

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

DECISIONS OF 123RD MEETING OF THE MEDICAL DEVICE BOARD (MDB) HELD ON
25-02-2026 (MANUAL APPLICATIONS PART-II)

123rd meeting of the Medical Device Board (MDB) was held in the committee room of Drug Regulatory Authority of Pakistan (DRAP), Prime Minister Health Complex, Chak Shahzad, Islamabad on 25th February, 2026. The meeting was chaired by Dr. Babar Khan, Chairman Medical Device Board, DRAP, Islamabad and attended by the following:

S. No.	Name and Designation/Department	Position in the MDB
1.	Dr. Babar Khan, Director, Medical Devices & Medicated Cosmetics, Drug Regulatory Authority of Pakistan, Islamabad.	Chairman
2.	Mr. Salik Zahid, Chief Drug Inspector, Balochistan, a nominee of Director General Health, Health Department, Government of Balochistan	Member (attended meeting through videolink)
3.	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)
4.	Prof. Dr. Saqib Shafi Sheikh, Interventional Cardiologist, 98, Babar Block, New Garden Town, Lahore.	Member (attended meeting through videolink)
5.	Mr. Wajahat Ali, Biomedical Manager, Liaquat College of Medicine and Dentistry & Darul Sehat Hospital, Karachi.	Member (attended meeting through videolink)
6.	Abdul Aleem Awan, Asstt. Prof. Pharmacy Department, Abbottabad University of Science & Technology Havelian.	Member
7.	Dr. Farid Khan, Senior Consultant Neuro Surgery/Director Trauma & Emergency/Focal Person MSDS, Primary & Secondary Healthcare Department, Punjab.	Member (attended meeting through videolink)
8.	Dr. Ayesha Ali, Department of Pharmacy, Pakistan Institute of Medical Sciences, Islamabad (Hospital Pharmacist).	Member (attended meeting through videolink)
9.	Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad.	Member (attended meeting through videolink)
10.	Mrs. Tazeen Saeed Bukhari, 192 Cavalry Ground, Street 4, Shami Road Khalid Yaqoob Chowk, Lahore	Co-expert (attended meeting through videolink)
11.	Mr. Ayyaz Ahmed, Additional Director (MD&MC), DRAP, Islamabad.	Member-cum-Secretary

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

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

EVALUATOR: MR. MUHAMMAD AMIN (DEPUTY DIRECTOR)

Item No. I: APPLICATIONS FOR RENEWAL OF LICENSE TO IMPORT MEDICAL DEVICES UNDER MEDICAL DEVICES RULES, 2017.

(FRESH RENEWAL CASES OF ELI):

S.No	Name of Establishment	Name of Qualified Technical Person	Name of Management	Decision
1.	M/s F.W Distributors, Office/godown: Opposite Poonch House, Adamjee Road, Saddar, Rawalpindi ELI-00221	Sekandar Hayat Pharm D	Muhammad Yunas Muhammad faisal Ali	Approved
2.	M/s AGP Limited, Office/godown: B-23-C, SITE, Karachi ELI-00571	Wajeeha Mateen Pharm D	Mr. Tariq Moinuddin Khan Mr. Mahmud Yar Hira Mr. Kamran Nishat Mr. Nusrat Munshi Mr. Naved Abid Khan Mr. Zafar Iqbal Sobani Mr. Muhammad Kamran Mirza	Approved
3.	M/s New Pakistan Traders, Office: Office No 306/I, Trade Tower, Altaf Hussain Road,new challi. Karachi Godown: 1st Floor, Puri House,West Wharf Road, Karachi. ELI-00161	Syed hammad ali Pharm D	Muhammad Rafiq CEO	Approved
4.	M/s Gene-Tech Laboratories, Office: 246/B, P.E.C.H.S Block- 6, Karachi. Godown: 246/B, P.E.C.H.S Block- 6, Karachi. ELI-00089	Sidra Tul Muntaha Pharm d	Zubair Khalil khan CEO	Approved

5.	M/s Best - Med Traders, Office/godown: Bungalow No. E-16, Gulshan-e-iqbal, Block- 7, Karachi. ELI-00236	Kamran Hayat Nizami Pharm D	Adnan Hayat Nizami CEO	Approved
6.	M/s FY Diagnostic & Surgicals, Office: Suit No. 203, near duty free shop, BL-7/8, Anum Blessing, 2nd Floor, KCHSU, Shahrah-e- Faisal Karachi, Godown: 1 st Floor, Suit No. 115, near duty free shop, BL-7/8, Anum Blessing, KCHSU, Shahrah-e-Faisal Karachi. ELI-00323	Fatima Rabia Awan B. Pharmacy	Mr. Younus Ali Khan Ms. Farah Younus	Approved
7.	M/s Madina pharma links, Office/godown: MPL Mansion, 142 G-1, MA Johar town, Lahore. ELI-00556	Sayeda Kamber Rizvi Pharm D	Muhammad Asim Munir CEO	Approved
8.	M/s Ghazi Brothers, Office: Ghazi House, D-35, KDA Scheme No.1, Miran Muhammad Shah Road, Karachi Godown: Ghazi House, B-32, Al-Hilal Society, KDA Scheme No.7, University Road, Karachi ELI-00002	Fabiha Ijmal Pharm D	Muhammad Irfan Ghazi CEO	Approved
9.	M/s Medisurg Innovatives HealthCare (Private) Limited, Office: Godown: SF-11 Saima Square-1, Block 10-A, Gulshan e Iqbal Karachi ELI-00242	Maryam Kanwal, Pharm D	Muhammad Rizwan CEO	Approved

<p>10.</p>	<p>M/s Mediland Pakistan (Pvt) Ltd, Office No. B-09, 2nd Floor, Masood Arcade, IJP Road, Near Saidpur Road, Rawalpindi. Proposed Godown address: Lower ground , shop B-16, Masood arcade, IJP, road, near Saidpur road, Rawalpindi. ELI-00202</p>	<p>Naveed Akhtar</p>	<p>Naveed Akhtar</p>	<p>The board considered the inspection report of the firm and took a serious note of the shortcomings identified during inspection of establishment. It was also noted that the firm was inspected 2nd time for renewal of license and on both occasions firm failed to satisfy inspector in regards to compliance with medical devices rules 2017. Therefore, it was decided to issue show cause notice to the firm and to provide opportunity of personal hearing before a final decision is taken on renewal application of the firm.</p>
<p>11.</p>	<p>M/s Sapphire International, Office / godown: Room no 903, 9th floor, Uni center, I.I. chundrigar, road, Karachi. ELI-00430 M-110 & M-115</p>	<p>Mirza Adil baig Pharm D</p>	<p>M Nadeem Malik CEO</p>	<p>The board considered the inspection report of the firm and also obtained comments of Mr. Wajahat Ali Biomedical Engineer, Member MDB, Islamabad who was part of inspection panel. He apprised the board that the firm has taken serious steps towards removal of shortcomings and compliance to medical devices rules 2017. Keeping in view the inspection report and positive remarks of member MDB the board decided to grant renewal of establishment license to import medical devices.</p>

Item No. II: REGISTRATION / ENLISTMENT OF MEDICAL DEVICE FOR IMPORT / LOCAL PRODUCTS.

EVALUATOR: SAADAT ALI KHAN (DEPUTY DIRECTOR)

IMPORTED PRODUCT AGENDA:

S. No	Name of Applicant(s)	Name of Manufacturer	Medical Device	Decision
1.	M/s. Galaxy Pharma Pvt. Ltd. Karachi. (License No. ELI-00402) Date of R&I 18-02-2020 Fee Details: Paid Fee: 5,000/- Challan No. 0790294 dated 18-02-2020	Legal Manufacturer & Site as per FSC (Germany): Gynemed GmbH & Co. KG Lubecker StraBe 9, D-23738 Lensahn, Alemania. Germany. LOA Type: Scan copy of non-notarized copy. Issuance Date: 11-04-2025 Validity: <u>This agreement is valid until further notice.</u> FSC Type: Scan copy of non-notarized copy Issued By: Germany Issued date: 24-02-2021 Validity: not mentioned ISO 13485: Type: Scan copy of non-notarized copy Validity: 26-07-2025	GM501 Gradient Applied as Cluster. Class-C Service Life: 18 months Model/Codes/Size: Ref No, Size 4 GM 501G-100-50, 1 x 50 ml 4 GM 501G-100-100, 1 x 100 ml 4 GM 501G-100-250, 1 x 250 ml 4 GM 501G-100-500, 1 x 500 ml 4 GM 501G-90-10, 1 x 10 ml 4 GM 501G-90-50, 1 x 50 ml 4 GM 501G-90-100, 1 x 100 ml	Deferred for submission of the followings: <ol style="list-style-type: none">1. Valid notarized LOA issued by the legal manufacturer with clear validity.2. Clarification is required that why Multiple products & codes like GM501 SpermAir, SpermActive, Gradient & PVP are applied in single application & fee. One product shall be considered in the current application while the remaining shall be applied separately through online MDMC portal.3. Scan copy of Form-7A duly signed along with all information & relevant annexures are required.4. Verifiable fee slip for the applied product with the prescribed fee for Class-C.5. Multiple codes needs justification with catalog & respective group fee.6. Valid notarized ISO 13485 for the applied manufacturing sites.
7.	M/s. Galaxy Pharma Pvt. Ltd. Karachi. (License No. ELI-00402) Date of R&I 07-12-2020	Legal Manufacturer & Site as per FSC (Germany): Gynemed GmbH & Co. KG Lubecker StraBe 9, D-23738 Lensahn, Alemania. Germany.	Bromelain in Dulbecco 's PBS Contains 10 IU/ml Bromelain Applied as Cluster. Class-C Service Life: 6 months	Deferred for submission of the followings: <ol style="list-style-type: none">1. Valid notarized LOA issued by the legal manufacturer with clear validity.2. Clarification is required that why Multiple products & codes like Bromelain in Dulbecco 's PBS & GM501

	<p>Fee Details: Paid Fee: 5,000/- Challan No. 1979352 dated 07-12-2020</p>	<p>LOA Type: Scan copy of non-notarized copy. Issuance Date: 11-04-2025 Validity: <u>This agreement is valid until further notice.</u></p> <p>FSC Type: Scan copy of non-notarized copy Issued By: Germany Issued date: 24-02-2021 Validity: not mentioned</p> <p>ISO 13485: Type: Scan copy of non-notarized copy Validity: 26-07-2025</p>	<p>Model/Codes/Size: 4 GM 501BROM10 (1 x 10 ml)</p>	<p>Collagenase are applied in single application & fee. One product shall be considered in the current application while the remaining shall be applied separately through online MDMC portal.</p> <ol style="list-style-type: none"> 3. Scan copy of Form-7A duly signed along with all information & relevant annexures are required. 4. Verifiable fee slip for the applied product with the prescribed fee for Class-C. 5. Multiple codes needs justification with catalog & respective group fee. 6. Valid notarized ISO 13485 for the applied manufacturing sites.
7.	<p>M/s. Galaxy Pharma Pvt. Ltd. Karachi. (License No. ELI-00402)</p> <p>Date of R&I 18-02-2020 Fee Details: Paid Fee: 5,000/- Challan No. 0790293 dated 18-02-2020</p>	<p>Legal Manufacturer & Site as per FSC (Germany): Gynemed GmbH & Co. KG Lubecker StraBe 9, D-23738 Lensahn, Alemania. Germany.</p> <p>LOA Type: Scan copy of non-notarized copy. Issuance Date: 11-04-2025 Validity: <u>This agreement is valid until further notice.</u></p> <p>FSC Type: Scan copy of non-notarized copy Issued By: Germany Issued date: 24-02-2021 Validity: not mentioned</p> <p>ISO 13485: Type: Scan copy of non-</p>	<p>GM501 Basic Applied as Cluster. Class-C</p> <p>Service Life: 6 months</p> <p>Model/Codes/Size: Ref No.: Size 4 GM 501-20 20ml 4 GM 501-50 1 x 50 ml 4 GM 501-100 1 x 150 ml 4 GM 501-250 1 x 250 ml 4 GM 501-500 1 x 500 ml</p>	<p>Deferred for submission of the followings:</p> <ol style="list-style-type: none"> 1. Valid notarized LOA issued by the legal manufacturer with clear validity. 2. Clarification is required that why Multiple products are applied in single application & fee. One product shall be considered in the current application while the remaining shall be applied separately through online MDMC portal. 3. Scan copy of Form-7A duly signed along with all information & relevant annexures are required. 4. Verifiable fee slip for the applied product with the prescribed fee for Class-C. 5. Multiple codes needs justification with catalog & respective group fee. 6. Valid notarized ISO 13485 for the applied manufacturing sites.

		notarized copy Validity: 26-07-2025		
8.	M/s. Galaxy Pharma Pvt. Ltd. Karachi. (License No. ELI-00402) Date of R&I 18-02-2020 Fee Details: Paid Fee: 5,000/- Challan No. 0790295 dated 18-02-2020	Legal Manufacturer & Site as per FSC (Germany): Gynemed GmbH & Co. KG Lubecker StraBe 9, D-23738 Lensahn, Alemania. Germany. LOA Type: Scan copy of non-notarized copy. Issuance Date: 11-04-2025 Validity: <u>This agreement is valid until further notice.</u> FSC Type: Scan copy of non-notarized copy Issued By: Germany Issued date: 24-02-2021 Validity: not mentioned ISO 13485: Type: Scan copy of non-notarized copy Validity: 26-07-2025	GM501 Insemination Kit Applied as Cluster. Class-D Service Life: 6 months Model/Codes/Size: 4SA-KIT-002-standard 4SA-KIT-002-memo	Deferred for submission of the followings: <ol style="list-style-type: none">1. Valid notarized LOA issued by the legal manufacturer with clear validity.2. Clarification is required that why Multiple products are applied in single application & fee. One product shall be considered in the current application while the remaining shall be applied separately through online MDMC portal.3. Scan copy of Form-7A duly signed along with all information & relevant annexures are required.4. Verifiable fee slip for the applied product with the prescribed fee for Class-C.5. Multiple codes needs justification with catalog & respective group fee.6. Valid notarized ISO 13485 for the applied manufacturing sites.
9.	M/s. Galaxy Pharma Pvt. Ltd. Karachi. (License No. ELI-00402) Date of R&I 18-02-2020 Fee Details: Paid Fee: 5,000/- Challan No. 0790292 dated 18-02-2020	Legal Manufacturer & Site as per FSC (Germany): Gynemed GmbH & Co. KG Lubecker StraBe 9, D-23738 Lensahn, Alemania. Germany. LOA Type: Scan copy of non-notarized copy. Issuance Date: 11-04-2025 Validity: <u>This agreement is valid until further notice.</u>	GM501 Flush Heparin (2.5 IU/ml) Applied as Cluster. Class-D Service Life: 6 months Model/Codes/Size: 4 GM 501F-50 1 x 50 ml 4 GM 501F-500 1 x 500 ml	Deferred for submission of the followings: <ol style="list-style-type: none">1. Valid notarized LOA issued by the legal manufacturer with clear validity.2. Clarification is required that why Multiple products & codes are applied in single application & fee. One product shall be considered in the current application while the remaining shall be applied separately through online MDMC portal.3. Scan copy of Form-7A duly signed along with all information & relevant annexures are required.

		<p>FSC Type: Scan copy of non-notarized copy Issued By: Germany Issued date: 24-02-2021 Validity: not mentioned</p> <p>ISO 13485: Type: Scan copy of non-notarized copy Validity: 26-07-2025</p>		<p>4. Verifiable fee slip for the applied product with the prescribed fee for Class-C. 5. Multiple codes needs justification with catalog & respective group fee. 6. Valid notarized ISO 13485 for the applied manufacturing sites.</p>
10.	<p>M/s. Galaxy Pharma Pvt. Ltd. Karachi. (License No. ELI-00402)</p> <p>Date of R&I 18-02-2020 Fee Details: Paid Fee: 5,000/- Challan No. 0790296 dated 18-02-2020</p>	<p>Legal Manufacturer & Site as per FSC (Germany): Gynemed GmbH & Co. KG Lubecker StraBe 9, D-23738 Lensahn, Alemania. Germany.</p> <p>LOA Type: Scan copy of non-notarized copy. Issuance Date: 11-04-2025 Validity: <u>This agreement is valid until further notice.</u></p> <p>FSC Type: Scan copy of non-notarized copy Issued By: Germany Issued date: 24-02-2021 Validity: not mentioned</p> <p>ISO 13485: Type: Scan copy of non-notarized copy Validity: 26-07-2025</p>	<p>GM 501-EmbryoStore Contains Human Serum Albumin Embryo Freeze 15 g/liter Embryo Thaw 1 14 g/liter Embryo Thaw 2 14 g/liter Embryo Thaw 3 14 g/liter</p> <p>Applied as Cluster.</p> <p>Class-D Service Life: 18 months Model/Codes/Size: Ref No.: Size 4 EMF01_P_KIT1 1 x Kit 4 EMF01_P_F 1 x 10 ml Freeze 4 EMF01_P_T1 1 x 10 ml Thaw 1 4 EMF01_P_T2 1 x 10 ml Thaw 2 4 EMF01_P_T3 1 x 10 ml Thaw 3</p>	<p>Deferred for submission of the followings:</p> <ol style="list-style-type: none"> 1. Valid notarized LOA issued by the legal manufacturer with clear validity. 2. Clarification is required that why Multiple products & codes are applied in single application & fee. One product shall be considered in the current application while the remaining shall be applied separately through online MDMC portal. 3. Scan copy of Form-7A duly signed along with all information & relevant annexures are required. 4. Verifiable fee slip for the applied product with the prescribed fee for Class-C. 5. Multiple codes needs justification with catalog & respective group fee. 6. Valid notarized ISO 13485 for the applied manufacturing sites.
11.	<p>Medequips SMC PVT Ltd., Lahore (License No. ELI-00402)</p>	<p>Imaxeon Pty Ltd Unit 1, 38-46 South Street Rydalmere 2116 New South Wales, Australia. Manufacturing Site (as per FSC) for code</p>	<p>MEDRAD Salient Multi-Patient Assembly Injection Syringes and Sterile Extension Tubing</p> <p>Applied as System.</p>	<p>One product Salient Multi-Patient Syringe MP1001 approved. The firm is advised to apply separately for other products/codes via online MDMC portal.</p>

	<p>Date of R&I 27-01-2025</p> <p>Fee Details: Paid Fee: 31,000/-</p> <p>Challan No. 7652675877 for MEDRAD Salient MP Assembly.</p>	<p>MP1001 & SP1003: Vincent Medical (Dong Guan) Mfg. Co., Ltd 11 ShaBu Street, Qiao Long District, Tang Xia Town, 523730 Dong Guan City, Guangdong Province, People's Republic of China.</p> <p>Manufacturing Site (as per FSC) for code MP1002: Bayer Medical Care Inc 1 Bayer Drive Indianola, PA 15051-0780 U.S.A.</p> <p>LOA Type: Scan copy of non-notarized copy. Validity: 31-01-2026</p> <p>FSC Type: Scan copy of non-notarized copy Issued By: TGA Australia Issued date: 28-08-2024 Validity: not mentioned</p> <p>ISO 13485: Type: Scan copy of non-notarized copy Validity: 28-10-2027</p> <p>EU QMS: Type: Scan copy of non-notarized copy Validity: 25-08-2026</p>	<p>Class-B</p> <p>Service Life: 3 Yrs</p> <p>Model/Codes/Size: Salient Multi-Patient Syringe MP1001, Salient Multi-Patient Transfer Set MP1002, Salient Single Patient Disposable SP1003</p>	
12.	<p>M/s Save On Health Care, 101-B, Panjpeer Road, Lalpur Mughalpura, Lahore ELI-00027</p> <p>Date of R&I 08-05-2025</p>	<p>Hitec Medical CO., LTD. 501, Building 2 Lane 1505, Lane Hang Road, Minhang District 201112 Shanghai, People Republic of China.</p> <p>LOA</p>	<p>Hitecare Nasal Oxygen Cannula</p> <p>Applied as Single.</p> <p>Class-B</p> <p>Service Life: 5 Yrs</p> <p>Model/Codes/Size: Infant, Pediatric, Adult</p>	<p>Deferred for submission of the followings:</p> <ol style="list-style-type: none"> Valid notarized CE Certificate. Multiple codes need justification with catalog & Family fee. Valid legalized Free Sale Certificate issued by the respective regulatory authority of country of origin

	<p>Fee Details: Paid Fee: 31,000/- Challan No. 11094891288</p>	<p>Type: Scan copy of non-notarized copy. Validity: 30-12-2028</p> <p>FSC Type: Scan copy of non-notarized copy Issued By: China Chamber of Commerce Validity: 23-09-2026</p> <p>ISO 13485: Type: Scan copy of non-notarized copy Validity: 02-11-2026</p> <p>EC Certificate not attached.</p>		<p>or any RRA country.</p>
13.	<p>NI healthcare Products Pvt Ltd Office No. A, Unit 10 Survey No. 263, Damlotte Road District Malir, Karachi (ELI-01117)</p> <p>Date of R&I 31-12-2024</p> <p>Fee Details: Paid Fee: 31,000/- Challan No. 57245832</p>	<p>Legal manufacturer (as per Form-7A) Vincent Medical Manufacturing Co., Ltd Flat/RM B2, 7/F. Hang Fung Industrial Building Phase 2, 2G Hok Yuen St., Hung Hom, Kowloon, Hong Kong.</p> <p>Manufacturing Site (as per form-7A):</p> <p>Site No.1: Vincent Medical (Dongguan) Technology Company Limited RM 101 and 201, Block 10, 1st Taoyuan Road, Songshan Lake Zone, 523 808 Dongguan, Guangdong, China.</p> <p>Site No.2: Vincent Medical (Dong Guan) Manufacturing Co., Ltd 11 ShaBu Street, Qiao Long District, Tang Xia Town, 523730 Dong Guan City, Guangdong Province, China.</p>	<p>Vincent /Inspired Humidification Chambers Applied as Family. Class-B Service Life: 5 Yrs Model/Codes/Size: VHC10, VHC20, VHC25, VHC50</p>	<p>Deferred for submission of the followings:</p> <ol style="list-style-type: none"> 1. Valid legalized Free Sale Certificate issued by the respective regulatory authority of country of origin 2. Valid notarized CE Certificate or FSC of RRA. 3. Valid notarized products specific LOA issued by the legal manufacturer. 4. Multiple codes need justification with catalog & Family fee.

		<p>Legal manufacturer & manufacturing Site (as per FSC (china): Vincent Medical (Dong Guan) Manufacturing Co., Ltd</p> <p>11 ShaBu Street, Qiao Long District, Tang Xia Town, 523730 Dong Guan City, Guangdong Province, China.</p> <p>LOA Type: Scan copy of non-notarized copy. Validity: 01-12-2026</p> <p>FSC Type: Scan copy of non-notarized copy Issued By: issuance authority is mentioned in Chinese language. Validity: 28-12-2025</p> <p>ISO 13485: Type: Scan copy of non-notarized copy Validity: 16-04-2027</p> <p>CE Certificate: Type: Scan copy of non-notarized copy Validity: 26-05-2024</p>		
14.	<p>Uni Brand International Rawalpindi (ELI-00213)</p> <p>Date of R&I 03-06-2024 Fee Details: Paid Fee: 5,000/- Challan No. 22449032</p>	<p>Legal Manufacturer & manufacturing Site as per Form-7A: Sakura Finetek USA Inc. 1750 W. 124m Street Torrance, CA 90501 USA.</p> <p>Legal Manufacturer as per FSC: Sakura Seiki Co., Ltd., 75-5, Imojiya, Chikuma City, Nagano Pref., Japan.</p> <p>Manufacturing Site as per FSC: Sakura Seiki Co., Ltd., Nagano Headquarters Plant, 75-5, Imojiya, Chikuma City, Nagano</p>	<p>Tissue Tek Cover Slipping Film Cover Slipping Film Applied as Family. Class-B Service Life: 2 Yrs Model/Codes/Size: 4770</p>	<p>Deferred for submission of the followings:</p> <ol style="list-style-type: none"> 1. Valid notarized LOA issued by the legal manufacturer with clear validity. 2. Valid legalized FSC with applied codes & all the manufacturing sites. 3. Scan copy of prescribed Form duly signed along with all information & relevant annexures are required. 4. Clarification of the Class of the product & its respective prescribed fee.

		<p>Pref., Japan.</p> <p>LOA Type: Scan copy of non-notarized copy. Validity: 31-12-2025</p> <p>FSC Type: Scan copy of non-notarized copy Issued By: Japan. Issuance date: 30-08-2021 Validity: Not mentioned</p> <p>ISO 13485: Type: Scan copy of non-notarized copy Validity: 09-05-2023</p>		
15.	<p>Uni Brand International Rawalpindi (ELI-00213)</p> <p>Date of R&I 03-06-2024 Fee Details: Paid Fee: 5,000/- Challan No. 68556175276</p>	<p>Legal Manufacturer & manufacturing Site as per Form-7A: Sakura Finetek USA Inc. 1750 W. 124m Street Torrance, CA 90501 USA. LOA Type: Scan copy of non-notarized copy. Validity: 31-12-2025</p> <p>FSC not attached.</p> <p>ISO 13485: Type: Scan copy of non-notarized copy Validity: 14-02-2027</p>	<p>Tissue Tek OCT Compound</p> <p>Applied as Family.</p> <p>Class-B</p> <p>Service Life: 2 Yrs Model/Codes/Size: 4583 (118ml Bottle)</p>	<p>Deferred for submission of the followings:</p> <ol style="list-style-type: none"> Valid notarized LOA issued by the legal manufacturer with clear validity. Valid legalized FSC with applied codes & all the manufacturing sites. Scan copy of prescribed Form duly signed along with all information & relevant annexures are required. Clarification of the Class of the product & its respective prescribed fee.
16.	<p>M/s. Ali Gohar & Company (Pvt) Ltd. (ELI-00004)</p> <p>Date of R&I 04-06-2024 Fee Details: Paid Fee: 50,000/- Challan No. 525287607180</p>	<p>Legal Manufacturer: Smiths Medical ASD Inc. 6000 Nathan Lane North Minneapolis MN 55442, USA. Manufacturing Site: Smiths Healthcare Manufacturing SA de CV, Avenida Calidad No 4, Parque Industrial Internacional Tijuana, Tijuana B.C.C.P. 22425 Mexico.</p>	<p>Deltec Proport Implantable Venous Access System Tray Proport</p> <p>Applied as.</p> <p>Class-D</p> <p>Service Life: 5 Yrs Model/Codes/Size: 21-4052-24, 21-4452-24, 21-4053-24, 21-4453-24</p>	<p>Deferred for submission of the followings:</p> <ol style="list-style-type: none"> Valid notarized LOA issued by the legal manufacturer with clear validity. Valid legalized FSC with applied codes & all the manufacturing sites. Scan copy of prescribed Form duly signed along with all information & relevant annexures are required. Multiple codes need justification with catalog & Family fee. Codes as per

		<p>LOA Type: Scan copy of non-notarized copy. Issuance date: 14-12-2022 Validity: Not mentioned</p> <p>FSC Type: Scan copy of non-notarized copy Issued By: MHRA. Validity: 26-05-2025</p> <p>ISO 13485: Type: Scan copy of non-notarized copy Validity: 05-04-2027.</p> <p>CE (FQA): Type: Scan copy of non-notarized copy Validity: 18-03-2023 CE (Design Examination Certificate): Type: Scan copy of non-notarized copy Validity: 26-05-2024</p>	<p>21-4055-24, 21-4455-24 21-4071-24, 21-4471-24 21-4083-24, 21-4483-24</p>	<p>FSC required.</p>
17.	<p>M/s Medtronic Pakistan Private Limited. Ocean Tower, 21st Floor, Plot # G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi. (ELI-00273)</p> <p>Date of R&I 24-02-2025 Fee Details: Paid Fee: 6,000/- Challan No. 73637900455</p>	<p>Legal Manufacturer: Medtronic Inc, 710 Medtronic Parkway Minneapolis, MN, USA 55432 Manufacturing site (as per Form-7A): 1. M/s PLEXUS CORP. located at 2400 Millbrook Dr, BUFFALO GROVE,IL,USA 60089 2. CEA Medical Manufacturing Inc located at d.b.a Nissha Medical Technologies, 1755 Merchants Ct, Colorado Springs, CO, USA 80916 , 3. CEA Global Dominicana d.b.a Nissha Medical Technologies located at Zona Franca</p>	<p>Catheter Connecting Cable Cable Applied as. Class-A Service Life: 2 Yrs Model/Codes/Size: 2ACHC</p>	<p>Approved with manufacturing site as per FSC.</p>

		<p>Industrial, San Pedro de Macoris, San Pedro de Macoris, DOMINICAN REPUBLIC 21000, 4. Lake Region Medical located at 340 Lake Hazeltine Dr, CHASKA, MN USA 55318 5. Covidien located at Michael Collins Road, H91, W9N4 Mervue, Galway, IRELAND</p> <p>Manufacturing Site (as per FSC): CEA Medical Manufacturing Inc located at d.b.a Nissha Medical Technologies, 1755 Merchants Ct, Colorado Springs, CO, USA 80916,</p> <p>LOA Type: Scan copy of non-notarized copy. Issuance date: 26-02-2025 Validity: Not mentioned</p> <p>FSC Type: Scan copy of non-notarized copy Issued By: MHRA. Validity: 13-02-2026</p> <p>ISO 13485: Type: Scan copy of non-notarized copy Validity: 28-11-2025.</p>		
18.	<p>M/s Ghazali Brothers Karachi, ELI-00240</p> <p>Date of R&I 03-06-2024 Fee Details: Paid Fee: 5,000/-</p>	<p>Hospital & Homecare Imp. & Exp. Co., Ltd, Room 618-611 No.5 Zhongtai International Plaza No.311, Jiangdong Road, Nanjing, China.</p> <p>LOA</p>	<p>Hospital & Homecare Non-Woven Tape Applied as Single Class-A Service Life: 5 Yrs Model/Codes/Size: MC168</p>	<p>Approved the product Hospital & Homecare Non-Woven Tape (MC168) only one size “7.5x3Yards”</p>

	Challan No. 0719204381	<p>Type: Scan copy of non-notarized copy. Issuance date: 10-02-2023 Validity: Five years</p> <p>FSC Type: Scan copy of non-notarized copy Issued By: MHRA. Validity: 26-05-2025</p> <p>FSC Type: Scan copy of non-notarized copy Issued By: China Chamber of Commerce. Validity: 05-08-2027</p> <p>ISO 13485: Type: Scan copy of non-notarized copy Validity: 31-05-2028.</p>	Sizes mentioned below:	
19.	<p>ZEDCO, No.203, 602, Sky Mark Tower, Plot No. A-13, Block 7/8,K.C.H, S.U Shahrah-e- Faisal Road, Karachi</p> <p>ELi No: ELI- 00347</p> <p>Date of R&I 02-02-2024 Fee Details: Paid Fee: 50,000/- Challan No. 61969775712</p>	<p>Haemokinesis Ltd Address: 16 Technology Circuit, Hallam, Victoria, 3803, Australia</p> <p>LOA Type: Scan copy of non-notarized copy. Validity: 01-12-2025</p> <p>FSC Type: Scan copy of non-notarized copy Issued By: Swiss Medics. Validity: 24-06-2025</p> <p>ISO 13485: Type: Scan copy of non-notarized copy Validity: 13-01-2027.</p>	<p>STATUS 1 –Group Check Status 1 Group check gel card</p> <p>Applied as. Class-C Service Life: 16 months.</p> <p>Model/Codes/Size: TT1001(Reagent, TT1003(Buffer)</p>	<p>Deferred for submission of the followings:</p> <ol style="list-style-type: none"> 1. Valid notarized LOA issued by the legal manufacturer with clear validity. 2. Valid legalized FSC with applied codes & all the manufacturing sites. 3. Scan copy of prescribed Form duly signed along with all information & relevant annexures are required. 4. Multiple codes need justification with catalog & Family fee. Codes as per FSC required.

20.	<p>M/s. SIND MEDICAL STORES, 13-B, Block 6, PECHS, Shahrah e Faisal, Karachi – 75400, Lic. No.: ELI-00010.</p> <p>Date of R&I 04-03-2025 Fee Details: Paid 62,000/- Fee: Challan No. 85321744965</p>	<p>M/s. MEDTRADE PRODUCTS Ltd located at Electra House, Electra Way, Crewe CW1 6GL UK.</p> <p>LOA Type: Scan copy of non-notarized copy. Validity: 26-05-2029</p> <p>FSC Type: Scan copy of non-notarized copy Issued By: Swiss Medics. Validity: 15-03-2028</p> <p>ISO 13485: Type: Scan copy of non-notarized copy Validity: 26-04-2027.</p>	<p>CELOX –A (Celox Applicator with 6g Haemostatic Granules)</p> <p>Applied as.</p> <p>Class-C</p> <p>Service Life: 5 yrs Model/Codes/Size: (Model/REF: FG08832021)</p>	<p>Deferred for submission of the followings:</p> <ol style="list-style-type: none"> 1. Scan copy of prescribed Form duly signed along with all information & relevant annexures are required. 2. Justification of Class & the product as medical device with catalog, brushier or any document .
21.	<p>Coral Pharmaceuticals, A - 85 S.M.C.H.S, Karachi.</p> <p>Lic. No.: ELI-00065.</p> <p>Date of R&I 13-01-2022 Fee Details: Paid 25,000/- Fee: Challan No. 79800146234</p>	<p>Dynek Pty Ltd 9 Circuit Drive, Hendon, SA 5014, Australia.</p> <p>LOA Type: Scan copy of non-notarized copy. Validity: 17-01-2026</p> <p>FSC Type: Scan copy of non-notarized copy Issued By: TGA Australia Issuance Date: 24-11-2021 Validity: Not mentioned</p> <p>ISO 13485: Type: Scan copy of non-notarized copy Validity: 19-04-2025.</p>	<p>Chromic Gut Chromic Catgut</p> <p>Applied as.</p> <p>Class-C</p> <p>Service Life: 5 yrs Model/Codes/Size:</p>	<p>Deferred for submission of the followings:</p> <ol style="list-style-type: none"> 1. The product is of Class-D while applied in Class-C. Prescribed fee of Class-D family is required. Along with justification of the ingredient/ material from which the product is made. 2. Valid notarized LOA issued by the legal manufacturer with clear validity. 3. Valid legalized FSC with applied codes & all the manufacturing sites. 4. Scan copy of prescribed Form duly signed along with all information & relevant annexures are required. 5. Multiple codes need justification with catalog & Family fee. Codes as per FSC required. 6. Valid notarized ISO 13485
22.	<p>Coral Pharmaceuticals, A - 85 S.M.C.H.S,</p>	<p>Dynek Pty Ltd 9 Circuit Drive, Hendon, SA 5014, Australia.</p>	<p>Dysilk Silk</p> <p>Applied as.</p>	<p>Deferred for submission of the followings:</p> <ol style="list-style-type: none"> 1. The clarification of class & type of silk along with

	<p>Karachi. Lic. No.: ELI-00065.</p> <p>Date of R&I 13-09-2021</p> <p>Fee Details: Paid Fee: 25,000/- Challan No. 499322168</p>	<p>LOA Type: Scan copy of non-notarized copy. Validity: 17-01-2026</p> <p>FSC Type: Scan copy of non-notarized copy Issued By: TGA Australia Issuance Date: 24-11-2021 Validity: Not mentioned</p> <p>ISO 13485: Type: Scan copy of non-notarized copy Validity: 19-04-2025.</p>	<p>Class-C Service Life: 5 yrs Model/Codes/Size:</p>	<p>Prescribed fee of respective Class family is required.</p> <ol style="list-style-type: none"> 2. Valid notarized LOA issued by the legal manufacturer with clear validity. 3. Valid legalized FSC with applied codes & all the manufacturing sites. 4. Scan copy of prescribed Form duly signed along with all information & relevant annexures are required. 5. Multiple codes need justification with catalog & Family fee. Codes as per FSC required. 6. Valid notarized ISO 13485
--	---	---	---	---

ADDITIONAL AGENDA CASES

EVALUATOR: AMMAR ASHRAF AWAN, DEPUTY DIRECTOR

Sr. No.	Name of Applicant(s)	Name of Manufacturer	Medical Device	Decision
1.	<p>M/s. Hoor Pharma (Pvt.) Ltd. Korangi Creek Industrial Park. Korangi, Karachi (ELI-00037)</p> <p>R&I Date: 23-08-2024 CMS tracking ID: EH8-S26-H3Z1 Fee: 25,000/-</p>	<p>Manufacturing site: GE Healthcare Austria GmbH & Co OG Address: Tiefenbach 15 4871 Zipf, Austria LOA Notarization: Yes Issued: 02-04-2024</p> <p>• FSC Legalized: Legalized Issued by: BASG, Austria Valid: 03-08-2025 ISO – Certificate: Notarization: yes Valid till: 23-04-2027</p> <p>EU Quality Management certificate valid till 13-05-2030</p>	<p>Brand Name: Voluson Expert 20/ 5934553 Generic Name: General-purpose ultrasound imaging system Applied as: Single Class: B</p> <p>Models/Code/sizes (as per FSC & application: 5934553</p> <p>Expected service life: 7 years</p>	Approved
2.	<p>M/s. Hoor Pharma (Pvt.) Ltd. Korangi Creek Industrial Park. Korangi, Karachi (ELI-00037)</p> <p>R&I Date: 23-08-2024 CMS tracking ID: 2QZ-GEY-3GJ3 Fee: 25,000/-</p>	<p>Manufacturing site: GE Ultrasound Korea, Ltd. Address: 9, Sunhwan-ro 214beon-gil, Jungwon-gu, Seongnam-si, Gyeonggi- do 13204, Republic of Korea LOA Notarization: Yes Issued: 14-03-2024</p> <p>• FSC Legalized: Apostille Issued by: NIMDSI, Korea Issued: 21-02-2024 ISO – Certificate: Notarization: yes Valid till: 18-10-2027</p> <p>EU Quality Management certificate valid till 09-10-2025</p>	<p>Brand Name: Voluson Signature 18 Generic Name: General-purpose ultrasound imaging system Applied as: Single Class: B</p> <p>Models/Code/sizes (as per FSC & application: 5932093 SC400</p> <p>Expected service life: 7 years</p>	Approved

<p>3.</p>	<p>M/s. Hoor Pharma (Pvt.) Ltd. Korangi Creek Industrial Park. Korangi, Karachi (ELI-00037)</p> <p>R&I Date: 23-08-2024</p> <p>CMS tracking ID: 2QZ-GEY-3GJ3</p> <p>Fee: 25,000/-</p>	<p>Manufacturing site: GE Ultrasound Korea, Ltd. Address: 9, Sunhwan-ro 214beon-gil, Jungwon-gu, Seongnam-si, Gyeonggi- do 13204, Republic of Korea</p> <p>LOA Notarization: Yes Issued: 14-03-2024</p> <p>• FSC Legalized: Apostille Issued by: NIMDSI, Korea Issued: 21-02-2024 ISO – Certificate: Notarization: yes Valid till: 18-10-2027</p> <p>EU Quality Management certificate valid till 09-10-2025</p>	<p>Brand Name: Voluson Signature 20</p> <p>Generic Name: General-purpose ultrasound imaging system</p> <p>Applied as: Single Class: B</p> <p>Models/Code/sizes (as per FSC & application): 5928194DDW_Voluson Signature 20</p> <p>Expected service life: 7 years</p>	<p>Approved</p>
<p>4.</p>	<p>M/s. Hoor Pharma (Pvt.) Ltd. Korangi Creek Industrial Park. Korangi, Karachi (ELI-00037)</p> <p>R&I Date: 13-07-2023</p> <p>CMS tracking ID: LHL-5ZX-127N</p> <p>Fee: 25,000/-</p>	<p>Manufacturing site: Terumo BCT,Inc Address: 10811 W.Collins Ave. Lakewood, CO 80215- 4440 United States</p> <p>LOA Notarization: No Issued: 14—02-2023</p> <p>• FSC Legalized: Legalized Issued by: FAMHP, Belgium Issued: 16-12-2022 ISO – Certificate: Notarization: yes Valid till: 21-04-2028</p> <p>EU Quality Management certificate valid till 01-03-2026</p>	<p>Brand Name: Reveos Automated Blood Processing System</p> <p>Generic Name: Blood Bank Centrifuge</p> <p>Applied as: System Class: B</p> <p>Models/Code/sizes (as per FSC & application): 23000</p> <p>Shelf life: N/A</p>	<p>Deferred for submission of valid notarized LOA and the FSC in which the name of the applied product should be mentioned.</p>

DEFERRED CASES AGENDA

S#	Importer Name	Manufacturer Details	Name of MD / Class / Codes / Shelf life / etc.	Brief Description of Product	Reason of Deferred	Remarks	Decision
DEFERRED CASES IMPORT							
1.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160</p> <p>Date of R&I 07-05-2024</p> <p>Fee: PKR 25,000/-</p> <p>Slip #613659120</p> <p>Dated: 29-01-2024</p>	<p>Erba Lachema s.r.o. located at Karásek 2219/1d 62100 Brno Czech Republic</p> <p>Documents submitted:</p> <p>ISO 13485 certificate validity: 01-12-2027</p> <p>LOA validity: 31-Dec-2025</p> <p>FSC country of origin validity: 21-07-2025</p>	<p>Brand name: MicroalbuPHAN</p> <p>Generic Name: Multiple urine analyte IVD</p> <p>Models/ Specification (as per Free sale certificate): URPH0020</p> <p>Class-B</p> <p>Shelf life: 21 Months</p> <p>Storage Conditions: 2 - 30°C</p>	<p>The diagnostic strip MicroalbuPHAN® is intended for semi-quantitative determination of albumin and creatinine in urine. The diagnostic strip MicroalbuPHAN® can be used for screening of the microalbuminuria; positive results should be confirmed by quantitative methods. The diagnostic strip MicroalbuPHAN® is intended for in vitro diagnostics for professional use only for visual determination.</p>	<p>Previous Remarks: The firm does not provide CE Certificate (FQA) or FSC of the reference country.</p> <p>79th MDB Decision Deferred for comments of the legal affairs division regarding the court cases.</p>	<p>Firm has submitted: 1. that there is no ongoing legal case concerning their ERBA related products. 2. Firm has submitted undertaking that MDB decision in 79th meeting dated 28.02.2025 is not appropriate, if later found that decision is correct, Martin Dow will be held responsible.</p> <p>The firm has not provided CE Certificate (FQA) or FSC of the reference country.</p>	<p>The Board deferred the case and decided as follows: 1.To seek comments from the Legal Affairs Division regarding the pending court cases. 2. The firm shall submit the following documents: i. CE Certificate or FSC of RRA. ii. A manufacturer's declaration confirming that Martin Dow Specialty is the sole distributor of their products in Pakistan.</p>

2.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160</p> <p>Date of R&I 07-05-2024</p> <p>Fee: PKR 25,000/- Slip #109321809142 Dated: 29-01-2024</p>	<p>Erba Lachema s.r.o. located at Karásek 2219/1d 62100 Brno Czech Republic</p> <p>Documents submitted:</p> <p>ISO 13485 certificate validity: 01-12-2027</p> <p>LOA validity: 31-Dec-2025</p> <p>FSC country of origin validity: 21-07-2025</p>	<p>Brand name: DekaPHAN Leuco</p> <p>Generic Name: DEKAPHAN LEUCO (50 strips) Multiple urine analyte IVD</p> <p>Models/ Specification (as per Free sale certificate): URPH0017</p> <p>Class-B</p> <p>Shelf life: 15 Months</p> <p>Storage Conditions: 2 - 30°C</p>	<p>DEKAPHAN LEUCO The diagnostic test strips PHAN@are intended for semiquantitative analysis of urine. The diagnostic test strips PHAN@ are intended for in vitro diagnostics for professional use only.</p>	<p>Previous Remarks: The firm does not provide CE Certificate (FQA) or FSC of the reference country.</p> <p>79th MDB Decision Deferred for comments of the legal affairs division regarding the court cases.</p>	<p>Firm has submitted: 1. that there is no ongoing legal case concerning their ERBA related products. 2. Firm has submitted undertaking that MDB decision in 79th meeting dated 28.02.2025 is not appropriate, if later found that decision is correct, Martin Dow will be held responsible.</p> <p>The firm has not provided CE Certificate (FQA) or FSC of the reference country.</p>	<p>The Board deferred the case and decided as follows: 1.To seek comments from the Legal Affairs Division regarding the pending court cases. 2. The firm shall submit the following documents: i. CE Certificate or FSC of RRA. ii. A manufacturer's declaration confirming that Martin Dow Specialty is the sole distributor of their products in Pakistan</p>
3.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160</p>	<p>Erba Lachema s.r.o. located at Karásek 2219/1d 62100 Brno Czech Republic</p> <p>Documents submitted:</p> <p>ISO 13485 certificate validity: 01-12-2027</p> <p>LOA validity: 31-Dec-2025</p>	<p>Brand name: DekaPHAN Leuco</p> <p>Generic Name: DEKAPHAN LEUCO (100 strips) Multiple urine analyte IVD</p> <p>Models/ Specification (as per Free sale certificate): URPH0018</p> <p>Class-B</p> <p>Shelf life: 15 Months</p>	<p>DEKAPHAN LEUCO The diagnostic test strips PHAN@are intended for semiquantitative analysis of urine. The diagnostic test strips PHAN@ are intended for in vitro diagnostics for professional use only.</p>	<p>Previous Remarks: The firm does not provide CE Certificate (FQA) or FSC of the reference country.</p> <p>79th MDB Decision Deferred for comments of the legal affairs division regarding the court cases.</p>	<p>Firm has submitted: 1. that there is no ongoing legal case concerning their ERBA related products. 2. Firm has submitted undertaking that MDB decision in 79th meeting dated 28.02.2025 is not appropriate, if later found that</p>	<p>The Board deferred the case and decided as follows: 1.To seek comments from the Legal Affairs Division regarding the pending court cases. 2. The firm shall submit the following documents: i. CE Certificate or FSC of RRA. ii. A manufacturer's declaration confirming that Martin Dow</p>

	Date of R&I 07-05-2024 Fee: PKR 25,000/- Slip #141605050874 Dated: 29-01-2024	FSC country of origin validity: 21-07-2025	Storage Conditions: 2 - 30°C			decision is correct, Martin Dow will be held responsible. The firm has not provided CE Certificate (FQA) or FSC of the reference country.	Specialty is the sole distributor of their products in Pakistan
4.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R&I 07-05-2024 Fee: PKR 25,000/- Slip #9904756543 Dated: 29-01-2024	Erba Lachema s.r.o. located at Karásek 2219/1d 62100 Brno Czech Republic Documents submitted: ISO 13485 certificate validity: 01-12-2027 LOA validity: 31-Dec-2025 FSC country of origin validity: 21-07-2025	Brand name: NefroPHAN Leuco Generic Name: Multiple urine analyte IVD Models/ Specification (as per Free sale certificate): URPH0016 Class-B Shelf life: 15 Months Storage Conditions: 2 - 30°C	NEPHROPHAN LEUCO The diagnostic test strips PHAN@are intended for semiquantitative analysis of urine. The diagnostic test strips PHAN@ are intended for in vitro diagnostics for professional use only	Previous Remarks: The firm does not provide CE Certificate (FQA) or FSC of the reference country. 79th MDB Decision Deferred for comments of the legal affairs division regarding the court cases.	Firm has submitted: 1. that there is no ongoing legal case concerning their ERBA related products. 2. Firm has submitted undertaking that MDB decision in 79 th meeting dated 28.02.2025 is not appropriate, if later found that decision is correct, Martin Dow will be held responsible. The firm has not provided CE Certificate (FQA) or FSC of the reference country.	The Board deferred the case and decided as follows: 1.To seek comments from the Legal Affairs Division regarding the pending court cases. 2. The firm shall submit the following documents: i. CE Certificate or FSC of RRA. ii. A manufacturer's declaration confirming that Martin Dow Specialty is the sole distributor of their products in Pakistan
5.	M/s Martin Dow Specialties	Erba Lachema s.r.o. located at Karásek	Brand name: NonaPHAN SG Generic Name:	NonaPHAN SG The diagnostic test strips	Previous Remarks: The firm does not provide CE	Firm has submitted: 1. that there is no ongoing	The Board deferred the case and decided as follows: 1.To seek

	<p>(Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160</p> <p>Date of R&I 07-05-2024</p> <p>Fee: PKR 25,000/- Slip #6673505618 Dated: 29-01-2024</p>	<p>2219/1d 62100 Brno Czech Republic Documents submitted:</p> <p>ISO 13485 certificate validity: 01-12-2027</p> <p>LOA validity: 31-Dec-2025</p> <p>FSC country of origin validity: 21-07-2025</p>	<p>Multiple urine analyte IVD</p> <p>Models/ Specification (as per Free sale certificate): URPH0015</p> <p>Class-B</p> <p>Shelf life: 27 Months</p> <p>Storage Conditions: 2 - 30°C</p>	<p>PHAN@are intended for semiquantitative analysis of urine. The diagnostic test strips PHAN@ are intended for in vitro diagnostics for professional use only.</p>	<p>Certificate (FQA) or FSC of the reference country.</p> <p>79th MDB Decision Deferred for comments of the legal affairs division regarding the court cases.</p>	<p>legal case concerning their ERBA related products. 2. Firm has submitted undertaking that MDB decision in 79th meeting dated 28.02.2025 is not appropriate, if later found that decision is correct, Martin Dow will be held responsible.</p> <p>The firm has not provided CE Certificate (FQA) or FSC of the reference country.</p>	<p>comments from the Legal Affairs Division regarding the pending court cases. 2. The firm shall submit the following documents: i. CE Certificate or FSC of RRA. ii. A manufacturer's declaration confirming that Martin Dow Specialty is the sole distributor of their products in Pakistan</p>
6.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160</p> <p>Date of R&I 07-05-2024</p>	<p>Erba Lachema s.r.o. located at Karásek 2219/1d 62100 Brno Czech Republic Documents submitted:</p> <p>ISO 13485 certificate validity: 01-12-2027</p> <p>LOA validity: 31-Dec-2025</p> <p>FSC country of origin validity: 21-07-2025</p>	<p>Brand name: HeptaPHAN (50 Strips)</p> <p>Generic Name: Multiple urine analyte IVD</p> <p>Models/ Specification (as per Free sale certificate): URPH0013</p> <p>Class-B</p> <p>Shelf life: 24 Months</p> <p>Storage Conditions: 2 - 30°C</p>	<p>HeptaPHAN The diagnostic test strips PHAN@are intended for semiquantitative analysis of urine. The diagnostic test strips PHAN@ are intended for in vitro diagnostics for professional use only.</p>	<p>Previous Remarks: The firm does not provide CE Certificate (FQA) or FSC of the reference country.</p> <p>79th MDB Decision Deferred for comments of the legal affairs division regarding the court cases.</p>	<p>Firm has submitted: 1. that there is no ongoing legal case concerning their ERBA related products. 2. Firm has submitted undertaking that MDB decision in 79th meeting dated 28.02.2025 is not appropriate, if later found that decision is correct, Martin Dow will be held</p>	<p>The Board deferred the case and decided as follows: 1.To seek comments from the Legal Affairs Division regarding the pending court cases. 2. The firm shall submit the following documents: i. CE Certificate or FSC of RRA. ii. A manufacturer's declaration confirming that Martin Dow Specialty is the sole distributor of their products in Pakistan</p>

	Fee: PKR 25,000/- Slip # 53779396194 Dated: 29-01-2024					responsible. The firm has not provided CE Certificate (FQA) or FSC of the reference country.	
7.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R&I 07-05-2024 Fee: PKR 25,000/- Slip # 8346757763 Dated: 29-01-2024	Erba Lachema s.r.o. located at Karásek 2219/1d 62100 Brno Czech Republic Documents submitted: ISO 13485 certificate validity: 01-12-2027 LOA validity: 31-Dec-2025 FSC country of origin validity: 21-07-2025	Brand name: HeptaPHAN (100 Strips) Generic Name: Multiple urine analyte IVD Models/ Specification (as per Free sale certificate): URPH0014 Class-B Shelf life: 24 Months Storage Conditions: 2 - 30°C	HeptaPHAN The diagnostic test strips PHAN@are intended for semiquantitative analysis of urine. The diagnostic test strips PHAN@ are intended for in vitro diagnostics for professional use only.	Previous Remarks: The firm does not provide CE Certificate (FQA) or FSC of the reference country. 79th MDB Decision Deferred for comments of the legal affairs division regarding the court cases.	Firm has submitted: 1. that there is no ongoing legal case concerning their ERBA related products. 2. Firm has submitted undertaking that MDB decision in 79 th meeting dated 28.02.2025 is not appropriate, if later found that decision is correct, Martin Dow will be held responsible. The firm has not provided CE Certificate (FQA) or FSC of the reference country.	The Board deferred the case and decided as follows: 1.To seek comments from the Legal Affairs Division regarding the pending court cases. 2. The firm shall submit the following documents: i. CE Certificate or FSC of RRA. ii. A manufacturer's declaration confirming that Martin Dow Specialty is the sole distributor of their products in Pakistan
8.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade	Erba Lachema s.r.o. located at Karásek 2219/1d 62100 Brno Czech Republic	Brand name: HexaPHAN Generic Name: HexaPHAN (50 Strips) Multiple urine analyte IVD	HexaPHAN The diagnostic test strips PHAN@are intended for semiquantitative analysis	Previous Remarks: The firm does not provide CE Certificate (FQA) or FSC of the reference	Firm has submitted: 1. that there is no ongoing legal case concerning their ERBA related	The Board deferred the case and decided as follows: 1.To seek comments from the Legal Affairs Division regarding the pending court

	<p>Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160</p> <p>Date of R&I 07-05-2024</p> <p>Fee: PKR 25,000/-</p> <p>Slip # 4542120796</p> <p>Dated: 29-01-2024</p>	<p>Documents submitted:</p> <p>ISO 13485 certificate validity: 01-12-2027</p> <p>LOA validity: 31-Dec-2025</p> <p>FSC country of origin validity: 21-07-2025</p>	<p>Models/ Specification (as per Free sale certificate): URPH0011</p> <p>Class-B</p> <p>Shelf life: 27 Months</p> <p>Storage Conditions: 2 - 30°C</p>	<p>of urine. The diagnostic test strips PHAN® are intended for in vitro diagnostics for professional use only</p>	<p>country.</p> <p>79th MDB Decision Deferred for comments of the legal affairs division regarding the court cases.</p>	<p>products.</p> <p>2. Firm has submitted undertaking that MDB decision in 79th meeting dated 28.02.2025 is not appropriate, if later found that decision is correct, Martin Dow will be held responsible.</p> <p>The firm has not provided CE Certificate (FQA) or FSC of the reference country.</p>	<p>cases.</p> <p>2. The firm shall submit the following documents:</p> <p>i. CE Certificate or FSC of RRA.</p> <p>ii. A manufacturer's declaration confirming that Martin Dow Specialty is the sole distributor of their products in Pakistan</p>
9.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160</p> <p>Date of R&I 07-05-2024</p> <p>Fee: PKR 25,000/-</p> <p>Slip # 54903276966</p>	<p>Erba Lachema s.r.o. located at Karásek 2219/1d 62100 Brno Czech Republic</p> <p>Documents submitted:</p> <p>ISO 13485 certificate validity: 01-12-2027</p> <p>LOA validity: 31-Dec-2025</p> <p>FSC country of origin validity: 21-07-2025</p>	<p>Brand name: HexaPHAN</p> <p>Generic Name: HexaPHAN (100 Strips) Multiple urine analyte IVD</p> <p>Models/ Specification (as per Free sale certificate): URPH0012</p> <p>Class-B</p> <p>Shelf life: 27 Months</p> <p>Storage Conditions: 2 - 30°C</p>	<p>HexaPHAN The diagnostic test strips PHAN® are intended for semiquantitative analysis of urine. The diagnostic test strips PHAN® are intended for in vitro diagnostics for professional use only</p>	<p>Previous Remarks: The firm does not provide CE Certificate (FQA) or FSC of the reference country.</p> <p>79th MDB Decision Deferred for comments of the legal affairs division regarding the court cases.</p>	<p>Firm has submitted:</p> <p>1. that there is no ongoing legal case concerning their ERBA related products.</p> <p>2. Firm has submitted undertaking that MDB decision in 79th meeting dated 28.02.2025 is not appropriate, if later found that decision is correct, Martin Dow will be held responsible.</p> <p>The firm has not provided</p>	<p>The Board deferred the case and decided as follows:</p> <p>1. To seek comments from the Legal Affairs Division regarding the pending court cases.</p> <p>2. The firm shall submit the following documents:</p> <p>i. CE Certificate or FSC of RRA.</p> <p>ii. A manufacturer's declaration confirming that Martin Dow Specialty is the sole distributor of their products in Pakistan</p>

	Dated: 29-01-2024					CE Certificate (FQA) or FSC of the reference country.	
10.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R&I 07-05-2024 Fee: PKR 25,000/- Slip # 0649190354 Dated: 29-01-2024	Erba Lachema s.r.o. located at Karásek 2219/1d 62100 Brno Czech Republic Documents submitted: ISO 13485 certificate validity: 01-12-2027 LOA validity: 31-Dec-2025 FSC country of origin validity: 21-07-2025	Brand name: PentaPHAN Generic Name: Multiple urine analyte IVD Models/ Specification (as per Free sale certificate): URPH0012 Class-B Shelf life: 27 Months Storage Conditions: 2 - 30°C	PentaPHAN The diagnostic test strips PHAN@are intended for semiquantitative analysis of urine. The diagnostic test strips PHAN@ are intended for in vitro diagnostics for professional use only	Previous Remarks: The firm does not provide CE Certificate (FQA) or FSC of the reference country. 79th MDB Decision Deferred for comments of the legal affairs division regarding the court cases.	Firm has submitted: 1. that there is no ongoing legal case concerning their ERBA related products. 2. Firm has submitted undertaking that MDB decision in 79 th meeting dated 28.02.2025 is not appropriate, if later found that decision is correct, Martin Dow will be held responsible. The firm has not provided CE Certificate (FQA) or FSC of the reference country.	The Board deferred the case and decided as follows: 1.To seek comments from the Legal Affairs Division regarding the pending court cases. 2. The firm shall submit the following documents: i. CE Certificate or FSC of RRA. ii. A manufacturer's declaration confirming that Martin Dow Specialty is the sole distributor of their products in Pakistan
11.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6,	Erba Lachema s.r.o. located at Karásek 2219/1d 62100 Brno Czech Republic Documents submitted: ISO 13485	Brand name: TetraPHAN Dia Generic Name: Multiple urine analyte IVD Models/ Specification (as per Free sale certificate): URPH0009 Class-B	TetraPHAN Dia The diagnostic test strips PHAN@are intended for semiquantitative analysis of urine. The diagnostic test strips PHAN@ are	Previous Remarks: The firm does not provide CE Certificate (FQA) or FSC of the reference country. 79th MDB Decision	Firm has submitted: 1. that there is no ongoing legal case concerning their ERBA related products. 2. Firm has submitted undertaking	The Board deferred the case and decided as follows: 1.To seek comments from the Legal Affairs Division regarding the pending court cases. 2. The firm shall submit the following

	<p>PECHS, Razi Road, Shahrah-e- Faisal, Karachi ELI-00160</p> <p>Date of R&I 07-05-2024</p> <p>Fee: PKR 25,000/- Slip # 706202457 4 Dated: 29- 01-2024</p>	<p>certificate validity: 01-12-2027</p> <p>LOA validity: 31-Dec-2025</p> <p>FSC country of origin validity: 21-07-2025</p>	<p>LOA validity: 31-Dec-2025 Shelf life: 30 Months</p> <p>Storage Conditions: 2 - 30°C</p> <p>FSC country of origin validity: 21-07-2025</p> <p>FSC RRA validity: N/A</p>	<p>intended for in vitro diagnostics for professional use only</p>	<p>Deferred for comments of the legal affairs division regarding the court cases.</p>	<p>that MDB decision in 79th meeting dated 28.02.2025 is not appropriate, if later found that decision is correct, Martin Dow will be held responsible.</p> <p>The firm has not provided CE Certificate (FQA) or FSC of the reference country.</p>	<p>documents: i. CE Certificate or FSC of RRA. ii. A manufacturer's declaration confirming that Martin Dow Specialty is the sole distributor of their products in Pakistan</p>
12.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e- Faisal, Karachi ELI-00160</p> <p>Date of R&I 07-05-2024</p> <p>Fee: PKR 25,000/- Slip # 498355295 Dated: 29- 01-2024</p>	<p>Erba Lachema s.r.o. located at Karásek 2219/1d 62100 Brno Czech Republic</p> <p>Documents submitted:</p> <p>ISO 13485 certificate validity: 01-12-2027</p> <p>LOA validity: 31-Dec-2025</p> <p>FSC country of origin validity: 21-07-2025</p>	<p>Brand name: TriPHAN</p> <p>Generic Name: TriPHAN (50 Strips) Multiple urine analyte IVD</p> <p>Models/ Specification (as per Free sale certificate): URPH0007</p> <p>Class-B</p> <p>LOA validity: 31-Dec-2025</p> <p>Shelf life: 30 Months</p> <p>Storage Conditions: 2 - 30°C</p> <p>FSC country of origin validity: 21-07-2025</p> <p>FSC RRA validity: N/A</p>	<p>TriPHAN The diagnostic test strips PHAN@are intended for semiquantitative analysis of urine. The diagnostic test strips PHAN@ are intended for in vitro diagnostics for professional use only</p>	<p>Previous Remarks: The firm does not provide CE Certificate (FQA) or FSC of the reference country.</p> <p>79th MDB Decision Deferred for comments of the legal affairs division regarding the court cases.</p>	<p>Firm has submitted: 1. that there is no ongoing legal case concerning their ERBA related products. 2. Firm has submitted undertaking that MDB decision in 79th meeting dated 28.02.2025 is not appropriate, if later found that decision is correct, Martin Dow will be held responsible.</p> <p>The firm has not provided CE Certificate (FQA) or FSC of the</p>	<p>The Board deferred the case and decided as follows: 1.To seek comments from the Legal Affairs Division regarding the pending court cases. 2. The firm shall submit the following documents: i. CE Certificate or FSC of RRA. ii. A manufacturer's declaration confirming that Martin Dow Specialty is the sole distributor of their products in Pakistan</p>

						reference country.	
13.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160</p> <p>Date of R&I 07-05-2024</p> <p>Fee: PKR 25,000/-</p> <p>Slip # 509485305936</p> <p>Dated: 29-01-2024</p>	<p>Erba Lachema s.r.o. located at Karásek 2219/1d 62100 Brno Czech Republic</p> <p>Documents submitted:</p> <p>ISO 13485 certificate validity: 01-12-2027</p> <p>LOA validity: 31-Dec-2025</p> <p>FSC country of origin validity: 21-07-2025</p>	<p>Brand name: TriPHAN</p> <p>Generic Name: TriPHAN (100 Strips) Multiple urine analyte IVD</p> <p>Models/ Specification (as per Free sale certificate): URPH0008</p> <p>Class-B</p> <p>LOA validity: 31-Dec-2025</p> <p>Shelf life: 30 Months</p> <p>Storage Conditions: 2 - 30°C</p> <p>FSC country of origin validity: 21-07-2025</p> <p>FSC RRA validity: N/A</p>	<p>TriPHAN The diagnostic test strips PHAN@are intended for semiquantitative analysis of urine. The diagnostic test strips PHAN@ are intended for in vitro diagnostics for professional use only</p>	<p>Previous Remarks: The firm does not provide CE Certificate (FQA) or FSC of the reference country.</p> <p>79th MDB Decision Deferred for comments of the legal affairs division regarding the court cases.</p>	<p>Firm has submitted: 1. that there is no ongoing legal case concerning their ERBA related products. 2. Firm has submitted undertaking that MDB decision in 79th meeting dated 28.02.2025 is not appropriate, if later found that decision is correct, Martin Dow will be held responsible.</p> <p>The firm has not provided CE Certificate (FQA) or FSC of the reference country.</p>	<p>The Board deferred the case and decided as follows: 1.To seek comments from the Legal Affairs Division regarding the pending court cases. 2. The firm shall submit the following documents: i. CE Certificate or FSC of RRA. ii. A manufacturer's declaration confirming that Martin Dow Specialty is the sole distributor of their products in Pakistan</p>
14.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal,</p>	<p>Erba Lachema s.r.o. located at Karásek 2219/1d 62100 Brno Czech Republic</p> <p>Documents submitted:</p> <p>ISO 13485 certificate validity: 01-12-2027</p>	<p>Brand name: IktoPHAN</p> <p>Generic Name: Multiple urine analyte IVD</p> <p>Models/ Specification (as per Free sale certificate): URPH0006</p> <p>Class-B</p> <p>LOA validity: 31-Dec-2025</p>	<p>IktoPHAN The diagnostic test strips PHAN@are intended for semiquantitative analysis of urine. The diagnostic test strips PHAN@ are intended for in vitro diagnostics for</p>	<p>Previous Remarks: The firm does not provide CE Certificate (FQA) or FSC of the reference country.</p> <p>79th MDB Decision Deferred for comments of the legal affairs division</p>	<p>. Firm has submitted: 1. that there is no ongoing legal case concerning their ERBA related products. 2. Firm has submitted undertaking that MDB decision in 79th meeting dated 28.02.2025 is</p>	<p>The Board deferred the case and decided as follows: 1.To seek comments from the Legal Affairs Division regarding the pending court cases. 2. The firm shall submit the following documents: i. CE Certificate or FSC of RRA. ii. A manufacturer's</p>

	<p>Karachi ELI-00160</p> <p>Date of R&I 07-05-2024</p> <p>Fee: PKR 25,000/- Slip # 6391862520 Dated: 29-01-2024</p>	<p>LOA validity: 31-Dec-2025</p> <p>FSC country of origin validity: 21-07-2025</p>	<p>Shelf life: 24 Months</p> <p>Storage Conditions: 2 - 30°C</p> <p>FSC country of origin validity: 21-07-2025</p> <p>FSC RRA validity: N/A</p>	<p>professional use only</p>	<p>regarding the court cases.</p>	<p>not appropriate, if later found that decision is correct, Martin Dow will be held responsible.</p> <p>The firm has not provided CE Certificate (FQA) or FSC of the reference country.</p>	<p>declaration confirming that Martin Dow Specialty is the sole distributor of their products in Pakistan</p>
15.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160</p> <p>Date of R&I 07-05-2024</p> <p>Fee: PKR 25,000/- Slip # 75238921714 Dated: 29-01-2024</p>	<p>Erba Lachema s.r.o. located at Karásek 2219/1d 62100 Brno Czech Republic</p> <p>Documents submitted:</p> <p>ISO 13485 certificate validity: 01-12-2027</p> <p>LOA validity: 31-Dec-2025</p> <p>FSC country of origin validity: 21-07-2025</p>	<p>Brand name: DiaPHAN</p> <p>Generic Name: Multiple urine analyte IVD</p> <p>Models/ Specification (as per Free sale certificate): URP0005</p> <p>Class-B</p> <p>LOA validity: 31-Dec-2025</p> <p>Shelf life: 33 Months</p> <p>Storage Conditions: 2 - 30°C</p> <p>FSC country of origin validity: 21-07-2025</p> <p>FSC RRA validity: N/A</p>	<p>DiaPHAN</p> <p>The diagnostic test strips PHAN@are intended for semiquantitative analysis of urine. The diagnostic test strips PHAN@ are intended for in vitro diagnostics for professional use only</p>	<p>Previous Remarks: The firm does not provide CE Certificate (FQA) or FSC of the reference country.</p> <p>79th MDB Decision Deferred for comments of the legal affairs division regarding the court cases.</p>	<p>Firm has submitted: 1. that there is no ongoing legal case concerning their ERBA related products. 2. Firm has submitted undertaking that MDB decision in 79th meeting dated 28.02.2025 is not appropriate, if later found that decision is correct, Martin Dow will be held responsible.</p> <p>The firm has not provided CE Certificate (FQA) or FSC of the reference country.</p>	<p>The Board deferred the case and decided as follows: 1.To seek comments from the Legal Affairs Division regarding the pending court cases. 2. The firm shall submit the following documents: i. CE Certificate or FSC of RRA. ii. A manufacturer's declaration confirming that Martin Dow Specialty is the sole distributor of their products in Pakistan</p>
16.	<p>M/s</p>	<p>Erba</p>	<p>Brand name: KetoPHAN</p>	<p>KetoPHAN</p>	<p>Previous</p>	<p>Firm has</p>	<p>The Board deferred</p>

	<p>Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160</p> <p>Date of R&I 07-05-2024</p> <p>Fee: PKR 25,000/- Slip #78329982 4794 Dated: 29-01-2024</p>	<p>Lachema s.r.o. located at Karásek 2219/1d 62100 Brno Czech Republic</p> <p>Documents submitted:</p> <p>ISO 13485 certificate validity: 01-12-2027</p> <p>LOA validity: 31-Dec-2025</p> <p>FSC country of origin validity: 21-07-2025</p>	<p>Generic Name: Multiple urine analyte IVD</p> <p>Models/ Specification (as per Free sale certificate): URPH0004 Class-B</p> <p>LOA validity: 31-Dec-2025</p> <p>Shelf life: 36 Months</p> <p>Storage Conditions: 2 - 30°C</p> <p>FSC country of origin validity: 21-07-2025</p> <p>FSC RRA validity: N/A</p>	<p>The diagnostic test strips PHAN@are intended for semiquantitative analysis of urine. The diagnostic test strips PHAN@ are intended for in vitro diagnostics for professional use only</p>	<p>Remarks: The firm does not provide CE Certificate (FQA) or FSC of the reference country.</p> <p>79th MDB Decision Deferred for comments of the legal affairs division regarding the court cases.</p>	<p>submitted: 1. that there is no ongoing legal case concerning their ERBA related products. 2. Firm has submitted undertaking that MDB decision in 79th meeting dated 28.02.2025 is not appropriate, if later found that decision is correct, Martin Dow will be held responsible.</p> <p>The firm has not provided CE Certificate (FQA) or FSC of the reference country.</p>	<p>the case and decided as follows: 1.To seek comments from the Legal Affairs Division regarding the pending court cases. 2. The firm shall submit the following documents: i. CE Certificate or FSC of RRA. ii. A manufacturer's declaration confirming that Martin Dow Specialty is the sole distributor of their products in Pakistan</p>
17.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160</p> <p>Date of R&I</p>	<p>Erba Lachema s.r.o. located at Karásek 2219/1d 62100 Brno Czech Republic</p> <p>Documents submitted:</p> <p>ISO 13485 certificate validity: 01-12-2027</p> <p>LOA validity: 31-Dec-2025</p>	<p>Brand name: HemoPHAN</p> <p>Generic Name: Multiple urine analyte IVD</p> <p>Models/ Specification (as per Free sale certificate): URPH0003 Class-B</p> <p>LOA validity: 31-Dec-2025</p> <p>Shelf life: 24 Months</p> <p>Storage</p>	<p>HemoPHAN The diagnostic test strips PHAN@are intended for semiquantitative analysis of urine. The diagnostic test strips PHAN@ are intended for in vitro diagnostics for professional use only</p>	<p>Previous Remarks: The firm does not provide CE Certificate (FQA) or FSC of the reference country.</p> <p>79th MDB Decision Deferred for comments of the legal affairs division regarding the court cases.</p>	<p>Firm has submitted: 1. that there is no ongoing legal case concerning their ERBA related products. 2. Firm has submitted undertaking that MDB decision in 79th meeting dated 28.02.2025 is not appropriate, if later found that decision is</p>	<p>The Board deferred the case and decided as follows: 1.To seek comments from the Legal Affairs Division regarding the pending court cases. 2. The firm shall submit the following documents: i. CE Certificate or FSC of RRA. ii. A manufacturer's declaration confirming that Martin Dow Specialty is the sole</p>

	07-05-2024 Fee: PKR 25,000/- Slip #642081440 Dated: 29-01-2024	FSC country of origin validity: 21-07-2025	Conditions: 2 - 30°C FSC country of origin validity: 21-07-2025 FSC RRA validity: N/A			correct, Martin Dow will be held responsible. The firm has not provided CE Certificate (FQA) or FSC of the reference country.	distributor of their products in Pakistan
18.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R&I 07-05-2024 Fee: PKR 25,000/- Slip #396021192864 Dated: 29-01-2024	Erba Lachema s.r.o. located at Karásek 2219/1d 62100 Brno Czech Republic Documents submitted: ISO 13485 certificate validity: 01-12-2027 LOA validity: 31-Dec-2025 FSC country of origin validity: 21-07-2025	Brand name: GlukoPHAN Generic Name: Multiple urine analyte IVD Models/ Specification (as per Free sale certificate): URPH0002 Class-B LOA validity: 31-Dec-2025 Shelf life: 33 Months Storage Conditions: 2 - 30°C FSC country of origin validity: 21-07-2025 FSC RRA validity: N/A	GlukoPHAN The diagnostic test strips PHAN@are intended for semiquantitative analysis of urine. The diagnostic test strips PHAN@ are intended for in vitro diagnostics for professional use only	Previous Remarks: The firm does not provide CE Certificate (FQA) or FSC of the reference country. 79th MDB Decision Deferred for comments of the legal affairs division regarding the court cases.	Firm has submitted: 1. that there is no ongoing legal case concerning their ERBA related products. 2. Firm has submitted undertaking that MDB decision in 79 th meeting dated 28.02.2025 is not appropriate, if later found that decision is correct, Martin Dow will be held responsible. The firm has not provided CE Certificate (FQA) or FSC of the reference country.	The Board deferred the case and decided as follows: 1.To seek comments from the Legal Affairs Division regarding the pending court cases. 2. The firm shall submit the following documents: i. CE Certificate or FSC of RRA. ii. A manufacturer's declaration confirming that Martin Dow Specialty is the sole distributor of their products in Pakistan
19.	M/s Martin Dow Specialties (Pvt)	Erba Lachema s.r.o. located at Karásek 2219/1d	Brand name: AlbuPHAN Generic Name: Multiple urine analyte IVD	AlbuPHAN The diagnostic test strips PHAN@are	Previous Remarks: The firm does not provide CE Certificate	Firm has submitted: 1. that there is no ongoing legal case	The Board deferred the case and decided as follows: 1.To seek comments from the

	<p>Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e- Faisal, Karachi ELI-00160</p> <p>Date of R&I 07-05-2024</p> <p>Fee: PKR 25,000/- Slip #48025335 515 Dated: 29- 01-2024</p>	<p>62100 Brno Czech Republic Documents submitted:</p> <p>ISO 13485 certificate validity: 01- 12-2027</p> <p>LOA validity: 31- Dec-2025</p> <p>FSC country of origin validity: 21- 07-2025</p>	<p>Models/ Specification (as per Free sale certificate): URPH0001</p> <p>Class-B</p> <p>LOA validity: 31-Dec-2025</p> <p>Shelf life: 33 Months</p> <p>Storage Conditions: 2 - 30°C</p> <p>FSC country of origin validity: 21-07-2025</p> <p>FSC RRA validity: N/A</p>	<p>intended for semiquantita tive analysis of urine. The diagnostic test strips PHAN® are intended for in vitro diagnostics for professional use only</p>	<p>(FQA) or FSC of the reference country.</p> <p>79th MDB Decision Deferred for comments of the legal affairs division regarding the court cases.</p>	<p>concerning their ERBA related products. 2. Firm has submitted undertaking that MDB decision in 79th meeting dated 28.02.2025 is not appropriate, if later found that decision is correct, Martin Dow will be held responsible.</p> <p>The firm has not provided CE Certificate (FQA) or FSC of the reference country.</p>	<p>Legal Affairs Division regarding the pending court cases. 2. The firm shall submit the following documents: i. CE Certificate or FSC of RRA. ii. A manufacturer's declaration confirming that Martin Dow Specialty is the sole distributor of their products in Pakistan</p>
20.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e- Faisal, Karachi ELI-00160</p> <p>Date of R&I 07-05-2024</p> <p>Fee: PKR 25,000/-</p>	<p>Erba Lachema s.r.o. located at Karásek 2219/1d 62100 Brno Czech Republic Documents submitted:</p> <p>ISO 13485 certificate validity: 01- 12-2027</p> <p>LOA validity: 31- Dec-2025</p> <p>FSC country of origin validity: 21- 07-2025</p>	<p>Brand name: MicroalbuPHAN LAURA</p> <p>Generic Name: Multiple urine analyte IVD</p> <p>Models/ Specification (as per Free sale certificate): URPH0029</p> <p>Class-B</p> <p>LOA validity: 31-Dec-2025</p> <p>Shelf life: 15 Months</p> <p>Storage Conditions: 5 - 25°C</p>	<p>MicroalbuP HAN LAURA The diagnostic test strips are intended for semiquantita tive analysis of urine. The diagnostic test strips PHAN® LAURAare intended for in vitro diagnostics for professional use only</p>	<p>Previous Remarks: The firm does not provide CE Certificate (FQA) or FSC of the reference country.</p> <p>79th MDB Decision Deferred for comments of the legal affairs division regarding the court cases.</p>	<p>Firm has submitted: 1. that there is no ongoing legal case concerning their ERBA related products. 2. Firm has submitted undertaking that MDB decision in 79th meeting dated 28.02.2025 is not appropriate, if later found that decision is correct, Martin Dow will be held responsible.</p>	<p>The Board deferred the case and decided as follows: 1.To seek comments from the Legal Affairs Division regarding the pending court cases. 2. The firm shall submit the following documents: i. CE Certificate or FSC of RRA. ii. A manufacturer's declaration confirming that Martin Dow Specialty is the sole distributor of their products in Pakistan</p>

	<p>Slip #34830196 616 Dated: 29-01-2024</p>		<p>FSC country of origin validity: 21-07-2025</p> <p>FSC RRA validity: N/A</p>			<p>The firm has not provided CE Certificate (FQA) or FSC of the reference country.</p>	
21.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160</p> <p>Date of R&I 07-05-2024</p> <p>Fee: PKR 25,000/-</p> <p>Slip #97774278 Dated: 29-01-2024</p>	<p>Erba Lachema s.r.o. located at Karásek 2219/1d 62100 Brno Czech Republic</p> <p>Documents submitted:</p> <p>ISO 13485 certificate validity: 01-12-2027</p> <p>LOA validity: 31-Dec-2025</p> <p>FSC country of origin validity: 21-07-2025</p>	<p>Brand name: DekaPHAN LAURA</p> <p>Generic Name: Multiple urine analyte IVD</p> <p>Models/ Specification (as per Free sale certificate): URPH0028 Class-B</p> <p>LOA validity: 31-Dec-2025</p> <p>Shelf life: 18 Months</p> <p>Storage Conditions: 2 - 30°C</p> <p>FSC country of origin validity: 21-07-2025</p> <p>FSC RRA validity: N/A</p>	<p>DekaPHAN LAURA The diagnostic test strips are intended for semiquantitative analysis of urine. The diagnostic test strips PHAN@ LAURA are intended for in vitro diagnostics for professional use only</p>	<p>Previous Remarks: The firm does not provide CE Certificate (FQA) or FSC of the reference country.</p> <p>79th MDB Decision Deferred for comments of the legal affairs division regarding the court cases.</p>	<p>Firm has submitted:</p> <p>1. that there is no ongoing legal case concerning their ERBA related products.</p> <p>2. Firm has submitted undertaking that MDB decision in 79th meeting dated 28.02.2025 is not appropriate, if later found that decision is correct, Martin Dow will be held responsible.</p> <p>The firm has not provided CE Certificate (FQA) or FSC of the reference country.</p>	<p>The Board deferred the case and decided as follows:</p> <p>1.To seek comments from the Legal Affairs Division regarding the pending court cases.</p> <p>2. The firm shall submit the following documents:</p> <p>i. CE Certificate or FSC of RRA.</p> <p>ii. A manufacturer's declaration confirming that Martin Dow Specialty is the sole distributor of their products in Pakistan</p>
22.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit</p>	<p>Erba Lachema s.r.o. located at Karásek 2219/1d 62100 Brno Czech Republic</p> <p>Documents</p>	<p>Brand name: HeptaPHAN LAURA</p> <p>Generic Name: Multiple urine analyte IVD</p> <p>Models/ Specification</p>	<p>HeptaPHAN LAURA The diagnostic test strips are intended for semiquantitative analysis of urine. The diagnostic</p>	<p>Previous Remarks: The firm does not provide CE Certificate (FQA) or FSC of the reference country.</p>	<p>Firm has submitted:</p> <p>1. that there is no ongoing legal case concerning their ERBA related products.</p> <p>The firm has not provided CE Certificate (FQA) or FSC of the reference country.</p>	<p>The Board deferred the case and decided as follows:</p> <p>1.To seek comments from the Legal Affairs Division regarding the pending court cases.</p>

	<p>Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160</p> <p>Date of R&I 07-05-2024</p> <p>Fee: PKR 25,000/-</p> <p>Slip #34956294 9212</p> <p>Dated: 29-01-2024</p>	<p>submitted:</p> <p>ISO 13485 certificate validity: 01-12-2027</p> <p>LOA validity: 31-Dec-2025</p> <p>FSC country of origin validity: 21-07-2025</p>	<p><i>(as per Free sale certificate):</i> URPH0027</p> <p>Class-B</p> <p>LOA validity: 31-Dec-2025</p> <p>Shelf life: 24 Months</p> <p>Storage Conditions: 2 - 30°C</p> <p>FSC country of origin validity: 21-07-2025</p> <p>FSC RRA validity: N/A</p>	<p>test strips PHAN@ LAURA are intended for in vitro diagnostics for professional use only</p>	<p>79th MDB Decision</p> <p>Deferred for comments of the legal affairs division regarding the court cases.</p>	<p>2. Firm has submitted undertaking that MDB decision in 79th meeting dated 28.02.2025 is not appropriate, if later found that decision is correct, Martin Dow will be held responsible.</p> <p>The firm has not provided CE Certificate (FQA) or FSC of the reference country.</p>	<p>2. The firm shall submit the following documents:</p> <p>i. CE Certificate or FSC of RRA.</p> <p>ii. A manufacturer's declaration confirming that Martin Dow Specialty is the sole distributor of their products in Pakistan</p>
23.	<p>M/s Martin Dow Specialties (Pvt) Limited</p> <p>7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160</p> <p>Date of R&I 07-05-2024</p> <p>Fee: PKR 25,000/-</p> <p>Slip #61778039 067</p> <p>Dated: 29-</p>	<p>Erba Lachema s.r.o. located at Karásek 2219/1d 62100 Brno Czech Republic</p> <p>Documents submitted:</p> <p>ISO 13485 certificate validity: 01-12-2027</p> <p>LOA validity: 31-Dec-2025</p> <p>FSC country of origin validity: 21-07-2025</p>	<p>Brand name: PentaPHAN LAURA</p> <p>Generic Name: Multiple urine analyte IVD</p> <p>Models/ Specification <i>(as per Free sale certificate):</i> URPH0026</p> <p>Class-B</p> <p>LOA validity: 31-Dec-2025</p> <p>Shelf life: 21 Months</p> <p>Storage Conditions: 2 - 30°C</p> <p>FSC country of origin validity: 21-07-2025</p>	<p>PentaPHAN LAURA The diagnostic test strips are intended for semiquantitative analysis of urine. The diagnostic test strips PHAN@ LAURA are intended for in vitro diagnostics for professional use only</p>	<p>Previous Remarks:</p> <p>The firm does not provide CE Certificate (FQA) or FSC of the reference country.</p> <p>79th MDB Decision</p> <p>Deferred for comments of the legal affairs division regarding the court cases.</p>	<p>Firm has submitted:</p> <p>1. that there is no ongoing legal case concerning their ERBA related products.</p> <p>2. Firm has submitted undertaking that MDB decision in 79th meeting dated 28.02.2025 is not appropriate, if later found that decision is correct, Martin Dow will be held responsible.</p> <p>The firm has not provided CE</p>	<p>The Board deferred the case and decided as follows:</p> <p>1. To seek comments from the Legal Affairs Division regarding the pending court cases.</p> <p>2. The firm shall submit the following documents:</p> <p>i. CE Certificate or FSC of RRA.</p> <p>ii. A manufacturer's declaration confirming that Martin Dow Specialty is the sole distributor of their products in Pakistan</p>

			FSC RRA validity: N/A			Certificate (FQA) or FSC of the reference country.	
24.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R&I 07-05-2024 Fee: PKR 25,000/- Slip # 78077116 Dated: 29-01-2024	Erba Lachema s.r.o. located at Karásek 2219/1d 62100 Brno Czech Republic Documents submitted: ISO 13485 certificate validity: 01-12-2027 LOA validity: 31-Dec-2025 FSC country of origin validity: 21-07-2025	Brand name: TetraPHAN SG LAURA Generic Name: Multiple urine analyte IVD Models/ Specification (as per Free sale certificate): URPH0025 Class-B LOA validity: 31-Dec-2025 Shelf life: 21 Months Storage Conditions: 2 - 30°C FSC country of origin validity: 21-07-2025 FSC RRA validity: N/A	TetraPHAN SG LAURA The diagnostic test strips are intended for semiquantitative analysis of urine. The diagnostic test strips PHAN@ LAURA are intended for in vitro diagnostics for professional use only	Previous Remarks: The firm does not provide CE Certificate (FQA) or FSC of the reference country. 79th MDB Decision Deferred for comments of the legal affairs division regarding the court cases.	Firm has submitted: 1. that there is no ongoing legal case concerning their ERBA related products. 2. Firm has submitted that MDB decision in 79 th meeting dated 28.02.2025 is not appropriate, if later found that decision is correct, Martin Dow will be held responsible. The firm has not provided CE Certificate (FQA) or FSC of the reference country.	The Board deferred the case and decided as follows: 1.To seek comments from the Legal Affairs Division regarding the pending court cases. 2. The firm shall submit the following documents: i. CE Certificate or FSC of RRA. ii. A manufacturer's declaration confirming that Martin Dow Specialty is the sole distributor of their products in Pakistan
25.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS,	Erba Lachema s.r.o. located at Karásek 2219/1d 62100 Brno Czech Republic Documents submitted: ISO 13485 certificate	Brand name: Urinorm XL Generic Name: Multiple urine analyte IVD Models/ Specification (as per Free sale certificate): REG00060 Class-B	URINORM XL control urines are liquid synthetic material with concentrations in the normal (URINORM XL N) and pathological (URINORM	Previous Remarks: The firm does not provide CE Certificate (FQA) or FSC of the reference country. 79th MDB Decision Deferred for	Firm has submitted: 1. that there is no ongoing legal case concerning their ERBA related products. 2. Firm has submitted that MDB	The Board deferred the case and decided as follows: 1.To seek comments from the Legal Affairs Division regarding the pending court cases. 2. The firm shall submit the following documents:

	<p>Razi Road, Shahrah-e-Faisal, Karachi ELI-00160</p> <p>Date of R&I 07-05-2024</p> <p>Fee: PKR 25,000/- Slip # 404416253372 Dated: 29-01-2024</p>	<p>validity: 01-12-2027</p> <p>LOA validity: 31-Dec-2025</p> <p>FSC country of origin validity: 21-07-2025</p>	<p>LOA validity: 31-Dec-2025</p> <p>Shelf life: 24 Months</p> <p>Storage Conditions: 2 - 30°C</p> <p>FSC country of origin validity: 21-07-2025</p> <p>FSC RRA validity: N/A</p>	<p>XL P) ranges. URINORM XL control urines are designed to verify the precision and accuracy of PHAN AUTO diagnostic strips and automatic urine analyzer LAURA XL intended for in vitro diagnostics. This product is intended also for evaluation of sediment. For professional use only.</p>	<p>comments of the legal affairs division regarding the court cases.</p>	<p>decision in 79th meeting dated 28.02.2025 is not appropriate, if later found that decision is correct, Martin Dow will be held responsible.</p> <p>The firm has not provided CE Certificate (FQA) or FSC of the reference country.</p>	<p>i. CE Certificate or FSC of RRA. ii. A manufacturer's declaration confirming that Martin Dow Specialty is the sole distributor of their products in Pakistan</p>
26.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160</p> <p>Date of R&I 07-05-2024</p> <p>Fee: PKR 25,000/- Slip #</p>	<p>Erba Lachema s.r.o. located at Karásek 2219/1d 62100 Brno Czech Republic</p> <p>Documents submitted:</p> <p>ISO 13485 certificate validity: 01-12-2027</p> <p>LOA validity: 31-Dec-2025</p> <p>FSC country of origin validity: 21-07-2025</p>	<p>Brand name: EC Cartridge plus iCa</p> <p>Generic Name: EC cartridge S plus iCa EC cartridge M plus iCa EC cartridge L plus iCa</p> <p>Models/ Specification (as per Free sale certificate): EC cartridge S plus iCa – REG00061 EC cartridge M plus iCa – REG00062 EC cartridge L plus iCa – REG00063</p> <p>Class-B</p> <p>LOA validity: 31-Dec-2025</p> <p>Shelf life: 18</p>	<p>EC cartridge plus is an IVD kit intended for calibration and quantification of sodium (Na+), potassium (K+), ionized calcium (iCa2+) and chloride (Cl-) on the EC 90 analyzer series. Intended only for IVD use by a professionally trained person.</p>	<p>Previous Remarks: The firm does not provide CE Certificate (FQA) or FSC of the reference country.</p> <p>79th MDB Decision Deferred for comments of the legal affairs division regarding the court cases.</p>	<p>Firm has submitted: 1. that there is no ongoing legal case concerning their ERBA related products. 2. Firm has submitted undertaking that MDB decision in 79th meeting dated 28.02.2025 is not appropriate, if later found that decision is correct, Martin Dow will be held responsible.</p>	<p>The Board deferred the case and decided as follows: 1.To seek comments from the Legal Affairs Division regarding the pending court cases. 2. The firm shall submit the following documents: i. CE Certificate or FSC of RRA. ii. A manufacturer's declaration confirming that Martin Dow Specialty is the sole distributor of their products in Pakistan</p>

	7697400978 Dated: 29-01-2024		Months Storage Conditions: 2 - 30°C FSC country of origin validity: 11-12-2025 FSC RRA validity: N/A			The firm has not provided CE Certificate (FQA) or FSC of the reference country.	
27.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R&I 02-04-2024 Fee: PKR 25,000/- Slip # 79767401 Dated: 18-05-2023	Erba Lachema s.r.o. located at Karásek 2219/1d 62100 Brno Czech Republic Documents submitted: ISO 13485 certificate validity: 01-12-2027 LOA validity: 31-Dec-2025 FSC country of origin validity: 21-07-2025	Brand name: DiaPHAN LAURA Generic Name: Multiple urine analyte IVD Models/ Specification (as per Free sale certificate): URPH0024 Class-B LOA validity: 31-Dec-2025 Shelf life: 24 Months Storage Conditions: 2 - 30°C FSC country of origin validity: 21-07-2025 FSC RRA validity: N/A	DiaPHAN LAURA The diagnostic test strips are intended for semiquantitative analysis of urine. The diagnostic test strips PHAN@ LAURA are intended for in vitro diagnostics for professional use only.	Previous Remarks: The firm does not provide CE Certificate (FQA) or FSC of the reference country. 79th MDB Decision Deferred for comments of the legal affairs division regarding the court cases.	Firm has submitted: 1. that there is no ongoing legal case concerning their ERBA related products. 2. Firm has submitted undertaking that MDB decision in 79 th meeting dated 28.02.2025 is not appropriate, if later found that decision is correct, Martin Dow will be held responsible. The firm has not provided CE Certificate (FQA) or FSC of the reference country.	The Board deferred the case and decided as follows: 1.To seek comments from the Legal Affairs Division regarding the pending court cases. 2. The firm shall submit the following documents: i. CE Certificate or FSC of RRA. ii. A manufacturer's declaration confirming that Martin Dow Specialty is the sole distributor of their products in Pakistan
28.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade	Erba Lachema s.r.o. located at Karásek 2219/1d 62100 Brno Czech Republic	Brand name: Dekaphan Auto Generic Name: Multiple urine analyte IVD	Dekaphan Auto diagnostic test strips are intended for semiquantitative analysis of urine.	Previous Remarks: The firm does not provide CE Certificate (FQA) or FSC of the reference	Firm has submitted: 1. that there is no ongoing legal case concerning their ERBA related	The Board deferred the case and decided as follows: 1.To seek comments from the Legal Affairs Division regarding the pending court

	<p>Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160</p> <p>Date of R&I 02-04-2024</p> <p>Fee: PKR 25,000/-</p> <p>Slip # 929997829</p> <p>Dated: 18-05-2023</p>	<p>Documents submitted:</p> <p>ISO 13485 certificate validity: 01-12-2027</p> <p>LOA validity: 31-Dec-2025</p> <p>FSC country of origin validity: 21-07-2025</p>	<p>Models/ Specification (as per Free sale certificate): URPH0030 Class-B</p> <p>LOA validity: 31-Dec-2025</p> <p>Shelf life: 12 Months</p> <p>Storage Conditions: 2 - 30°C</p> <p>FSC country of origin validity: 21-07-2025</p> <p>FSC RRA validity: N/A</p>		<p>country.</p> <p>79th MDB Decision Deferred for comments of the legal affairs division regarding the court cases.</p>	<p>products.</p> <p>2. Firm has submitted undertaking that MDB decision in 79th meeting dated 28.02.2025 is not appropriate, if later found that decision is correct, Martin Dow will be held responsible.</p> <p>The firm has not provided CE Certificate (FQA) or FSC of the reference country.</p>	<p>cases.</p> <p>2. The firm shall submit the following documents:</p> <p>i. CE Certificate or FSC of RRA.</p> <p>ii. A manufacturer's declaration confirming that Martin Dow Specialty is the sole distributor of their products in Pakistan</p>
29.	<p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160</p> <p>Date of R&I 02-04-2024</p> <p>Fee: PKR 25,000/-</p> <p>Slip # #22073852948</p>	<p>Erba Lachema s.r.o. located at Karásek 2219/1d 62100 Brno Czech Republic</p> <p>Documents submitted:</p> <p>ISO 13485 certificate validity: 01-12-2027</p> <p>LOA validity: 31-Dec-2025</p> <p>FSC country of origin validity: 21-07-2025</p>	<p>Brand name: EC Cartridge</p> <p>Generic Name: EC Cartridge S EC Cartridge M EC Cartridge L EC Cartridge XS</p> <p>Models/ Specification (as per Free sale certificate):</p> <p>EC Cartridge S – REG00058 EC Cartridge M – REG00056 EC Cartridge L – REG00057 EC Cartridge XS – REG00065</p> <p>Class-B</p> <p>LOA validity: 31-Dec-2025</p> <p>Shelf life: 18 Months</p>	<p>EC cartridge is an IVD kit intended for calibration and quantification of sodium (Na+), potassium (K+), ionized calcium (iCa2+) and chloride (Cl-) on the EC 90 analyzer series. Intended only for IVD use by a professionally trained person.</p>	<p>Previous Remarks: The firm does not provide CE Certificate (FQA) or FSC of the reference country.</p> <p>79th MDB Decision Deferred for comments of the legal affairs division regarding the court cases.</p>	<p>Firm has submitted:</p> <p>1. that there is no ongoing legal case concerning their ERBA related products.</p> <p>2. Firm has submitted undertaking that MDB decision in 79th meeting dated 28.02.2025 is not appropriate, if later found that decision is correct, Martin Dow will be held responsible.</p> <p>The firm has not provided</p>	<p>The Board deferred the case and decided as follows:</p> <p>1. To seek comments from the Legal Affairs Division regarding the pending court cases.</p> <p>2. The firm shall submit the following documents:</p> <p>i. CE Certificate or FSC of RRA.</p> <p>ii. A manufacturer's declaration confirming that Martin Dow Specialty is the sole distributor of their products in Pakistan</p>

	Dated: 18-05-2023		Storage Conditions: 2 - 30°C FSC country of origin validity: 11-12-2025 FSC RRA validity: N/A			CE Certificate (FQA) or FSC of the reference country.	
30.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Date of R&I 02-04-2024 Fee: PKR 25,000/- Slip # 27823119484 Dated: 29-01-2024	Erba Lachema s.r.o. located at Karásek 2219/1d 62100 Brno Czech Republic Documents submitted: ISO 13485 certificate validity: 01-12-2027 LOA validity: 31-Dec-2025 FSC country of origin validity: 21-07-2025	Brand name: Urinorm Generic Name: Multiple urine analyte IVD Models/ Specification (as per Free sale certificate): REG00053 Class-B LOA validity: 31-Dec-2025 Shelf life: 12 Months Storage Conditions: 2 - 30°C FSC country of origin validity: 21-07-2025 FSC RRA validity: N/A	URINORM control urines are designed for verification and confirmation of precision and accuracy of PHAN diagnostics strips as well as LAURA, LAURA smart.	Previous Remarks: The firm does not provide CE Certificate (FQA) or FSC of the reference country. 79th MDB Decision Deferred for comments of the legal affairs division regarding the court cases.	Firm has submitted: 1. that there is no ongoing legal case concerning their ERBA related products. 2. Firm has submitted undertaking that MDB decision in 79 th meeting dated 28.02.2025 is not appropriate, if later found that decision is correct, Martin Dow will be held responsible. The firm has not provided CE Certificate (FQA) or FSC of the reference country.	The Board deferred the case and decided as follows: 1.To seek comments from the Legal Affairs Division regarding the pending court cases. 2. The firm shall submit the following documents: i. CE Certificate or FSC of RRA. ii. A manufacturer's declaration confirming that Martin Dow Specialty is the sole distributor of their products in Pakistan
31.	M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit	Erba Lachema s.r.o. located at Karásek 2219/1d 62100 Brno Czech Republic Documents	Brand name: UndekaPHAN Generic Name: Multiple urine analyte IVD Models/ Specification	UndekaPHAN diagnostic test strips are intended for semiquantitative analysis of urine.	Previous Remarks: The firm does not provide CE Certificate (FQA) or FSC of the reference country.	Firm has submitted: 1. that there is no ongoing legal case concerning their ERBA related products.	The Board deferred the case and decided as follows: 1.To seek comments from the Legal Affairs Division regarding the pending court cases.

	<p>Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160</p> <p>Date of R&I 02-04-2024</p> <p>Fee: PKR 25,000/-</p> <p>Slip # 02221345</p> <p>Dated: 18-05-2023</p>	<p>submitted:</p> <p>ISO 13485 certificate validity: 01-12-2027</p> <p>LOA validity: 31-Dec-2025</p> <p>FSC country of origin validity: 21-07-2025</p>	<p>(as per Free sale certificate): URPH0019</p> <p>Class-B</p> <p>LOA validity: 31-Dec-2025</p> <p>Shelf life: 15 Months</p> <p>Storage Conditions: 2 - 30°C</p> <p>FSC country of origin validity: 21-07-2025</p> <p>FSC RRA validity: N/A</p>		<p>79th MDB Decision</p> <p>Deferred for comments of the legal affairs division regarding the court cases.</p>	<p>2. Firm has submitted undertaking that MDB decision in 79th meeting dated 28.02.2025 is not appropriate, if later found that decision is correct, Martin Dow will be held responsible.</p> <p>The firm has not provided CE Certificate (FQA) or FSC of the reference country.</p>	<p>2. The firm shall submit the following documents:</p> <p>i. CE Certificate or FSC of RRA.</p> <p>ii. A manufacturer's declaration confirming that Martin Dow Specialty is the sole distributor of their products in Pakistan</p>
32.	<p>M/s BAIN Medical SMC-Pvt) Ltd, Shop No. 2, Ground Floor, Plot 58-C, Street No. 24, Touheed Commercial Area, phase 5 DHA karachi (ELI-00614) 3730</p> <p>R&I Date 07-08-2025</p>	<p>Vital Healthcare SDN. BHD., Lot 3, Jalan Sultan Mohamed 3, Bandar Sultan Sulaiman, 42000 Pelabuhan Klang, Selangor Darul Ehsan, Malaysia</p> <p>FSC: Malaysia Validity: 08 Nov 2022</p> <p>FSC: Germany Validity: 02 Jun 2021</p>	<p>Hemodialysis Bicarbonate / Vital</p> <p>Codes and sizes:</p> <p>HB001 650g cartridge</p> <p>HB002 720g cartridge</p> <p>HB003 750g cartridge</p> <p>HB004 760g cartridge</p> <p>HB005 650g bag</p> <p>HB006 700g bag</p> <p>Class-C Shelf life: 2 Years</p>	<p>Hemodialysis Bicarbonate Concentrate Non-sterilized</p>	<p>Deferred in 49th meeting:</p> <p>Deferred for clarification/provision of following documents: -</p> <p>i. Clarify/justify with documentary evidence regarding grouping of medical device in the light of Schedule-B read with Chapter-III - Rule 11 of MDR, 2017. Special focus on different type of constituent-components of different codes/model of the medical device that are grouped</p>	<p>Firm has submitted that:</p> <p>1. that device is from same manufacturer, same risk classification, same propriety name and same intended purpose and within the scope of permissible variants. Cartridge HB001 to HB004 are for Baxter, Gambro, Nikkiso, B. Braun etc and HB005-HB006 are for Fresinium Machines.</p> <p>2. copy of the FSC Germany issue date 26.05.2025. The only code HB001 mentioned in it.</p> <p>3. copy of the ISO13485 valid till 25.12.2026.</p> <p>The name & address of the</p>	<p>Approved Product: Hemodialysis Bicarbonate Product Code: HB001</p> <p>Manufacturer: Vital Healthcare Sdn. Bhd. PT 83718, Jalan Bestari 1A/KU7 Taman Perindustrian Kapar Bestari 42200 Kapar, Selangor Malaysia</p>

					<p>together e.g. HB001 650g cartridge; HB002 720g cartridge; HB003 750g cartridge; HB004 760g cartridge; HB005 650g bag; & HB006 700g bag. Furthermore, the IFUs for HB001 to HB004 is different from HB005 & HB006.</p> <p>ii. Clarify that why the Free Sale Certificate (Germany) have been issued by the Ministry of Environment and consumer Protection. The provided FSC (Germany) is expired on 02 Jun 2021 and doesn't contain applied product i.e. Hemodialysis Bicarbonate / Vital. Provide Original Valid FSC duly attested by embassy of Pakistan containing Hemodialysis Bicarbonate / Vital.</p> <p>The provided ISO 13485 certificate is expired even upon submission. Provide valid certificate duly notarized in country of origin as per law.</p>	<p>manufacturer on FSC and ISO is Vital Healthcare Sdn. Bhd. PT 83718, Jalan Bestari 1A/KU7, Taman Perindustrian Kapar Bestari 42200 Kapar, Selangor, Malaysia.</p>
--	--	--	--	--	---	--

33.	<p>M/s Roche Pakistan Limited, 1st Floor, 37-B, Block-6, P.E.C.H.S., Karachi East 75400.</p> <p>(ELI-00009)</p> <p>Date of R&I 14-05-2025</p> <p>Fee: PKR 6,000/- Slip # 1427587001 82</p> <p>R&I Date 30-09-2025.</p>	<p>Manufacturer: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany</p> <p>Manufacturing Site: Ventana Medical Systems Inc. (Tucson) 1910 E. Innovation Park Drive Tucson, AZ 85755, USA.</p> <p>• LOA: Type: Copy of notarized Notarization: Notarized Validity: 31-12-2026</p> <p>• FSC Type: Copy of legalized Issued By: Govt. Body Legalization: Legalized Issue Date: 03-11-2022 Validity: Not mentioned</p> <p>• ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 19-08-2027</p>	<p>Brand Name: Ventana CLDN18 (43-14A) Assay</p> <p>Generic Name: Claudin 18 (CLDN18) protein assay.</p> <p>Applied as: Single</p> <p>Class: A</p> <p>Code/sizes: 08504148001</p> <p>Shelf Life: 24 Months (2-8°C)</p>	<p>VENTANA CLDN18 (43-14A) RxDx Assay is an FDA-approved qualitative immunohistochemistry (IHC) companion diagnostic designed for the detection and assessment of Claudin 18 (CLDN18) protein expression in formalin-fixed, paraffin-embedded (FFPE) gastric adenocarcinoma tissue.</p>	<p>Deferred in 94th meeting:</p> <p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • The license to Import issued to the applicant does not mention storage facility at 2-8°C. • Original FSC, LOA & ISO Certificate has not been submitted. 	<p>Firm has submitted:</p> <ol style="list-style-type: none"> 1. that they have 2-8 °C and 15-25 °C facility but not mentioned in the ELI and don't have any other documentary evidence. 2. copy of the FSC Germany issue date 03.11.2022. 3. copy of the LOA issue date 18 January 2023. 4. ISO 13485 valid till 29.06.2027. 5. ISO of the manufacturing site valid till 19.08.2027. 	Approved.
34.	<p>Roche Pakistan Limited. 1st Floor, 37- B, Block 6, P.E.C.H.S., Karachi. (ELI-00009)</p> <p>R&I: 16/05/2025</p>	<p>Legal Manufacturer: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany</p> <p>Manufacturing Site:</p>	<p>VENTANA ROS1 (SP384) Rabbit Monoclonal Primary Antibody</p> <p>Class: C</p> <p>Product Name: 1. VENTANA ROS1 (SP384) Rabbit Monoclonal Primary Antibody</p>	<p>VENTANA ROS1 (SP384) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the qualitative immunohistochemical</p>	<p>Deferred in 94th meeting:</p> <p>Deferred for the provision of original documents including notarized LOA, legalized FSC, notarized ISO 13485 and</p>	<p>Firm has submitted:</p> <ol style="list-style-type: none"> 1. That original documents have already been submitted in DRAP. 2. Firm has submitted the following copies: i. copy of the FSC Germany issue 	Approved.

	<p>Fees: 62,000/- Challan No. 4381148859 77</p> <p>R&I Date 30-09-2025.</p>	<p>Ventana Medical Systems, Inc. 1910 E. Innovation Park Dr. Tucson, AZ 85711 USA</p> <p>FSC: 02-11-2027</p> <p>LOA Validity: 17-01-2028</p> <p>EU QMS Certificate: Validity: 14-12-2025</p> <p>ISO 13485: RDG ISO Validity: 29-06-2027 Ventana ISO Validity: 19-08-2027</p>	<p>CAT #: 09365575001 Pack size: 50 Tests Shelf life: 24 months at 2-8°C</p> <p>1. VENTANA ROS1 (SP384) Rabbit Monoclonal Primary Antibody CAT #: 08404160001 Pack size: 50 Tests Shelf life: 08 months at 2-8°C</p>	<p>detection of ROS1 protein by light microscopy in sections of formalin-fixed, paraffin-embedded tissue stained on a BenchMark IHC/ISH instrument.</p>	<p>notarized EU QMS certificate.</p>	<p>date 03.11.2022. ii. copy of the LOA issue date 18 January 2023. iii. ISO 13485 valid till 29.06.2027. iv. ISO of the manufacturing site valid till 19.08.2027.</p>	
35.	<p>M/s Roche Pakistan Limited, 1st Floor, 37-B, Block-6, P.E.C.H.S., Karachi East 75400.</p> <p>ELI-00009</p> <p>Date of R&I 14-05-2025</p> <p>Fee: PKR 62,000/- Slip # 6895473471 5 Dated: 15-04-2025</p> <p>R&I Date 30-09-2025.</p>	<p>Manufacturer: Ventana Medical Systems Inc., 1910 E. Innovation Park Dr. Tucson, AZ 85711, USA.</p> <p>• LOA: Not Provided.</p> <p>• FSC Type: Copy of apostilled</p> <p>Issued By: Govt. Body</p> <p>Legalization: Apostilled</p> <p>Validity: 20-08-2026</p> <p>• ISO – Certificate: Type: Copy of notarized</p> <p>Notarization: Notarized</p> <p>Validity: 19-08-2027</p>	<p>Brand Name: Ventana PTEN (SP218) Rabbit Monoclonal Primary Antibody</p> <p>Generic Name: Ventana PTEN (SP218) Rabbit Monoclonal Primary Antibody</p> <p>Applied as: Single</p> <p>Class: C</p> <p>Code/sizes: 07970200001</p> <p>Shelf Life: 24 Months (2-8°C)</p>	<p>VENTANA PTEN (SP218) Rabbit Monoclonal Primary Antibody is intended for laboratory use in the qualitative immunohistochemical detection of the phosphatase and tensin homolog (PTEN) protein.</p>	<p>Deferred in 94th meeting:</p> <p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • The license to Import issued to the applicant does not mention storage facility at 2-8°C. • LOA from Legal manufacturer/distributor mentioned on FSC, has not been submitted. • Original FSC and ISO certificate has not been submitted. 	<p>Firm has submitted:</p> <p>1. that they have 2-8 °C and 15-25 °C facility but not mentioned in the ELI and don't have any other documentary evidence.</p> <p>2. That original documents have already been submitted in DRAP.</p> <p>3. Firm has submitted the following copies: i. copy of the CFG USA valid till 20.08.2026. The legal manufacturer as per FSC is Ventana Medical System Inc. ii ISO of Ventana Medical Systems, Inc. manufacturing</p>	Approved.

		<ul style="list-style-type: none"> • EU QMS Certificate: Type: Copy of notarized Notarization: Notarized Validity: 03-11-2026 				<p>site valid till 19.08.2027. The LOA from Ventana not submitted but statement from the Roche submitted that they are distributor of Ventana.</p>	
36.	<p>M/s Roche Pakistan Limited, 1st Floor, 37-B, Block-6, P.E.C.H.S., Karachi East 75400.</p> <p>(ELI-00009)</p> <p>Date of R&I 14-05-2025</p> <p>Fee: PKR 6,000/- Slip # 03971997</p> <p>R&I Date 30-09-2025.</p>	<p>Manufacturer: Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany</p> <p>Manufacturing Site: Ventana Medical Systems Inc. (Tucson) 1910 E. Innovation Park Drive Tucson, AZ 85755, USA.</p> <ul style="list-style-type: none"> • LOA: Type: Copy of notarized Notarization: Notarized Validity: 31-12-2026 • FSC Type: Copy of legalized Issued By: Govt. Body Legalization: Legalized Issue Date: 03-11-2022 Validity: Not mentioned • ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 19-08-2027 	<p>Brand Name: Ventana pan-TRK (EPR17341) Assay</p> <p>Generic Name: Tropomyosin receptor kinase (TRK) proteins assay.</p> <p>Applied as: Single</p> <p>Class: A</p> <p>Code/sizes: 08494665001</p> <p>Shelf Life: 24 Months (2-8°C)</p>	<p>The VENTANA pan-TRK (EPR17341) Assay is, fully automated immunohistochemical test used for qualitative detection of the C-terminal region of TRK proteins A, B, and C in formalin-fixed, paraffin-embedded tissues.</p>	<p>Deferred in 94th meeting:</p> <p>The Board deferred the case due to following deficiencies in the application;</p> <ul style="list-style-type: none"> • The license to Import issued to the applicant does not mention storage facility at 2-8°C. • Original FSC, LOA & ISO Certificate has not been submitted. 	<p>Firm has submitted:</p> <ol style="list-style-type: none"> 1. that they have 2-8 °C and 15-25 °C facility but not mentioned in the ELI and don't have any other documentary evidence. 2. 2. copy of the FSC Germany issue date 03.11.2022. 3. copy of the LOA issue date 18 January 2023. 4. ISO 13485 valid till 29.06.2027. 5. ISO of the manufacturing site valid till 19.08.2027. 	Approved.

Case 2. Correction Case:

Importer Name	Legal Manufacturer:	Product details	Remarks	Decision
<p>M/s A ONE TRADERS name with complete address as per Form-4. House No.45 , Street No.4 Haroon Abad ,Near Malik Tariq Awan Qilla ,Ring Road Peshawar , KPK. (ELI-00480)</p> <p>R&I Dated: 28- Sep-2023</p> <p>Fee Challan No.: 846955557 Fee Challan Date: 03.08.2023</p> <p>PKR: 25,000/-</p>	<p>Tianchang City Anrui Medical Equipments Co.,Ltd. Add:Renhe Industrial District 239331 Tianchang City, Anhui Province, China.</p> <p>Website: www.anruimedical.com</p> <p>Tel: 0086-550-7834188</p> <p>LOA Validity: 13/07/2028</p> <p>FSC Validity: 15- 01-2026</p>	<p>SAFE+ Sterile Latex Surgical Gloves (POWDERED)</p> <p>Sizes: 6, 6.5, 7, 7.5, 8, 8.5, 9</p> <p>Class: B</p> <p>Shelf Life: 5 years</p>	<p>The firm has stated that they were issued registration letter in 78th Meeting for the said product vide MDIR-0008173 dated 22-03-2025 (copy provided). The firm has stated that the manufacturer name has mistakenly written as M/s Anrui Medical Equipments Co., Ltd, Tianchang City, Renhe Industrial District 239331, Tianchang City, Anhui Province, China instead of M/s Tianchang City Anrui Medical Equipments Co., Ltd., Renhe Industrial District 239331 Tianchang City, Anhui Province, China.</p> <p>The firm has also provided copies of FSC and CE Certificates for reference.</p>	<p>The MDB acceded the request of the firm.</p>

**Case No.3 M/S GLOBAL MARKETING SERVICES, RAWALPINDI ESTABLISHMENT
LICENSE NUMBER: ELI-00109 HAS APPLIED FOR THE FOLLOWING PRV
CASES.**

Sr. No.	Product Name Registration No.	Data to be changed	Decision
1	Xpert HCV Viral Load MDIR-0000513	<p>Previous Shelf Life</p> <p>Shelf Life: 12 Months</p> <p>New Shelf Life</p> <p>Shelf Life: 18 months</p>	Approved.

2	Xpert HBV Viral Load MDIR-0001193	Shelf Life: 10 Months Proposed Shelf Life: 18 months	Approved.
3	Xpert Xpress Flu/RSV MDIR-0002040	Shelf Life: 18 Months Proposed Shelf Life: 24 months	Approved.
4	Xpert Xpress SARS-CoV-2 MDIR-0002662	Shelf Life: 12 Months Proposed Shelf Life: 18 months	Approved.
5	Xpert MTB/RIF Ultra MDIR-0001195	Shelf Life: 16 Months Proposed Shelf life: 18 months	Approved.

Item No. 4. POST LICENSE VARIATIONS.

S. No.	Name of Establishment	Existing Details of ELI	Proposed Details for ELI	Decision
1.	M/s Al Hamd Enterprises, FL-11/1/1 , Block- 6, Gulshan-e-Iqbal , Karachi ELI-00285 issued on 22-10-2018 Change of management (Directors/Partners)	Existing Management/ Proprietors Mr. Aslam Ullah Khan, Nouse No.FL-11/1/1, Block-6, Gulshan-e-Iqbal, Karachi. CNIC: 42101-3645836-9	Proposed Management/ Proprietors Mr. Imran Khan, C-93, Block-15,tan-e-Johar, Karachi. CNIC:42101-0997924-9 Ms. Sundus Imran, C-93, Block-15,tan-e-Johar, Karachi. CNIC:42201-6331046-6 Mr. Aslam Ullah Khan, Nouse No.FL-11/1/1, Block-6, Gulshan-e-Iqbal, Karachi. CNIC: 42101-3645836-9	To verify the factual and legal position, the Board decided as under: 1. Directed Mr. Aslam Ullah Khan to appear before the Board/authorized forum to confirm their respective positions regarding the sale/transfer of the firm and associated rights and liabilities. 2. Fresh undertaking duly attested by an Oath Commissioner, explicitly confirming that: <ul style="list-style-type: none"> • the transfer has been made voluntarily; • no claim, dispute, or liability shall be raised in future against DRAP or MDB in respect of the requested change.