



No.F.4-6/2024-MD (M-69)  
Government of Pakistan  
Ministry of National Health Services, Regulations & Coordination  
Drug Regulatory Authority of Pakistan  
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Islamabad the 4<sup>th</sup> September, 2024

Subject: **DEFERRED CASES OF ENLISTMENT/REGISTRATION OF MEDICAL DEVICES TO LOCAL MANUFACTURE – SUBMISSION OF DEFICIENT INFORMATION/ DOCUMENTS THEREOF**

The applications of following applicants were considered by Medical Device Board (MDB) in its 69<sup>th</sup> meeting held on 26<sup>th</sup> & 27<sup>th</sup> June, 2024 and Board deferred these applications being deficient of the information/documents as specified in last column (IV) of the Table below: -


Sr. No.	Name & Address of Establishment	Name of Medical Devices with Size	Decision
1.	M/s Unisa Pvt. Ltd. Main GT Road\, Adamzai Akora Khattak, Nowshera KPK Pakistan (ELM-0002)  Approved Section: Disposable syringes I.V Sets	UnigriSet Irrigation Set  CLASS: B SHELF LIFE: 5 YEARS	<b>Deferred</b> for verification of manufacturing and testing facility.
2.	M/sUnisa Pvt. Ltd. Main GT Road\, Adamzai Akora Khattak, Nowshera KPK Pakistan (ELM-0002)  [286-7L] Approved Section: Disposable syringes I.V Sets	UNIFLY Siliconized Needle (18 Gauge to 27 Gauge) with Butterfly Wings with Tube Length Ranges from 200mm to 350mm with Leur lock Sterile Single Pack  CLASS: B SHELF LIFE: 5 YEARS	<b>Deferred</b> for verification of manufacturing and testing facility
3.	M/s Unisa Pvt. Ltd. Main GT Road\, Adamzai Akora Khattak, Nowshera KPK Pakistan (ELM-0002)  [287-7L] Approved Section: Disposable syringes I.V Sets	UNIRET 100ml Burette Infusion Set  CLASS: B SHELF LIFE: 5 YEARS	<b>Deferred</b> for verification of manufacturing and testing facility
4.	M/s 5G Healthcare (PVT) Ltd, F-35, SITE II, Scheme 33, Main Superhighway, Karachi [ELM-0072 ]  [396-7L]  Approved Section: Syringes Section (AD 2cc 3cc 5cc & Disposable 1cc 10cc 20cc 30cc 50cc & 60cc) IV Cannula (Pen; Wing with Heparin Cap & Port Types of all sizes)	5G D-Set with Burette Infusion Set with Graduated Burette  Class: B Shelf-life: 5 Years  Sizes: 100ML, 150ML	<b>Deferred</b> for confirmation that whether the applied product could be manufactured in the already approved section/ premises of the 5G Healthcare (PVT) Ltd.  For this purpose, the Board nominated Mr. Saadat Ali Khan Deputy Director MDMC & Dr. Asfandiyar Ajab Khan, Assistant Director, DRAP, Karachi for verification of the above

	IV Set & Tubing section including Feeding Tubes Stomach Tubes Nelaton Tubes Suction Catheters/ Tubes		
5.	M/s Arsons Pharmaceutical Industries Pvt Ltd 2.5 km Defence Road, off Multan Road Lahore [ELM No. 0051]  <b>Approved Section:</b> Adhesive Plaster/ Tape Section Medicated Plaster Bandage Section First Aid Bandage Section Care Gauze Bandage Section ArsoTulle/ArsoTin Section (Sterile) Medi-Swab Section Crepe Bandage	MB-Tulle (Chlorhexidine Acetate B.P.....0.5%)  Class-D  Shelf-life: 3 years Sizes: 10cm x 10cm 15cm x 20cm 15cm x 1.50m	<b>Deferred</b> for confirmation of sterilization facility.
6.	M/s Arsons Pharmaceutical Industries Pvt Ltd 2.5 km Defence Road, off Multan Road Lahore [ELM No. 0051]  <b>Approved Section:</b> Adhesive Plaster/ Tape Section Medicated Plaster Bandage Section First Aid Bandage Section Care Gauze Bandage Section ArsoTulle/ArsoTin Section (Sterile) Medi-Swab Section Crepe Bandage	Sofray Tulle (Export Purpose) Framycetin Sulphate....1% B.P....1% Class-D  Shelf-life: 3 years Sizes: 10cm x 10cm 15cm x 20cm 15cm x 1.50m	<b>Deferred</b> for confirmation of sterilization facility.
7.	M/s Arsons Pharmaceutical Industries Pvt Ltd 2.5 km Defence Road, off Multan Road Lahore [ELM No. 0051]  <b>Approved Section:</b> Adhesive Plaster/ Tape Section Medicated Plaster Bandage Section First Aid Bandage Section Care Gauze Bandage Section ArsoTulle/ArsoTin Section (Sterile) Medi-Swab Section Crepe Bandage	Arso-Tulle (Chlorhexidine Acetate B.P....0.5%) Sterile Gauze Tulle Dressing  Class-D Form-7 See rule 14(2) (b),16(1) and 17(2)  Shelf-life: 3 years Sizes: 10cm x 10cm 15cm x 20cm 15cm x 1.50m	<b>Deferred</b> for confirmation of sterilization facility.
8.	M/s Arsons Pharmaceutical Industries Pvt Ltd 2.5 km Defence Road, off Multan Road Lahore [ELM No. 0051]  <b>Approved Section:</b> Adhesive Plaster/ Tape Section Medicated Plaster Bandage Section First Aid Bandage Section Care Gauze Bandage Section ArsoTulle/ArsoTin Section (Sterile) Medi-Swab Section Crepe Bandage	ArsoTin (Sofra-Tulle) Framycetin Sulphate B.P....1% Class-D  Shelf-life: 3 years Sizes: 10cm x 10cm 15cm x 20cm 15cm x 1.50m	<b>Deferred</b> for confirmation of sterilization facility.

*Shiraz D. on 9/24.*

9.	<p>M/s Arsons Pharmaceutical Industries Pvt Ltd 2.5 km Defence Road, off Multan Road Lahore [ELM No. 0051]</p> <p>Approved Section:          Adhesive Plaster/ Tape Section          Medicated Plaster Bandage Section          First Aid Bandage Section          Care Gauze Bandage Section          Arsolulle/Arsotin Section (Sterile)          Medi-Swab Section          Crepe Bandage</p>	<p>Belladerma Fast Plaster (Diclofenac Diethylamine....2%)          Class-B          5 years          Sizes:          12cm x 14.5cm          12cm x 15.5cm          12cm x 16.5cm          Pack Size          24 Plasters, (Patch)          20 Plasters</p>	<p><b>Deferred</b> the case for the following:</p> <p>i. Submission of evidence any reference product approved as medical Device in any reference regulatory authority.</p> <p>ii. Clarification regarding the brand name which contains the word "Belladerma" which is similar to <b>Belladonna plaster</b> while the product is not Bella dona.</p> <p>ii. Comments from PE&amp;R division regarding the product classification as drug or Medical Device if the product containing pharmaceutical drug in a plaster/patch form &amp; the active ingredient (Pharmaceutical drug) acts pharmacologically after absorption &amp; the plaster/patch acts only as delivery system.</p>
10.	<p>M/s Hafiz Pharma Industry          Address: 44-KM, G.T Road, Kamoke, District Gujranwala.    <b>ELM-0012</b></p>	<p>Surgeon Gauze Swabs / Sponges X-Ray Detectable Thread BP Light-13          Gauze Swabs / Sponges X-Ray Detectable Thread BP Light-13            Class: Class B          Shelf-life: 3-Years            Sizes:          5cm x 5cm, 7.5cm x 7.5cm, 10cm x 10cm, 15cm x 15cm and 10cm X 25cm in 4-Ply, 8-Ply, 12-Ply, 15-Ply, 16)</p>	<p><b>Deferred</b> for confirmation of sterilization facility.</p>

2. It is requested to furnish the requisite information/documents within 30 days after uploading of this letter on official website of DRAP.

  
 (AYYAZ AHMAD) 04/9  
 Additional Director (MDMC)/  
 Secretary MDB