258 Dated: 22-03-2025	Name of Manufacturer: M/s. Zibo Eastmed Healthcare Products Co., Ltd. Address: No. 118 Huaguang Road, Zhangdian District, Zibo 255000 Shandong, China LOA Validity: 02-03-2030 FSC: CHINA Validity: 02-03-2027 CE Validity: 31-12-2028 ISO Validity: 16-08-2026	Brand name: Star AF Latex Examination Gloves, Powder-Free Generic Name: Latex Examination Gloves, Powder-Free Class-A Shelf life: 05 years Models/ Specification S, M, L, XL	Approved
211.	Applicant Name: M/s. A.Feroz & Co. Address: Medicine Street No.1, Marriot Road, Karachi (ELI-00066) Date of R&I 28-03-2025 Fee: PKR 31,000/- Fee Challan: 813293244	Legal Manufacturer: M/s Jiangxi Yikang Medical Instrument Group Co., Ltd. Address: No. 188 LiduAihua Ave., Jinxian County, Nanchang, Jiangxi, China LOA Validity: 11-11-2029 FSC: CHINA Validity: 11-11-2026 CE Validity: 31-12-2028 ISO Validity: 04-08-2027	Brand name: Star Yikang Sterile Tracheal Tube for Single Use (without Cuff/Balloon) Generic Name: Yikang Sterile Tracheal Tube for Single Use (without Cuff/Balloon) Class-B Shelf life: 05 years Models/ Specification 2.0mm, 2.5mm, 3.0mm, 3.5mm, 4.0mm, 4.5mm, 5.0mm, 5.5mm, 6.0mm, 6.5mm, 7.0mm, 7.5mm, 8.0mm, 8.5mm, 9.0mm, 10.0mm, 10.5mm, 11.0mm	Approved
212.	Applicant Name:	Legal Manufacturer:	Brand name:	Approved.

	<p>M/s. A.Feroz & Co. Address: Medicine Street No.1, Marriot Road, Karachi</p> <p>(ELI-00066)</p> <p>Date of R&I 28-03-2025</p> <p>Fee: PKR 31,000/- Fee Challan: 875767995</p>	<p>M/s. Besmed Health Business Corp.</p> <p>Address: No. 5, lane 116, Wu-Kong 2nd Road, Wu-Ku District, New Taipei City, Taiwan</p> <p>LOA Validity: 18-03-2030</p> <p>FSC: CHINA Validity: 30-10-2025</p> <p>CE Validity: 31-12-2028</p> <p>ISO Validity: 16-11-2027</p>	<p>Besmed Humidifier (Non-Sterile)</p> <p>Generic Name: Humidifier (Non-Sterile)</p> <p>Class-B</p> <p>Shelf life: 05 years</p> <p>Models/ Specification</p> <p>HB-72650, HB-72600, HB-72460, HB-72120, PN-1132, PN-1134, PN-1134A, PN-1130</p>	<p>The firm shall submit fee as per revised SRO for family before the issuance of registration letter.</p>
213.	<p>Applicant Name:</p> <p>M/s Noor International, Noor House 29-D, Block-06, PECHS, Karachi.</p> <p>(ELI-00061)</p> <p>Date of R&I: 17-01-2025</p> <p>Fee details: Slip: 9248237625 Paid: PKR 62000/- Dated: 16-01-2025</p>	<p>Legal Manufacturer:</p> <p>Keewell Medical Technology Co. Ltd. Xiananyi Industry Zone, Pingzhou Nanhai District Foshan City Guangdong Province, China.</p> <p>FSC (China): Validity: 11-07-2026</p> <p>LOA Validity: 04-01-2027</p> <p>EC Certificate Not given</p> <p>ISO 13485 Validity: 25-09-2025</p>	<p>Brand name:</p> <p>KPW 3000 Body Warmer</p> <p>Medical Mattress Patient Warming Unit</p> <p>Class C</p> <p>Control Unit KPW3000</p> <p>Shelf life: 08 years</p> <p>Full Mattress (M1): KPW310</p> <p>Shelf life: 05 years</p> <p>Full Blanket (B1): KPW320</p> <p>Shelf life: 05 years Upper Blanket (B2): KPW330</p> <p>Shelf life: 05 years Lower Blanket (B3): KPW340</p> <p>Shelf life: 05 years</p> <p>Models: KPW3000-M1, KPW3000-B1,</p>	<p>Deferred for</p> <ul style="list-style-type: none"> -provision of following: - justification for applying multiple models in single application. -Notrized CE certificate OR Legalized FSC of SRA -firm needs to submit differential fee of PKR 38,000/- to complete the requisite total fee of PKR 100,000/- for the registration of medical devices under the system/family category, as outlined in SRO 1324(I)/2024 dated 30-08-2024.

			KPW3000B2, KPW3000B3, KPW3000-M1-B1, KPW3000-M1-B2, KPW3000-M1-B3, KPW3000-B1-B2, KPW3000B1-B3, KPW3000-B2-B3	
214.	<p>Applicant Name:</p> <p>M/s Noor International, Noor House 29-D, Block-06, PECHS, Karachi.</p> <p>(ELI-00061)</p> <p>Date of R&I: 17-01-2025</p> <p>Fee details: Slip: 488375276 Paid: PKR 62000/- Dated: 16-01-2025</p>	<p>Legal Manufacturer:</p> <p>Keewell Medical Technology Co. Ltd. Xiananyi Industry Zone, Pingzhou Nanhai District Foshan City Guangdong Province, China.</p> <p>FSC (China): (KPW4000) Validity: 11-07-2026</p> <p>LOA Validity: 04-01-2027</p> <p>EC Certificate Not given</p> <p>ISO 13485 Validity: 25-09-2025</p>	<p>Brand name:</p> <p>(Forced-Air) Patient Warming Unit KPW4000</p> <p>Class C</p> <p>Package contains: Warming Unit KPW4000</p> <p>Shelf life: 08 years with components Hose, Power Cord, Screw & Screw Driver, Clip for Hose.</p> <p>Models of warming blankets: Shelf life: 03 years (for all blankets mentioned below) Full Body: KWB 011 Lower Body: KWB 012 Upper Body: KWB 013 Upper arm extension: KWB 014 Lithotomy under body: KWB 020 Pediatric full body: KWB 0111 Pediatric lower body: KWB 0121 Abdominal Surgery: KWB 0151 Full access under-body: KWB 0171 Full access under-body upper arm extension: KWB 0172 Pediatric child under-body: KWB 0181 Pediatric full access</p>	<p>Deferred for following:</p> <ul style="list-style-type: none"> -justification for applying multiple models in single application. -Provision of original legalized FSC of SRA or notarized CE. -firm needs to submit differential fee of PKR 38,000/- to complete the requisite total fee of PKR 100,000/- for the registration of medical devices under the system/family category, as outlined in SRO 1324(I)/2024 dated 30-08-2024.

			under-body: KWB 0191	
215.	Applicant Name: M/s Rolls Royce Surgical. Surgical, 10 Kiyani Plaza, Kiyani Shaheed Road, Karachi. (ELI-00936) Date of R&I: 20-03-2025 Fee details: Slip: 033903659 Paid: PKR 25000/- Dated: 14-05-2025	Legal Manufacturer: Zhejiang J&J Mobility Co. Ltd. No. 18, Baiyang Street, Wuyi, Jinhua City, Zhejiang, China. FSC (China): Validity: 11-11-2026 LOA Validity: 29-06-2029 EC Certificate Eudamed verified ISO 13485 Validity: 10-01-2027	Brand name: J & J Mobility Power Wheelchair JJW-5001 series Class A Model: JJW-5001, JJW-500111, JJW-500112, JJW-500113, JJW-500114, JJW-500115, JJW-500116, JJW-500117, JJW-500118, JJW-500121, JJW-500131, JJW-500141, JJW-500151, JJW-500161, JJW-500171, JJW-500181, JJW-500155, JJW-500156, JJW-500157, JJW-500118 Shelf life: 05 years	Approved. The firm shall submit fee as per revised SRO for family before the issuance of registration letter.
216.	Applicant Name: M/s Rolls Royce Surgical. Surgical, 10 Kiyani Plaza, Kiyani Shaheed Road, Karachi. (ELI-00936) Date of R&I: 20-03-2025 Fee details: Slip: 30047362 Paid: PKR 25000/- Dated: 14-05-2025	Legal Manufacturer: Zhejiang J&J Mobility Co. Ltd. No. 18, Baiyang Street, Wuyi, Jinhua City, Zhejiang, China. FSC (China): Validity: 11-11-2026 LOA Validity: 29-06-2029 EC Certificate Eudamed verified ISO 13485 Validity: 10-01-2027	Brand name: J & J Mobility Power Wheelchair JJW-6001 series Class A Model: JJW-6001, JJW-600111, JJW-600112, JJW-600113, JJW-600114, JJW-600115, JJW-600116, JJW-600117, JJW-600118, JJW-600183, JJW-600184, JJW-600185, JJW-600186, JJW-600127, JJW-600129 Shelf life: 05 years	Approved. The firm shall submit fee as per revised SRO for family before the issuance of registration letter.
217.	Applicant Name: M/s HAM International. First Floor Portion of House	Legal Manufacturer: M/s Disposet Tibbi URUNLER SANAYI VETICARET ANONIM SIRKETI.	Brand name: Disposet Extension Line M/F 120cm Class B	Deferred for provision of valid and notarized CE Certificate, and ISO 13485 certificate.

	<p>No. B-49, Block No. 16, K.D.A, Scheme-36 Gulshan-e-Jouhar, Karachi.</p> <p>(ELI-00008)</p> <p>Date of R&I: 22-01-2025</p> <p>Fee details: Slip: 0917727025 Paid: PKR 31000/- Dated: 13-02-2025</p>	<p>ASO 2-3 ALCi OSB, 2000. Cadde NO:20, Malikoy, Sincan, Ankara, Turkey.</p> <p><u>FSC (Turkey):</u> Validity: 05-01-2028</p> <p><u>LOA Validity:</u> 31-12-2027</p> <p><u>DOC:</u> Dated: 18-11-2024</p> <p><u>EC Certificate</u> 27-05-2024</p> <p>ISO 13485 Validity: 28-02-2025</p>	<p>Shelf life: 03 years</p>	
218.	<p>Applicant Name:</p> <p>M/s HAM International. First Floor Portion of House No. B-49, Block No. 16, K.D.A, Scheme-36 Gulshan-e-Jouhar, Karachi.</p> <p>(ELI-00008)</p> <p>Date of R&I: 17-02-2025</p> <p>Fee details: Slip: 475688615074 Paid: PKR 31000/- Dated: 12-02-2025</p>	<p><u>Legal Manufacturer:</u></p> <p>M/s Disposet Tibbi URUNLER SANAYI VETICARET ANONIM SIRKETI. ASO 2-3 ALCi OSB, 2000. Cadde NO:20, Malikoy, Sincan, Ankara, Turkey.</p> <p><u>FSC (Turkey):</u> Validity: 05-01-2028</p> <p><u>LOA Validity:</u> 31-12-2027</p> <p><u>EC Certificate</u> Not provided</p> <p>ISO 13485 Validity: 28-02-2025</p>	<p>Brand name:</p> <p>Disposet Aortic Punch</p> <p>Class B</p> <p>Shelf life: 03 years</p>	<p>Deferred for provision of valid and notrized CE Certificate AND ISO 13485 certificate & declaration of conformity.</p> <p>Firm should also inform the model to be registered from free sale certificate/CE Certificate.</p>
219.	<p>Applicant Name:</p> <p>M/s. United Healthcare Address: Plot No. 330/A 2nd Floor, Block 3, DMCHS, Alamgir Road, Karachi</p>	<p><u>Legal Manufacturer:</u></p> <p>M/s Linhai Shuangmei Medical Supplies Co. Ltd. Gexi Village, Dongcheng Town, Linhai City, Taizhou Zhejiang, 317000, China</p> <p><u>FSC (China):</u> Validity: 03-08-2026</p>	<p>Brand name:</p> <p>Safety Urine Meter</p> <p>Model: 2-way Type Sizes: II-400ml+2000ml II-500ml+2000ml II-600ml+2000ml II-400ml+2600ml</p>	<p>Approved.</p>

	<p>ELI:00293</p> <p>Date of R&I: 18-02-2025</p> <p>Fee details: Slip: 1939387253 Paid: PKR 6000/- Dated: 14-02-2025</p>	<p>LOA Validity: 29-12-2029</p> <p>DOC: Dated: 17-12-2023</p> <p>EC Certificate Verified from Eudamed</p> <p>ISO 13485 Validity: 04-07-2027</p>	<p>II-500ml+2600ml</p> <p>Class A</p> <p>Shelf life: 03 years</p>	
220.	<p>Applicant Name:</p> <p>M/s. United Healthcare Address: Plot No. 330/A 2nd Floor, Block 3, DMCHS, Alamgir Road, Karachi</p> <p>ELI:00293</p> <p>Date of R&I: 18-02-2025</p> <p>Fee details: Slip: 55967300144 Paid: PKR 6000/- Dated: 14-02-2025</p>	<p>Legal Manufacturer:</p> <p>M/s Linhai Shuangmei Medical Supplies Co. Ltd. Gexi Village, Dongcheng Town, Linhai City, Taizhou Zhejiang, 317000, China</p> <p>FSC (China): Validity: 03-08-2026</p> <p>LOA Validity: 29-12-2029</p> <p>DOC letter: Dated: 17-12-2023</p> <p>EC Certificate Verified from Eudamed</p> <p>ISO 13485 Validity: 04-07-2027</p>	<p>Brand name:</p> <p>Safety Urine Bag Model: Single-pass Type Sizes: I-1000ml, I-1500ml, I-2000ml</p> <p>Class A</p> <p>Shelf life: 03 years</p>	Approved
221.	<p>Applicant Name:</p> <p>M/s. Martin Dow Specialities Private Limited. Nice Trade Orbit Building 7th Floor, 44-A, Block 6, PECHS, Shahrah0-e-Karachi.</p> <p>ELI:00160</p> <p>Date of R&I: 25-02-2025</p>	<p>Legal Manufacturer:</p> <p>M/s Nova Biomedical Corporation, 200 Prospect Street, Waltham, MA 02454-9141, USA</p> <p>FSC (USA): Validity: 21-01-2026</p> <p>LOA Validity: 27-03-2025</p> <p>ISO 13485 Validity: 24-10-2027</p>	<p>Brand name:</p> <p>Prime CCS Comp Stat Profile Prime CCS Analyzer System</p> <p>Class A</p> <p>Shelf life: not applicable</p>	Deffered for submission of original, valid and notrized LOA Shelf life Product codes fee as per revised SRO for system

	Fee details: Slip: 1968105377 Paid: PKR 6000/- Dated: 14-02-2025			
222.	Applicant Name: M/s. Martin Dow Specialities Private Limited. Nice Trade Orbit Building 7 th Floor, 44-A, Block 6, PECHS, Shahrah0-e-Karachi. ELI:00160 Date of R&I: 25-02-2025 Fee details: Slip: 522832587 Paid: PKR 6000/- Dated: 14-02-2025	Legal Manufacturer: M/s Nova Biomedical Corporation, 200 Prospect Street, Waltham, MA 02454-9141, USA FSC (USA): Validity: 21-01-2026 LOA Validity: 27-03-2025 ISO 13485 Validity: 24-10-2027	Brand name: Prime CCS Analyzer Consumable Kit Class A <ul style="list-style-type: none"> • Prime Sensor Card CCS Comp (shelf life: 12 month) • Prime Sensor Card CCS Comp 100 (shelf life: 12 month) • Prime Sensor Card CCS Comp (High Volume) (shelf life: 12 month) • Prime Reference Cartridge (shelf life: 18 month) • Prime Pump Harness (shelf life: N/A) • Prime Auto QC Cartridge CCS 100 Sample (shelf life: 18 month) • Prime Ampuled Control ABG/CCS (shelf life: 18 month) • Prime Calibrator Cartridge CCS Comp 200 (shelf life: 18 month) • Prime Calibrator Cartridge CCS Comp 400 (shelf life: 18 month) 	Deffered for submission of original, valid and notarized LOA, clarification of Class of medical device
223.	Applicant Name: M/s. Shirazi Trading Company Private Limited. ELI:00263	Legal Manufacturer: M/s ergoline GmbH Lindenstrasse 5 72475 Bitz Germany FSC (Germany):	Brand name: EBike III Basic Ergometer, Bicycle Class B Expected Service Life:	Deffered for valid EC certificate and product codes.

	<p>Head Office: 114-C, Al Murtaza Commercial Lane 3, Khayaban-e-Iqbal, Phase 8, D.H.A., Karachi.</p> <p>Date of R&I: 04-02-2025</p> <p>Fee details: Slip: 3982378959 Paid: PKR 50000/- Dated: 23-01-2025</p>	<p>Issued on: 04-09-2023</p> <p><u>LOA issuance date:</u> 05-10-2023</p> <p>ISO 13485 Validity: 24-10-2027</p>	<p>05 years</p> <p>EC Certificate validity: 26-05-2024</p>																																	
224.	<p>Applicant Name: M/s. Shirazi Trading Company Private Limited. ELI:00263</p> <p>Head Office: 114-C, Al Murtaza Commercial Lane 3, Khayaban-e-Iqbal, Phase 8, D.H.A., Karachi.</p> <p>Date of R&I: 04-02-2025</p> <p>Fee details: Slip: 415604743643 Paid: PKR 100000/- Dated: 09-01-2025</p>	<p><u>Distributor:</u> M/s GE Medical System, LLC 3000 North Grandview Blvd, Waukesha, WI 53188 USA Manufacturing site: GE Hualun Medical Systems Co. Ltd. No. 01Yong Chang North Road Beijing Economic Technological Development Zone Beijing China.</p> <p><u>CFG (USA):</u> Validity: 14-04-2026</p> <p><u>LOA issuance date:</u> 05-10-2023</p> <p>ISO 13485 Validity: USA:17-12-2026 <u>China: 12-11-2026</u></p> <p>EC Certificate validity: 05-12-2026</p>	<p>Brand name: Omni Legend Positron Emission Tomography. Class C Models:</p> <table><tr><td colspan="2">Omni Legend 6R (32cm)</td></tr><tr><td>PET Gantry</td><td>BGO 6 ring</td></tr><tr><td>CT Gantry</td><td>Taix CT</td></tr><tr><td>PDU</td><td>NGPDU-61</td></tr><tr><td>Console</td><td>Z8G4</td></tr><tr><td>PARC</td><td>PARC 4.2</td></tr><tr><td>Table</td><td>GT2000</td></tr><tr><td colspan="2">Omni Legend 3R (16cm)</td></tr><tr><td>PET Gantry</td><td>BGO 3 ring</td></tr><tr><td>CT Gantry</td><td>Taix CT</td></tr><tr><td>PDU</td><td>NGPDU-61</td></tr><tr><td>Console</td><td>Z8G4</td></tr><tr><td>PARC</td><td>PARC 4.2</td></tr><tr><td>Table</td><td>GT2000</td></tr><tr><td colspan="2">Omni Legend 4R (21cm)</td></tr><tr><td>PET Gantry</td><td>BGO 4 ring</td></tr></table>	Omni Legend 6R (32cm)		PET Gantry	BGO 6 ring	CT Gantry	Taix CT	PDU	NGPDU-61	Console	Z8G4	PARC	PARC 4.2	Table	GT2000	Omni Legend 3R (16cm)		PET Gantry	BGO 3 ring	CT Gantry	Taix CT	PDU	NGPDU-61	Console	Z8G4	PARC	PARC 4.2	Table	GT2000	Omni Legend 4R (21cm)		PET Gantry	BGO 4 ring	Approved Omni Legend 6R (32cm).
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			<table><tr><td>CT Gantry</td><td>Taix CT</td></tr><tr><td>PDU</td><td>NGPDU-61</td></tr><tr><td>Console</td><td>Z8G4</td></tr><tr><td>PARC</td><td>PARC 4.2</td></tr><tr><td>Table</td><td>GT2000</td></tr></table> <p>Software: 5926303, 5927334, 5940858, 5951443, 5957707</p>	CT Gantry	Taix CT	PDU	NGPDU-61	Console	Z8G4	PARC	PARC 4.2	Table	GT2000	
CT Gantry	Taix CT													
PDU	NGPDU-61													
Console	Z8G4													
PARC	PARC 4.2													
Table	GT2000													
225.	<p>Applicant Name: M/s. Meditec Instrument Co. ELI:00233 Suit # 202, Tahir Plaza, A-20, KCSHU, Near Duty Free Shop, Karachi.</p> <p>Date of R&I: 28-01-2025</p> <p>Fee details: Slip: 08731499688 Paid: PKR 6000/- Dated: 28-01-2025</p>	<p><u>Legal Manufacturer:</u> M/s Guangzhou Wondfo Biotech Co. No. 08 Lizhishan Road, Science City, Luogang Distrixt, 510663, Guangzhou, China.</p> <p><u>FSC (China):</u> Validity: 26-04-2026</p> <p><u>LOA validity:</u> document not provided</p> <p>ISO 13485 Validity: 31-01-2027</p> <p>EC Certificate validity: Not provided</p> <p>EU DOC: dated: 11-06-2024 (Declaring as Class A device)</p>	<p>Brand name: Finecare FIA Meter X2 (FS-2000) Class B Shelf life: 05 years</p>	Deferred for provision of notarized and valid letter of authorization and Notrized CE or FSC of any SRA. Differential fee of 25000 as per new SRO.										
226.	<p>Applicant Name: M/s. Meditec Instrument Co. ELI:00233 Suit # 202, Tahir Plaza, A-20, KCSHU, Near Duty Free Shop, Karachi.</p> <p>Date of R&I: 28-01-2025</p>	<p><u>Legal Manufacturer:</u> M/s Guangzhou Wondfo Biotech Co. No. 08 Lizhishan Road, Science City, Luogang Distrixt, 510663, Guangzhou, China.</p> <p><u>FSC (China):</u> Validity: 21-12-2025</p> <p><u>FSC (Spain):</u> Issuance date:</p>	<p>Brand name: Automatic Blood Gas Analyzer (UCARE 6000) Class A Shelf life: 05 years</p>	Deferred for provision of notarized and valid letter of authorization and Notrized DoC										

	Fee details: Slip: 4823213941 Paid: PKR 6000/- Dated: 28-01-2025	07-12-2024 EC Certificate validity: Not provided LOA validity: document not provided ISO 13485 Validity: 31-01-2027		
227.	Applicant Name: M/s. Cure Connect Pakistan. Plot No. B-204, First Floor, Sector 6-F, Mehran Town, Korangi, Karachi. ELI:01234 Date of R&I: 29-01-2025 Fee details: Slip: 546969721679 Paid: PKR 6000/- Dated: 21-01-2025	Legal Manufacturer: M/s Tianchang Ganor Medical Device Co., Ltd. Shuangliu Village, Datong Town, 239361, Tianching City, Anhui Province, People Republic of China. FSC (China): Validity: 14-08-2025 LOA Validity: 09-11-2026 DOC dated: 28-02-2025 EC Certificate validity: 13-12-2028 ISO 13485 Validity: 19-07-2027	Brand name: Cure Sure Urine Drainage Bag. Class A Sizes: 500ml, 1000ml, 1500ml, 2000ml Shelf life: 05 years	Approved.
228.	Applicant Name: M/s. Cure Connect Pakistan. Plot No. B-204, First Floor, Sector 6-F, Mehran Town, Korangi, Karachi. ELI:01234 Date of R&I: 29-01-2025 Fee details: Slip: 9830681471 Paid: PKR 31000/- Dated: 21-01-2025	Legal Manufacturer: M/s Bonree Medical Co. Ltd. 1 st floor of building No. 02, Building No. 04, Longzhou Village Economic Estate, Longzhu Avenue, Nanlang, 528451 Zhongshan, Guangdong, China. FSC (China): Validity: 24-10-2025 LOA Validity: 09-11-2026 DOC dated: 10-12-2024 EC Certificate validity: 31-12-2028	Brand name: Cure Sure Non rebreathing mask. Class B Sizes: Pediatric standard, pediatric elongated, adult standard, adult elongated Shelf life: 05 years	Approved.

		ISO 13485 Validity: 31-07-2025		
229.	Applicant Name: M/s. Roche Pakistan Limited. 1 st floor, 37-B, Block 6, P.E.C.H.S., Karachi. ELI:00009 Date of R&I: 29-01-2025 Fee details: Slip: 55145261703 <i>(expired challan)</i> Paid: PKR 62000/- Dated: 21-01- 2025	Legal Manufacturer: M/s Roche Diabetes Care GmbH, Sandhofer Str. 116, 68305 Mannheim, Germany. Manufacturing site: Flextronics Romania S.R.L Calea Torontalului DN6, km 5.7, R.O-300000 Timisoara Romania. FSC (Germany): Not provided LOA Validity: 09-11-2026 EC Certificate validity: Not provided ISO 13485 Validity: Germany: 31-10-2027 Romania: 18-03-2026	Brand name: Accu-Chek Smart Guide Device - 09907050343 Class C Sizes: Pediatric standard, pediatric elongated, adult standard, adult elongated Shelf life: 06 months DOC dated: 08-07-2024	Deferred for submission of valid & legalized free sale certificate, Notrized CE Certificate & valid fee challan as previous challan has been expired.
230.	Applicant Name: M/s BATLA IMPEX SHOP NO.40 NAMCO CENTRE CAMBELL STREET KARACHI ELI-00170 R&I Details 27/03/2025 Fee: 50000/- Vide: Slip:16564578 & 2035539310	Legal Manufacture M/s HUAIN HELEN MEDICAL INSTRUMENT Co. Ltd. No. 01 Zhengtai, Matou Town Huaiyin District Huaian Jiangsu China. LOA Validity: 31-12-2028 FSC (China): Validity: 08-01-2026 EC Certificate: Validity: 28-09-2026 ISO 13485 Validity: 18-08-2025 DOC Isuance date: 22-08- 2022	Brand name: Brand Name Golden + Disposable Surgical Blade Material: Carbon Steel Class B Shelf life: 05 Years Sizes: 09#, 10# 11# 12# 13# 14# 15# 16# 18# 19# 20# 21# 22# 23# 24# 25# 26# 27# 34# 36#	Approved
231.	Applicant Name: M/s BATLA	Legal Manufacture M/s ZHUHAI LINTE	Brand Name: B care B.P MONITOR	Approved

	IMPEX SHOP NO.40 NAMCO CENTRE CAMBELL STREET KARACHI ELI-00170 R&I Details 17/03/2025 Fee: 31000/- Slip: 891783755 Dated: 13-03-2025	MEDICAL INSTRUMENTS Co. Ltd. Jinliang Road, Hongqui town, Jinwan Dist. Guangdong peoples, China. <u>LOA Validity:</u> 03-12-2026 <u>FSC (China):</u> Validity: 29-07-2025 <u>EC Certificate:</u> Validity: 28-09-2025 <u>ISO 13485 Validity:</u> 28-12-2027	Electronic Sphygmomanometer Class B Shelf life: 05Years Model: LT-P30	
232.	Applicant Name: M/s BATLA IMPEX SHOP NO.40 NAMCO CENTRE CAMBELL STREET KARACHI ELI-00170 R&I Details 27/03/2025 Fee: 50000/- Slip: 8686919548 & 5249162215	<u>Legal Manufacture</u> M/s ZIBO EASTMED HEALTHCARE PRODUCTS Co. Ltd. No. 118, Huaguang Road, Zhangdian District Zibo Shandong, China. <u>LOA Validity:</u> 25-10-2029 <u>FSC (MHRA)</u> Issuance date: 27-09-2019 <u>ISO 13485:</u> Validity: 31-12-2028 <u>EC Certificate:</u> Validity: 16-08-2025 <u>FSC (China)</u> Validity: 20-03-2026	Brand Name: Golden + disposable stomach tube (Ryles tube) Class B Shelf life: 05 Years Model: FR (4, 6, 8, 10, 12, 14, 16,18, 20, 22, 24, 26)	Approved
233.	Applicant Name: M/s BATLA IMPEX SHOP NO.40 NAMCO CENTRE CAMBELL STREET KARACHI	<u>Legal Manufacture</u> M/s ZHUHAI LINTE MEDICAL INSTRUMENTS Co. Ltd. Jinliang Road, Hongqui town, Jinwan Dist. Guangdong peoples, China. <u>LOA Validity:</u> 03-12-2026	Brand Name B care NEBULIZER Class B Shelf life: 05Years Model: LT-N400	Approved.

	ELI-00170 R&I Details 17-03-2025 Fee: 31000/- Fee Challan No.01077120722 Date 16/04/25.	<u>FSC (China):</u> Validity: 29-07-2025 <u>EC Certificate:</u> Validity: 28-09-2025 <u>ISO 13485 Validity:</u> 28-12-2027		
234.	Applicant Name: M/s BATLA IMPEX SHOP NO.40 NAMCO CENTRE CAMBELL STREET KARACHI ELI-00170 R&I Details 27/03/2025 Fee: 31000/- Slip: 6451822092 Date 24/03/2025.	<u>Legal Manufacture</u> M/s HUAIN HELEN MEDICAL INSTRUMENT Co. Ltd. No. 01 Zhengtai, Matou Town Huaiyin District Huaian Jiangsu China. <u>LOA Validity:</u> 31-12-2028 <u>FSC (China):</u> Validity: 08-01-2026	Brand Name B care BLOOD LANCET Class B Shelf life: 05Years Sizes: 21G, 23G,26G, 28G, 30G	Deffered for notrized ISO 13485 Certificate and CE certificate.
235.	Applicant Name: M/s BATLA IMPEX SHOP NO.40 NAMCO CENTRE CAMBELL STREET KARACHI ELI-00170 R&I Details 27/03/2025 Fee: 6000/- Slip: 5344270646 Date 18/03/25.	<u>Legal Manufacture</u> M/s HUAIN HELEN MEDICAL INSTRUMENT Co. Ltd. No. 01 Zhengtai, Matou Town Huaiyin District Huaian Jiangsu China. <u>LOA Validity:</u> 31-12-2028 <u>FSC (China):</u> Validity: 08-01-2026 <u>EC Certificate:</u> Validity: 28-09-2026 <u>ISO 13485 Validity:</u> 18-08-2025	Brand Name GOLDEN + ALCOHOL PAD Class A Shelf life: 05Years Size: 3cm x 6cm	Approved
236.	Applicant Name: M/s BATLA IMPEX SHOP NO.40	<u>Legal Manufacture</u> M/s HUAIN HELEN MEDICAL INSTRUMENT Co. Ltd.	Brand Name B care NIGHT DRAINAGE URINE BAG	Approved

	<p>NAMCO CENTRE CAMBELL STREET KARACHI</p> <p>ELI-00170</p> <p>R&I Details 27/03/2025</p> <p>Fee: 6000/- Slip: 88531395919 Date 24/03/25.</p>	<p>No. 01 Zhengtai, Matou Town Huaiyin District Huaian Jiangsu China.</p> <p><u>LOA Validity:</u> 31-12-2028</p> <p><u>FSC (China):</u> Validity: 08-01-2026</p> <p><u>EC Certificate:</u> Validity: 28-09-2026</p> <p><u>ISO 13485 Validity:</u> 18-08-2025</p>	<p>Class A</p> <p>Shelf life: 05 Years</p> <p>Sizes: 200ml, 500ml, 1000ml, 1500ml, 2000ml</p>	
237.	<p>Applicant Name:</p> <p>M/s Essity Pakistan Limited A/69, S.I.T.E, Manghopir Road, Karachi.</p> <p>ELI-00011</p> <p>Date of Submission: 24-03-2025</p> <p>Fee: 62000/- Slip: 11674158 Dated: 19-03- 2025</p>	<p><u>Legal Manufacturer:</u> ABIGO Medical AB, Vapenvägen 1, SE-696 33 Askersund, Sweden</p> <p><u>FSC (Sweden)</u> Issuance date: 26-08-2024</p> <p><u>ISO 13485 Validity:</u> 02-08-2027</p> <p>FQA Validity: 26-06-2028</p> <p>LOA Issuance date: 221- 10-2024</p>	<p>Brand name:</p> <p>Cutimed® Sorbact Contact®</p> <p>(Bacteria and fungi binding dressing.) (Swab)</p> <p>Class C</p> <p>Shelf Life: 5 years</p> <p>Size 4cm x 6cm 7cm x 9cm 10cm x 100cm</p>	Approved
238.	<p>Applicant Name:</p> <p>M/s Essity Pakistan Limited A/69, S.I.T.E, Manghopir Road, Karachi 75700. PAKISTAN</p> <p>ELI-00011</p> <p>Date of Submission: 24-03-2025</p> <p>Fee: 62000/- Slip: 64775237 Dated: 19-03- 2025</p>	<p><u>Legal Manufacturer:</u> ABIGO Medical AB, Vapenvägen 1, SE-696 33 Askersund, Sweden</p> <p><u>FSC (Sweden)</u> Issuance date: 26-08-2024</p> <p><u>ISO 13485 Validity:</u> 02-08-2027</p> <p>FQA Validity: 26-06-2028</p> <p>LOA Issuance date: 221- 10-2024</p>	<p>Brand name:</p> <p>Cutimed® Sorbact® Hydro</p> <p>(Bacteria and fungi binding dressing.) (Swab with hydrogel)</p> <p>Class C</p> <p>Shelf Life: 5 years</p> <p>Size and model 7.5cm x 7.5cm 7.5cm x 15cm 15cm x 20cm 20cm x 25cm</p>	Approved

239.	<p>Applicant Name:</p> <p>M/s A.M. Distributors Address: 4th Floor, Plot 37-C, Bukhari Commercial Lane 8, Phase VI, D.H.A, Karachi, Pakistan 75500</p> <p>ELI-00248</p> <p>Date of Receiving: 13-March-2025</p> <p>Fee: PKR 19,000/- + 6,000/- Slip: 3434713477 & 77260843364</p>	<p>Legal Manufacturer:</p> <p>Legal Manufacturer: M/s ANHUI TIANRUN MEDICAL PACKAGING MATERIALS CO., LTD Address: No. 29 of Chaoyang Road, Yixiu District 246003 Anqing City, Anqing Province - China</p> <p>FSC (China) Validity: 27-02-2027</p> <p>LOA Validity: 20-June-2027</p>	<p>Brand Name:</p> <p>Medical Packaging Material to Sterilize Medical Devices</p> <p>Class A</p> <p>Shelf life: 5 Years</p> <table><tr><th>Descripti on</th><th>Sizes</th></tr><tr><td rowspan="9">Crepe Paper</td><td>20 cm x 20cm</td></tr><tr><td>30 cm x 30cm</td></tr><tr><td>40 cm x 40cm</td></tr><tr><td>50 cm x 50cm</td></tr><tr><td>60 cm x 60cm</td></tr><tr><td>75 cm x 75cm</td></tr><tr><td>90 cm x 90cm</td></tr><tr><td>100 cm x 100cm</td></tr><tr><td>120 cm x 120cm</td></tr><tr><td rowspan="9">Sterilizati on Flat Rolls</td><td>50mm*200m</td></tr><tr><td>75mm*200m</td></tr><tr><td>100mm*200m</td></tr><tr><td>150mm*200m</td></tr><tr><td>200mm*200m</td></tr><tr><td>250mm*200m</td></tr><tr><td>300mm*200m</td></tr><tr><td>350mm*200m</td></tr><tr><td>400mm*200m</td></tr><tr><td>450mm*200m</td></tr></table>	Descripti on	Sizes	Crepe Paper	20 cm x 20cm	30 cm x 30cm	40 cm x 40cm	50 cm x 50cm	60 cm x 60cm	75 cm x 75cm	90 cm x 90cm	100 cm x 100cm	120 cm x 120cm	Sterilizati on Flat Rolls	50mm*200m	75mm*200m	100mm*200m	150mm*200m	200mm*200m	250mm*200m	300mm*200m	350mm*200m	400mm*200m	450mm*200m	<p>Deffered for:</p> <p>Brand name</p> <p>Different types in single application and type to be considered in this application.</p>
Descripti on	Sizes																										
Crepe Paper	20 cm x 20cm																										
	30 cm x 30cm																										
	40 cm x 40cm																										
	50 cm x 50cm																										
	60 cm x 60cm																										
	75 cm x 75cm																										
	90 cm x 90cm																										
	100 cm x 100cm																										
	120 cm x 120cm																										
Sterilizati on Flat Rolls	50mm*200m																										
	75mm*200m																										
	100mm*200m																										
	150mm*200m																										
	200mm*200m																										
	250mm*200m																										
	300mm*200m																										
	350mm*200m																										
	400mm*200m																										
450mm*200m																											

				500mm* 200m	
			Sterilizati on Gusseted Rolls	75mm*1 00m	
				100mm* 100m	
				150mm* 100m	
				200mm* 100m	
				250mm* 100m	
				300mm* 100m	
				350mm* 100m	
				400mm* 100m	
				450mm* 100m	
				500mm* 100m	
			Plasma Rolls	75mm x 70m	
				100mm x 70m	
				150mm x 70m	
				200mm x 70m	
				250mm x 70m	
				300mm x 70m	
				350mm x 70m	
				400mm x 70m	
				450mm x 70m	
			Self- Sealing Sterilizati on Pouch	57mm*1 30mm	
				70mm*2 30mm	
				70mm*2 60mm	
				90mm*1 65mm	
				90mm*2	

				<div>30mm</div> <div>90mm*260mm</div> <div>135mm*280mm</div> <div>150mm*250mm</div> <div>190mm*360mm</div> <div>200mm*300mm</div> <div>250mm*400mm</div> <div>300mm*450mm</div>																						
240.	<p>Applicant Name:</p> <p>M/s A.M. Distributors Address: 4th Floor, Plot 37-C, Bukhari Commercial Lane 8, Phase VI, D.H.A, Karachi, Pakistan 75500</p> <p>ELI-00248</p> <p>Date of Receiving: 13-March-2025</p> <p>Fee: PKR 19,000/- + 6,000/- Slip: 63367766560 & 95417733</p>	<p>Legal Manufacturer:</p> <p>M/s ANHUI TIANRUN MEDICAL PACKAGING MATERIALS CO., LTD Address: No. 29 of Chaoyang Road, Yixiu District 246003 Anqing City, Anqing Province - China</p> <p>FSC (China) Validity: 27-02-2027</p> <p>LOA Validity: 20-June-2027</p>	<p>Brand Name:</p> <p>Medical Sterilization Indicators Class A Shelf life: 2 Years</p> <table><tr><th>S #</th><th>Codes</th></tr><tr><td>1</td><td>Steam Indicator Strips Class 4</td></tr><tr><td>2</td><td>Steam Indicator Strips Class 5</td></tr><tr><td>3</td><td>Steam Indicator Strips Class 6</td></tr><tr><td>4</td><td>Formaldehyde Indicator Strips Class 4</td></tr><tr><td>5</td><td>Plasma Chemical Indicator Strips</td></tr><tr><td>6</td><td>Plasma sterilization Biological Indicator</td></tr><tr><td>7</td><td>Plasma sterilization Biological Indicator 0.5h</td></tr><tr><td>8</td><td>Steam Sterilization Biological Indicator</td></tr><tr><td>9</td><td>Steam sterilization Biological Indicator 0.5h</td></tr><tr><td>1</td><td>ETO sterilization</td></tr></table>	S #	Codes	1	Steam Indicator Strips Class 4	2	Steam Indicator Strips Class 5	3	Steam Indicator Strips Class 6	4	Formaldehyde Indicator Strips Class 4	5	Plasma Chemical Indicator Strips	6	Plasma sterilization Biological Indicator	7	Plasma sterilization Biological Indicator 0.5h	8	Steam Sterilization Biological Indicator	9	Steam sterilization Biological Indicator 0.5h	1	ETO sterilization	<p>Deffered for: Brand name Different types in single application and type to be considered in this application.</p>
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1	Steam Indicator Strips Class 4																									
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1	ETO sterilization																									

			<table><tr><td>0</td><td>Biological Indicator 24h</td></tr><tr><td>1</td><td>Bowie & Dick Test Sheet</td></tr><tr><td>1</td><td>Plasma Tape 19mm x 50m</td></tr><tr><td>1</td><td>Autoclave Tape (Steam)</td></tr><tr><td>1</td><td>Bowie & Dick Test Pack</td></tr><tr><td>1</td><td>EO Tape</td></tr><tr><td>1</td><td>EO indicator strip class 4</td></tr></table>	0	Biological Indicator 24h	1	Bowie & Dick Test Sheet	1	Plasma Tape 19mm x 50m	1	Autoclave Tape (Steam)	1	Bowie & Dick Test Pack	1	EO Tape	1	EO indicator strip class 4	
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1	EO Tape																	
1	EO indicator strip class 4																	
241.	<p>Applicant Name:</p> <p>M/s Jasani Scientifics SC-45, Marium Square, Chandni Chowk, Stadium Road, Karachi.</p> <p>Lic: ELI-00416</p> <p>Date of Submission: 07-03-2025</p> <p>Fee: 31000/- Slip: 60783694 Dated: 29-01-2025</p>	<p><u>Legal Manufacturer:</u></p> <p>AIVIMED Medical Optics. Borsigstr. 34, 65205 Wiesbaden, Germany.</p> <p><u>FSC (Germany)</u> Validity: <i>(FSC submitted, is not issued by the regulatory authority of the region)</i></p> <p><u>ISO 13485 Validity:</u> <i>(submitted of another firm)</i></p> <p>EC certificate validity: <i>(not submitted)</i></p> <p>LOA validity: 22-07-2024 <i>(expired)</i></p>	<p>Brand name:</p> <p>Medio-Clear 2,4% OVD HPMC 2ml Disposable Glass Syringe with needle 23G <i>(Non-implantable, non-active, Sterile, clear, viscous solution for intraocular use)</i></p> <p>Model: 80001574</p> <p>Class B</p> <p>Shelf Life: 04 years</p>	<p>Deferred for provision of</p> <p>- Valid & legalized Free Sale Certificate issued by the regulatory authority of the country of origin.</p> <p>- Valid & notarized Letter of authorization, Notarized EC and ISO 13485 certificate. And Declaration of Conformity</p>														
242.	<p>Applicant Name:</p> <p>M/s Life-Tec</p> <p>Address: Unit B&C, 1st Floor, Block 20-D, G-8 Markaz, Islamabad.</p> <p>(ELI- 00155)</p> <p>R& I Date: (06/03/2025)</p> <p>Fee details: Amount paid:</p>	<p>Name of Manufacturer:</p> <p>M/S. SCW Medicath Ltd. No.4, Baolong 6th Road, Baolong Industrial Town, Longgang District, Shenzhen, 518116, China TEL: (86)755-89312160 89312258 FAX: (86)755-89312239 www.scwmed.com</p> <p>Free Sale Certificate Validity: (13/10/2026)</p> <p>ISO 13485 certificate validity: (08/07/2027)</p>	<p>Brand Name:</p> <p>Hemodialysis Catheterization</p> <p>Generic: Hemodialysis Catheterization Kit (Double-lumen)</p> <p>Models / Sizes: DC-12F /16 CM</p> <p>MD Group: Kit</p> <p>Class-C</p> <p>Declaration of</p>	<p>Approved.</p> <p>The firm shall submit valid EC Certificate and Brand name.</p>														

	PKR 62000/- Paid Slip / challan No.:57029781753 Dated: (21/02/2025)	EC certificate Validity: (26/05/2024) Letter of authorization: Validity: (31/12/2027)	conformity: Issuance date: (26/05/2024) Shelf life:03 Storage Conditions: Room Temperature	
243.	Applicant Name: M/s. United Healthcare Address: Plot No. 330/A 2nd Floor, Block 3, DMCHS, Alamgir Road, Karachi (ELI-00293) Date of R&I 27-03-2025 Fee: PKR 6,000/- Fee Challan: 02890637	(Legal Manufacturer) Name: M/s Taian Dalu Medical Instrument Co., Ltd. Address: No. 3988 Yitianmen Street, Hi-Tech Zone, Taian, Shandong, China 271000 LOA Validity: 16-02-2030 FSC: CHINA Validity: 09-12-2026 CE Validity: NA ISO Validity: 21-10-2027	Brand name: Safety Ocean Sea Water Nasal Spray Generic Name: Ocean Sea Water Nasal Spray Class-A Shelf life: 02 years Models/ Specification DL-NS-30, DL-NS-60, DL-NP-60, DL-NP-120	Deffered for following: Justification with evidence from SRA of applied product as medical device. Justification for applying various model sin single application.
244.	Applicant Name: M/s. United Healthcare Address: Plot No. 330/A 2nd Floor, Block 3, DMCHS, Alamgir Road, Karachi (ELI-00293) Date of R&I 27-03-2025 Fee: PKR 31,000/- Fee Challan: 4062067113	(Legal Manufacturer) Name: M/s Taian Dalu Medical Instrument Co., Ltd. Address: No. 3988 Yitianmen Street, Hi-Tech Zone, Taian, Shandong, China 271000 LOA Validity: 16-02-2030 FSC: CHINA Validity: 05-02-2027 CE Validity: 20-04-2028 ISO Validity: 21-10-2027	Brand name: Safety Spacer for Aerosol Generic Name: Spacer for Aerosol Class-B Shelf life: 03 years Models/ Specification DL-01, DL-01A, DL- 01B, DL-01C, DL- 01D, DL-02, DL-02A, DL-02B, DL-03, DL- 03A, DL-03B, DL- 03C, DL-04, DL-05, DL-06,	Approved. The firm shall submit fee as per revised SRO for family.

			DL-06A, DL-06B, DL-06C, DL-07, DL-08, DL-08A, DL-08B, DL-08C, DL-08D, DL-09, DL-10, DL-11, DL-12, DL-13, DL-14, DL-15, DL-16, DL-17, DL-18, DL-19, DL-20, DL-21	
245.	<p>Applicant Name: M/s. United Healthcare Address: Plot No. 330/A 2nd Floor, Block 3, DMCHS, Alamgir Road, Karachi</p> <p>(ELI-00293)</p> <p>Date of R&I 27-03-2025</p> <p>Fee: PKR 6,000/- Fee Challan: 506046358549</p>	<p>(Legal Manufacturer)</p> <p>Name: M/s Taian Dalu Medical Instrument Co., Ltd.</p> <p>Address: No. 3988 Yitianmen Street, Hi-Tech Zone, Taian, Shandong, China 271000</p> <p>LOA Validity: 16-02-2030</p> <p>FSC: CHINA Validity: 14-01-2026</p> <p>CE Validity: NA</p> <p>ISO Validity: 21-10-2027</p>	<p>Brand name: Safety Dry Powder Inhaler</p> <p>Generic Name: Dry Powder Inhaler</p> <p>Class-A</p> <p>Shelf life: 03 years</p> <p>Models/ Specification DL-D01, DL-D01A, DL-D01B, DL-D02, DL-D03, DL-D04, DL-D04A, DL-D04B, DL-D05, DL-D06, DL-D07, DL-D08, DL-D09, DL-D10, DL-D11, DL-D12, DL-D13, DL-D14, DL-D15, DL-D16, DL-D17, DL-D18, DL-D19, DL-D20</p>	<p>Approved.</p> <p>The firm shall submit fee as per revised SRO for family.</p>
246.	<p>Applicant Name: M/s. United Healthcare Address: Plot No. 330/A 2nd Floor, Block 3, DMCHS, Alamgir Road, Karachi</p> <p>(ELI-00293)</p> <p>Date of R&I 10-05-2024</p>	<p>(Legal Manufacturer)</p> <p>M/s Blue Sail Medical Co., Ltd</p> <p>No. 21, Qingtian Road, Qilu Chemical Industrial Park, Zibo City, Shandong Province, People's Republic of China</p> <p>FSC: China Validity: 19/05/2026</p> <p>LOA Validity: 28/03/2029</p>	<p>Brand name: Safety Fine Disposable Nitrile Examination Gloves</p> <p>Generic Name: Disposable Nitrile Examination Gloves</p> <p>Class A</p> <p>Shelf Life: 05 years</p> <p>Codes / Sizes (if any) XS, S, M, L, XL</p>	<p>Approved</p>

	Fee Challan: 14369642	ISO 13485 Validity: 31/07/2025		
247.	Applicant Name: M/s. United Healthcare Address: Plot No. 330/A 2nd Floor, Block 3, DMCHS, Alamgir Road, Karachi (ELI-00293) Date of R&I 30-09-2024 Fee challan: 74728177	(Legal Manufacturer) M/s Zhejiang Runqiang Medical Instruments Co., Ltd Manufacturing Site: 599 Ruifeng Street, Gaozhao District, Xiuzhou, District Jiaxing City, Zhejiang Province FSC: Country: CHINA Validity: 26-03-2025 LOA Validity: 28-06-2029 CE Certificate Validity: 31-12-2027 Design Examination Validity: 31-12-2027 ISO 13485 Validity: 06-05-2025	Brand Name Safety Aero Disposable Anesthesia Needles-Spinal Needle Generic Name: Disposable Anesthesia Needles-Spinal Needle Class-D Shelf Life: 05 years Codes/Sizes: AN-S	Approved subject to submission of valid original FSC & ISO Certificate.
248.	Applicant Name: M/s. A.Feroz & Co. Address: Medicine Street No.1, Marriot Road, Karachi (ELI-00066) Date of R&I 24-03-2025 Fee Details: Paid Fee: 31,000/- Fee Challan No: 4105071979 Dated: 15-03-2025	Name of Manufacturer: Super Health Medical (Qingdao) Co., Ltd No. 236, Heyuan Road, High-tech Zone, Qingdao, Shandong Province, China FSC: Country of Origin Validity: 27-04-2025 LOA Validity: 21-02-2030 EC Certificate Validity: 31-12-2028 ISO 13485 Validity: 29-03-2026	Brand name: Star Flo I.V Catheter (Pen Type) Generic name: I.V Catheter Models: 26G, 24G, 22G, 20G, 18G Class-B Shelf Life: 5 Years	Approved. The firm shall submit valid original FSC.

249.	<p>Applicant Name:</p> <p>M/s. A.Feroz & Co. Address: Medicine Street No.1, Marriot Road, Karachi</p> <p>(ELI-00066)</p> <p>Date of R&I 24-03-2025</p> <p>Fee Details: Paid Fee: 31,000/- Fee Challan No: 707493748 Dated: 27-03-2025</p>	<p>Name of Manufacturer:</p> <p>Super Health Medical (Qingdao) Co., Ltd</p> <p>No. 236, Heyuan Road, High-tech Zone, Qingdao, Shandong Province, China</p> <p><u>FSC:</u> Country of Origin Validity: 27-04-2025</p> <p><u>LOA</u> Validity: 21-02-2030</p> <p><u>EC Certificate</u> Validity: 31-12-2028</p> <p><u>ISO 13485</u> Validity: 29-03-2026</p>	<p>Brand name:</p> <p>Star Flo I.V Catheter (with Injection Port + Wings)</p> <p>Generic name: I.V Catheter</p> <p>Models: 26G, 24G, 22G, 20G, 18G</p> <p>Class-B</p> <p>Shelf Life: 5 Years</p>	<p>Approved.</p> <p>The firm shall submit valid original FSC.</p>
250.	<p>Applicant Name:</p> <p>M/s. A.Feroz & Co. Address: Medicine Street No.1, Marriot Road, Karachi</p> <p>(ELI-00066)</p> <p>Date of R&I 24-03-2025</p>	<p>Name of Manufacturer:</p> <p>Super Health Medical (Qingdao) Co., Ltd</p> <p>No. 236, Heyuan Road, High-tech Zone, Qingdao, Shandong Province, China</p> <p><u>FSC:</u> Country of Origin Validity: 27-04-2025</p>	<p>Brand name:</p> <p>Star Flo I.V Catheter (with Wings + Heparin Cap)</p> <p>Generic name: I.V Catheter</p> <p>Models: 26G, 24G, 22G, 20G, 18G</p> <p>Class-B</p>	<p>Approved.</p> <p>The firm shall submit valid original FSC.</p>

	Fee Details: Paid Fee: 31,000/- Fee Challan No: 239994190847 Dated: 15-03-2025	LOA Validity: 21-02-2030 EC Certificate Validity: 31-12-2028 ISO 13485 Validity: 29-03-2026	Shelf Life: 5 Years	
251.	Applicant Name: M/s. A.Feroz & Co. Address: Medicine Street No.1, Marriot Road, Karachi (ELI-00066) Date of R&I 28-03-2025 Fee Details: Paid Fee: 31,000/- Fee Challan No: 42759525047 Dated: 22-03-2025	Name of Manufacturer: M/s. Zibo Eastmed Healthcare Products Co., Ltd. Address: No. 118 Huaguang Road, Zhangdian District, Zibo 255000 Shandong, China LOA Validity: 02-03-2030 FSC: CHINA Validity: 02-03-2027 CE Validity: 31-12-2028 ISO Validity: 16-08-2026	Brand name: Safety Pro Sterile Heparin Cap for Single Use Generic Name: Sterile Heparin Cap for Single Use Class-B Shelf life: 05 years Models/ Specification Yellow type, transparent type	Approved. The firm shall submit fee as per revised SRO for Family.
252.	Applicant Name: M/s. A.Feroz & Co. Address: Medicine Street No.1, Marriot Road, Karachi (ELI-00066) Date of R&I 28-03-2025 Fee Details: Paid Fee: 31,000/- Fee Challan No: 09114794816 Dated: 22-03-	Name of Manufacturer: M/s. Zibo Eastmed Healthcare Products Co., Ltd. Address: No. 118 Huaguang Road, Zhangdian District, Zibo 255000 Shandong, China LOA Validity: 02-03-2030 FSC: CHINA Validity: 02-03-2027 CE Validity: 31-12-2028 ISO Validity:	Brand name: Star AF Infusion Set with Burette Generic Name: Infusion Set with Burette Class-B Shelf life: 05 years Models/ Specification 100ml, 150ml	Approved

	2025	16-08-2026		
253.	Applicant Name: M/s. A.Feroz & Co. Address: Medicine Street No.1, Marriot Road, Karachi (ELI-00066) Date of R&I 28-03-2025 Fee Details: Paid Fee: 31,000/- Fee Challan No: 21420213 Dated: 22-03-2025	Name of Manufacturer: M/s. Zibo Eastmed Healthcare Products Co., Ltd. Address: No. 118 Huaguang Road, Zhangdian District, Zibo 255000 Shandong, China LOA Validity: 02-03-2030 FSC: CHINA Validity: 02-03-2027 CE Validity: 31-12-2028 ISO Validity: 16-08-2026	Brand name: Safety Pro Three-way Stopcock with Extension Tube Generic Name: Three-way Stopcock and Extension Tube Class-B Shelf life: 05 years	Approved. Firm will submit codes , if any.
254.	Applicant Name: M/s. A.Feroz & Co. Address: Medicine Street No.1, Marriot Road, Karachi (ELI-00066) Date of R&I 28-03-2025 Fee Details: Paid Fee: 31,000/- Fee Challan No: 841262171561 Dated: 22-03-2025	Name of Manufacturer: M/s. Zibo Eastmed Healthcare Products Co., Ltd. Address: No. 118 Huaguang Road, Zhangdian District, Zibo 255000 Shandong, China LOA Validity: 02-03-2030 FSC: CHINA Validity: 02-03-2027 CE Validity: 31-12-2028 ISO Validity: 16-08-2026	Brand name: Safety Pro I.V. Flow Regulator for Single Use Generic Name: I.V. Flow Regulator for Single Use Class-B Shelf life: 05 years Models/ Specification 250ml/h	Approved
255.	Applicant Name: M/s. A.Feroz & Co. Address: Medicine Street No.1, Marriot Road, Karachi	Name of Manufacturer: M/s. Zibo Eastmed Healthcare Products Co., Ltd. Address: No. 118 Huaguang Road,	Brand name: Star AF Sterile Infusion Set for Single Use Generic Name:	Approved. The firm shall submit fee as per revised SRO for Family before the issuance of registration letter.

	<p>(ELI-00066)</p> <p>Date of R&I 28-03-2025</p> <p>Fee Details: Paid Fee: 31,000/- Fee Challan No: 69464402178 Dated: 22-03-2025</p>	<p>Zhangdian District, Zibo 255000 Shandong, China</p> <p>LOA Validity: 02-03-2030</p> <p>FSC: CHINA Validity: 02-03-2027</p> <p>CE Validity: 31-12-2028</p> <p>ISO Validity: 16-08-2026</p>	<p>Sterile Infusion Set for Single Use</p> <p>Class-B</p> <p>Shelf life: 05 years</p> <p>Models/ Specification DM003, DM004, DM018, DM019, DM020, DM005, DM002</p>	
256.	<p>Applicant Name:</p> <p>M/s. A.Feroz & Co. Address: Medicine Street No.1, Marriot Road, Karachi</p> <p>(ELI-00066)</p> <p>Date of R&I 28-03-2025</p> <p>Fee Details: Paid Fee: 31,000/- Fee Challan No: 06770257 Dated: 22-03-2025</p>	<p>Name of Manufacturer:</p> <p>M/s. Zibo Eastmed Healthcare Products Co., Ltd.</p> <p>Address: No. 118 Huaguang Road, Zhangdian District, Zibo 255000 Shandong, China</p> <p>LOA Validity: 02-03-2030</p> <p>FSC: CHINA Validity: 02-03-2027</p> <p>CE Validity: 31-12-2028</p> <p>ISO Validity: 16-08-2026</p>	<p>Brand name:</p> <p>Star AF Sterile Hypodermic Needle for Single Use</p> <p>Generic Name: Sterile Hypodermic Needle for Single Use</p> <p>Class-B</p> <p>Shelf life: 05 years</p> <p>Models/ Specification 14G, 15G, 16G, 17G, 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G, 31G</p>	Approved
257.	<p>Applicant Name:</p> <p>M/s. A.Feroz & Co. Address: Medicine Street No.1, Marriot Road, Karachi</p> <p>(ELI-00066)</p> <p>Date of R&I 28-03-2025</p> <p>Fee Details: Paid Fee:</p>	<p>Name of Manufacturer:</p> <p>M/s. Zibo Eastmed Healthcare Products Co., Ltd.</p> <p>Address: No. 118 Huaguang Road, Zhangdian District, Zibo 255000 Shandong, China</p> <p>LOA Validity: 02-03-2030</p> <p>FSC: CHINA Validity: 02-03-2027</p>	<p>Brand name:</p> <p>Star AF Sterile Intravenous Needle for Single Use</p> <p>Generic Name: Sterile Intravenous Needle for Single Use</p> <p>Class-B</p> <p>Shelf life: 05 years</p> <p>Models/ Specification 18G, 19G, 20, 21G, 22G, 23G, 24G, 25G, 27G,</p>	Approved

	31,000/- Fee Challan No: 543190296 Dated: 22-03- 2025	CE Validity: 31-12-2028 ISO Validity: 16-08-2026	26G	
258.	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 14-03-2025 Rs.31,000/- Slip# 411610136229	Legal Manufacturer: 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 CE Certificate Validity: 08-04-2029 ISO 13485 Validity: 27-02-2027	Brand Name: DYCO Nebulizer Mask Class B Shelf Life: 5 years Codes/Sizes (if any) Sizes: Pediatric Standard(S) Pediatric Elongated(M) Adult Standard (L) Adult Elongated (XL) Code: R030103 Aerosol Therapy Masks and System	Deferred since the same brand name already applied by Noor International Karachi.
259.	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 14-03-2025 Rs.31,000/- Slip# 569205412587	Legal Manufacturer: 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 CE Certificate Validity: 08-04-2029 ISO 13485 Validity: 27-02-2027	Brand Name: DYCO Oxygen Mask Class B Shelf Life: 5 Years Codes/sizes (If any) Sizes: Pediatric Standard (S) Pediatric Elongated (M) Adult Standard (L) Adult Elongated (XL) Code: R030102 Air/Oxygen Masks and Nasal Cannula	Deferred since the same brand name already applied by Noor International Karachi.
260.	Applicant Name: M/s. NI healthcare	Legal Manufacturer: Jiangsu Hitec Medical Co. Ltd., Jiangxin Road North,	Brand Name: DYCO Nasal Oxygen Cannula	Deferred since the same brand name already applied by

	<p>Products Pvt Ltd.</p> <p>Address: Office No. A, Unit 10 Survey No. 263, Damlotte Road District Malir, Karachi</p> <p>(ELI-01117)</p> <p>Date of R&I 14-03-2025 Rs.31,000/- Slip# 63032555</p>	<p>Tongzhou Bay River Sea Joint Development Demonstration Zone, Jiangsu Province, China</p> <p>FSC: Validity: 27-12-2026</p> <p>LOA Validity: 17-12-2027</p> <p>CE Certificate Validity: 08-04-2029</p> <p>ISO 13485 Validity: 27-02-2027</p>	<p>Class B</p> <p>Shelf Life:5 Years</p> <p>Code/Sizes (If any) Neonate (S) Infant (M) Child (M) Adult (XL)</p> <p>Size: R030102 Air/Oxygen Masks and Nasal Cannulas</p>	Noor International Karachi.
261.	<p>Applicant Name:</p> <p>M/s. NI healthcare Products Pvt Ltd.</p> <p>Address: Office No. A, Unit 10 Survey No. 263, Damlotte Road District Malir, Karachi</p> <p>(ELI-01117)</p> <p>Date of R&I 14-03-2025 Rs.31,000/- Slip# 07733267928</p>	<p>Legal Manufacturer:</p> <p>Jiangsu Hitec Medical Co. Ltd., Jiangxin Road North, Tongzhou Bay River Sea Joint Development Demonstration Zone, Jiangsu Province, China</p> <p>FSC: Validity: 27-12-2026</p> <p>LOA Validity: 17-12-2027</p> <p>CE Certificate Validity: 08-04-2029</p> <p>ISO 13485 Validity: 27-02-2027</p>	<p>Brand Name:</p> <p>DYCO Suction Connecting Tube with Yankauer handle</p> <p>Class B</p> <p>Shelf Life:5 years</p> <p>Codes/Sizes (If any) Sizes: with Yankauer handle 8.2mm 9.0mm 9.7mm 10.0mm 10.7mm 11.2mm</p> <p>Code: A060102 Surgical Drainage Connection Medical tubes</p>	Deferred since the same brand name already applied by Noor International Karachi and clarification of sizes and code.
262.	<p>Applicant Name:</p> <p>M/s. NI healthcare Products Pvt Ltd.</p> <p>Address: Office No. A, Unit 10 Survey No. 263, Damlotte Road District Malir,</p>	<p>Legal Manufacturer:</p> <p>Jiangsu Hitec Medical Co. Ltd., Jiangxin Road North, Tongzhou Bay River Sea Joint Development Demonstration Zone, Jiangsu Province, China</p> <p>FSC: Validity: 27-12-2026</p>	<p>Brand Name:</p> <p>DYCO Non-Rebreath Mask</p> <p>Class B</p> <p>Shelf Life:5 years</p> <p>Codes/Sizes (If any) Sizes:</p>	Deferred since the same brand name already applied by Noor International Karachi and clarification of sizes and code.

	Karachi (ELI-01117) Date of R&I 14-03-2025 Rs.31,000/- Slip# 58730598	LOA Validity: 17-12-2027 CE Certificate Validity: 08-04-2029 ISO 13485 Validity: 27-02-2027	Pediatric Standard (S) Pediatric Elongated (M) Adult Standard (L) Adult Elongated (XL) Code: R030102 Air/Oxygen Masks and Nasal Cannulas	
263.	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 14-03-2025 Rs.62,000/- Slip# 57980624392	Legal Manufacturer: 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 CE Certificate Validity: 08-04-2029 ISO 13485 Validity: 27-02-2027	Brand Name: DYCO Endotracheal tube Class C Shelf Life: 5 years Codes/Sizes (If any) Size: with Cuffed and uncuffed Oral/Nasal uncuffed Oral/Nasal cuffed Oral performed uncuffed Oralperformed cuffed nasal performed uncuffed nasal performed cuffed Reinforced uncuffed Rienforced cuffed With suction lumen cuffed 2.0 mm 2.5 mm 3.0 mm 3.5 mm 4.0 mm 4.5 mm 5.0 mm 5.5 mm 6.0 mm 6.5 mm 7.0 mm 7.5 mm 8.0 mm 8.5 mm 9.0 mm	Deferred since the same brand name alrady applied by Noor International Karachi. Justification for applying various types in single application.

			9.5 mm 10.0 mm	
264.	<p>Applicant Name:</p> <p>M/s. NI healthcare Products Pvt Ltd.</p> <p>Address: Office No. A, Unit 10 Survey No. 263, Damlotte Road District Malir, Karachi</p> <p>(ELI-01117)</p> <p>Date of R&I 06-09-2024 Rs.31,000 Slip# 748289600806</p>	<p>Legal Manufacturer:</p> <p>Feellife Health Inc. Address: Room 2501, 1903, 2002, Building A, No.9 Furong Road, Tantou Community, Songgang Subdistrict, Bao'an District, Shenzhen, 518104 Guangdong, P.R. China</p> <p>FSC: Validity: 04-02-2026</p> <p>LOA Validity: 13-01-2028</p> <p>CE Certificate Validity: 26-05-2024 with extension letter 31-12-2028</p> <p>ISO 13485 Validity: 29-09-2026</p>	<p>Brand Name:</p> <p>AIR ICU (Portable Mesh Nebulizer)</p> <p>Class: B</p> <p>Shelf Life: 5 years</p> <p>Codes/size (If any) Code: AirICU ICU MC10 ICU TP1 ICU AS1 L1 M1 ICU LT1 ICU YT1 SINGOF-6E-050120 ICU SFC1 AIRICU ICU MC10H ICU TP1 ICUTP5 ICU MC10SH ICU M1 ICU ATI ICU NA1H ICUI SRN ICUSRN-T</p>	<p>Approved with codes available in FSC subject to submission of fee as per revised SRO</p>
265.	<p>Applicant Name:</p> <p>M/s. NI healthcare Products Pvt Ltd.</p> <p>Address: Office No. A, Unit 10 Survey No. 263, Damlotte Road District Malir, Karachi</p> <p>(ELI-01117)</p>	<p>Legal Manufacturer:</p> <p>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.</p>	<p>Brand Name:</p> <p>Video Laryngoscope Blade</p> <p>Generic Name: Video Laryngoscope Blade M1, M2, M3, M3D and M4</p> <p>Class A</p> <p>Shelf Life: 5 years</p>	<p>Deferred for clarification regarding the class of medical device and Brand name.</p>

	<p>Date of R&I 28-03-2025 Rs. 6000 Slip# 953813925934</p>	<p>FSC: Validity: 08-09-2026</p> <p>LOA Validity: 10-01-2028</p> <p>CE Certificate Validity: 26-05-2024 with Extension letter Expiry 31- 12-2028</p> <p>ISO 13485 Validity: 16-06-2025</p>		
266.	<p>Applicant Name:</p> <p>M/s. NI healthcare Products Pvt Ltd.</p> <p>Address: Office No. A, Unit 10 Survey No. 263, Damlotte Road District Malir, Karachi</p> <p>(ELI-01117)</p> <p>Date of R&I 28-03-2025 Rs.62,000/- Slip# 141905652</p>	<p><u>Legal Manufacturer:</u></p> <p>Vincent Medical Manufacturing Co., Ltd</p> <p>Address: Flat/RM B2, 7/F. Hang Fung Industrial Building Phase 2, 2G Hok Yuen St., Hung Hom, Kowloon, Hong Kong</p> <p>Telephone number: 00852- 2365 5688</p> <p>FSC: China Validity: 06-02-2027</p> <p>LOA Validity: 01-12-2026</p> <p>CE Certificate Validity: 06-05-2024 with extension letter 31-12-2028</p> <p>ISO 13485 Validity: 16-04-2027</p>	<p>Brand Name:</p> <p>O2FLO High flow Heated Humidifier</p> <p>Class: C</p> <p>Shelf Life: 5 years</p> <p>Code: VUN-001 VUN-003-A</p>	<p>Approved subject to submission of fee as per revised SRO</p>
267.	<p>Applicant Name:</p> <p>Zenith International, Room #104, Tahir Plaza, A/20, Block 7&8, K.C.H.S.U. Karachi, Pakistan</p> <p>(ELI-00090)</p>	<p><u>Legal Manufacturer:</u></p> <p>M/s. Wenzhou Longwan Medical Device Factory</p> <p>Manufacturing site: Unit 4, Building 27, No. 706 Yanyun Road, Oujiangkou Industrial Cluster District, 325026 Wenzhou, Zhejiang, China</p> <p>FSC: China</p>	<p>Brand Name</p> <p>“PRECISION +” Stethoscope</p> <p>Class A</p> <p>Shelf Life: 05 years</p> <p>Codes / Sizes (if any)</p> <p>(Model # TY-S02, TY- S04, TY-S05)</p>	<p>Approved Model # TY-S02.</p>

	Date of R&I 20 th March 2025 Fees Challan No: 0999425856 Dated: 17/03/2025 Case Management Ref # QXN-3NM-XAW5	Validity: 12-01-2027 LOA Validity: 24-11-2029		
268.	Applicant Name: Zenith International, Room #104, Tahir Plaza, A/20, Block 7&8, K.C.H.S.U. Karachi, Pakistan (ELI-00090) Date of R&I 05 March 2025 Fees Challan No: 27550554961 Dated: 27/02/2025 Case Management Ref # TU6-X1X-96V8	Legal Manufacturer: M/s. . Ningbo Pinmed Instruments Co., Ltd., Manufacturing Site: Room (22-1) (22-2) , No. 455, East Zhongshan Road, Yinzhou District, 315040 Ningbo, China FSC: China Validity: 01-07 -2026 LOA Validity: 12-08-2029	Brand Name “PERFECT” brand Stethoscope Class A Shelf Life: 05 years Codes / Sizes (if any) (Model # GT002-200, GT002-210, GT002-220, GT002-230, GT002-270, GT002-300, GT002-310)	Case already decided in 82 nd meeting of MDB.
269.	Applicant Name: Zenith International, Room #104, Tahir Plaza, A/20, Block 7&8, K.C.H.S.U. Karachi, Pakistan	Legal Manufacturer: M/s. Wenzhou Longwan Medical Device Factory Manufacturing Site: Unit 4, Building 27, No. 706 Yanyun Road, Oujiangkou Industrial Cluster District, 325026 Wenzhou, Zhejiang, China	Brand Name PRECISION+ brand Aneroid Sphygmomanometer Class B Shelf Life: 05 years Codes / Sizes (if any) (Model # TY-A01,TY-	Approved TY-A01

	(ELI-00090) Date of R&I 20 March 2025 Fees Challan No: 74531225018 Dated: 17/03/2025 Case Management Ref # T5L-HMW-MY42	<u>FSC:</u> valid till 12-01 -2027 <u>LOA</u> Notarized LOA Valid till 24-11-2029 <u>EC Certificate</u> Validity: 18-03-2029 ISO 13485 Validity: 24-11-2027	A04)	
270.	Applicant Name: Zenith International, Room #104, Tahir Plaza, A/20, Block 7&8, K.C.H.S.U. Karachi, Pakistan (ELI-00090) Date of R&I 05 March 2025 Fees Challan No: 983486527844 Dated: 27/02/2025 Case Management Ref# TRS-D7J-AP21	<u>Legal Manufacturer:</u> M/s. . Ningbo Pinmed Instruments Co., Ltd., Manufacturing Site: Room (22-1) (22-2) , No. 455, East Zhongshan Road, Yinzhou District, 315040 Ningbo, China. <u>FSC:</u> valid till 01-07 -2026 <u>LOA</u> Notarized LOA Valid till 12-08-2029 <u>EC Certificate</u> Validity: 26-05-2024 With CE Extension letter ISO 13485 Validity: 21-08-2025	Brand Name “PERFECT FINE +” brand Feeding Tube, Sterile (Ryle Tube) Class B Shelf Life: 05 years Codes / Sizes (if any) (Sizes: 4fr, 5fr, 6fr, 7fr, 8fr, 10fr)	Case already decided in 82 nd meeting of MDB.
271.	Applicant Name: Zenith International, Room #104, Tahir Plaza, A/20, Block 7&8, K.C.H.S.U. Karachi, Pakistan	<u>Legal Manufacturer:</u> M/s. . Ningbo Pinmed Instruments Co., Ltd., Manufacturing Site: Room (22-1) (22-2) , No. 455, East Zhongshan Road, Yinzhou District, 315040 Ningbo, China.	Brand Name “PERFECT FINE +” brand Suction Catheter, Sterile Class B Shelf Life: 05 years Codes / Sizes (if any)	Case already decided in 82 nd meeting of MDB.

	<p>(ELI-00090)</p> <p>Date of R&I 05 March 2025</p> <p>Fees Challan No: 45990784829</p> <p>Dated: 27/02/2025</p> <p>Case Management Ref# TRA-NL2-T782</p>	<p><u>FSC:</u> valid till 01-07 -2026</p> <p><u>LOA</u> Notarized LOA Valid till 12-08-2029</p> <p><u>EC Certificate</u> Validity: 26-05-2024 With CE Extension letter</p> <p>ISO 13485 Validity: 21-08-2025</p>	<p>(Sizes: 6fr, 8fr,10fr, 12fr, 14fr, 16fr, 18fr, 20fr)</p>	
272.	<p>Applicant Name:</p> <p>Zenith International, Room #104, Tahir Plaza, A/20, Block 7&8, K.C.H.S.U. Karachi, Pakistan</p> <p>(ELI-00090)</p> <p>Date of R&I 05 March 2025</p> <p>Fees Challan No: 556755410310</p> <p>Dated: 27/02/2025</p> <p>Case Management Ref# 14V-7B6-VJAW</p>	<p><u>Legal Manufacturer:</u></p> <p>M/s. . Ningbo Pinmed Instruments Co., Ltd.,</p> <p>Manufacturing Site: Room (22-1) (22-2) , No. 455, East Zhongshan Road, Yinzhou District, 315040 Ningbo, China.</p> <p><u>FSC:</u> valid till 01-07 -2026</p> <p><u>LOA</u> Notarized LOA Valid till 12-08-2029</p> <p><u>EC Certificate</u> Validity: 26-05-2024 With CE Extension letter</p> <p>ISO 13485 Validity: 21-08-2025</p>	<p>Brand Name</p> <p>“PERFECT +” brand Rebreathing Oxygen Mask, Sterile</p> <p>Class B</p> <p>Shelf Life: 05 years</p> <p>Codes / Sizes (if any)</p>	Case already decided in 82 nd meeting of MDB.
273.	<p>Applicant Name:</p> <p>Zenith International, Room #104, Tahir Plaza, A/20, Block 7&8, K.C.H.S.U. Karachi,</p>	<p><u>Legal Manufacturer:</u></p> <p>M/s. . Ningbo Pinmed Instruments Co., Ltd.,</p> <p>Manufacturing Site: Room (22-1) (22-2) , No. 455, East Zhongshan Road, Yinzhou District, 315040 Ningbo, China.</p>	<p>Brand Name</p> <p>“PERFECT” brand Aneroid Sphygmomanometer</p> <p>Class B</p> <p>Shelf Life: 05 years</p>	Case already decided in 82 nd meeting of MDB.

	<p>Pakistan</p> <p>(ELI-00090)</p> <p>Date of R&I 05 March 2025</p> <p>Fees Challan No: 437204974</p> <p>Dated: 27/02/2025</p> <p>Case Management Ref# 4M2-AY8-AURJ</p>	<p><u>FSC:</u> valid till 01-07 -2026</p> <p><u>LOA</u> Notarized LOA Valid till 12-08-2029</p> <p><u>EC Certificate</u> Validity: 26-05-2024 With CE Extension letter</p> <p>ISO 13485 Validity: 21-08-2025</p>	<p>Codes / Sizes (if any)</p> <p>Model # GT001-101, GT001-130)</p>	
274.	<p>Applicant Name:</p> <p>Zenith International, Room #104, Tahir Plaza, A/20, Block 7&8, K.C.H.S.U. Karachi, Pakistan</p> <p>(ELI-00090)</p> <p>Date of R&I 05 March 2025</p> <p>Fees Challan No: 92146349996</p> <p>Dated: 27/02/2025</p> <p>Case Management Ref# QLG-EPP-39TH</p>	<p><u>Legal Manufacturer:</u></p> <p>M/s. . Ningbo Pinmed Instruments Co., Ltd.,</p> <p>Manufacturing Site: Room (22-1) (22-2) , No. 455, East Zhongshan Road, Yinzhou District, 315040 Ningbo, China.</p> <p><u>FSC:</u> valid till 01-07 -2026</p> <p><u>LOA</u> Notarized LOA Valid till 12-08-2029</p> <p><u>EC Certificate</u> Validity: 26-05-2024 With CE Extension letter</p> <p>ISO 13485 Validity: 21-08-2025</p>	<p>Brand Name</p> <p>“PERFECT +” brand Three Way Stopcock with tube, Sterile</p> <p>Class B</p> <p>Shelf Life: 05 years</p> <p>Codes / Sizes (if any)</p>	Case already decided in 82 nd meeting of MDB.
275.	<p>Applicant Name:</p> <p>Zenith International, Room #104, Tahir Plaza, A/20, Block 7&8,</p>	<p><u>Legal Manufacturer:</u></p> <p>M/s. . Ningbo Pinmed Instruments Co., Ltd.,</p> <p>Manufacturing Site: Room (22-1) (22-2) , No. 455, East Zhongshan Road,</p>	<p>Brand Name</p> <p>“PERFECT FINE +” brand Nelaton Catheter, Sterile (Urology Catheter)</p> <p>Class B</p>	Case already decided in 82 nd meeting of MDB.

	<p>K.C.H.S.U. Karachi, Pakistan</p> <p>(ELI-00090)</p> <p>Date of R&I 05 March 2025</p> <p>Fees Challan No: 559418028659</p> <p>Dated: 27/02/2025</p> <p>Case Management Ref# AG6-A3P-XP3P</p>	<p>Yinzhou District, 315040 Ningbo, China.</p> <p>FSC: valid till 01-07 -2026</p> <p>LOA Notarized LOA Valid till 12-08-2029</p> <p>EC Certificate Validity: 26-05-2024 With CE Extension letter</p> <p>ISO 13485 Validity: 21-08-2025</p>	<p>Shelf Life: 05 years</p> <p>Codes / Sizes (if any) (Sizes: 6fr, 8fr, 10fr, 12fr, 14fr, 16fr, 18fr, 20fr, 22fr, 24fr)</p>	
276.	<p>Applicant Name:</p> <p>Zenith International, Room #104, Tahir Plaza, A/20, Block 7&8, K.C.H.S.U. Karachi, Pakistan</p> <p>(ELI-00090)</p> <p>Date of R&I 05 March 2025</p> <p>Fees Challan No: 48199097164</p> <p>Dated 27/02/2025</p> <p>Case Management Ref# D2X-279-12B1</p>	<p>Legal Manufacturer:</p> <p>M/s Hangzhou Tongzhou Biotechnology Co., Ltd.,</p> <p>Manufacturing Site: Room 102, Building 4, No. 191, Xintian Road, Yunhe Street, Linping District, Hangzhou, China.</p> <p>FSC: China Validity: 17-09-2026</p> <p>FSC: FSC of Reference Country EU FSC From Spain</p> <p>LOA Validity: 19-01-2030</p> <p>EC Certificate Validity: 25-01-2027</p> <p>ISO 13485 Validity: 19-07-2026</p>	<p>Brand Name</p> <p>“HINDERING” HbA1c Rapid Test Cassette</p> <p>Class B</p> <p>Shelf Life: 02 years</p> <p>Codes / Sizes (if any)</p>	Case already decided in 82 nd meeting of MDB.
277.	<p>Applicant Name:</p> <p>Zenith International, Room #104,</p>	<p>Legal Manufacturer:</p> <p>Suzhou Health Plastic Products Co., Ltd,</p>	<p>Brand Name</p> <p>PERFECT FINE Three way Stopcock, Sterile with ExtensionTube</p>	Approved subject to submission of valid EC Certificate & original valid FSC.

	<p>Tahir Plaza, A/20, Block 7&8, K.C.H.S.U. Karachi, Pakistan</p> <p>(ELI-00090)</p> <p>Date of R&I 07 June 2023</p> <p>Fees Challan No: 4864532896 Dated: 07/06/2023</p> <p>Case Management Ref# N55-MNE-9DNR</p>	<p>Manufacturing Site: No. 699, Ping'an Road, Linhu Town Wuzhong District, 215105, Suzhou, Jiangsu, China</p> <p><u>FSC:</u> China Legalized FSC No. 2023YB0083J valid till 14- 04-2025</p> <p><u>LOA</u> Validity: 21-02-2028</p> <p><u>EC Certificate</u> Validity: 26-05-2024</p> <p>ISO 13485 Validity: 29-08-2025</p>	<p>Class B</p> <p>Shelf Life: 05 years</p> <p>Codes / Sizes (if any)</p>	
278.	<p>Applicant Name:</p> <p>M/s. United Healthcare Address: Plot No. 330/A 2nd Floor, Block 3, DMCHS, Alamgir Road, Karachi</p> <p>(ELI-00293)</p> <p>Date of R&I 30-09-2024</p> <p>Fee Challan: 93967998931</p>	<p>Legal Manufacturer:</p> <p>M/s Shanghai Kindly Enterprise Development Group Co., Ltd</p> <p>Address: No. 658, Gaochao road, Jiang Qiao Town, Jiading District, Shanghai, China 201803.</p> <p>FSC: China Validity: 16-01-2025</p> <p>LOA Validity: 01-07-2029</p> <p>ISO 13485 Validity: 31-10-2026</p>	<p>Brand Name:</p> <p>Safety Flo Urine Collection Bag</p> <p>Generic Name: Urine Collection Bags / Urinal Bag for Single Use</p> <p>Class A</p> <p>Shelf Life: 05 Years</p> <p>Codes / Sizes (if any)</p> <p>LJQ-1000, LJN- 1000, LNQ-1000, LNN-1000, LJQ- 2000, LJN-2000. LNQ-2000, LNN- 2000, SJQ-1000, SJN-1000, SNQ- 1000, SNN-1000, SJQ-2000, SJN- 2000, SNQ-2000, SNN-2000, ZJQ- 1000, ZJN-1000, ZNQ-1000, ZNN- 1000, ZJQ-2000, ZJN-2000, ZNQ-</p>	<p>Approved with sizes as per FSC subject to submission of valid FSC certificate</p>

			2000, ZNN-2000	
279.	<p>Applicant Name:</p> <p>M/s. United Healthcare Address: Plot No. 330/A 2nd Floor, Block 3, DMCHS, Alamgir Road, Karachi</p> <p>(ELI-00293)</p> <p>Date of R&I 14-11-2023</p>	<p>Legal Manufacturer:</p> <p>M/s. Thai Nippon Rubber Industry Public Company Limited</p> <p>Manufacturing Site: 789/139 Moo 1 Pinthong Industrial State Nongkham, Sriracha, Chonburi 20110, Thailand</p> <p>FSC: Country: THAILAND Validity: 05-02-2026</p> <p>LOA Validity: 02-07-2029</p> <p>CE Certificate Validity: 30-05-2027</p> <p>ISO 13485 Validity: 07-02-2026</p>	<p>Brand Name</p> <p>SafeIn</p> <p>Generic Name: Natural Rubber Latex Male Condom</p> <p>Class-C</p> <p>Shelf Life: 05 years</p> <p>Codes/Sizes: As per FSC</p>	<p>Approve with codes /sizes of Natural Rubber Latex available in FSC.</p>
280.	<p>Applicant Name:</p> <p>M/s. United Healthcare Address: Plot No. 330/A 2nd Floor, Block 3, DMCHS, Alamgir Road, Karachi</p> <p>(ELI-00293)</p> <p>Date of R&I 20-02-2023</p> <p>Fee Challan: 896859302262</p>	<p>Legal Manufacturer:</p> <p>M/s Foshan Kaiyang Medical Equipment Co., Ltd.</p> <p>3 of No. 21, The 3rd Hongling Road, Shishan Town, Nanhai District, Foshan City, Guangdong Province, China</p> <p>FSC: China Validity: 13/09/2026</p> <p>LOA Validity: 06/10/2027</p> <p>ISO 13485 Validity:21/12/2025</p>	<p>Brand Name:</p> <p>Safety Wheel Walker</p> <p>Generic Name: Wheel Walker</p> <p>Class A</p> <p>Shelf Life: NA</p> <p>Codes / Sizes (if any) KY912L-2.5, KY912L-3, KY912L-4, KY912L-5</p>	<p>Approved.</p> <p>The firm shall submit fee as per revised SRO.</p>

281.	Applicant Name: M/s. United Healthcare Address: Plot No. 330/A 2nd Floor, Block 3, DMCHS, Alamgir Road, Karachi (ELI-00293) Date of R&I 20-02-2023 Fee Challan: 03353269	Legal Manufacturer: M/s Foshan Kaiyang Medical Equipment Co., Ltd. 3 of No. 21, The 3rd Hongling Road, Shishan Town, Nanhai District, Foshan City, Guangdong Province, China FSC: China Validity: 13/09/2026 LOA Validity: 06/10/2027 ISO 13485 Validity: 21/12/2025	Brand Name: Safety Axillary Crutches Generic Name: Axillary Crutches Class A Shelf Life: NA Codes / Sizes (if any) KY925L(S), KY925L(M), KY925L(L)	Approved
282.	Applicant Name: M/s. United Healthcare Address: Plot No. 330/A 2nd Floor, Block 3, DMCHS, Alamgir Road, Karachi (ELI-00293) Date of R&I 20-02-2023 Fee Challan: 19366361172	Legal Manufacturer: M/s Foshan Kaiyang Medical Equipment Co., Ltd. 3 of No. 21, The 3rd Hongling Road, Shishan Town, Nanhai District, Foshan City, Guangdong Province, China FSC: China Validity: 13/09/2026 LOA Validity: 06/10/2027 ISO 13485 Validity: 21/12/2025	Brand Name: Safety Manual Hospital Bed Generic Name: Manual Hospital Bed Class A Shelf Life: NA Codes / Sizes (if any) KY211S-32	Approved
283.	Applicant Name: M/s. United Healthcare Address: Plot No. 330/A 2nd Floor, Block 3, DMCHS, Alamgir Road, Karachi (ELI-00293)	Legal Manufacturer: M/s Foshan Kaiyang Medical Equipment Co., Ltd. 3 of No. 21, The 3rd Hongling Road, Shishan Town, Nanhai District, Foshan City, Guangdong Province, China FSC: China	Brand Name: Safety Walking Sticks Generic Name: Walking Sticks Class A Shelf Life: NA Codes / Sizes (if any)	Approved. The firm shall submit fee as per revised SRO for family.

	<p>Date of R&I 06-10-2023</p> <p>Fee Challan: 3018835297</p>	<p>Validity: 13/09/2026</p> <p>LOA Validity: 06/10/2027</p> <p>ISO 13485 Validity:21/12/2025</p>	<p>KY924, KY920L, KY927L, KY911L-A, KY9201L, KY910L, KY932</p>	
284.	<p>Applicant Name:</p> <p>M/s. United Healthcare Address: Plot No. 330/A 2nd Floor, Block 3, DMCHS, Alamgir Road, Karachi</p> <p>(ELI-00293)</p> <p>Date of R&I 08-09-2023</p> <p>Fee Challan: 68300485</p>	<p>Legal Manufacturer:</p> <p>M/s Jiangsu Yuyue Medical Equipment & Supply Co., Ltd.</p> <p>No.1 Baisheng Road, Development Zone, 212300 Danyang City, Jiangsu, PEOPLE'S REPUBLIC OF CHINA</p> <p>FSC: China Validity: 10/10/2024</p> <p>LOA Validity: 04/01/2027</p> <p>ISO 13485 Validity:01/11/2025</p>	<p>Brand Name:</p> <p>Safety Aneroid Sphygmomanometer</p> <p>Generic Name: Aneroid Sphygmomanometer</p> <p>Class A</p> <p>Shelf Life: 05 years</p> <p>Codes / Sizes (if any) YM100, YM200</p>	<p>Deffered for: Class, differebtial fee as per class, valid original FSC certificate.</p>
285.	<p>Applicant Name:</p> <p>M/s. United Healthcare Address: Plot No. 330/A 2nd Floor, Block 3, DMCHS, Alamgir Road, Karachi</p> <p>(ELI-00293)</p> <p>Date of R&I 04-06-2024</p> <p>Fee Challan: 055995722</p>	<p>Legal Manufacturer:</p> <p>M/s Jinhua Jingdi Medical Supplies Co Ltd.</p> <p>88 Innovation Road, Xiaoshun Town, Jindong, Jinhua, Zhejiang, China</p> <p>FSC: China Validity: 01/12/2025</p> <p>LOA Validity: 28/02/2029</p> <p>ISO 13485 Validity:02/03/2026</p>	<p>Brand Name:</p> <p>Safety Corn Cap Plaster</p> <p>Generic Name: Corn Cap Plaster</p> <p>Class A</p> <p>Shelf Life: 05 years</p> <p>Codes / Sizes (if any) 60mm×20mm 70mm×20mm Φ22mm, Φ25mm, 72mm×25mm, 72×22mm, 72mm×20mm 72×19mm,72mm×38m m, 38mm×38mm, 56mm×19mm, 72mm x 30mm, 76mm x</p>	<p>Approved</p>

			38mm	
286.	Applicant Name: M/s. United Healthcare Address: Plot No. 330/A 2nd Floor, Block 3, DMCHS, Alamgir Road, Karachi (ELI-00293) Date of R&I 04-06-2024 Fee Challan: 8601050005	Legal Manufacturer: M/s Jinhua Jingdi Medical Supplies Co Ltd. 88 Innovation Road, Xiaoshun Town, Jindong, Jinhua, Zhejiang, China FSC: China Validity: 01/12/2025 LOA Validity: 28/02/2029 ISO 13485 Validity:02/03/2026	Brand Name: Safety Eye Pad Generic Name: Eye Pad Class A Shelf Life: 05 years Codes / Sizes (if any) 80mm x 60mm	Approved
287.	Applicant Name: M/s. United Healthcare Address: Plot No. 330/A 2nd Floor, Block 3, DMCHS, Alamgir Road, Karachi (ELI-00293) Date of R&I 04-06-2024 Fee Challan: 14750808095	Legal Manufacturer: M/s Jinhua Jingdi Medical Supplies Co Ltd. 88 Innovation Road, Xiaoshun Town, Jindong, Jinhua, Zhejiang, China FSC: China Validity: 01/12/2025 LOA Validity: 28/02/2029 ISO 13485 Validity: 02/03/2026	Brand Name: Safety First Aid Bandage Generic Name: First Aid Bandage Class A Shelf Life: 05 years Codes / Sizes (if any) Φ22mm, Φ25mm, 72mm×25mm, 72×22mm, 72mm×20mm 72×19mm,72mm×38m m, 38mm×38mm, 56mm×19mm, 72mm x 30mm, 72mm x 25mm, 76mm x 38mm	Approved
288.	Applicant Name: M/s. United Healthcare Address:	Legal Manufacturer: M/s Jinhua Jingdi Medical Supplies Co Ltd.	Brand Name: Safety PE Tape Generic Name:	Approved

<p>Plot No. 330/A 2nd Floor, Block 3, DMCHS, Alamgir Road, Karachi</p> <p>(ELI-00293)</p> <p>Date of R&I 04-06-2024</p> <p>Fee Challan: 2739863917</p>	<p>88 Innovation Road, Xiaoshun Town, Jindong, Jinhua, Zhejiang, China</p> <p>FSC: China Validity: 01/12/2025</p> <p>LOA Validity: 28/02/2029</p> <p>ISO 13485 Validity:02/03/2026</p>	<p>PE Tape</p> <p>Class A</p> <p>Shelf Life: 05 years</p> <p>Codes / Sizes (if any) 2.5×1yd , 2.5×2yd, 2.5×3yd, 2.5×4yd, 2.5×5yd, 2.5×6yd, 2.5×7yd, 2.5×8yd, 2.5×9yd, 2.5×10yd , 5×1yd, 5×2yd, 5×3yd , 5×4yd, 5×5yd, 5×6yd, 5×7yd, 5×8yd , 5×9yd, 5×10yd, 7.5×1yd,7.5×2yd, 7.5×3yd, 7.5×4yd, 7.5×5yd, 7.5×6yd, 7.5×7yd, 7.5×8yd, 7.5×9yd, 7.5×10yd, 10×1yd,10×2yd, 10×3yd, 10×4yd, 10×5yd, 10×6yd, 10×7yd, 10×8yd, 10×9yd, 10×10yd; 2.5×1m , 2.5×2m, 2.5×3m, 2.5×4m, 2.5×5m, 2.5×6m, 2.5×7m, 2.5×8m, 2.5×9m, 2.5×10m , 5×1m, 5×2m, 5×3m, 5×4m, 5×5m, 5×6m , 5×7m, 5×8m, 5×9m, 5×10m, 7.5×1m,7.5×2m, 7.5×3m, 7.5×4m, 7.5×5m, 7.5×6m,</p>	
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			7.5×7m, 7.5×8m, 7.5×9m, 7.5×10m, 10×1m,10×2m, 10×3m , 10×4m, 10×5m, 10×6m, 10×7m, 10×8m, 10×9m, 10×10m	
289.	Applicant Name: M/s. United Healthcare Address: Plot No. 330/A 2nd Floor, Block 3, DMCHS, Alamgir Road, Karachi (ELI-00293) Date of R&I 31-07-2024 Fee Challan: 0572159201	Legal Manufacturer: M/s Wuxi Exanovo Medical Instrument Co., Ltd. Address: C2-LianDong U Gu, Xibei Town, Xishan District, Wuxi 214194 Jiangsu, P.R. China FSC: China Validity: 11-05-2025 LOA Validity: 19-06-2029 ISO 13485 Validity: 21-10-2026	Brand Name: SeniorMed Aneroid Sphygmomanometer Generic Name: Aneroid Sphygmomanometer Class A Shelf Life: N/A Codes / Sizes (if any) MC-20(-50)	Deffered for Class, differential fee and shelf life
290.	Applicant Name: M/s. United Healthcare Address: Plot No. 330/A 2nd Floor, Block 3, DMCHS, Alamgir Road, Karachi (ELI-00293) Date of R&I 31-07-2024 Fee Challan: 8218692534	Legal Manufacturer: M/s Wuxi Exanovo Medical Instrument Co., Ltd. Address: C2-LianDong U Gu, Xibei Town, Xishan District, Wuxi 214194 Jiangsu, P.R. China. FSC: China Validity: 21-02-2025 LOA Validity: 19-06-2029 ISO 13485 Validity: 21-10-2026	Brand Name: SeniorMed Stethoscope Generic Name: Stethoscope Class A Shelf Life: N/A Codes / Sizes (if any) MC-220, MC-230	Approved subject to submission of valid original FSC certificate.
291.	Applicant Name: M/s. FREESIA ENTERPRISES	Name of Manufacturer: Ideal Medical Industries Co Ltd.	Brand Name: IDEAL Medical Latex Surgical Gloves	Approved powdered Subject to the submission of valid

	Address: 104, Dawn Plaza, Bank Road, Saddar Rawalpindi. (ELI-00201) R&I detail: 27-August-2021 Fee Challan details: Challan No. 2045786 Dated:27-08-2021 Paid Fee: 25000	Manufacturing Site address: Lutian Base, Poyang Industry Zone,Shang Rao, Jiangxi,China LOA Validity: 05-05-2024 FSC from Germany. Validity: 25-05-2024 ISO 13485 Validity: 31-10-2021	(Powder & Powder Free) Generic Name: Latex Surgical Gloves (Powder & Powder Free) Class B Shelf Life: 5 Years Codes/sizes: 6, 6.5, 7, 7.5, 8, 8.5, 9	original FSC of SRA, LOA and ISO 13485.
292.	Applicant Name: M/s. FREESIA ENTERPRISES Address: 104, Dawn Plaza, Bank Road, Saddar Rawalpindi. (ELI-00201) R&I detail: 25-04-2024 Fee Challan details: Challan No. 057485417537 Dated:22-02-2024 Paid Fee: 25000	Name of Manufacturer: Shaoxing Shangyu Xinyue Medical Appliance Co Ltd. Manufacturing Site(s): Tianjia Village, Xiaoyue Town, Shangyu City 312367, Zhejiang, China LOA Validity: 08-07-2026 FSC: Spain Validity: 26-05-2024 ISO 13485 Validity:06-04-2025	Brand Name: WIPE Disposable Electrosurgical Control Pencil. Generic Name: Disposable Electro Surgical Pencil Class B Shelf Life: 3 Years Codes/sizes: XY-P401, XY-P401-2, XY-P402, XY-P403, XY-P301, XY-P302, XY-P303, XY-P201, XY-P202, XY-P203, XY-P101, XY-P102, XY-P103, XY-F401, XY-F401-1, XY-F401-2, XY-F401-3, XY-R401	Approved Subject to the submission of valid original FSC of SRA and ISO 13485.

REGISTRATION OF MEDICAL DEVICES FOR LOCAL MANUFACTURING.

Sr. No.	Name & Address of Establishment	Name of Medical Devices With Size	Decision
1.	Lab Diagnostic Systems (SMC) Pvt Ltd., Plot No. 36-A, PSIC, SIE, Taxila, Rawalpindi	GLOW Ferritin Fluorescence Immunochromatography Kit Ref: G-44040	Approved

	(ELM-0028 valid till 26-10-2025.) [886-7L] R & I Dy.No. 11100 dated 30-04-2025.	Class: B Shelf Life:18 Months Fee: 25000 Fee Slip No. 31919406001	
2.	Pak Poly Products Pvt Ltd. 3.5 Km, Ferozpur Road, Kahna Kacha Road, Lahore (ELM-0095 valid till 12-03-2030) [894-6L] R & I Dy.No. 11072 dated 30-04-2025.	TSARA Soft Long Lasting Insecticidal Net Class: A Shelf Life: 2 Years Fee: 6000 Fee Slip No. 3423259330	Approved
3.	Pak Poly Products Pvt Ltd. 3.5 Km, Ferozpur Road, Kahna Kacha Road, Lahore (ELM-0095 valid till 12-03-2030) [895-6L] R & I Dy.No. 11073 dated 30-04-2025.	TSARA Net Insecticidal Treated Net (ITN) Class: A Shelf Life: 2 Years Fee: 6000 Fee Slip No. 1257141857	Approved
4.	Pak Poly Products Pvt Ltd. 3.5 Km, Ferozpur Road, Kahna Kacha Road, Lahore (ELM-0095 valid till 12-03-2030) [896-6L] R & I Dy.No. 11074 dated 30-04-2025.	TSARA PLUS Insecticidal Treated Net (ITN) Class: A Shelf Life: 2 Years Fee: 6000 Fee Slip No. 28396282	Approved
5.	Pak Poly Products Pvt Ltd. 3.5 Km, Ferozpur Road, Kahna Kacha Road, Lahore (ELM-0095 valid till 12-03-2030) [897-6L] R & I Dy.No. 11075 dated 30-04-2025.	TSARA BOOST Insecticidal Treated Net (ITN) Class: A Shelf Life: 2 Years Fee: 6000 Fee Slip No. 28396282	Approved
6.	Anax Associates Pvt 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.	MedPro Flex Cystoscopy Drape Pack Class: A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 2765736166 Reference Code: • 7012	Deferred for the following: Confirmation whether all the components will be manufactured by the manufacturer, since as per details provided in application form, the product pack contains seven components including a Medical hand towel.

			Grouping of medical device mentioned as NA, however, as per details in application form such as Formulation, labels etc, the product that is MedPro Flex Cystoscopy Drape Pack contains multiple medical devices and accordingly, the requisite fee may be submitted.
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: <ul style="list-style-type: none"> • 2060 (60cm × 60cm) • 2100 (100cm × 100cm) • 2150 (100cm × 150cm) 	Deferred for the following: confirmation/clarification that the label states “MedPro Eye Drape with drain Pouch”. Brochure not provided, so clarification from applicant requires whether the drain pouch makes part of final packing.

DEFERRED CASES OF PRODUCT REGISTRATION IMPORT

S#	Name of Applicant	Manufacturer/legal manufacturer	Name of Medical Device	Decision
1.	Name: Fresenius Medical Care Pakistan Pvt. Ltd Address: TAMC, First Floor, 27-C III, M.M. Alam Road Gulberg III, Lahore	Legal Manufacturer: Nipro Corporation 3-26, Senriokashinmachi, Settsu, Osaka, 566-8510, JAPAN Manufacturing Site: Nipro (Thailand) Corporation Limited Address:	AV Fistula Needle Class B Shelf Life: 05 Years Codes/Sizes: 14GA-R25L-R (F00012655) 15GA-R25L-R (F00012656) 16GA-R25L-R (F00012657)	Approved. Firm will submit original valid FSC and valid CE/FSC of SRA.

	Warehouse Address: 1. Al-Madina Warehouse, 28-Km, Multan Road, Lahore 2. Plot No. A6-A7, Northwestern Industrial Zone, Port Qasim, Karachi	10/2 Moo 8 Bangnomko, Sena Phra Nakhon Si Ayutthaya 13110 THAILAND	17GA-R25L-R (F00012658) 14GV-R25L-R (F00012665) 15GV-R25L-R (F00012666) 16GV-R25L-R (F00012667) 17GV-R25L-R (F00012668)	
2.	Moazzam Traders, Shop No. 4, Jalil Plaza, Gujranwala. ELI-00775 5490-P	Legal Manufacturer: Hangzhou Rollmed Co., Ltd, Room 913, Yuanmao Mansion. No. 5 wen'er west Rd Hangzhou, Zhejiang Province, P.R of China. FSC: missing	Doctor Check Disposable Infusion Set Class-C Shelf Life: 3 Years Models/ sizes: NRM3820 (Straight and y port)	Approved in class B. Firm will submit original valid FSC and valid CE/FSC of SRA.

DEFERRED CASES OF PRODUCT REGISTRATION OF LOCAL MANUFACTURING

Sr#	Manufacturer Name	Name of Medical Device/ Class/ Shelf life/ Codes/ Etc	Decision
1.	NISA.SF Private Limited. 10-Km, Muridke, Sheikhpura Road, Muridke, Distt. Sheikhpura ELM-0001 Sections: 1. Auto Disable Syringes 2. Disposable Syringe 3. I.V. Cannula 4. I.V Products	Injectocan Auto Disable syringe Class:B Shelf-life:5Years Sizes: 3ml syringe,5ml syringe,10ml syringe Needle sizes: 3ml Auto disable syringe Needle sizes: 21G x 1" (0.8mm x 25mm) 21 G x 1 1/2" (0.8mm x 38mm) 21G x 1 1/4" (0.8mm x 32mm) 22G (0.7mm x 30mm) 22G x 1 1/4" (0.7mm x 32mm) 22G x 1 1/2" (0.7mm x 38mm) 22G (0.7mm x 40mm) 23G x 1" (0.6mm x 25mm) 23G x 1 1/4" (0.6mm x 32mm) 23G x 1 1/2" (0.6mm x 38mm) 24G x 1" (0.55mm x 25mm) 24G x 1 1/4" (0.55mm x 32mm) 25G x 1/2" (0.5mm x 13mm) 25G x 1" (0.5mm x 0.25mm) 5ml Auto disable syringe Needle sizes: 21G x 1" (0.8mm x 25mm) 21 G x 1 1/2" (0.8mm x 38mm) 21G x 1 1/4" (0.8mm x 32mm) 22G (0.7mm x 30mm) 22G x 1 1/4" (0.7mm x 32mm)	Board approved Injectocan Auto Disable syringe Sizes: 3ml syringe,5ml syringe,10ml syringe.

		22G x 1 ½" (0.7mm x 38mm) 22G (0.7mm x 40mm) 23G x 1" (0.6mm x 25mm) 23G x 1 ¼" (0.6mm x 32mm) 23G x 1 ½" (0.6mm x 38mm) 24G x 1" (0.55mm x 25mm) 24G x 1 ¼" (0.55mm x 32mm) 25G x ½" (0.5mm x 13mm) 25G x 1" (0.5mm x 25mm) 10ml Auto disable syringe Needle sizes: 21G x 1 ½" (0.80mm x 38mm) 21G x 1" (0.80mm x 25mm) 21G x 1 ¼" (0.80mm x 32mm) 22G (0.7mm x 30mm) 22G (0.7mm x 40mm) 23G x 1" (0.6mm x 25mm) 23G x 1 ¼" (0.6mm x 32mm) 24G x 1" (0.55mm x 25mm) 25G x 1/2" (0.5mm x 13mm) 25G x 1" (0.5mm x 25mm)	
2.	5G Healthcare (PVT) Ltd F-35, SITE II, Scheme 33, Main Superhighway, Karachi [ELM-0072] [396-7L] Approved Section: Syringes Section (AD 2cc 3cc 5cc & Disposable 1cc 10cc 20cc 30cc 50cc & 60cc) IV Cannula (Pen; Wing with Heparin Cap & Port Types of all sizes) IV Set & Tubing section including Feeding Tubes Stomach Tubes Nelaton Tubes Suction Catheters/ Tubes	5G D-Set with Burette Infusion Set with Graduated Burette Class: B Shelf-life: 5 Years Sizes: 100ML, 150ML Fee: 20000/-	Approved 5G D-Set with Burette Infusion Set with Graduated Burette.

DECISIONS OF ADDITIONAL AGENDA OF 91ST MEETING OF MDB

REGISTRATION/ENLISTMENT OF MEDICAL DEVICES FOR IMPORT.

S#	Name of Applicant	Manufacturer/legal manufacturer	Name of Medical Device	Decision
1.	<p>Hipra Pakistan (Pvt) Ltd, House No. 86-88, J-1, Sunflower Society, M.A Johar Town Lahore.</p> <p>ELI-01204 5338-P 25,000/-</p>	<p><u>Legal Manufacturer:</u> Hipra Laboratories, Avda. La Selva, 135, 17170 Amer (Girona), Espana.</p> <p>FSC: Spain. Date of Issuance: 19-02-2024.</p>	<p>Hipraspray</p> <p>Class-B</p> <p>Shelf Life: N/A</p>	<p>Deferred for following:</p> <p>clarification that whether the subject product is a medical device in the country of origin or not.</p> <p>Credentials.</p> <p>Issuance and validity dates are not mentioned on LOA.</p> <p>Original valid legalized FSC issued by concerned regulatory authority as the issued certificate is by Chamber of commerce, industry, services and navigation of Girona.</p> <p>Notrized ISO 13485 certificate. Notarized FQA certificate.</p> <p>Declaration of Conformity.</p> <p>Generic name of the device. Shelf life</p>
2.	<p>Hipra Pakistan (Pvt) Ltd, House No. 86-88, J-1, Sunflower Society, M.A Johar Town Lahore.</p> <p>ELI-01204 5339-P 25,000/-</p>	<p><u>Legal Manufacturer:</u> Hipra Laboratories, Avda. La Selva, 135, 17170 Amer (Girona), Espana.</p> <p>FSC: Spain. Date of Issuance: 19-02-2024.</p>	<p>Hipraject</p> <p>Class-B</p> <p>Shelf Life: N/A</p>	<p>Deferred for following:</p> <p>clarification that whether the subject product is a medical device in the country of origin or not.</p> <p>Credentials.</p> <p>Issuance and validity dates are not mentioned on LOA.</p> <p>Original valid legalized FSC issued by concerned regulatory authority as the issued certificate is by Chamber of commerce,</p>

				<p>industry, services and navigation of Girona.</p> <p>Notrized ISO 13485 certificate. Notarized FQA certificate.</p> <p>Declaration of Conformity.</p> <p>Generic name of the device. Shelf life</p>
3.	<p>KISWA CARES,</p> <p>Office No. 7, 1st Floor Gulf Phaza Chandni Chowk Rawalpindi, Pakistan.</p> <p>ELI-00211 6024-P 62,000/-</p>	<p><u>Legal Manufacturer:</u> Ophthalmo Pro GmbH Im Reihersbruch I D-66386 St. Ingbert Germany.</p> <p>FSC: Germany. Date of Issuance: 27-08-2021</p>	<p>ZOE Hydrophobic Acrylic Intraocular Lenses (IOLs)</p> <p>Class-B</p> <p>Shelf Life: 5 Years</p> <p>Codes as per FSC</p>	<p>Deferred for the provision of following:</p> <p>LOA.</p> <p>Original FSC.</p> <p>Valid notarized ISO 13485 and FQA.</p> <p>Stability studies are missing for the claimed shelf life.</p> <p>Essential Principle checklist</p>
4.	<p>TECHNOLINKS,</p> <p>Office No. 30, Ground Floor, Jalal Centre, 59-A Mozang Road, Lahore.</p> <p>ELI-01249 1539-P 6,000/-</p>	<p><u>Legal Manufacturer:</u> ESCHWEILER GmbH & Co. KG Holzkoppelweg 35 D-24118 keil, Germany.</p> <p>FSC: Germany. Date of Issuance: 27-01-2023. LOA issuance 02-01-2023 ISO 13485 validity 02-06-2025</p>	<p>ESCHWEILER 1. Eschweiler Modular pro 2. Eschweiler CombiLine II Blood Gas Analyzer</p> <p>Class-A</p> <p>Shelf Life: N/A</p>	<p>Deferred for the provision of following:</p> <p>Original LOA. Original legalized FSC Notarized ISO 13485. Manufacturing details.</p> <p>Two products applied in Single application</p>
5.	<p>M/s Global Biotech Medical Devices Private Limited First Floor of Plot No: 35-N/3, PECHS Block 6, Near ROHAIL KHUND SOCIETY KARACHI (ELI-01292)</p> <p>R&I date: 18-03-2025</p>	<p><u>Legal Manufacturer:</u> M/s AndraTec GmbH, Simmerner Str. 70, 56075 Koblenz Germany</p> <p>LOA/sole agency :09-06-2025 (copy of LOA)</p> <p>FSC (Germany) Issue date: 17-03-2024 (Notarized FSC)</p>	<p>AltoSa-XL PTA Balloon Catheter</p> <p>Class: D</p> <p>Shelf life: 6 Years</p> <p>Codes/Sizes as per FSC</p>	<p>Deferred for the clarification of Class of medical device, claimed shelf life since the time of study is 5 years. Legalized FSC Original notarized LOA.</p>

	Fee Rs 62000/- vide Challan no. 7929936511	EC Certificate 28-10-2028 (Notarized EC certificate) ISO-13485 Validity: 13-10-2027(Notarized ISO Certificate)		
6.	M/s Global Biotech Medical Devices Private Limited First Floor of Plot No: 35-N/3, PECHS Block 6, Near ROHAIL KHUND SOCIETY KARACHI (ELI-01292) R&I date: 18-03-2025 Fee Rs 62000/- vide Challan no. 71044293	<u>Legal Manufacturer:</u> M/s AndraTec GmbH, Simmerner Str. 70, 56075 Koblenz Germany LOA/sole agency :09-06-2025 (copy of LOA) FSC (Germany) Issue date: 17-03-2024 (Notarized FSC) EC Certificate 28-10-2028 (Notarized EC certificate) ISO-13485 Validity: 13-10-2027(Notarized ISO Certificate)	AltoSa-XL Gemini Balloon Catheter PTA Balloon Catheter Class: D Shelf life: 6 Years Codes/Sizes as per FSC	Deferred for the clarification of Class of medical device and claimed shelf life since the time of study is 5 years. Legalized FSC Original notarized LOA.
7.	M/s Global Biotech Medical Devices Private Limited First Floor of Plot No: 35-N/3, PECHS Block 6, Near ROHAIL KHUND SOCIETY KARACHI (ELI-01292) R&I date: 18-03-2025 Fee Rs 62000/- vide Challan no. 578461584572	<u>Legal Manufacturer:</u> M/s AndraTec GmbH, Simmerner Str. 70, 56075 Koblenz Germany LOA/sole agency :09-06-2025 (copy of LOA) FSC (Germany) Issue date: 17-03-2024 (Notarized FSC) EC Certificate 28-10-2028 (Notarized EC certificate) ISO-13485 Validity: 13-10-2027(Notarized ISO Certificate)	Lokum Amplatz Type Guide Wire Class: D Shelf life: 5 Years Codes/Sizes as per FSC	Deferred for the clarification since the device is already registered for M/s SES Associates 148-Ejaz Park, Model Town Link Road, Lahore. Legalized FSC Original notarized LOA.

8.	<p>M/s Global Biotech Medical Devices Private Limited First Floor of Plot No: 35-N/3, PECHS Block 6, Near ROHAIL KHUND SOCIETY KARACHI (ELI-01292)</p> <p>R&I date: 18-03-2025</p> <p>Fee Rs 62000/- vide Challan no. 922023750630</p>	<p><u>Legal Manufacturer:</u> M/s AndraTec GmbH, Simmerner Str. 70, 56075 Koblenz Germany</p> <p>LOA/sole agency :09-06-2025 (copy of LOA)</p> <p>FSC (Germany) Issue date: 17-03-2024 (Notarized FSC)</p> <p>EC Certificate 28-10-2028 (Notarized EC certificate)</p> <p>ISO-13485 Validity: 13-10-2027(Notarized ISO Certificate)</p>	<p>Exeter Retrieval Snare preloaded</p> <p>Class: D</p> <p>Shelf life: 5 Years</p> <p>Codes/Sizes as per FSC</p>	<p>Deferred for the clarification since the device is already registered for M/s SES Associates 148-Ejaz Park, Model Town Link Road, Lahore. Legalized FSC Original notarized LOA.</p>
9.	<p>M/s Global Biotech Medical Devices Private Limited First Floor of Plot No: 35-N/3, PECHS Block 6, Near ROHAIL KHUND SOCIETY KARACHI (ELI-01292)</p> <p>R&I date: 18-03-2025</p> <p>Fee Rs 62000/- vide Challan no. 276311473</p>	<p><u>Legal Manufacturer:</u> M/s AndraTec GmbH, Simmerner Str. 70, 56075 Koblenz Germany</p> <p>LOA/sole agency :09-06-2025 (copy of LOA)</p> <p>FSC (Germany) Issue date: 17-03-2024 (Notarized FSC)</p> <p>EC Certificate 28-10-2028 (Notarized EC certificate)</p> <p>ISO-13485 Validity: 13-10-2027(Notarized ISO Certificate)</p>	<p>Optimus-CVS PTFE-Covered Stent</p> <p>Class: D</p> <p>Shelf life: 6 Years</p> <p>Codes/Sizes as per FSC</p>	<p>Deferred for the clarification since the device is already registered for M/s SES Associates 148-Ejaz Park, Model Town Link Road, Lahore. Legalized FSC Original notarized LOA.</p>
10.	<p>M/s Global Biotech Medical Devices Private Limited First Floor of Plot No: 35-N/3, PECHS Block 6, Near ROHAIL KHUND SOCIETY KARACHI</p>	<p><u>Legal Manufacturer:</u> M/s AndraTec GmbH, Simmerner Str. 70, 56075 Koblenz Germany</p> <p>LOA/sole agency :09-06-2025 (copy of LOA)</p>	<p>Optimus CoCr Stent</p> <p>Class: D</p> <p>Shelf life: 6 Years</p> <p>Codes/Sizes as per FSC</p>	<p>Deferred for the clarification since the device is already registered for M/s SES Associates 148-Ejaz Park, Model Town Link Road, Lahore. Legalized FSC Original notarized LOA.</p>

	(ELI-01292) R&I date: 18-03-2025 Fee Rs 62000/- vide Challan no. 667274866	FSC (Germany) Issue date: 17-03-2024 (Notarized FSC) EC Certificate 28-10-2028 (Notarized EC certificate) ISO-13485 Validity: 13-10-2027(Notarized ISO Certificate)		
11.	M/s Global Biotech Medical Devices Private Limited First Floor of Plot No: 35-N/3, PECHS Block 6, Near ROHAIL KHUND SOCIETY KARACHI (ELI-01292) R&I date: 26-03-2025 Fee Rs 31000/- vide Challan no. 0044851296	<u>Legal Manufacturer:</u> M/s AndraTec GmbH, Simmerner Str. 70, 56075 Koblenz Germany LOA/sole agency :09-06-2025 (copy of LOA) FSC (Germany) Issue date: 17-03-2024 (Notarized FSC) EC Certificate 28-10-2028 (Notarized EC certificate) ISO-13485 Validity: 13-10-2027(Notarized ISO Certificate)	Exeter Retrieval Snare Micro Preloaded Class: B Shelf life: 5 Years Codes/Sizes as per FSC ESM-2 ESM-4 ESM-7	deffered for confirmation of class of medical device accordingly, submit differential fee as per revised SRO. Legalized FSC Original notarized LOA.
12.	M/s Global Biotech Medical Devices Private Limited First Floor of Plot No: 35-N/3, PECHS Block 6, Near ROHAIL KHUND SOCIETY KARACHI (ELI-01292) R&I date: 26-03-2025 Fee Rs 31000/- vide Challan no. 8119755416	<u>Legal Manufacturer:</u> M/s AndraTec GmbH, Simmerner Str. 70, 56075 Koblenz Germany LOA/sole agency :09-06-2025 (copy of LOA) FSC (Germany) Issue date: 17-03-2024 (Notarized FSC) EC Certificate 28-10-2028 (Notarized EC certificate)	AltoSa-SFT Tacking Balloon Catheter PTA Balloon Catheter Class: B Shelf life: 6 Years Codes/Sizes as per FSC AL-46-65 AL-46-100	deffered for confirmation of class of medical device accordingly, submit differential fee as per revised SRO. Legalized FSC Original notarized LOA.

		ISO-13485 Validity: 13-10-2027(Notarized ISO Certificate)		
13.	<p>M/s Interex Company, 195, Block #7/8, 2nd Floor, KMCHS, Justice Inamullah Road, Near Hill Park Karachi</p> <p>(ELI-00249)</p> <p>R&I date: 17-03-2025</p> <p>Fee Rs 62000/- vide Challan no. 0030227312</p>	<p><u>Legal Manufacturer:</u> M/s Neurosafe Medical Co., Ltd., Building B, NO. 10, Keji 1st Rd, Hi-Tech Industrial Development Zone Zhuahi, Guangdong, China</p> <p>LOA/sole agency valid till :31-08-2026(Notarized LOA)</p> <p>FSC Spain Issue date: 29-08-2023(attested FSC of reference country)</p> <p>EC Certificate valid till: 27-05-2024 (Notarized EC Certificate with Extension notification)</p> <p>DE Certificate valid till: 27-05-2024 (Notarized EC Certificate with Extension notification)</p> <p>ISO-13485 Validity: 08-10-2025(Notarized ISO Certificate)</p>	<p>Lava Liquid Embolic System</p> <p>Class: D</p> <p>Shelf life: 3 Years</p> <p>Codes/Sizes as per FSC LAVA-12 LAVA-18 LAVA-34</p>	<p>Approved LAVA-12 as System and the firm shall submit fee as per revised SRO for System.</p>
14.	<p>Amson Vaccines & Pharma (Pvt) Ltd, 115 Industrial Triangle Kahuta Road Islamabad.</p> <p>ELI-00673 62,000/-</p>	<p><u>Legal Manufacturer:</u> Bioplus Co Ltd A-#901, #902, #903, #904, #905, #906, #907, 14, Sagimakgol-ro 45beon-gil, Jungwon-gu, Seongnam-si, Gyeonggi-do, Republic of Korea.</p> <p>Original FSC: Korea Date of Issuance: 30-08-2024. LOA validity 18-12-2029</p>	<p>EXTRA I Sterile Absorbable Hyaluronic Acid Dermal Filler</p> <p>Class-D</p> <p>Shelf Life: 30 Months</p> <p>Model/ codes as per FSC.</p>	<p>Deferred for the provision of following:</p> <p>Legalized FSC of reference country or notarized CE marked documents.</p> <p>DE certificate since the device falls in Class-D.</p> <p>Stability studies for the claimed shelf life</p> <p>DoC.</p>

		ISO 13485 validity 29-03-2026		
15.	Amson Vaccines & Pharma (Pvt) Ltd, 115 Industrial Triangle Kahuta Road Islamabad. ELI-00673 62,000/-	Legal Manufacturer: Bioplus Co Ltd A-#901, #902, #903, #904, #905, #906, #907, 14, Sagimakgol-ro 45beon-gil, Jungwon-gu, Seongnam-si, Gyeonggi-do, Republic of Korea. Original FSC: Korea Date of Issuance: 30-08-2024. LOA validity 18-12-2029 ISO 13485 validity 29-03-2026	EXTRA II Sterile Absorbable Hyaluronic Acid Dermal Filler Class-D Shelf Life: 30 Months Model/ codes as per FSC.	Deferred for the provision of following: Legalized FSC of reference country or notarized CE marked documents. DE certificate since the device falls in Class-D. Stability studies for the claimed shelf life DoC.
16.	Amson Vaccines & Pharma (Pvt) Ltd, 115 Industrial Triangle Kahuta Road Islamabad. ELI-00673 62,000/-	Legal Manufacturer: Bioplus Co Ltd A-#901, #902, #903, #904, #905, #906, #907, 14, Sagimakgol-ro 45beon-gil, Jungwon-gu, Seongnam-si, Gyeonggi-do, Republic of Korea. Original FSC: Korea Date of Issuance: 30-08-2024. LOA validity 18-12-2029 ISO 13485 validity 29-03-2026	EXTRA III Sterile Absorbable Hyaluronic Acid Dermal Filler Class-D Shelf Life: 30 Months Model/ codes as per FSC.	Deferred for the provision of following: Legalized FSC of reference country or notarized CE marked documents. DE certificate since the device falls in Class-D. Stability studies for the claimed shelf life DoC.
17.	Amson Vaccines & Pharma (Pvt) Ltd, 115 Industrial Triangle Kahuta Road Islamabad. ELI-00673 62,000/-	Legal Manufacturer: Bioplus Co Ltd A-#901, #902, #903, #904, #905, #906, #907, 14, Sagimakgol-ro 45beon-gil, Jungwon-gu, Seongnam-si, Gyeonggi-do, Republic of Korea. Original FSC: Korea Date of Issuance: 30-08-2024. LOA validity 18-12-2029 ISO 13485 validity 29-03-2026	EXTRA S Sterile Absorbable Hyaluronic Acid Dermal Filler Class-D Shelf Life: 36 Months Model/ codes as per FSC.	Deferred for the provision of following: Legalized FSC of reference country or notarized CE marked documents. DE certificate since the device falls in Class-D. Stability studies for the claimed shelf life DoC.

18.	<p>Amson Vaccines & Pharma (Pvt) Ltd, 115 Industrial Triangle Kahuta Road Islamabad.</p> <p>ELI-00673 62,000/-</p>	<p>Legal Manufacturer: Bioplus Co Ltd A-#901, #902, #903, #904, #905, #906, #907, 14, Sagimakgol-ro 45beon-gil, Jungwon-gu, Seongnam-si, Gyeonggi-do, Republic of Korea.</p> <p>Original FSC: Korea Date of Issuance: 30-08-2024. LOA validity 18-12-2029 ISO 13485 validity 29-03-2026</p>	<p>EXTRA H Sterile Absorbable Hyaluronic Acid Dermal Filler</p> <p>Class-D</p> <p>Shelf Life: 36 Months</p> <p>Model/ codes as per FSC.</p>	<p>Deferred for the provision of following:</p> <p>Legalized FSC of reference country or notarized CE marked documents.</p> <p>DE certificate since the device falls in Class-D.</p> <p>Stability studies for the claimed shelf life</p> <p>DoC.</p>
19.	<p>Applicant Name: M/s. Samarian's Enterprises. First Floor , H.J. Centre Kutchi Gali # 2, Marriot Road Karachi-Pakistan</p> <p>ELI-00425</p> <p>Date of issuance: 03-06-2019</p> <p>Renewal Date 02-06-2024 Valid Till 28-02-2029</p> <p>R&I Date: 24-03-2025</p> <p>Fee challan No 710114750999 PKR.6,000/-</p>	<p>Name of Manufacturer: M/s. TOP GLOVES SDN BHD Lot No 4969, Jalan Teratai, Batu 6, Of Jalan Meru, 41050 Klang Selangor D.C Malaysia</p> <p>FSC Malaysia 27-01-2030</p> <p>FSC: China Validity: 2029/06/27</p> <p>LOA Validity: 2025/07/26</p> <p>ISO Validity: 2027/08/06</p> <p>DOC: 2026/03/25</p>	<p>Brand Name : MASTER Latex Disposable Gloves Powdered</p> <p>Generic Name : Latex Disposable Gloves Powdered</p> <p>MD Group: Single</p> <p>Class A</p> <p>Shelf Life: 5years</p> <p>Storage Condition: Store at room Temperature</p> <p>Codes / Sizes XS, S, M, L & XL</p>	<p>Approved</p>
20.	<p>Applicant Name: M/s. Samarian's Enterprises First Floor , H.J. Centre Kutchi Gali # 2, Marriot Road Karachi-Pakistan</p> <p>ELI-00425</p>	<p>Name of Manufacturer: M/S TOP GLOVES SDN BHD Lot No 4969, Jalan Teratai, Batu 6, Of Jalan Meru, 41050 Klang Selangor D.C Malaysia</p> <p>FSC Malaysia</p>	<p>Brand Name : MASTER Latex Gloves Powdered Free</p> <p>Generic Name : Latex Gloves Powdered Free</p> <p>Class A</p>	<p>Approved</p>

	Date of issuance: 03-06-2019 Renewal Date 02-06-2024 Valid Till 28-02-2029 R&I Date: 24-03-2025 Fee challan No 30009821598 PKR.6,000/-	27-01-2030 FSC: China Validity: 2029/06/27 LOA Validity: 2029/07/26 ISO Validity: 2027/08/06 DOC: 2026/03/25	Shelf Life: 5years Storage Condition: Store at room Temperature Codes / Sizes XS, S, M, L & XL	
21.	Applicant Name: M/s. Samarian's Enterprises First Floor , H.J. Centre Kutchi Gali # 2, Marriot Road Karachi-Pakistan ELI-00425 Date of issuance: 03-06-2019 Renewal Date 02-06-2024 Valid Till 28-02-2029 R&I Date: 24-03-2025 Fee challan No 97462685 PKR.6,000/-	Name of Manufacturer: M/S TOP GLOVES SDN BHD Lot No 4969, Jalan Teratai, Batu 6, Of Jalan Meru, 41050 Klang Selangor D.C Malaysia FSC Malaysia 27-01-2030 FSC: China Validity: 2029/06/27 LOA Validity: 2029/07/26 ISO Validity: 2027/08/06 DOC: 2026/03/25	Brand Name : MASTER Nitrile Disposable Gloves Powdered Free Generic Name : Master Nitrile Disposable Gloves Powdered Free Class A Shelf Life: 5years Storage Condition: Store at room Temperature Codes / Sizes XS, S, M, L & XL	Approved
22.	Applicant Name: M/s. Samarian's Enterprises First Floor , H.J. Centre Kutchi Gali # 2, Marriot Road Karachi-Pakistan ELI-00425 Date of issuance: 03-06-2019 Renewal Date	Name of Manufacturer: M/S TOP GLOVES SDN BHD Lot No 4969, Jalan Teratai, Batu 6, Of Jalan Meru, 41050 Klang Selangor D.C Malaysia FSC: China Validity: 2029/06/27	Brand Name : MASTER Latex Surgical Disposable Gloves Powdered Generic Name : Master Latex Surgical Disposable Gloves Powdered Class B Shelf Life:	Approved subject to submission of CE certificate.

	02-06-2024 Valid Till 28-02-2029 R&I Date: 24-03-2025 Fee challan No 5517977583 PKR.31,000/-	FSC Malaysia 27-01-2030 LOA Validity: 2029/07/26 ISO Validity: 2027/08/06 DOC: 2026/03/25	5years Storage Condition: Store at room Temperature Codes / Sizes XS, S, M, L & XL	
23.	Applicant Name: M/s. Rahman Medicine Co. Shop No. 1 & 2, First Floor , H.J. Centre Kutchi Gali # 2, Marriot Road Karachi-Pakistan ELI # 00423 Date of issuance: 03-06-2019 Renewal Date 02-06-2024 Valid Till 28-02-2029 R&I Date: 28-03-2025 Fee challan No 770105048363 PKR.31,000/-	Name of Manufacturer: M/s. Anhui Anyu Latex Products Co., Ltd. No. 95 Yuhu Road. 233010 Bengbu, Anhui Peoples Republic of China FSC Validity: 13-10-2026 Agency Agreement/ LOA Validity: 15-01-2030 ISO: 2026/08/07 DOC: 2026/03/10	Brand Name : Master A Sterile Latex Surgical Gloves Generic Name : Sterile Latex Surgical Gloves MD Group: Single Class B Shelf Life: 5years Storage Condition: Store at room Temperature Codes / Sizes XS, S, M, L & XL	Approved subject to submission of CE certificate.
24.	Applicant Name: M/s. Rahman Medicine Co. Shop No. 1 & 2, First Floor , H.J. Centre Kutchi Gali # 2, Marriot Road Karachi-Pakistan ELI # 00423 Date of issuance:	Name of Manufacturer: M/s Changzhou Hualine Health Dressing Co., Ltd, China FSC Validity: 25-02-2027 LOA Validity: 2029/01/25	Brand Name : Master Elastic Bandage Generic Name : Elastic Bandage MD Group: Single Class A Shelf Life: N/A Storage Condition:	Approved Self-Adhesive. The firm will submit shelf life before issuance of letter.

	03-06-2019 Renewal Date 02-06-2024 Valid Till 28-02-2029 R&I Date: 24-03-2025 Fee challan No 70074454258 PKR.6,000/-	ISO : 2027/01/25 CE: 26-05-2024	Store at room Temperature Codes / Sizes : 0~30cm x 0~2000cm (Self-Adhesive & Non- Self Adhesive) The Gradient of width is 0.05cm & Length is 1cm	
25.	Applicant Name: M/s. Rahman Medicine Co. Shop No. 1 & 2, First Floor , H.J. Centre Kutchi Gali # 2, Marriot Road Karachi-Pakistan ELI # 00423 Date of issuance: 03-06-2019 Renewal Date 02-06-2024 Valid Till 28-02-2029 R&I Date: 24-03-2025 Fee challan No 983098564 PKR. 6,000/-	Name of Manufacturer: M/s Changzhou Hualine Health Dressing Co., Ltd, China FSC Validity: 25-02-2027 LOA Validity: 2029/01/25 ISO : 2027/01/25 CE: 26-05-2024	Brand Name : Master Surgical Tape Generic Name : Surgical Tape MD Group: Single Class A Shelf Life: N/A Storage Condition: Store at room Temperature Codes / Sizes : 10~400mm x 10~10000mm The Gradient of width & Length is 1mm	Approved The firm will submit shelf life before issuance of letter.
26.	Applicant Name: M/s. Rahman Medicine Co. Shop No. 1 & 2, First Floor , H.J. Centre Kutchi Gali # 2, Marriot Road Karachi-Pakistan ELI # 00423 Date of issuance: 03-06-2019	Name of Manufacturer: M/s Changzhou Hualine Health Dressing Co., Ltd, China FSC Validity: 25-02-2027 LOA Validity: 2029/01/25 ISO :	Brand Name : Master Wound Dressing Generic Name : Wound Dressing (PE Plaster, Silk Plaster, Non- woven Plaster) MD Group: Single Class A Shelf Life: N/A	Deffered for justification for different types applied in single application, type of prodct to be considered for this application, shelf life

	Renewal Date 02-06-2024 Valid Till 28-02-2029 R&I Date: 24-03-2025 Fee challan No 983098564 PKR. 6,000/-	2027/01/25 CE: 26-05-2024	Storage Condition: Store at room Temperature Codes / Sizes : 0~30cm x 0~2000cm The Gradient of width is 0.05cm & Length is 1cm A-Nonwoven Fabric, B- Silk, C-PE, D-paper, E- Cotton, F-Foam, G- Laminating Fabric	
27.	Applicant Name: M/s. Rahman Medicine Co. Shop No. 1 & 2, First Floor , H.J. Centre Kutchi Gali # 2, Marriot Road Karachi-Pakistan ELI # 00423 Date of issuance: 03-06-2019 Renewal Date 02-06-2024 Valid Till 28-02-2029 R&I Date: 24-03-2025 Fee challan No 6267597737 PKR. 6,000/-	Name of Manufacturer: M/s Changzhou Hualine Health Dressing Co., Ltd, China FSC Validity: 25-02-2027 LOA Validity: 2029/01/25 ISO : 2027/01/25 CE: 26-05-2024	Brand Name : Master Zinc Oxide Adhesive Plaster Generic Name : Zinc Oxide Adhesive Plaster MD Group: Single Class A Shelf Life: N/A Storage Condition: Store at room Temperature Codes / Sizes : 0~30cm x 0~2000cm The Gradient of width is 0.05cm & Length is 1cm	Approved The firm will submit shelf life before issuance of letter.
28.	Applicant Name: M/s. Rahman Medicine Co. Shop No. 1 & 2, First Floor , H.J. Centre Kutchi Gali # 2, Marriot Road Karachi-Pakistan	Name of Manufacturer: M/s Changzhou Hualine Health Dressing Co., Ltd, China FSC Validity: 25-02-2027	Brand Name : Master Aneroid Sphygmomanometer Generic Name : Aneroid Sphygmomanometer MD Group: Single	Approved The firm will submit shelf life before issuance of letter.

	ELI # 00423 Date of issuance: 03-06-2019 Renewal Date 02-06-2024 Valid Till 28-02-2029 R&I Date: 24-03-2025 Fee challan No 62690532305 PKR.31,000/-	LOA Validity: 2029/01/25 ISO : 2027/01/25 CE: 26-05-2024	Class B Shelf Life: N/A Storage Condition: Store at room Temperature Codes / Sizes : XB.11.300	
29.	Applicant Name: M/s. Rahman Medicine Co. Shop No. 1 & 2, First Floor , H.J. Centre Kutchi Gali # 2, Marriot Road Karachi-Pakistan ELI # 00423 Date of issuance: 03-06-2019 Renewal Date 02-06-2024 Valid Till 28-02-2029 R&I Date: 24-03-2025 Fee challan No 0480554999 PKR.31,000/-	Name of Manufacturer: M/s Wenzhou Kangju Medical Instrument Co. Ltd, China Republic Of China FSC Validity: 2025/01/18 LOA Validity: 2029/01/25 ISO : 2026/09/30 DOC: 2026/03/10	Brand Name : Master Stethoscope Generic Name : Stethoscope MD Group: Single Class B Shelf Life: N/A Storage Condition: Store at room Temperature Codes / Sizes : All Models	Deferred for clarification of different models applied, Original valid FSC, and CE certificate and shelf life.
30.	Applicant Name: M/s. Rahman Medicine Co. Shop No. 1 & 2, First Floor , H.J. Centre Kutchi Gali # 2, Marriot Road Karachi-Pakistan ELI # 00423	Name of Manufacturer: M/s Sri Trang Gloves (Thailand) Public Company Limited, No. 110 Kanjanavanit Road, Pahtong Hat Yei, Songkhla 90230, Thailand	Brand Name : Sritrang Inter Viva Hand (Latex Examination Gloves, Powdered, Non-Sterile) Generic Name : Latex Examination Gloves, Powdered, Non- Sterile	Approved The firm will submit shelf life before issuance of letter.

	Date of issuance: 03-06-2019 Renewal Date 02-06-2024 Valid Till 28-02-2029 R&I Date: 28-03-2025 Fee challan No 53920322599 PKR.6,000/-	FSC Validity: 2026/05/22 GMP LOA Validity: 2029/01/25 ISO : 2026/07/05 DOC: 2026/03/10	MD Group: Single Class A Shelf Life: N/A Storage Condition: Store at room Temperature Codes / Sizes : XS, S, M, L & XL	
31.	Applicant Name: M/s. Rahman Medicine Co. Shop No. 1 & 2, First Floor , H.J. Centre Kutchi Gali # 2, Marriot Road Karachi-Pakistan ELI # 00423 Date of issuance: 03-06-2019 Renewal Date 02-06-2024 Valid Till 28-02-2029 R&I Date: 24-03-2025 Fee challan No 232931606152 PKR.6,000/-	Name of Manufacturer: M/s. Zhejiang Huikang Medicinal Articles Co., Ltd No. 08, Hetian Road, Shangxi Town, Yiwu City, Zhejian Province, 322000, P.R.China FSC Validity: 2026/06/03 LOA Validity: 2029/01/25 ISO : 2025/09/08 DOC: 2026/03/10	Brand Name : Master Heat Reducing Plaster (Medical Cooling Gel Sheet) Generic Name : Heat Reducing Plaster (Medical Cooling Gel Sheet) MD Group: Single Class A Shelf Life: N/A Storage Condition: Store at room Temperature Codes / Sizes : 110x40, 110x50, 120x50, 150x70, 200x90, 90x40, 80x40, 100x40	Approved. The firm will submit shelf life before issuance of letter.

REGISTRATION OF MEDICAL DEVICES LOCAL DEFERRED.

S#	Manufacture Name	Name of Medical Device/ Class/ Codes/ shelf Life, etc	Decision
1.	Surgioplast.Plot No 78, Road No L-4, Industrial Estate Gadoon Amazai, Swabi ELM No 0030 Sections:	Clinic Disposable Butterfly Scalp Vein Set Codes and Sizes: 16G/18G/21G/22G/23G/24G/26G	Approved

1. Syringe Section 2. IV sets section	Class.B Shelf life:05 Years Fee Challan: Rs.20,000	
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REGISTRATION OF MEDICAL DEVICES LOCAL.

Sr. No.	Name & Address of Establishment	Name of Medical Devices With Size	Decision
1.	<p>Bioron Medics (Pvt) Ltd. 6-Km, Off Manga Raiwind Road, Glamour Stop, Sunder Industrial Estate, Lahore. (ELM-0084 valid till 27-10-2029) [885-7L] Dy. No. 11860 dated 06-05-2025</p> <p>Approved Sections:</p> <ol style="list-style-type: none"> 1. Syringes (Auto-disable) Section. 2. Syringes (Disposable) Section. 3. Tubes Section (Endocrine, Stomach, Feeding, Nelaton, Nasogastric, Foley catheter tube). 4. IV Burette Set, Blood Transfusion Set (IV Set, IV Y-port set, Scalp Vein Set). 5. IV Dialysis Set Section. 6. Foley Catheter Section. 7. Needle assembly section (Dental, spine, hypodermic, fistula, scalp vein, biopsy, tonsil needle). 8. Assembling and Repacking Section (Threeway stopper, umbilical card clump, heparin cap, Endocrine Tube, IV cannula, IV Burette Set, Blood transfusion, IV set, Y-port set, Scalp vein set, Dialysis set, Endotracheal tubes, stomach tubes, feeding tubes, Nelaton tubes, Nasogastric tube, Foley catheter). 9. Gauze swabs and sponges sterile and non-sterile Section. 10. Gauze Roll Section (Non sterile). 11. Medicated dressing Section (Tulle Gras Dressing and Paraffin Gauze Dressing, Non-Woven dressing,). 12. Bandage Section (Cotton Bandages, Crepe Bandage, Eye pad, Non-Woven surgical tape). 13. Lap sponges with X-Ray Threads Section <p>D. No. 11860 dated 06-05-2025</p>	<p>Venus Guide Wire (Guide Wire)</p> <p>Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 86180666035</p>	<p>Deferred for confirmation of manufacturing & testing facility for the applied product and section in which product proposed to be manufactured along with the submission of the following:</p> <ol style="list-style-type: none"> i. Manufacturing & QC process. ii. Type of guide wire iii. Confirmation about finished product whether it is a guide wire or tube

2.	<p>Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096 valid till 08/04/2030) [887-6L] Dy. No. 11861 dated 06-05-2025</p> <p>Approved Sections:</p> <ul style="list-style-type: none"> i. Sachet/Dry Powder Section (For Hemodialysis Concentrates) ii. Hydrocolloid and Soft Silicone Foam Dressings iii. Liquid Section (Diluents and cleaning solutions for analyzers) iv. General IVDs cleaning solutions. v. Disinfectant solutions for laboratory equipment. vi. Hematology diluent solutions. vii. Semi-solid Section (For Ostomy gel only) <p>D. No. 11861 dated 06-05-2025</p>	<p>Glim Ostomy Paste</p> <p>Composition: MonoButyl ester of Poly (Methyl vinyl ether / Maleic Acid), Gelatin, Pectin (USP Grade), Sodium Carboxy methyl cellulose (Na CMC) FCC Grade, Glyceryl 12-Hydroxylstearate, Glyceryl Triacetate FCC, Alcohol L90 proof-USP.</p> <p>Class: A Shelf Life: 3 Years Pack Size: 60gm × 1 tube, 14gm × 20 tubes. Fee: 6000 Fee Slip No. 3181244968</p>	<p>Deferred for the following:</p> <ul style="list-style-type: none"> i. Manufacturing & QC process. ii. Properly signed & stamp Form iii. Functionality and quantities of ingredients iv. Label of product v. justification/ clarification regarding the class of applied medical device vi. in which section to be manufactured.
3.	<p>Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096) [888-6L] Dy. No. 11862 dated 06-05-2025</p> <p>Approved Sections:</p> <ul style="list-style-type: none"> i. Sachet/Dry Powder Section (For Hemodialysis Concentrates) ii. Hydrocolloid and Soft Silicone Foam Dressings iii. Liquid Section (Diluents and cleaning solutions for analyzers) iv. General IVDs cleaning solutions. v. Disinfectant solutions for laboratory equipment. vi. Hematology diluent solutions. vii. Semi-solid Section (For Ostomy gel only) <p>D. No. 11862 dated 06-05-2025</p>	<p>Glim Ostomy Powder</p> <p>Composition: Pectin, Gelatin, Sodium Carboxy methyl cellulose</p> <p>Class: A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 2185735027</p>	<p>Deferred for confirmation of manufacturing & testing facility for the applied product along with the submission of the following:</p> <ul style="list-style-type: none"> i. Manufacturing & QC process. ii. Properly signed & stamp Form iii. Functionality and quantities of ingredients iv. Label of product v. confirmation/ clarification regarding the class of applied medical device. vi. in which section to be manufactured.
4.	<p>Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096) [889-6L] Dy. No. 11863 dated 06-05-2025</p> <p>Approved Sections:</p>	<p>Surgilit</p> <p>Composition per 100gm; Propan-2-ol....45gm, Propan-1-ol.....30gm, Mecetronium Ethyl Sulphate.....0.2gm</p> <p>Class: A</p>	<p>Deferred for clarification/justification and evidence regarding the nature of the product whether the applied product is Medical Device as per MDR or otherwise and in which section to be manufactured.</p>

	i. Sachet/Dry Powder Section (For Hemodialysis Concentrates) ii. Hydrocolloid and Soft Silicone Foam Dressings iii. Liquid Section (Diluents and cleaning solutions for analyzers) iv. General IVDs cleaning solutions. v. Disinfectant solutions for laboratory equipment. vi. Hematology diluent solutions. vii. Semi-solid Section (For Ostomy gel only) D. No. 11863 dated 06-05-2025	Shelf Life: 3 Years Fee: 6000 Fee Slip No. 46740700341	
5.	Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096) [890-6L] Approved Sections: i. Sachet/Dry Powder Section (For Hemodialysis Concentrates) ii. Hydrocolloid and Soft Silicone Foam Dressings iii. Liquid Section (Diluents and cleaning solutions for analyzers) iv. General IVDs cleaning solutions. v. Disinfectant solutions for laboratory equipment. vi. Hematology diluent solutions. vii. Semi-solid Section (For Ostomy gel only) Dy. No. 11864 dated 06-05-2025	Surgilit Med Ethanol....85gm/100gm Class: A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 282317116	Deferred for clarification/justification and evidence regarding the nature of the product whether the applied product is Medical Device as per MDR or otherwise and in which section to be manufactured.
6.	Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096) [891-6L] Approved Sections: i. Sachet/Dry Powder Section (For Hemodialysis Concentrates) ii. Hydrocolloid and Soft Silicone Foam Dressings iii. Liquid Section (Diluents and cleaning solutions for analyzers) iv. General IVDs cleaning solutions.	Surgilit Classic Pure Composition per 100gm. Propan-2-ol....45gm, Propan-1-ol.....30gm Mecetronium Ethyl Sulphate.....0.2gm Class: A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 4501717555	Deferred for clarification/justification and evidence regarding the nature of the product whether the applied product is Medical Device as per MDR or otherwise and in which section to be manufactured.

	v.Disinfectant solutions for laboratory equipment. vi. Hematology diluent solutions. vii. Semi-solid Section (For Ostomy gel only) Approved Sections: i. Sachet/Dry Powder Section (For Hemodialysis Concentrates) ii. Hydrocolloid and Soft Silicone Foam Dressings iii.Liquid Section (Diluents and cleaning solutions for analyzers) iv. General IVDs cleaning solutions. v.Disinfectant solutions for laboratory equipment. vi. Hematology diluent solutions. vii. Semi-solid Section (For Ostomy gel only) Dy. No. 11865 dated 06-05-2025		
7.	Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096) [892-6L] Approved Sections: i. Sachet/Dry Powder Section (For Hemodialysis Concentrates) ii. Hydrocolloid and Soft Silicone Foam Dressings iii.Liquid Section (Diluents and cleaning solutions for analyzers) iv. General IVDs cleaning solutions. v.Disinfectant solutions for laboratory equipment. vi. Hematology diluent solutions. vii. Semi-solid Section (For Ostomy gel only) Dy. No. 11866 dated 06-05-2025	Surgilit Gel Pure Composition: Ethanol.....85gm Class: A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 617288259	Deferred for clarification/justification and evidence regarding the nature of the product whether the applied product is Medical Device as per MDR or otherwise and in which section to be manufactured.
8.	Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096) [893-6L] Approved Sections: i. Sachet/Dry Powder Section (For Hemodialysis Concentrates)	Surgilit Gel Composition: Ethanol....85gm Class: A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 7288137884	Deferred for clarification/justification and evidence regarding the nature of the product whether the applied product is Medical Device as per MDR or otherwise and in which section to be manufactured.

	ii. Hydrocolloid and Soft Silicone Foam Dressings iii. Liquid Section (Diluents and cleaning solutions for analyzers) iv. General IVDs cleaning solutions. v. Disinfectant solutions for laboratory equipment. vi. Hematology diluent solutions. vii. Semi-solid Section (For Ostomy gel only) Dy. No. 11867 dated 06-05-2025		
9.	Cotton Craft (Pvt) Ltd., 12-KM, Multan Road, Canal View Society, Lahore Plant: Plot No. 407-408, Sundar Industrial Estate, Raiwind Road, Lahore. (ELM-0015) [898-6L] D. No. 12930 dated 14-05-2025. Approved Sections: <ul style="list-style-type: none"> • Absorbent Cotton Wool Section • Plaster of Paris (POP) Bandage Section • Gauze Section (Gauze Swabs (Sterile/Non-Sterile) – Absorbent Gauze Ribbon • Surgical Tulle Dressing Section • Paraffin Gauze Section • Lint Section • Bandage Section • Lapponges Section • Cotton Crepe Bandage Section • Eye Pad Section • Gauze Roll Section • Packing Section • QC and Microbiological Lab D. No. 12930 dated 14-05-2025.	CuraField Disposable Drape Kit (Sterile) The pack has following composition: <ul style="list-style-type: none"> • Anesthesia Drape Sheet....150 × 220cm (1 Pc) • Foot Drape sheet....150 × 180cm (1Pc) • Side Adhesive Drape Sheet....75 × 90cm (4 Pcs) • Mayo Stand Cover....80 × 150cm (1 Pc) • OP Tape....10 × 50cm (1Pc) • Reinforced Surgical Gown.... XL (2 Pcs) • Medical Hand Towel...40 × 40cm (4 Pcs) • Back Table Cover....150 × 200cm (1 Pc) • Wrap Paper....100×100 (1 Pc) Class: B Fee: 25000/- Fee Slip No. 9942733482	Deferred for confirmation of manufacturing & testing facility for the applied product along with the submission of the following: <ul style="list-style-type: none"> i. Confirmation whether all the components will be manufactured by the manufacturer, since as per details provided in application form, the product pack contains multiple components including a Medical hand towel. ii. The product is set while applied as single so clarification & fee is required.
10	Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096) [899-6L] Approved Sections:	Levenida Foam Aqua, Butane, Cocamidopropyl Betaine, Isobutane, Propane, Peg-7, Glycerol Cocoate, Peg-75	Deferred for confirmation of manufacturing & testing facility (section) for the applied product along with the submission of the following:

	i. Sachet/Dry Powder Section (For Hemodialysis Concentrates) ii. Hydrocolloid and Soft Silicone Foam Dressings iii. Liquid Section (Diluents and cleaning solutions for analyzers) iv. General IVDs cleaning solutions. v. Disinfectant solutions for laboratory equipment. vi. Hematology diluent solutions. vii. Semi-solid Section (For Ostomy gel only) Dy. No. 13129 dated 15-05-2025	Lanolin, Phenoxyethanol, Glycerin, Cocamide Dea, Panthenol, parfum, Peg-40 hydrogenated Castor Oil, Trideceth-9, Ethylhexylglycerin, allantoin, Tetrasodium Edta, Benzyl Salicylate, Hexyl Cinnamal Class: A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 14739024326	i. Manufacturing & QC process. ii. Properly signed & stamp Form iii. Functionality and quantities of ingredients iv. Label of product v. confirmation/clarification regarding the nature of the product whether the applied product is Medical Device as per MDR or otherwise along with evidence.
11	Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096) [900-6L] Approved Sections: i. Sachet/Dry Powder Section (For Hemodialysis Concentrates) ii. Hydrocolloid and Soft Silicone Foam Dressings iii. Liquid Section (Diluents and cleaning solutions for analyzers) iv. General IVDs cleaning solutions. v. Disinfectant solutions for laboratory equipment. vi. Hematology diluent solutions. vii. Semi-solid Section (For Ostomy gel only) D. No. 13130 dated 15-05-2025	Levenida Plus Gel Composition: Poloxamer, Polyhexamethylene biguanide (Polyhexanide, 0.1%) water and auxiliary substances Class: A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 26256080016	Deferred for confirmation of manufacturing & testing facility (section) for the applied product along with the submission of the following: i. Manufacturing & QC process. ii. Properly signed & stamp Form iii. Functionality and quantities of ingredients iv. Label of product v. confirmation/ clarification regarding the class of applied medical device.
12.	Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096) [901-6L] Approved Sections: i. Sachet/Dry Powder Section (For Hemodialysis Concentrates) ii. Hydrocolloid and Soft Silicone Foam Dressings iii. Liquid Section (Diluents and cleaning solutions for analyzers) iv. General IVDs cleaning solutions.	Glim Scar Treatment Silicone Gel Composition: Polymerized Siloxanes (Silicone Gel) and Tocopherol (Vitamin E) Class: A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 3511160162	Deferred for confirmation of manufacturing & testing facility for the applied product along with the submission of the following: i. Manufacturing & QC process. ii. duly signed & stamp application Form iii. Functionality and quantities of ingredients iv. Label of product

	v.Disinfectant solutions for laboratory equipment. vi. Hematology diluent solutions. vii. Semi-solid Section (For Ostomy gel only) D. No. 13131 dated 15-05-2025		
13.	Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096) [902-6L] Approved Sections: i. Sachet/Dry Powder Section (For Hemodialysis Concentrates) ii. Hydrocolloid and Soft Silicone Foam Dressings iii. Liquid Section (Diluents and cleaning solutions for analyzers) iv. General IVDs cleaning solutions. v. Disinfectant solutions for laboratory equipment. vi. Hematology diluent solutions. vii. Semi-solid Section (For Ostomy gel only) D. No. 13132 dated 15-05-2025	Glim Bromellin Gel Composition: Methyl sulfonyl methane (MSM), Glucosamine Sulfate, Devil's Claw, Butcher's Broom Extract, Pinapple Extract, Arnica Montana, Centella, Vitamin C, Boswellia, Ivy Extract, Calendula, Menthol Class: A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 960956624319	Deferred for confirmation of manufacturing & testing facility for the applied product along with the submission of the following: i. Manufacturing & QC process. ii. Properly signed & stamp Form iii. Functionality and quantities of ingredients iv. Label of product v. Confirmation/ clarification regarding the nature of the product whether the applied product is Medical Device as per MDR or otherwise along with evidence.
14.	Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096) [903-6L] Approved Sections: i. Sachet/Dry Powder Section (For Hemodialysis Concentrates) ii. Hydrocolloid and Soft Silicone Foam Dressings iii. Liquid Section (Diluents and cleaning solutions for analyzers) iv. General IVDs cleaning solutions. v. Disinfectant solutions for laboratory equipment. vi. Hematology diluent solutions. vii. Semi-solid Section (For Ostomy gel only) D. No. 13133 dated 15-05-2025	Glim Vaginal Moisturizing Gel Composition: Aqua, Glycerine, Betaine, Panthenol, Hyaluronic acid, Allantoin, Aloe Vera Extract, Citric Acid, Perservative Class: A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 30742445	Deferred for confirmation of manufacturing & testing facility for the applied product along with the submission of the following: i. Manufacturing & QC process. ii. Properly signed & stamp Form iii. Functionality and quantities of ingredients iv. Label of product v. confirmation/ clarification regarding the class of applied medical device.
15.	Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir	Bilirubin (Total and Direct) Kit Composition:	Deferred for confirmation of manufacturing & testing facility (section) for the

	<p>(ELM-0096) [904-6L] Approved Sections: i. Sachet/Dry Powder Section (For Hemodialysis Concentrates) ii. Hydrocolloid and Soft Silicone Foam Dressings iii. Liquid Section (Diluents and cleaning solutions for analyzers) iv. General IVDs cleaning solutions. v. Disinfectant solutions for laboratory equipment. vi. Hematology diluent solutions. vii. Semi-solid Section (For Ostomy gel only)</p> <p>D. No. 13134 dated 15-05-2025</p>	<p>RT: Sulfanilic acid 29 mmol/L, HCl 0.24 mol/L, Duposol 3% (w/v) RD: Sulfanilic acid 29 mmol/L, HCl 0.24 mol/L. RN: Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 39983455</p>	<p>applied product along with the submission of the following: i. Manufacturing & QC process. ii. Properly signed & stamp application Form</p>
16.	<p>Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096) [905-6L] Approved Sections: i. Sachet/Dry Powder Section (For Hemodialysis Concentrates) ii. Hydrocolloid and Soft Silicone Foam Dressings iii. Liquid Section (Diluents and cleaning solutions for analyzers) iv. General IVDs cleaning solutions. v. Disinfectant solutions for laboratory equipment. vi. Hematology diluent solutions. vii. Semi-solid Section (For Ostomy gel only)</p> <p>D. No. 13135 dated 15-05-2025</p>	<p>Amylase MR (Modified Rate) Kit Composition: R1: MES (2-(N-morpholino) ethanesulfonic acid) buffer 50 mmol/L pH 6.0, Calcium acetate 5 mmol/L, Sodium Chloride 300 mmol/L, Sodium thiocyanate 450 mmol/L, CNP-G3 2.25 mmol/L Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 4306521741</p>	<p>Deferred for confirmation of manufacturing & testing facility (section) for the applied product along with the submission of the following: i. Manufacturing & QC process. ii. Properly signed & stamp application Form</p>
17.	<p>Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096) [906-6L] Approved Sections: i. Sachet/Dry Powder Section (For Hemodialysis Concentrates) ii. Hydrocolloid and Soft Silicone Foam Dressings iii. Liquid Section (Diluents and cleaning solutions for analyzers)</p>	<p>ALT / GPT BR Kit Composition: R1: ALT Substrate TRIS buffer 150 mmol/L, pH 7.3, L-alanine 750 mmol/L, Lactate dehydrogenase > 1350 U/L R2: ALT Co-enzyme NADH 1.3 mmol/L, 2-oxoglutarate 75 mmol/L, Biocides. Class: A</p>	<p>Deferred for confirmation of manufacturing & testing facility for the applied product along with the submission of the following: i. Manufacturing & QC process. ii. Properly signed & stamp application Form</p>

	iv. General IVDs cleaning solutions. v. Disinfectant solutions for laboratory equipment. vi. Hematology diluent solutions. vii. Semi-solid Section (For Ostomy gel only) D. No. 13136 dated 15-05-2025	Shelf Life: 5 Years Fee: 6000 Fee Slip No. 5115515169	
18.	Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096) [907-6L] Approved Sections: i. Sachet/Dry Powder Section (For Hemodialysis Concentrates) ii. Hydrocolloid and Soft Silicone Foam Dressings iii. Liquid Section (Diluents and cleaning solutions for analyzers) iv. General IVDs cleaning solutions. v. Disinfectant solutions for laboratory equipment. vi. Hematology diluent solutions. vii. Semi-solid Section (For Ostomy gel only) D. No. 13137 dated 15-05-2025	Glim Vaginal Gel Cream Composition: Curcumin, Docosanol, Emblica Officinalis. Aloe Vera Gel, Polidocanol, Glyceryl laurate, Fatty Acids C12-20 (8) OE, Imidazolidinyl urea, Sodium dehydroacetate, CM Betaglucan, Disodium EDTA, lactic Acid, Water, Vaseline oil, Parahydroxybenzoate of: Methyl, Ethyl, Propyl, Butyl Class: A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 0887136606	Deferred for confirmation of manufacturing & testing facility for the applied product along with the submission of the following: i. Manufacturing & QC process. ii. Properly signed & stamp Form iii. confirmation/clarification regarding the class of applied medical device. iv. Applied gel or cream
19.	Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096) [908-6L] Approved Sections: i. Sachet/Dry Powder Section (For Hemodialysis Concentrates) ii. Hydrocolloid and Soft Silicone Foam Dressings iii. Liquid Section (Diluents and cleaning solutions for analyzers) iv. General IVDs cleaning solutions. v. Disinfectant solutions for laboratory equipment. vi. Hematology diluent solutions. vii. Semi-solid Section (For Ostomy gel only) D. No. 13138 dated 15-05-2025	Glim Silicone Gel Composition: Polymerized Siloxanes (Silicone Gel) and Tocopherol (Vitamin E) Class: A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 269940210002	Deferred for confirmation of manufacturing & testing facility for the applied product along with the submission of the following: i. Manufacturing & QC process. ii. Properly signed & stamp Form iii. Functionality and quantities of ingredients iv. Correct Label of product v. Correct generic name/details, description and intended use. vi. Correct composition
20.	Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir	Glim Balanil Gel Composition: Aqua, Echinacea	Deferred for confirmation of manufacturing & testing facility for the applied

	<p>(ELM-0096) [909-6L]</p> <p>Approved Sections: i. Sachet/Dry Powder Section (For Hemodialysis Concentrates) ii. Hydrocolloid and Soft Silicone Foam Dressings iii. Liquid Section (Diluents and cleaning solutions for analyzers) iv. General IVDs cleaning solutions. v. Disinfectant solutions for laboratory equipment. vi. Hematology diluent solutions. vii. Semi-solid Section (For Ostomy gel only)</p> <p>D. No. 13139 dated 15-05-2025</p>	<p>Angustifolia extract, PEG-40 Hydrogenated Castor Oil, Sodium PCA, Adelmidrol (INN), Algin, Sodium hyaluronate, Sodium Hydroxide, Lactic Acid, 2-Bromo-2-Nitropropane-1,3-diol, Trans-2-dodecenedioic acid, Usnic acid, Phytosphingosine, Biotin</p> <p>Class: A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 21094205036</p>	<p>product along with the submission of the following: i. Manufacturing & QC process. ii. Properly signed & stamp Form iii. confirmation/clarification regarding the class of applied medical device. iv. Confirmation/clarification regarding the nature of the product whether the applied product is Medical Device as per MDR or otherwise along with evidence.</p>
21.	<p>Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096) [910-6L]</p> <p>Approved Sections: i. Sachet/Dry Powder Section (For Hemodialysis Concentrates) ii. Hydrocolloid and Soft Silicone Foam Dressings iii. Liquid Section (Diluents and cleaning solutions for analyzers) iv. General IVDs cleaning solutions. v. Disinfectant solutions for laboratory equipment. vi. Hematology diluent solutions. vii. Semi-solid Section (For Ostomy gel only)</p> <p>D. No. 13140 dated 15-05-2025</p>	<p>Glim Hemorrhoid Gel Composition: Aqua, Glycerine, Betaine, Panthenol, Ammonium acryloyldimethyltaurate / VP Copolymer, Laureth-9, Phenoxyethanol, Xanthan Gum, Allantoin, Ethylhexyl Glycerin, Sodium Carboxy methyl betaglukan, Opuntia ficus indica strain extract, Sodium hyaluronate, Citric Acid, Alcohol</p> <p>Class: A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 01238200520</p>	<p>Deferred for confirmation of manufacturing & testing facility for the applied product along with the submission of the following: i. Manufacturing & QC process. ii. Properly signed & stamp Form iii. confirmation/clarification regarding the class of applied medical device.</p>
22.	<p>Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096) [911-6L]</p> <p>Approved Sections: i. Sachet/Dry Powder Section (For Hemodialysis Concentrates) ii. Hydrocolloid and Soft Silicone Foam Dressings iii. Liquid Section (Diluents and cleaning solutions for analyzers)</p>	<p>Glim Chlorhexidine Scrub Composition: Chlorhexidine Gluconate, DI Water, Iso-Propyl Alcohol, Non-Ionic Surfactant Hydroxy ethyl cellulose, Lauramine Oxide, Glycerin, Propylene Glycol, EDTA, Fragrance</p> <p>Class: A Shelf Life: 3 Years</p>	<p>Deferred for confirmation of manufacturing & testing facility for the applied product along with the submission of the following: i. Manufacturing & QC process. ii. Properly signed & stamp Form iii. confirmation/clarification regarding the class of applied medical</p>

	iv. General IVDs cleaning solutions. v. Disinfectant solutions for laboratory equipment. vi. Hematology diluent solutions. vii. Semi-solid Section (For Ostomy gel only) D. No. 13141 dated 15-05-2025	Fee: 6000 Fee Slip No. 09116521187	device. iv. Correct Percentage /quantities of ingredients v. Functionality of ingredients
23.	Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096) [912-6L] Approved Sections: i. Sachet/Dry Powder Section (For Hemodialysis Concentrates) ii. Hydrocolloid and Soft Silicone Foam Dressings iii. Liquid Section (Diluents and cleaning solutions for analyzers) iv. General IVDs cleaning solutions. v. Disinfectant solutions for laboratory equipment. vi. Hematology diluent solutions. vii. Semi-solid Section (For Ostomy gel only) D. No. 13142 dated 15-05-2025	Efto Plus Cream Composition: Rigenase (Wheat extract), Polyhexanide, Polyethylene Glycol 400, Polyethylene Glycol 1500, Polyethylene Glycol 3000, Polyethylene Glycol 4000, Liquid paraffin, Cetyl alcohol, Stearyl Alcohol, Glycerin, Phenoxyethanol, Purified Water Class: A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 4022881735	Deferred for confirmation of manufacturing & testing facility for the applied product along with the submission of the following: i. Manufacturing & QC process. ii. Properly signed & stamp Form iii. confirmation/clarification regarding the class of applied medical device. iv. Correct Percentage /quantities of ingredients v. Functionality of ingredients. vi. Confirmation/clarification regarding the nature of the product whether the applied product is Medical Device as per MDR or otherwise along with the justification & evidence.
24.	Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096) [913-6L] Approved Sections: i. Sachet/Dry Powder Section (For Hemodialysis Concentrates) ii. Hydrocolloid and Soft Silicone Foam Dressings iii. Liquid Section (Diluents and cleaning solutions for analyzers) iv. General IVDs cleaning solutions. v. Disinfectant solutions for laboratory equipment. vi. Hematology diluent solutions. vii. Semi-solid Section (For Ostomy gel only) D. No. 13143 dated 15-05-2025	Efto Vaginal Gel Composition: Hyaluronic Acid, Soybean Extract (Titrated in 40% isoflavones and 25% Genistin), Glycolic Extract of Mallow, Boric Acid, Distilled Water of Calendula, Melaleuca (Terpinen-4-ol), Aloe Vera gel Class: A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 23227040465	Deferred for confirmation of manufacturing & testing facility for the applied product along with the submission of the following: i. Manufacturing & QC process. ii. Properly signed & stamp Form iii. confirmation/clarification regarding the class of applied medical device. iv. Correct Percentage /quantities of ingredients v. Functionality of ingredients. vi. Confirmation/clarification regarding the Class of the applied Medical Device.

25.	<p>Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096) [914-6L]</p> <p>Approved Sections:</p> <ul style="list-style-type: none"> i. Sachet/Dry Powder Section (For Hemodialysis Concentrates) ii. Hydrocolloid and Soft Silicone Foam Dressings iii. Liquid Section (Diluents and cleaning solutions for analyzers) iv. General IVDs cleaning solutions. v. Disinfectant solutions for laboratory equipment. vi. Hematology diluent solutions. vii. Semi-solid Section (For Ostomy gel only) <p>D. No. 13128 dated 15-05-2025</p>	<p>Glim Silicone Scar Repair Gel</p> <p>Composition: Polymerized Siloxanes (Silicone Gel) and Tocopherol (Vitamin E)</p> <p>Class: A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 29313271896</p>	<p>Deferred for confirmation of manufacturing & testing facility for the applied product along with the submission of the following:</p> <ul style="list-style-type: none"> i. Manufacturing & QC process. ii. Properly signed & stamp Form iii. Correct generic name/details, description and intended use.
26.	<p>Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096) [915-6L]</p> <p>Approved Sections:</p> <ul style="list-style-type: none"> i. Sachet/Dry Powder Section (For Hemodialysis Concentrates) ii. Hydrocolloid and Soft Silicone Foam Dressings iii. Liquid Section (Diluents and cleaning solutions for analyzers) iv. General IVDs cleaning solutions. v. Disinfectant solutions for laboratory equipment. vi. Hematology diluent solutions. vii. Semi-solid Section (For Ostomy gel only) <p>D. No. 13144 dated 15-05-2025</p>	<p>Glim Lubricating Jelly</p> <p>Class: A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 6168917971</p>	<p>Deferred for confirmation of manufacturing & testing facility for the applied product along with the submission of the following:</p> <ul style="list-style-type: none"> i. Manufacturing & QC process. ii. Properly signed & stamp Form iii. confirmation/clarification regarding the class of applied medical device. iv. Correct Composition
27.	<p>Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096) [916-6L]</p> <p>Approved Sections:</p> <ul style="list-style-type: none"> i. Sachet/Dry Powder Section (For Hemodialysis Concentrates) 	<p>Glim Scars Gel</p> <p>Composition: PolySiloxane Mixture, Silicone Dioxide</p> <p>Class: A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 60471822</p>	<p>Deferred for confirmation of manufacturing & testing facility for the applied product along with the submission of the following:</p> <ul style="list-style-type: none"> i. Manufacturing & QC process. ii. Properly signed & stamp Form

	ii. Hydrocolloid and Soft Silicone Foam Dressings iii. Liquid Section (Diluents and cleaning solutions for analyzers) iv. General IVDs cleaning solutions. v. Disinfectant solutions for laboratory equipment. vi. Hematology diluent solutions. vii. Semi-solid Section (For Ostomy gel only) D. No. 13145 dated 15-05-2025		iii. Quantities and functionality of ingredients.
28.	Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096) [917-6L] Approved Sections: i. Sachet/Dry Powder Section (For Hemodialysis Concentrates) ii. Hydrocolloid and Soft Silicone Foam Dressings iii. Liquid Section (Diluents and cleaning solutions for analyzers) iv. General IVDs cleaning solutions. v. Disinfectant solutions for laboratory equipment. vi. Hematology diluent solutions. vii. Semi-solid Section (For Ostomy gel only) D. No. 13146 dated 15-05-2025	Prostran Gel Composition: Betaine Surfactant, Polyhexanide (PHMB) and Purified Water, Glycerol and Hydroxyethylcellulose Class: A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 8502440539	Deferred for confirmation of manufacturing & testing facility for the applied product along with the submission of the following: i. Manufacturing & QC process. ii. Properly signed & stamp Form iii. confirmation/clarification regarding the class of applied medical device. iv. Quantities and functionality of ingredients
29.	Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096) [918-6L] Approved Sections: i. Sachet/Dry Powder Section (For Hemodialysis Concentrates) ii. Hydrocolloid and Soft Silicone Foam Dressings iii. Liquid Section (Diluents and cleaning solutions for analyzers) iv. General IVDs cleaning solutions. v. Disinfectant solutions for laboratory equipment.	Glim Pedi Gel Composition: Natural Extract, Chamomile Extract, Menthol Crystals, Vitamin E Class: A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 88474882	Deferred for confirmation/clarification regarding the nature of the product whether the applied product is Medical Device as per MDR or otherwise along with the justification & evidence.

	vi. Hematology diluent solutions. vii. Semi-solid Section (For Ostomy gel only) D. No. 13147 dated 15-05-2025		
30.	Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096) [919-6L] Approved Sections: i. Sachet/Dry Powder Section (For Hemodialysis Concentrates) ii. Hydrocolloid and Soft Silicone Foam Dressings iii. Liquid Section (Diluents and cleaning solutions for analyzers) iv. General IVDs cleaning solutions. v. Disinfectant solutions for laboratory equipment. vi. Hematology diluent solutions. vii. Semi-solid Section (For Ostomy gel only) D. No. 13148 dated 15-05-2025	Prostran Sol Composition: Betaine Surfactant, Polyhexanide (PHMB) and Purified Water, Glycerol and Hydroxyethylcellulose Class: A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 5232074399	Deferred for confirmation of manufacturing & testing facility for the applied product along with the submission of the following: i. Manufacturing & QC process. ii. Properly signed & stamp Form iii. Confirmation / clarification regarding the class of applied medical device. iv. Quantities and functionality of ingredients v. Correct Composition
31.	Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096) [920-6L] Approved Sections: i. Sachet/Dry Powder Section (For Hemodialysis Concentrates) ii. Hydrocolloid and Soft Silicone Foam Dressings iii. Liquid Section (Diluents and cleaning solutions for analyzers) iv. General IVDs cleaning solutions. v. Disinfectant solutions for laboratory equipment. vi. Hematology diluent solutions. vii. Semi-solid Section (For Ostomy gel only) D. No. 13149 dated 15-05-2025	Levenida Plus Sol Composition: Poloxamer, Polyhexamethylene biguanide (Polyhexanide, 0.1%) water and auxiliary substances Class: A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 94726079607	Deferred for confirmation of manufacturing & testing facility for the applied product along with the submission of the following: i. Manufacturing & QC process. ii. Properly signed & stamp Form iii. Confirmation / clarification regarding the class of applied medical device. iv. Quantities and functionality of ingredients
32.	Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial	Glim Sanitizer Spray Composition:	Deferred for confirmation/ clarification regarding the

	<p>Estate Bhimber Azad Kashmir (ELM-0096) [921-6L] Approved Sections: i. Sachet/Dry Powder Section (For Hemodialysis Concentrates) ii. Hydrocolloid and Soft Silicone Foam Dressings iii. Liquid Section (Diluents and cleaning solutions for analyzers) iv. General IVDs cleaning solutions. v. Disinfectant solutions for laboratory equipment. vi. Hematology diluent solutions. vii. Semi-solid Section (For Ostomy gel only)</p> <p>D. No. 13150 dated 15-05-2025</p>	<p>Ethyl alcohol, Aqua, Glycerin, Hydrogen peroxide, Fragrances, Preservatives</p> <p>Class: A Shelf Life: 2 Years Fee: 6000 Fee Slip No. 71114383</p>	<p>nature of the product whether the applied product is Medical Device as per MDR or otherwise along with the justification & evidence.</p>
33.	<p>Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096) [922-6L] Approved Sections: i. Sachet/Dry Powder Section (For Hemodialysis Concentrates) ii. Hydrocolloid and Soft Silicone Foam Dressings iii. Liquid Section (Diluents and cleaning solutions for analyzers) iv. General IVDs cleaning solutions. v. Disinfectant solutions for laboratory equipment. vi. Hematology diluent solutions. vii. Semi-solid Section (For Ostomy gel only)</p> <p>D. No. 13151 dated 15-05-2025</p>	<p>LeVanid Wound Gel</p> <p>Composition: Ringer's Solution, Glycerine Macrogol, Hydroxyethyl Cellulose, Polyhexanide 0.04%</p> <p>Class: A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 5706816442</p>	<p>Deferred for confirmation of manufacturing & testing facility for the applied product along with the submission of the following: i. Manufacturing & QC process. ii. Properly signed & stamp Form iii. Confirmation / clarification regarding the class of applied medical device. iv. Quantities and functionality of ingredients v. Evidence of availability of product/formulation as medical device</p>
34.	<p>Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096) [923-6L] Approved Sections: i. Sachet/Dry Powder Section (For Hemodialysis Concentrates) ii. Hydrocolloid and Soft Silicone Foam Dressings</p>	<p>AST / GOT BR Kit</p> <p>Composition: R1: AST Substrate (TRIS Buffer 121 mmol/L pH 7.8, L-Aspartate 362 mmol/L, Malate Dehydrogenase > 460 U/L) R2: AST Coenzyme (NADH 1.3 mmol/L, 2-Oxoglutarate 75 mmol/L,</p>	<p>Deferred for confirmation of manufacturing & testing facility for the applied product along with the submission of the following: i. Manufacturing & QC process. ii. Properly signed & stamp application Form. Brand name</p>

	<p>iii.Liquid Section (Diluents and cleaning solutions for analyzers)</p> <p>iv. General IVDs cleaning solutions.</p> <p>v.Disinfectant solutions for laboratory equipment.</p> <p>vi. Hematology diluent solutions.</p> <p>vii. Semi-solid Section (For Ostomy gel only)</p> <p>D. No. 13152 dated 15-05-2025</p>	<p>Biocides)</p> <p>Class: A</p> <p>Shelf Life: 5 Years</p> <p>Fee: 6000</p> <p>Fee Slip No. 260918008</p>	
35.	<p>Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096) [924-6L]</p> <p>Approved Sections:</p> <p>i.Sachet/Dry Powder Section (For Hemodialysis Concentrates)</p> <p>ii. Hydrocolloid and Soft Silicone Foam Dressings</p> <p>iii.Liquid Section (Diluents and cleaning solutions for analyzers)</p> <p>iv. General IVDs cleaning solutions.</p> <p>v.Disinfectant solutions for laboratory equipment.</p> <p>vi. Hematology diluent solutions.</p> <p>vii. Semi-solid Section (For Ostomy gel only)</p> <p>D. No. 13153 dated 15-05-2025</p>	<p>Alkaline Phosphatase</p> <p>R1: ALP Buffer (DEA Buffer 1.25 mmol/L pH 10.2, Magnesium Chloride 0.6 mmol/L, Biocides)</p> <p>R2: ALP Substrate (4-NPP 50 mmol/L, Biocides)</p> <p>Class: A</p> <p>Shelf Life: 5 Years</p> <p>Fee: 6000</p> <p>Fee Slip No. 3011607831</p>	<p>Deferred for confirmation of manufacturing & testing facility for the applied product along with the submission of the following:</p> <p>i.Manufacturing & QC process.</p> <p>ii.Properly signed & stamp application Form, brand name</p>
36.	<p>Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096) [925-6L]</p> <p>Approved Sections:</p> <p>i.Sachet/Dry Powder Section (For Hemodialysis Concentrates)</p> <p>ii. Hydrocolloid and Soft Silicone Foam Dressings</p> <p>iii.Liquid Section (Diluents and cleaning solutions for analyzers)</p> <p>iv. General IVDs cleaning solutions.</p> <p>v.Disinfectant solutions for laboratory equipment.</p> <p>vi. Hematology diluent solutions.</p> <p>vii. Semi-solid Section (For Ostomy gel only)</p> <p>D. No. 13154 dated 15-05-2025</p>	<p>Glim Albumin Kit</p> <p>R1: Bromocresol Reagent (Succinate Buffer 75 mmol/L pH 4.3, BCG 0.12 mmol/L, Tensioactive 2 gm/L (w/v))</p> <p>CAL: Albumin Standard (Bovine Serum Albumin 5 gm/dL (50gm/L)) Concentration Value is traceable to standard Reference Material 927c.</p> <p>Class: A</p> <p>Shelf Life: 5 Years</p> <p>Fee: 6000</p> <p>Fee Slip No. 32835922</p>	<p>Deferred for confirmation of manufacturing & testing facility for the applied product along with the submission of the following:</p> <p>i.Manufacturing & QC process.</p> <p>ii.Properly signed & stamp Form</p>

37.	<p>Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096) [926-6L]</p> <p>Approved Sections:</p> <ul style="list-style-type: none"> i. Sachet/Dry Powder Section (For Hemodialysis Concentrates) ii. Hydrocolloid and Soft Silicone Foam Dressings iii. Liquid Section (Diluents and cleaning solutions for analyzers) iv. General IVDs cleaning solutions. v. Disinfectant solutions for laboratory equipment. vi. Hematology diluent solutions. vii. Semi-solid Section (For Ostomy gel only) <p>D. No. 13155 dated 15-05-2025</p>	<p>Glim Acid Phosphate Kit</p> <p>R1: Citrate Buffer (Sodium Citrate, 1,5-Pentanediol), R2: Citrate / Tartrate Buffer (Sodium Citrate, 1,5-Pentanediol, L-Tartrate) R3: ACP Substrate (Powder α-Naphthyl Phosphate, Fast Red TR, after reconstitution) and R4: Stabilizer (Acetate Buffer)</p> <p>Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 10497199417</p>	<p>Deferred for confirmation of manufacturing & testing facility for the applied product along with the submission of the following:</p> <ul style="list-style-type: none"> i. Manufacturing & QC process. ii. Properly signed & stamp Form
38.	<p>Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096) [927-6L]</p> <p>Approved Sections:</p> <ul style="list-style-type: none"> i. Sachet/Dry Powder Section (For Hemodialysis Concentrates) ii. Hydrocolloid and Soft Silicone Foam Dressings iii. Liquid Section (Diluents and cleaning solutions for analyzers) iv. General IVDs cleaning solutions. v. Disinfectant solutions for laboratory equipment. vi. Hematology diluent solutions. vii. Semi-solid Section (For Ostomy gel only) <p>D. No. 13156 dated 15-05-2025</p>	<p>Bilirubin Direct Kit</p> <p>R1: (Phosphoric Acid, Sulfamic Acid, NaCl Stabilizers) R2: (2,4-DPD, HCl Stabilizers)</p> <p>Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 4892716932</p>	<p>Deferred for confirmation of manufacturing & testing facility for the applied product along with the submission of the following:</p> <ul style="list-style-type: none"> i. Manufacturing & QC process. ii. Properly signed & stamp Form iii. brand name
39.	<p>Caraway Diagnostics, Plot No. 12, Street N-3, National Industrial Zone Rawat, Rawalpindi (ELM-0092) [957-6L]</p> <p>License permits the manufacture of following medical devices in Liquid Section for IVD Products;</p> <ul style="list-style-type: none"> 1. Diluent for Hematology Analyzer, 	<p>Diluent -CA</p> <p>(Cell Diluent or Erythrocyte / Lysis Diluent)</p> <p>Ingredients:</p> <p>Sodium Chloride...<1.5% Buffers.... <1.0% Preservatives.... <0.5% Stabilizers.... <0.5% in ion free water.</p>	<p>Approved.</p> <p>Firm shall submit label and brand name.</p>

	2. Cleaning Solution for hematology analyzer 3. Lyse (IVD) 4. Reagent for quantitative determination of Hemoglobin (Hb) 5. -Reagent for quantitative determination of Total Protein 6. Reagent for quantitative determination of Creatinine 7. Reagent for quantitative determination for Bilirubin. D. No. 13157 dated 15-05-2025.	Class: A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 7723123331	
40.	Caraway Diagnostics, Plot No. 12, Street N-3, National industrial Zone Rawat, Rawalpindi (ELM-0092) [958-6L] License permits the manufacture of following medical devices in Liquid Section for IVD Products; 1. Diluent for Hematology Analyzer, 2. Cleaning Solution for hematology analyzer 3. Lyse (IVD) 4. Reagent for quantitative determination of Hemoglobin (Hb) 5. -Reagent for quantitative determination of Total Protein 6. Reagent for quantitative determination of Creatinine 7. Reagent for quantitative determination for Bilirubin. D. No. 13158 dated 15-05-2025.	Cleaner -CA Analyzer System Cleaner “Probe / Flow Cell Cleaner” “Maintenance Wash Solution” Ingredients: Detergents...<1.0 % Buffers.... <1.0% Preservatives.... <0.5% Stabilizers.... <0.5% in ion free water. Class: A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 7408981643	Deferred for confirmation/ justification regarding the nature of the product whether the applied product is Medical Device as per MDR or otherwise along with the justification & evidence. Label not provided.

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