

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

DECISIONS OF 124TH MEETING OF THE MEDICAL DEVICE BOARD (MDB)
HELD ON 05TH MARCH-2026 (MANUAL APPLICATIONS PART-II)

124th 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 5th March, 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
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
9.	Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad.	Member
10.	Mrs. Tazeen Saeed Bukhari, 192 Cavetry Ground, Street 4, Shami Road Khalid Yaqoob Chowk, Lahore	Co-opted expert (attended meeting through videolink)
11.	Mr. Ayyaz Ahmed, Additional Director (MD&MC), DRAP, Islamabad.	Member-cum-Secretary

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

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

EVALUATOR: MR. MUHAMMAD AMIN (DEPUTY DIRECTOR)

Item No. I(A): **APPLICATIONS FOR GRANT OF ESTABLISHMENT LICENSE TO MANUFACTURE MEDICAL DEVICES UNDER MEDICAL DEVICES RULES, 2017**

FRESH CASES-ELM:

S.No	Name and Address of Establishment	Name of Production Incharge	Name of QC Incharge	Decisions
1	M/s Sino-Pak United Industries, Office/godown: Plot # F2B, S.I.T.E , PTC Compound, Karachi.	Ms Maida Khan Pharm D	Adnan Zaheer Pharm D	The board considered inspection report and approved establishment license to manufacture medical devices for the following sections: 1. Fixation Dressing 2. Cannula Fixation Dressing 3. Wound Dressing 4. First Aid Bandage 5. Medical Paper Tape 6. Medical PE Tape 7. Zinc Oxide Adhesive Tape 8. Alcohol Prep Swab 9. Disposable Underpad Sheet N.B: The board deferred Adult Diaper section to confirm status of these products as medical devices.

Item No. I(B): **APPLICATIONS FOR GRANT OF ESTABLISHMENT LICENSE TO IMPORT MEDICAL DEVICES UNDER MEDICAL DEVICES RULES, 2017**

(FRESH CASES-ELI):

S.#	Name of Establishment	Name of Qualified Technical Person	Decision
1.	M/s Musab Traders, Office/godown: Office No. 321, 3 rd floor, Medicine markaz, denso hall, Karachi.	Muhammad ali nale mitho Pharm D	Approved
2.	M/s Al-Ahmed Traders, Office/godown: CB 22, Al falah society, near PSO petrol pump, shah faisal colony No. 2, Korangi shah faisal town, Karachi.	Areeba Qamar Khan biomedical Engineer	Approved
3.	M/s Genetics Pharmaceuticals Pvt. Ltd, Office/godown: 522, Sundar Industrial Estate, Raiwind Road, Lahore.	Muhammad Waqas Pharm D	Approved

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

(FRESH RENEWAL CASES-ELI):

S.No	Name of Establishment	Name of Qualified Technical Person	Name of Management	Decision
1.	M/s AJ International Company, Office/godown: Suit No 313, 3rd Floor Mashriq Center, Gulshan- e- Iqbal Block 14, Karachi ELI-00288	Shabnum Fatima B-Pharmacy	Rehan Mohsin Khan CEO	Approved
2.	M/s Nasir Brothers, Office: Office No 22B, 2nd Floor, Zeenat Medicine Market, North Napier Road, Karachi Godown: Plot No 149 150, Ground Floor , Block 7/8, Memon Cooperative Housing Society Karachi ELI-00036	Fahad Jawed Pharm D	Nasir Ahmed CEO	Approved
3.	M/s La-Vie (Pvt) Ltd, Office / godown: 450, G-III, johar town, Lahore. ELI-00113	Muhammad Munir tahir Pharm D	Nadeem Arfan rana Haseeb ahmed butt Qamar Shaheen Pervaiz Iqbal awan	Approved
4.	M/s Standard Supply Agencies, Shop No 20, 21 & 22, Khyber Bazar, Peshawer. ELI-00018	Haider khan Pharm D	Saleem Shahzad Waseem shahzad	Deferred. The firm shall submit documents and fee for approval of technical staff.
5.	M/s Unibrand International, Office/godown: office No. 206, 2 nd floor, 158 Executive complex civic centre bahria town phase IV, Islamabad. ELI-00213	Rashid Ali yaqub Biomedical Engineer	Abdul Rahim Shahid CEO Nadeem shahid Partner	Deferred. The firm shall submit fee and documents for approval of technical staff and change of godown.

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

The following firms have applied for Renewal of Establishment License to import medical devices under MDR, 2017 for which inspection panels were constituted for inspection of their establishments. The recommendations of the panels are as mentioned against each is submitted for consideration of MDB please:

(DEFERRED CASES FOR RENEWAL OF -ELI):

S. No	Name of Establishment	Name of Qualified Technical Person	Name of Management	Decision:
1.	M/s Universal Enterprises, Office/Godown: 29 Block 3 Overseas Cooperative Housing Society Stadium Road Karachi ELI-00079	Old Technical person : Azmat Waseem MSC Physics New technical person: Obedullah shaikh Bio medical engineer	Muhammad Aleem Mirza	Approved

Item No. III: ADDITIONAL AGENDA CASES

EVALUATOR: RANA AHSAN-UL-HAQ ATHAR

DEFERRED CASES AGENDA

DEFERRED CASES IMPORT

S#	Importer Name	Manufacturer Details	Name of MD / Class / Codes / Shelf life / etc.	Decision
1.	M/s Elite Traders Office 342-B 1st Floor, B-Block Satellite Town Rawalpindi. ELI-00193	<u>Legal manufacturer:</u> Beijing Chunlizhengda Medical Instruments Co., Ltd No.10 Xinmi West 2nd Road, South Area of Tongzhou Economic Development Zone, Beijing China. Legalized FSC issued by China validity dated 20-03-2024.	Hip Prosthesis System (Femoral Head TB) Class-D Shelf life: 5years Sizes: 28S, 28M, 28L, 28XL, 32S, 32M, 32L, 32XL, 36S, 36M, 36L, 36XL	Approved subject to submission of DEC and notarized NB Confirmation letter.

2.	M/s Nasir Brother 22B, Second Floor, Zeenat Medicine Market, North Napier Road, Karachi. ELI-00036 R&I details 01/09/23	Legal Manufacture M/s Wuxi Exanovo Medical Instruments Co., Ltd Address: C2-LianDong U Gu, Xebei Town, Xishan District, Wuxi2149, Jiangsu Province P.R China. FSC Validity: Different Product LOA Validity: 06/03/2028	Vcare V.well Digital Thermometer Class: A Claimed Shelf Life 3 Years Code/sizes Not Applicable	Approved V.Well brand name and following manufacturer address: M/s Wuxi Exanovo Medical Instruments Co., Ltd., No.42 Xixin Road, Zhangjing Xibei Town Wuxi City 214194 Jiangsu China.
3.	M/s. Health Tec, H. No. 10-B, Valley Road, St. 24, Opposite Rehmania Masjid, Westridge 1, Rawalpindi, Pakistan. (ELI-00046) R&I Date: 03-06-2025 Fee: 31000/- Slip # 949961765141	Name of Manufacturer: Ultra Med A/S, 64, Nakhla El-Motaiy Triomphe Square, Heliopolis Cairo, Egypt LOA Type: Original Notarization: Legalized Issue Date: 27-03-2025 Validity: 1 year • FSC Type: Original i. Issued By: Egyptian Drug Authority Legalization: Legalized Issue Date: 07-04-2025 Validity: 07-04-2027 ii. Issued by: AEMPS of Spain Type: Copy Legalization: Legalized Issue Date: 06-11-2019 Validity: N/A • ISO – Certificate: Type: Original Notarization: Legalized Validity: 26-05-2024	Brand Name: HT-Burette Set Generic Name: Measured Volume Fluid Administration Set Applied as: Set Class: B Models/Code/sizes (as per FSC & application Model: FSC issued by Egyptian Drug Authority does not declare any Model or Sizes. Shelf Life: 5 years (Room temperature)	Approved
4.	M/s. Health Tec, H. No. 10-B, Valley Road, St. 24, Opposite Rehmania Masjid, Westridge 1, Rawalpindi, Pakistan. (ELI-00046)	Name of Manufacturer: Ultra Med A/S, 64, Nakhla El-Motaiy Triomphe Square, Heliopolis Cairo, Egypt LOA Type: Original Notarization: Legalized Issue Date: 27-03-2025 Validity: 1 year • FSC Type: Original	Brand Name: HT-Latex Foley Balloon Catheter Generic Name: Indwelling Urinary Catheter Applied as: Set Class: B Models/Code/sizes (as per FSC & application Model: Silicon Coated Latex Foley Balloon Catheter 2 way and 3	Approved HT-Silicon Coated Latex Folly Balloon Catheter 2 way as per FSC.

	R&I Date: 03-06-2025 Fee: 31000/- Slip # 638591659997	i. Issued By: Egyptian Drug Authority Legalization: Legalized Issue Date: 07-04-2025 Validity: 07-04-2027 ii. Issued by: AEMPS of Spain Type: Copy Legalization: Legalized Issue Date: 06-11-2019 Validity: N/A • ISO – Certificate: Type: Original Notarization: Legalized Validity: 20-05-2026	way **FSC issued by Egyptian Drug Authority does not declare any further Model or Sizes. Shelf Life: 5 years (Room temperature)	
5.	M/s. Health Tec, H. No. 10-B, Valley Road, St. 24, Opposite Rehmania Masjid, Westridge 1, Rawalpindi, Pakistan. (ELI-00046) R&I Date: 03-06-2025 Fee: 31000/- Slip # 2664028627	Name of Manufacturer: Ultra Med A/S, 64, Nakhla El-Motaiy Triomphe Square, Heliopolis Cairo, Egypt LOA Type: Original Notarization: Legalized Issue Date: 27-03-2025 Validity: 1 year • FSC Type: Original i. Issued By: Egyptian Drug Authority Legalization: Legalized Issue Date: 07-04-2025 Validity: 07-04-2027 ii. Issued by: AEMPS of Spain Type: Copy Legalization: Legalized Issue Date: 06-11-2019 Validity: N/A • ISO – Certificate: Type: Original Notarization: Legalized Validity: 20-05-2026	Brand Name: HT-Surgical Gloves (Powder free) Generic Name: Surgical Gloves (Powder free) Applied as: Set Class: B Models/Code/sizes (as per FSC & application): 6.5, 7.0, 7.5, 8.0, 8.5 **FSC issued by Egyptian Drug Authority does not declare any Sizes. Shelf Life: 5 years	Approved.
6.	M/s. Health Tec, H. No. 10-B, Valley Road, St. 24, Opposite Rehmania Masjid, Westridge 1, Rawalpindi,	Name of Manufacturer: Ultra Med A/S, 64, Nakhla El-Motaiy Triomphe Square, Heliopolis Cairo, Egypt LOA Type: Original Notarization: Legalized Issue Date: 27-03-2025	Brand Name: HT-Blood Administration Set Generic Name: Blood Administration Set Applied as: Set Class: B Models/Code/sizes (as per FSC & application Model):	Approved

	Pakistan. (ELI-00046) R&I Date: 03-06-2025 Fee: 31000/- Slip # 2318455592	Validity: 1 year • FSC Type: Original i. Issued By: Egyptian Drug Authority Legalization: Legalized Issue Date: 07-04-2025 Validity: 07-04-2027 ii. Issued by: AEMPS of Spain Type: Copy Legalization: Legalized Issue Date: 06-11-2019 Validity: N/A • ISO – Certificate: Type: Original Notarization: Legalized Validity: 26-05-2024	FSC issued by Egyptian Drug Authority does not declare any Model or Sizes. Shelf Life: 5 years (Room temperature)	
7.	M/s. Health Tec, H. No. 10-B, Valley Road, St. 24, Opposite Rehmania Masjid, Westridge 1, Rawalpindi, Pakistan. (ELI-00046) R&I Date: 03-06-2025 Fee: 31000/- Slip # 450645153	Name of Manufacturer: Ultra Med A/S, 64, Nakhla El-Motaiy Triomphe Square, Heliopolis Cairo, Egypt LOA Type: Original Notarization: Legalized Issue Date: 27-03-2025 Validity: 1 year • FSC Type: Original i. Issued By: Egyptian Drug Authority Legalization: Legalized Issue Date: 07-04-2025 Validity: 07-04-2027 ii. Issued by: AEMPS of Spain Type: Copy Legalization: Legalized Issue Date: 06-11-2019 Validity: N/A • ISO – Certificate: Type: Original Notarization: Legalized Validity: 20-05-2026	Brand Name: Silicon Foley Balloon Catheter Generic Name: Indwelling Urinary Catheter Applied as: Set Class: B Models/Code/sizes (as per FSC & application Model): Silicon Foley Balloon Catheter 2 way and 3 way **FSC issued by Egyptian Drug Authority does not declare any further Model or Sizes. Shelf Life: 5 years (Room temperature)	Approved
8.	M/s. Health Tec, H. No. 10-B, Valley Road, St. 24, Opposite Rehmania	Name of Manufacturer: Ultra Med A/S, 64, Nakhla El-Motaiy Triomphe Square, Heliopolis Cairo, Egypt LOA	Brand Name: HT-Urine Collection bag with Non-Return valve Generic Name: Urine Collection Bag with	Approved HT-Urine collection Bag with non-return valve with code 3003 as per FSC.

	Masjid, Westridge 1, Rawalpindi, Pakistan. (ELI-00046) R&I Date: 03-06-2025 Fee: 31000/- Slip # 691480401310	Type: Original Notarization: Legalized Issue Date: 27-03-2025 Validity: 1 year • FSC Type: Original i. Issued By: Egyptian Drug Authority Legalization: Legalized Issue Date: 07-04-2025 Validity: 07-04-2027 • ISO – Certificate: Type: Original Notarization: Legalized Validity: 20-05-2026-	non return valve. Applied as: Set Class: B Models/Code/sizes (as per FSC & application Capacity: 2000ml **FSC issued by Egyptian Drug Authority does not declare any further Model or Sizes. Shelf Life: 5 years (Room temperature)	
9.	M/s. Health Tec, H. No. 10-B, Valley Road, St. 24, Opposite Rehmania Masjid, Westridge 1, Rawalpindi, Pakistan. (ELI-00046) R&I Date: 03-06-2025 Fee: 31000/- Slip # 942907471209	Name of Manufacturer: Head office: Ultra Med A/S Address:64, Nakhla El-Motaiy Triomphe Square, Heliopolis Cairo, Egypt Manufacturer: Ultra for medical products co. ((ULTRAMED)) U.M.I.C) S.A.E, Paret No. (304:310) & Part No. (312 – Industrial Area, Arab E1 Awamer-Abnoub-Assiut-Egypt), LOA Type: Original Notarization: Legalized Issue Date: 27-03-2025 Validity: 1 year • FSC Type: Original i. Issued By: Egyptian Drug Authority Legalization: Legalized Issue Date: 07-04-2025 Validity: 07-04-2027 ii. Issued by: AEMPS of Spain Type: Copy Legalization: Legalized Issue Date: 06-11-2019 Validity: N/A • ISO – Certificate: Type: Original Notarization: Legalized Validity: 26-05-2024	Brand Name: HT-Endotracheal tube Generic Name: Endotracheal tube Applied as: Set Class: B Models/Code/sizes (as per FSC & application Model: FSC issued by Egyptian Drug Authority does not declare any Model or Sizes. Shelf Life: 5 years (Room temperature)	Approved Endotracheal Tube with Cuff. Codes 4006-4, 4006-4.5, 4006-5, 4006-5.5, 4006-6, 4006-6.5, 4006-7, 4006-7.5, 4006-8, 4006-8.5, 4006-9 subject to submission of differential fee for family of class B.

10.	M/s. Health Tec, H. No. 10-B, Valley Road, St. 24, Opposite Rehmania Masjid, Westridge 1, Rawalpindi, Pakistan. (ELI-00046) R&I Date: 03-06-2025 Fee: 31000/- Slip # 07765173565	Name of Manufacturer: Head office: Ultra Med A/S Address:64, Nakhla El-Motaiy Triomphe Square, Heliopolis Cairo, Egypt Manufacturer: Ultra for medical products co. ((ULTRAMED)) U.M.I.C) S.A.E, Paret No. (304:310) & Part No. (312 – Industrial Area, Arab E1 Awamer-Abnoub-Assiut-Egypt), LOA Type: Original Notarization: Legalized Issue Date: 27-03-2025 Validity: 1 year • FSC Type: Original i. Issued By: Egyptian Drug Authority Legalization: Legalized Issue Date: 07-04-2025 Validity: 07-04-2027 ii. Issued by: AEMPS of Spain Type: Copy Legalization: Legalized Issue Date: 06-11-2019 Validity: N/A • ISO – Certificate: Type: Original Notarization: Legalized Validity: 26-05-2024	Brand Name: HT-IV Infusion set Generic Name: IV infusion set Applied as: Set Class: B Models/Code/sizes (as per FSC & application Model: FSC issued by Egyptian Drug Authority does not declare any Model or Sizes. Shelf Life: 5 years (Room temperature)	Approved Intravenous Fluid Infusion Set with Non-Vented Spike. code 1009 subject to submission of differential fee for family of class B.
11.	Health Tec, H. No. 10-B, Valley Road, St. 24, Opposite Rehmania Masjid, Westridge 1, Rawalpindi, Pakistan. ELI-00046 Date of R& I 03-06-2025	M/s Ultra Med A/S, 64, Nakhla El-Motaiy Triomphe Square, Heliopolis Cairo, Egypt LOA validity: 25-03-2026 (Copy) FSC validity (Egypt): 07-04-2027 (Copy) ISO validity: 20-05-2026 (Copy) EC Validity: 26-05-2024	HT-Ultraflon I.V. Cannula Generic Name: Intravenous Cannula with Injection port Code/Sizes: 14G, 16G, 18G, 20G, 22G, 24G & 26G Class-B Shelf life: 05 Years	Approved I.V. cannula with Luer & Injection Port. Codes:1001-14, 1001-16, 1001-18, 1001-20, 1001-22, 1001-24, 1001-26, subject to submission of differential fee for family.

	Fee: PKR 31,000/- Slip # 558915420 Dated: N/A	(Copy)		
12.	M/s Bajwa Sons House # 03, 1st and 2nd Floor, 13 Muslim street, Mayo Hospital Road, Lahore ELI-00314 Evaluator AD-IV [2753-P]	Manufacaturer: M/s Yancheng Huida Medical Instruments Co., Ltd, No. 2, Kujiyuan Road, Xuefu Town, Yandu District, Yancheng, City Jiangsu, China FSC China valid till 17.09.2022 (product not it)	Trugut Chromic (Catgut Chromic Absorbable suture) Codes & Sizes: Not mentioned in FSC Class D Shelf Life: 5 years (studies not provided)	After thorough deliberation, and keeping in view the established policy of conversion of previously registered drugs into medical devices in 107 th meeting of MDB, the Board unanimously decided to approve the registration of Trugut Chromic Catgut (Sterile Absorbable Surgical Suture) as medical device.
13.	M/s. SHAAD TRADERS Address 2nd floor, Ehasn Tower, Dalazak Road Peshawar. (ELI-00809) R&I Date: 21-05-2025 Fee: 31,000/- Slip # 5609741819	Name of Manufacturer: Jiangsu Eyoung Medical Devices Co., Ltd., No. 1 Dongtang Road, Zhenglu Town, Tianning District, Changzhou 213115 Jiangsu, China LOA Type: Copy Notarization: Apostille Issue Date: 10-02-2025 Validity: 10-02-2030 • FSC Type: Copy Issued By: China Chamber of Commerce For Import & Export of Medicines and Health Products Legalization: Apostille Issue Date: 13-01-2025 Validity: 12-01-2027 • ISO – Certificate: Type: Copy Notarization: Apostille Validity: 10-09-2027 • CE certificate: Copy submitted	Brand Name: Shaad Hypodermic Needle Generic Name: Hypodermic needle Applied as: Single Class: B Models/Code/sizes (as per FSC & application Model: 14G,16G,18G,19G,20G,21G, 22G,23G,24G,25G,26G,27G, 29G,30G,31G,32G,33G,34G Shelf Life: 3 years (below 35°C)	Approved.
14.	M/s. SHAAD TRADERS	Name of Manufacturer: Jiangsu Eyoung Medical	Brand Name: Shaad Auto-disable syringe	Rejected as the device is Disposable syringe as per

	Address 2nd floor, Ehasn Tower, Dalazak Road Peshawar. (ELI-00809) R&I Date: 21-05-2025 Fee: 31,000/- Slip # 4579290991	Devices Co., Ltd., No. 1 Dongtang Road, Zhenglu Town, Tianning District, Changzhou 213115 Jiangsu, China LOA Type: Copy Notarization: Apostille Issue Date: 10-02-2025 Validity: 10-02-2030 • FSC Type: Copy Issued By: China Chamber of Commerce For Import & Export of Medicines and Health Products Legalization: Apostille Issue Date: 13-01-2025 Validity: 12-01-2027 • ISO – Certificate: Type: Copy Notarization: Apostille Validity: 10-09-2027 • CE certificate: Copy submitted	Generic Name: Auto-disable syringe Applied as: Single Class: B Models/Code/sizes (as per FSC & application Model: 3ml,5ml,10ml Shelf Life: 3 years (below 35°C)	FSC.
15.	M/s. SHAAD TRADERS Address 2nd floor, Ehasn Tower, Dalazak Road Peshawar. (ELI-00809) R&I Date: 21-05-2025 Fee: 31,000/- Slip # 46146443	Name of Manufacturer: Jiangsu Eyoung Medical Devices Co., Ltd., No. 1 Dongtang Road, Zhenglu Town, Tianning District, Changzhou 213115 Jiangsu, China LOA Type: Copy Notarization: Apostille Issue Date: 10-02-2025 Validity: 10-02-2030 • FSC Type: Copy Issued By: China Chamber of Commerce For Import & Export of Medicines and Health Products Legalization: Apostille Issue Date: 13-01-2025 Validity: 12-01-2027 • ISO – Certificate: Type: Copy Notarization: Apostille Validity: 10-09-2027 • CE certificate: Copy submitted	Brand Name: Shaad Urine Bag Generic Name: Urine Bag Applied as: Single Class: B Models/Code/sizes (as per FSC & application Model: 500ml, 750ml, 1000ml, 1500ml, 2000ml Shelf Life: 3 years (below 35°C)	Approved.

16.	M/s. SHAAD TRADERS Address 2nd floor, Ehasn Tower, Dalazak Road Peshawar. (ELI-00809) R&I Date: 21-05-2025 Fee: 31,000/- Slip # 17128168642	Name of Manufacturer: Jiangsu Eyoung Medical Devices Co., Ltd., No. 1 Dongtang Road, Zhenglu Town, Tianning District, Changzhou 213115 Jiangsu, China LOA Type: Copy Notarization: Apostille Issue Date: 10-02-2025 Validity: 10-02-2030 • FSC Type: Copy Issued By: China Chamber of Commerce For Import & Export of Medicines and Health Products Legalization: Apostille Issue Date: 13-01-2025 Validity: 12-01-2027 • ISO – Certificate: Type: Copy Notarization: Apostille Validity: 10-09-2027 • CE certificate: Copy submitted	Brand Name: Shaad Three way Stopcok Generic Name: Three way Stopcok Applied as: Single Class: B Models/Code/sizes (as per FSC & application Model: Without extention line or with 5cm-30cm extension line Shelf Life: 3 years (below 35°C)	Rejected as the device was not mentioned in the FSC.
17.	M/s. SHAAD TRADERS Address 2nd floor, Ehasn Tower, Dalazak Road Peshawar. (ELI-00809) R&I Date: 21-05-2025 Fee: 31,000/- Slip # 448398266	Name of Manufacturer: Jiangsu Eyoung Medical Devices Co., Ltd., No. 1 Dongtang Road, Zhenglu Town, Tianning District, Changzhou 213115 Jiangsu, China LOA Type: Copy Notarization: Apostille Issue Date: 10-02-2025 Validity: 10-02-2030 • FSC Type: Copy Issued By: China Chamber of Commerce For Import & Export of Medicines and Health Products Legalization: Apostille Issue Date: 13-01-2025 Validity: 12-01-2027 • ISO – Certificate: Type: Copy Notarization: Apostille Validity: 10-09-2027	Brand Name: Shaad Insulin syringe Generic Name: Insulin syringe Applied as: Single Class: B Models/Code/sizes (as per FSC & application Model: 0.3ml,0.5ml,1.0ml Shelf Life: 3 years (below 35°C)	Rejected as the Insulin Syringe and sized 0.3ml & 0.5 ml not mentioned in the FSC.

		• CE certificate: Copy submitted		
18.	M/s. SHAAD TRADERS Address 2nd floor, Ehasn Tower, Dalazak Road Peshawar. (ELI-00809) R&I Date: 21-05-2025 Fee: 31,000/- Slip # 1186101292	Name of Manufacturer: Jiangsu Eyoung Medical Devices Co., Ltd., Address: No. 1 Dongtang Road, Zhenglu Town, Tianning District, Changzhou 213115 Jiangsu, China LOA Type: Copy Notarization: Apostille Issue Date: 10-02-2025 Validity: 10-02-2030 • FSC Type: Copy Issued By: China Chamber of Commerce For Import & Export of Medicines and Health Products Legalization: Apostille Issue Date: 13-01-2025 Validity: 12-01-2027 • ISO – Certificate: Type: Copy Notarization: Apostille Validity: 10-09-2027 • CE certificate: Not submitted	Brand Name: Shaad Infusion Set Generic Name: Infusion Set Applied as: Class: B Models/Code/sizes (as per FSC & application Model: HLIV01,HLIV02,HLIV03,HLIV04,HLIV05,HLIV06,HLIV07 Shelf Life: 3 years (below 35°C)	Rejected as the firm has not submitted CE certificate. The attached CE certificate & ISO 13485 are of M/s Changzhou Holinx Industries Co., Ltd.
19.	M/s. SHAAD TRADERS Address 2nd floor, Ehasn Tower, Dalazak Road Peshawar. (ELI-00809) R&I Date: 21-05-2025 Fee: 31,000/- Slip # 3948526144	Name of Manufacturer: Jiangsu Eyoung Medical Devices Co., Ltd., Address: No. 1 Dongtang Road, Zhenglu Town, Tianning District, Changzhou 213115 Jiangsu, China LOA Type: Copy Notarization: Apostille Issue Date: 10-02-2025 Validity: 10-02-2030 • FSC Type: Copy Issued By: China Chamber of Commerce For Import & Export of Medicines and Health Products Legalization: Apostille Issue Date: 13-01-2025 Validity: 12-01-2027 • ISO – Certificate: Type: Copy	Brand Name: Shaad Burette Infusion Set Generic Name: Burette Infusion Set Applied as: Class: B Models/Code/sizes (as per FSC & application Model: 100ml, 150ml Shelf Life: 3 years (below 35°C)	Rejected as the firm has not submitted CE certificate. The attached CE certificate & ISO 13485 are of M/s Changzhou Holinx Industries Co., Ltd.

		Notarization: Apostille Validity: 10-09-2027 • CE certificate: Not submitted		
20.	M/s. SHAAD TRADERS Address 2nd floor, Ehasn Tower, Dalazak Road Peshawar. (ELI-00809) R&I Date: 21-05-2025 Fee: 31,000/- Slip # 19890437	Name of Manufacturer: Jiangsu Eyoung Medical Devices Co., Ltd., Address: No. 1 Dongtang Road, Zhenglu Town, Tianning District, Changzhou 213115 Jiangsu, China LOA Type: Copy Notarization: Apostille Issue Date: 10-02-2025 Validity: 10-02-2030 • FSC Type: Copy Issued By: China Chamber of Commerce For Import & Export of Medicines and Health Products Legalization: Apostille Issue Date: 13-01-2025 Validity: 12-01-2027 • ISO – Certificate: Type: Copy Notarization: Apostille Validity: 10-09-2027 • CE certificate: Not submitted	Brand Name: Shaad Transfusion Set Generic Name: Transfusion Set Applied as: Class: B Models/Code/sizes (as per FSC & application Model: HLBV01,HLBV02,HBLBV03,HLBV04,HLBV05,HLBV06,HLBV07 Shelf Life: 3 years (below 35°C)	Rejected as the device name not mentioned in the FSC and CE certificate also not submitted. The attached CE certificate & ISO 13485 are of M/s Changzhou Holinx Industries Co., Ltd.

Case No.001

3-Neodura

Name Address of Importer	Name National Enterprises Address of Importer 409, 4 th floor Al-Sehat Centre Annexe Reagent Plaza, Shahrah-e-Faisal Karachi
Detail of ELM/ELI	ELI- 00043
Name Address of Manufacturer	(LEGAL MANUFACTEURER) Medprin Biotech GmbH (Address of Manufacturer) GutleutstraBe 163-167, 60327 Frankfurt am Main Germany (Manufacturing site) Medprin Regenerative Medical Technologies Co. Ltd Address: 3F and 7F, Zone E, 80 Lanyue Road Science City, New High-tech Industrial Park, Guangzhou 510663,P.R.China
Brand Name Generic name	Neodura (Dural Repair Patch)
Country of origin FSC	Fsc: Germany

	Original notarized embassy attested ,issuance date 10.12.2020,Validity not mentioned on FSC (1 st submission) Original Notarized ,Issuance date : 07-03-2024,,Validity not mentioned on FSC (Resubmission)
Whether the product is applied on CE certificate basis or free sale in reference country	Fsc: Germany Original Notarized ,Issuance date : 07-03-2024,,Validity not mentioned on FSC
Date of application received along with Fee	Date of R& I (Dossier Submission) 16 June 2022 Fee Rs. 50,000/ through slip no. 59461740417,dated 18.12.2023 Submission of some original documents (R & I) : 09-01-2023 Resubmission of some original documents (R & I): 26-08-2024
Class of medical device	D
Stability data/ service life	Shelf Life: 3 Years Shelf life validation certificate and validation report is provided.
Documents submitted	Marketing Authorization Letter: Original Notarized Embassy attested LOA. Issuance date 05.03.2024, Valid till 05.03 2027 Original Production Quality Management System Certificate (Iso 13485:2016) 1st submission Original Registration Date 26-11-2014, Effective Date 26-11-2020,Expiry date 25-11-2023 Original notarized Production Quality Management System Certificate (Iso 13485:2016) 2ndsubmission Original Registration Date 23-10-2015, Effective Date 01-01-2024,Expiry date 31-12-2026 Original notarized EC Certificate-Full Quality Assurance System: 1st issued: 11-02-2016 , Date: 12-02-2020, Expiry date: 26-05-2024 Notifying Body bsi Confirmation letter is provided. Validity 31-12-2027 Original notarized EC Design-Examination Certificate 1st issued: 11-02-2016 , Date: 17-06-2020, Expiry date: 26-05-2024 Notifying Body bsi Confirmation letter is provided. Validity 31-12-2027 Declaration of Conformity (Doc): Provided
Decision	After detailed deliberation and considering the availability of alternative devices derived from bovine sources, the Board decided to reject the current application for Neodura due to its porcine source. Further, the Board decided that show Cause notice/personal hearing shall be issued to M/s Anwar & Sons holding registration of following medical device manufactured from gelatin derived from porcine source: Cutanplast – MDIR-0000560

Item No. IV:

PERSONAL HEARING AGENDA

Evaluator: Rana Ahsan Ul Haq Attar:

Deferred Products:

S.#	Name of Importer	Manufacturer Details	Product Name	Decision of M-115
1.	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 Initial Submission: 02-Dec-2022 Final Submission: 27-Sept-2023	Legal Manufacturer: Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom embassy attested Free Sale Certificate Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom Date of Issue: 04-July-2023 Validity: 26-May-2025	VITROS Immunodiagnostic Product Anti-HBC IgM Reagent, Calibrator & Control Cal: 1100387 Rgt: 8577413 Cont: 6800834 Shelf life: Reagent: 52 weeks Calibrator: 52 weeks Control: 52 weeks Storage Conditions: 2-8°C Class: D Fees: 50,000/- Date of submission December 2022 then 27-Sept-23	The Board decided to call both M/s Martin Dow Speciality and M/s Sieco Scientific Traders, for personal hearing with the direction to present following documents before the Board; i. Valid, notarized Letter of Authorization issued by the legal manufacturer abroad. ii. Notarized Termination letter issued by the legal manufacturer, if any.
2.	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 Initial Submission: 02-Dec-2022 Final Submission: 27-Sept-2023	Legal Manufacturer: Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom embassy attested Free Sale Certificate Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom Date of Issue: 04-July-2023 Validity: 26-May-2025	VITROS Immunodiagnostic Product, Anti-HBe Reagent, Calibrator & HBe Control Cal: 1523984 Rgt: 8864860 Cont: 6800837 Shelf life: Reagent: 52 weeks Calibrator: 52 weeks Control: 52 weeks Storage Conditions: Reagent: 2-8°C Calibrator: 2-8°C Control: +25°C Class: D	The Board decided to call both M/s Martin Dow Speciality and M/s Sieco Scientific Traders, for personal hearing with the direction to present following documents before the Board; i. Valid, notarized Letter of Authorization issued by the legal manufacturer abroad. ii. Notarized Termination letter issued by the legal manufacturer, if any.

			Fees: 50,000/-	
3.	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 Initial Submission: 02-Dec-2022 Final Submission: 27-Sept-2023	Legal Manufacturer: Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom embassy attested Free Sale Certificate Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom Date of Issue: 04-July-2023 Validity: 26-May-2025	VITROS Immunodiagnostic Product HIV Combo Reagent & Calibrator Cal: 6842780 Rgt: 6842779 Shelf life: Reagent: 52 weeks Calibrator: 52 weeks Storage Conditions: 2-8°C Class: D Fees: 50,000/-	The Board decided to call both M/s Martin Dow Speciality and M/s Sieco Scientific Traders, for personal hearing with the direction to present following documents before the Board; i. Valid, notarized Letter of Authorization issued by the legal manufacturer abroad. ii. Notarized Termination letter issued by the legal manufacturer, if any.
4.	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 Initial Submission: 02-Dec-2022 Final Submission: 27-Sept-2023	Legal Manufacturer: Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom embassy attested Free Sale Certificate Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom Date of Issue: 04-July-2023 Validity: 26-May-2025	VITROS Immunodiagnostic Product AFP Reagent & Calibrator: Cal: 1515154 Rgt: 1925551 Shelf Life: Reagent: 52 weeks Calibrator: 52 weeks Storage Conditions: 2-8°C Class: C Fees: 50,000/- Date of submission 27-Sept-23	The Board decided to call both M/s Martin Dow Speciality and M/s Sieco Scientific Traders, for personal hearing with the direction to present following documents before the Board; i. Valid, notarized Letter of Authorization issued by the legal manufacturer abroad. ii. Notarized Termination letter issued by the legal manufacturer, if any.
5.	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	Legal Manufacturer: Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom	VITROS Immunodiagnostic Product CA 15-3 Reagent & Calibrator: Cal: 6800033 Rgt: 6800039 Shelf Life: Reagent: 12 months Calibrator: 12 months	The Board decided to call both M/s Martin Dow Specialty and M/s Sieco Scientific Traders, for personal hearing with the direction to present following documents before the Board; i. Valid, notarized Letter of Authorization issued by the legal manufacturer abroad.

	Initial Submission: 02-Dec-2022 Final Submission: 27-Sept-2023	embassy attested Free Sale Certificate Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom Date of Issue: 04-July-2023 Validity: 26-May-2025	Storage Conditions: 2-8°C Class: C Fees: 50,000/-	ii. Notarized Termination letter issued by the legal manufacturer, if any.
6.	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 Initial Submission: 02-Dec-2022 Final Submission: 27-Sept-2023	Legal Manufacturer: Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom embassy attested Free Sale Certificate Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom Date of Issue: 04-July-2023 Validity: 26-May-2025	VITROS Immunodiagnostic Product CA 125II Reagent & Calibrator: Cal: 6800034 Rgt: 6800038 Shelf Life: Reagent: 32 weeks Calibrator:32 weeks Storage Conditions: 2-8°C Class: C Fees: 50,000/-	The Board decided to call both M/s Martin Dow Specialty and M/s Sieco Scientific Traders, for personal hearing with the direction to present following documents before the Board; i. Valid, notarized Letter of Authorization issued by the legal manufacturer abroad. ii. Notarized Termination letter issued by the legal manufacturer, if any.
7.	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 Initial Submission: 02-Dec-2022 Final Submission: 27-Sept-2023	Legal Manufacturer: Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom embassy attested Free Sale Certificate Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom Date of Issue: 04-July-2023 Validity: 26-May-2025	VITROS Immunodiagnostic Product CA 19-9 Reagent & Calibrator: Cal: 6800035 Rgt: 6800040 Shelf Life: Reagent: 09 months Calibrator:09 months Storage Conditions: 2-8°C Class: C Fees: 50,000/-	The Board decided to call both M/s Martin Dow Specialty and M/s Sieco Scientific Traders, for personal hearing with the direction to present following documents before the Board; i. Valid, notarized Letter of Authorization issued by the legal manufacturer abroad. ii. Notarized Termination letter issued by the legal manufacturer, if any. M/s Martin Dow Specialty will submit undertaking on stamp paper.

8.	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 Initial Submission: 02-Dec-2022 Final Submission: 27-Sept-2023	Legal Manufacturer: Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom embassy attested Free Sale Certificate Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom Date of Issue: 04-July-2023 Validity: 26-May-2025	VITROS Immunodiagnostic Product CEA Reagent & Calibrator: Cal: 1062306 Rgt: 1920115 Shelf Life: Reagent: 32 weeks (+4 weeks post expiry) Calibrator:32 weeks (+4 weeks post expiry) Storage Conditions: 2-8°C Class: C Fees: 50,000/-	The Board decided to call both M/s Martin Dow Specialty and M/s Sieco Scientific Traders, for personal hearing with the direction to present following documents before the Board; i. Valid, notarized Letter of Authorization issued by the legal manufacturer abroad. ii. Notarized Termination letter issued by the legal manufacturer, if any. Martin Dow Specialty will provide undertaking of the stamp paper as required in Form7A. The MDB under the MDR 2017 will consider the shelf life as per stability studies provided i.e 32 weeks only.
9.	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 Initial Submission: 02-Dec-2022 Final Submission: 27-Sept-2023	Legal Manufacturer: Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom embassy attested Free Sale Certificate Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom Date of Issue: 04-July-2023 Validity: 26-May-2025	VITROS Immunodiagnostic Product HBeAg Reagent & Calibrator: Cal: 1914498 Rgt: 8211880 Shelf Life: Reagent: 52 weeks Calibrator:52 weeks Storage Conditions: 2-8°C Class: D Fees: 50,000/-	The Board decided to call both M/s Martin Dow Specialty and M/s Sieco Scientific Traders, for personal hearing with the direction to present following documents before the Board; i. Valid, notarized Letter of Authorization issued by the legal manufacturer abroad. ii. Notarized Termination letter issued by the legal manufacturer, if any. Martin Dow Specialty will provide undertaking of the stamp paper as required in Form7A.
10.	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 Initial Submission:	Legal Manufacturer: Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom embassy attested Free	VITROS Immunodiagnostic Product HBsAg ES Reagent, Calibrator & HBsAg Control : Vitros Immunodiagnostic Product HBsAg ES Reagent and Calibrator.	The Board decided to call both M/s Martin Dow Specialty and M/s Sieco Scientific Traders, for personal hearing with the direction to present following documents before the Board; i. Valid, notarized Letter of Authorization issued by the legal manufacturer abroad. ii. Notarized Termination letter issued by the legal

	02-Dec-2022 Final Submission: 27-Sept-2023	Sale Certificate Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom Date of Issue: 04-July-2023 Validity: 26-May-2025	Cal: 6802132 Rgt: 6802131 Cont: 6800598 Shelf Life: Reagent: 56 weeks 52 weeks Calibrator: 56 weeks 52 weeks Control: 56 weeks 52 weeks Storage Conditions: 2-8°C Class: D Fees: 50,000/-	manufacturer, if any. Martin Dow Specialty will provide undertaking of the stamp paper as required in Form7A.
11.	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 Initial Submission: 02-Dec-2022 Final Submission: 27-Sept-2023	Legal Manufacturer: Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom embassy attested Free Sale Certificate Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom Date of Issue: 04-July-2023 Validity: 26-May-2025	VITROS Immunodiagnostic Product hs Troponin-I Reagent & Calibrator: Cal: 6844437 Rgt: 6844436 Shelf Life: Reagent: 52 weeks Calibrator: 60 weeks Storage Conditions: 2-8°C Class: C Fees: 50,000/-	The Board decided to call both M/s Martin Dow Specialty and M/s Sieco Scientific Traders, for personal hearing with the direction to present following documents before the Board; i. Valid, notarized Letter of Authorization issued by the legal manufacturer abroad. ii. Notarized Termination letter issued by the legal manufacturer, if any.
12.	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 Initial Submission: 02-Dec-2022	Legal Manufacturer: Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom embassy attested Free	VITROS Immunodiagnostic Product FSH Reagent & Calibrator: Cal: 1901263 Rgt: 1931922 Shelf Life: Reagent: 52 weeks 36 weeks Calibrator: 52 weeks 36 weeks	The Board decided to call both M/s Martin Dow Specialty and M/s Sieco Scientific Traders, for personal hearing with the direction to present following documents before the Board; i. Valid, notarized Letter of Authorization issued by the legal manufacturer abroad. ii. Notarized Termination letter issued by the legal

	Final Submission: 27-Sept-2023	Sale Certificate Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom Date of Issue: 04-July-2023 Validity: 26-May-2025	Storage Conditions: 2-8°C Class: C Fees: 50,000/-	manufacturer, if any.
13.	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 Initial Submission: 02-Dec-2022 Final Submission: 27-Sept-2023	Legal Manufacturer: Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom embassy attested Free Sale Certificate Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom Date of Issue: 04-July-2023 Validity: 26-May-2025	VITROS Immunodiagnostic Product LH Reagent & Calibrator: Cal: 1090133 Rgt: 1350198 Shelf Life: Reagent: 52 weeks Calibrator: 52 weeks Storage Conditions: 2-8°C Class: C Fees: 50,000/-	The Board decided to call both M/s Martin Dow Specialty and M/s Sieco Scientific Traders, for personal hearing with the direction to present following documents before the Board; i. Valid, notarized Letter of Authorization issued by the legal manufacturer abroad. ii. Notarized Termination letter issued by the legal manufacturer, if any.
14.	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 Initial Submission: 02-Dec-2022 Final Submission: 27-Sept-2023	Legal Manufacturer: Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom Embassy attested Free Sale Certificate Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom Date of Issue: 04-July-2023 Validity: 26-May-2025	VITROS Immunodiagnostic Product Progesterone Reagent & Calibrator: Cal: 8254898 Rgt: 1938570 Shelf Life: Reagent: 52 weeks 30 weeks Calibrator: 52 weeks 30 weeks Storage Conditions: 2-8°C Class: C Fees: 50,000/-	The Board decided to call both M/s Martin Dow Specialty and M/s Sieco Scientific Traders, for personal hearing with the direction to present following documents before the Board; i. Valid, notarized Letter of Authorization issued by the legal manufacturer abroad. ii. Notarized Termination letter issued by the legal manufacturer, if any.
15.	Martin Dow Specialties (Pvt) Limited 7th Floor,	Legal Manufacturer: Ortho Clinical Diagnostics ,100 Indigo Creek Drive	VITROS Immunodiagnostic Product Testosterone	The Board decided to call both M/s Martin Dow Specialty and M/s Sieco Scientific Traders,

	Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Initial Submission: 02-Dec-2022 Final Submission: 27-Sept-2023	Rochester, NY, 14626 USA Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom Embassy attested Free Sale Certificate Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom Date of Issue: 04-July-2023 Validity: 26-May-2025	Reagent & Calibrator: Cal: 1306026 Rgt: 1435205 Shelf Life: Reagent: 30 weeks Calibrator:30 weeks Storage Conditions: 2-8°C Class: C Fees: 50,000/-	for personal hearing with the direction to present following documents before the Board; i. Valid, notarized Letter of Authorization issued by the legal manufacturer abroad. ii. Notarized Termination letter issued by the legal manufacturer, if any.
16.	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 Initial Submission: 02-Dec-2022 Final Submission: 27-Sept-2023	Legal Manufacturer: Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom Embassy attested Free Sale Certificate Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom Date of Issue: 04-July-2023 Validity: 26-May-2025	VITROS Immunodiagnostic Product Prolactin Reagent & Calibrator: Cal: 1113596 Rgt: 1849793 Shelf Life: Reagent: 52 weeks Calibrator:52 weeks Storage Conditions: 2-8°C Class: C Fees: 50,000/-	The Board decided to call both M/s Martin Dow Specialty and M/s Sieco Scientific Traders, for personal hearing with the direction to present following documents before the Board; i. Valid, notarized Letter of Authorization issued by the legal manufacturer abroad. ii. Notarized Termination letter issued by the legal manufacturer, if any.

Decision of 124 Meeting of the Board

The Board, after detailed deliberation, noted that M/s Sieco Scientific Traders has not been conducting business with the manufacturer Ortho Clinical Diagnostics since 2023 due to termination of the LOA, which constitutes a violation of Rule 19(3), (6), (15) and Rule 48 of the Medical Devices Rules, 2017, requiring that each medical device be made available in sufficient quantity to ensure its regular and adequate supply in the market. The Board observed that disruption in supply of these products may potentially impact public health.

In view of the foregoing, the Board decided as follows:

1. To initiate the de-registration process of the medical devices registered in the name of M/s Sieco Scientific Traders.

2. Upon completion of the de-registration process, the same devices may be registered in the name of M/s Martin Dow Specialty (Pvt.) Ltd., in accordance with the applicable provisions of the Medical Devices Rules, 2017.

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