



No.F.4-4/2024-MD (M-68)
Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
Drug Regulatory Authority of Pakistan

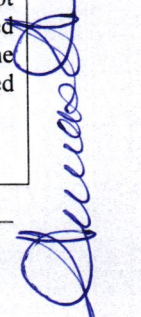
Islamabad the 7th June, 2024

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 68th meeting held on 8th May, 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 Faisal Pharmaceutical Industries,602 -B ,SIE,Sargodha Road, Faisalabad [ELM No -0019]	Actisil+ Nano silver film dressing Class: D Shelf-life: 3 Years Sizes: <ul style="list-style-type: none">• 10cm x 10cm film dressing with 20ml loading• 10cm x 20cm film dressing with 40ml loading• 15cm x 30cm film dressing with 60ml loading• 15cm x 1m film dressing with 100ml loading• 15cm x 1.5m film dressing with 120ml loading• 15cm x 2m film dressing with 150ml loading Fee Challan No. Paid Challan receipt not found in record.	Deferred for provision of evidence of fee submission.
2.	NISA.SF Private Limited. 10-Km,Muridke, Sheikhpura Road,Muridke,Distt. Sheikhpura ELM-0001	BM Disposable Heparin Cap Heparin Cap Class: B Shelf-life: 5Years Sizes: Connector: Male Luer Lock Connector Color: Yellow and transparent Length: 18mm 19.32mm 22mm Fee of 20,000 vide Challan No. 07486207625	Deferred for confirmation of manufacturing facility. The panel already constituted for renewal is mandated to verify the facility.
3.	NISA.SF Private Limited. 10-Km,Muridke, Sheikhpura	BM 100 Unit Disposable Insulin Syringe Disposable insulin syringe Class: B Shelf-life: 5Years	Deferred for confirmation of manufacturing facility. The panel already constituted for renewal is mandated to verify

	Road, Muridke, Distt. Sheikhupura ELM-0001	Sizes: 100 unit syringe Needle sizes: 29G x 5/16" (0.33mm x 8mm) 30G x 5/16" (0.30mm x 8mm) 31G x 5/16" (0.25mm x 8mm) 32G x 5/16" (0.23mm x 8mm) Fee of 20,000 vide Challan No. 38422505497	the facility.
4.	NISA.SF Private Limited. 10-Km, Muridke, Sheikhupura Road, Muridke, Distt. Sheikhupura ELM-0001	Dosiflow Plus Disposable flow regulator Extension Line Class: B Shelf-life: 3 Years Sizes: 30 cm Types: 1. Dosiflow Plus (with Y-port injection site). 2. Dosiflow Plus (with Needle free valve, and side clamp). 3. Dosiflow Plus (with Needle free Valve, side Clamp, and precision filter) Fee of 20,000 vide Challan No. 48643085	Deferred for confirmation of manufacturing facility. The panel already constituted for renewal is mandated to verify the facility.
5.	NISA.SF Private Limited. 10-Km, Muridke, Sheikhupura Road, Muridke, Distt. Sheikhupura ELM-0001	HP Disposable Stopcock with Extension Tube Stopcock Extension Tube (1 Way, 2 Way, 3 Way & 4 Way) Class: B Shelf-life: 5 Years Length: 10cm, 15cm, 20cm 25cm, 50cm, 100cm Fee of 20,000 vide Challan No. 51757256	Deferred for confirmation of manufacturing facility. The panel already constituted for renewal is mandated to verify the facility.
6.	NISA.SF Private Limited. 10-Km, Muridke, Sheikhupura Road, Muridke, Distt. Sheikhupura ELM-0001	Super Stopper Disposable Stopcock with Extension Tube Stopcock Extension Tube Class: B Shelf-life: 5 Years Length: (1 Way, 2 Way, 3 Way & 4 Way) 10cm 15cm 20cm 25cm 50cm 100cm Fee of 20,000 vide Challan No. 11296827	Deferred for confirmation of manufacturing facility. The panel already constituted for renewal is mandated to verify the facility.
7.	3N Lifemed Pharmaceuticals, 45-S.B, Abdullah Colony, Sargodha (ELM-0026) [337-7L]	Lifemed Blood Tubing Set for Hemodialysis (3NLHBTS) Blood Tubing Set for Hemodialysis CLASS: C SHELF LIFE: 3 YEARS FEE: 20000	Deferred as the firm does not possess the required approved facility/section for the manufacturing of applied product.

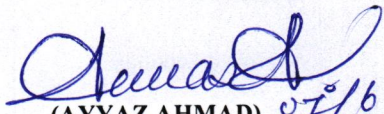
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	<p>Approved Sections:</p> <p>1. Dialysis Solutions</p> <p>2. Dry Powders (Sachet)</p>	<p>SLIP NO. 92164332171</p>	
8.	<p>3N Lifemed Pharmaceuticals, 45-S.B, Abdullah Colony, Sargodha (ELM-0026) [338-7L]</p> <p>Approved Sections:</p> <p>1. Dialysis Solutions</p> <p>2. Dry Powders (Sachet)</p>	<p>Lifemed TUR Bladder Irrigation Set (3NLTUR) TUR Bladder Irrigation Set</p> <p>CLASS: C SHELF LIFE: 3 YEARS FEE: 20000 SLIP NO. 65836787146</p>	<p>Deferred as the firm does not possess the required approved facility/section for the manufacturing of applied product.</p>
9.	<p>3N Lifemed Pharmaceuticals, 45-S.B, Abdullah Colony, Sargodha (ELM-0026) [339-7L]</p> <p>Approved Sections:</p> <p>1. Dialysis Solutions</p> <p>2. Dry Powders (Sachet)</p>	<p>Lifemed Disposable Nelton Tube Set (3NLNT) Disposable Nelton Tube Set</p> <p>CLASS: C SHELF LIFE: 5 YEARS FEE: 20000 SLIP NO. 03736212</p>	<p>Deferred as the firm does not possess the required approved facility/section for the manufacturing of applied product.</p>
10.	<p>3N Lifemed Pharmaceuticals, 45-S.B, Abdullah Colony, Sargodha (ELM-0026) [340-7L]</p> <p>Approved Sections:</p> <p>1. Dialysis Solutions</p> <p>2. Dry Powders (Sachet)</p>	<p>Lifemed Disposable Infusion Set (3NLDIS) Disposable Infusion Set</p> <p>CLASS: C SHELF LIFE: 3 YEARS FEE: 20000 SLIP NO. 890121403</p>	<p>Deferred as the firm does not possess the required approved facility/section for the manufacturing of applied product.</p>
11.	<p>3N Lifemed Pharmaceuticals, 45-S.B, Abdullah Colony, Sargodha (ELM-0026) [341-7L]</p> <p>Approved Sections:</p> <p>1. Dialysis Solutions</p> <p>2. Dry Powders (Sachet)</p>	<p>Lifemed Disposable Symmetrical Straps for ETT (3NLDSS) Disposable Symmetrical Straps for ETT</p> <p>CLASS: C SHELF LIFE: 5 YEARS FEE: 20000 SLIP NO. 14938370531</p>	<p>Deferred as the firm does not possess the required approved facility/section for the manufacturing of applied product.</p>
12.	<p>3N Lifemed Pharmaceuticals, 45-S.B, Abdullah Colony, Sargodha (ELM-0026) [342-7L]</p>	<p>Lifemed Redovac Set (3NLR) Redovac Set</p> <p>CLASS: C SHELF LIFE: 5 YEARS FEE: 20000 SLIP NO. 4167976499</p>	<p>Deferred as the firm does not possess the required approved facility/section for the manufacturing of applied product.</p>

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	<p>Approved Sections:</p> <p>1. Dialysis Solutions 2. Dry Powders (Sachet)</p>		
13.	<p>3N Lifemed Pharmaceuticals, 45-S.B, Abdullah Colony, Sargodha (ELM-0026) [343-7L]</p> <p>Approved Sections:</p> <p>1. Dialysis Solutions 2. Dry Powders (Sachet)</p>	<p>Lifemed Disposable NG Tube Set (3NLNG) Disposable NG Tube Set</p> <p>CLASS: C SHELF LIFE: 5 YEARS FEE: 20000 SLIP NO. 9981300132</p>	<p>Deferred as the firm does not possess the required approved facility/section for the manufacturing of applied product.</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) 07/16
 Additional Director (MDMC) / 24
 Secretary MDB



No.F.4-4/2024-MD (M-68)
Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
Drug Regulatory Authority of Pakistan

Islamabad the 7th June, 2024

Subject:- **DEFERRED CASES OF ENLISTMENT/REGISTRATION OF MEDICAL DEVICES TO IMPORT – SUBMISSION OF DEFICIENT INFORMATION/DOCUMENTS THEREOF.**

The applications of following applicants were considered by Medical Device Board (MDB) in its 68th meeting held on 8th May, 2024 and Board deferred these applications being deficient of the information/documents as specified in last column (V) of the Table below:-

S#	Name of Importer	Name of Manufacturer	Name of Medical Devices	Decision
(I)	(II)	(III)	(IV)	(V)
1.	Mediland Pakistan Pvt, Office No. b-09, 2nd Floor Masood Arcade IJP Road near Saidpur Road, Rawalpindi.	Getinge IC Production Poland Sp. Z.o.o ul. Szkolna 30, 62-064 Plewiska, Polska	HS33 Steam Sterilizer	Deferred for the provision of updated agency agreement (LOA).
2.	Medical Equipment & System, 60/61 F.C.C Syed Maratib Ali Road Gulberg IV, Lahore	M/s ZOLL Circulation, Inc. 2000 Ringwood Ave San Jose, CA USA 95131.	Thermogard HQ (Intravascular temperature Management System)	Deferred for the submission of following: - <ul style="list-style-type: none">• Manufacturing and QC tests details.• Stability studies for the claimed shelf life.• MRP of the device.
3.	Medical Equipment & System, 60/61 F.C.C Syed Maratib Ali Road Gulberg IV, Lahore	M/s ZOLL Circulation, Inc. 2000 Ringwood Ave San Jose, CA USA 95131.	Quattro Catheter Kit (Intravascular Heat exchange Catheter)	Deferred for the submission of following: - <ul style="list-style-type: none">• Manufacturing and QC tests details.• Stability studies for the claimed shelf life.• MRP of the device.
4.	Medical Equipment & System, 60/61 F.C.C Syed Maratib Ali Road Gulberg IV, Lahore	M/s ZOLL Circulation, Inc. 2000 Ringwood Ave San Jose, CA USA 95131.	ICY Catheter Kit (Intravascular Heat exchange Catheter)	Deferred for the submission of following: - <ul style="list-style-type: none">• Manufacturing and QC tests details.• Stability studies for the claimed shelf life.• MRP of the device.
5.	Medical Equipment & System, 60/61 F.C.C Syed Maratib Ali Road Gulberg IV, Lahore	M/s ZOLL Circulation, Inc. 2000 Ringwood Ave San Jose, CA USA 95131.	Thermoguard HP (Intravascular temperature Management System)	Deferred for the submission of following: - <ul style="list-style-type: none">• Manufacturing and QC tests details.• Stability studies for the claimed shelf life.• MRP of the device.

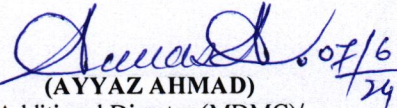
6.	Medical Equipment & System, 60/61 F.C.C Syed Maratib Ali Road Gulberg IV, Lahore	M/s ZOLL Circulation, Inc. 2000 Ringwood Ave San Jose, CA USA 95131.	Solex 7 Catheter Kit (Intravascular Heat exchange Catheter)	Deferred for the submission of following: - <ul style="list-style-type: none"> • Manufacturing and QC tests details. • Stability studies for the claimed shelf life. • MRP of the device.
7.	Novatek Pakistan, P-20, 1st Floor, Chenab Market, Susan Road, Madina Town, Faisalabad.	M/s Metronic Medicale S.r.l, Via Orio al Serio 15, 24050 Grassobbio Bergamo, Italy	Metronic Medicale S.r.l (CHELT)	Deferred for the submission of following: - <ul style="list-style-type: none"> • Updated and notarized ISO 13485 certificate. • Differential fee of Rs. 25000/- since the device falls in Class-C.
8.	M/s Uniplan Trade International Pvt Ltd, 132/1 Quaid-e-Azam Industrial Estate, Kot Lakhpt Lahore.	Legal Manufacturer M/s. Fresenius Kabi AG, 61346, Bad Homburg Germany. Manufacturing Sites: M/s Fresenius Kabi (Guangzhou) Co., Ltd., No.43 Baoying Street, Free Trade Zone, 510730 Guangzhou, China.	Compoflex® 1F 63ml CPDA-1 PDS-V	Deferred since the product is already registered for M/s Fresenius Kabi Pakistan (Pvt) Ltd., Lahore. The Board decided to call both the firms for personal hearing for the confirmation of valid letter of authorization.
9.	M/s Uniplan Trade International Pvt Ltd, 132/1 Quaid-e-Azam Industrial Estate, Kot Lakhpt Lahore.	Legal Manufacturer M/s. Fresenius Kabi AG, 61346, Bad Homburg Germany. Manufacturing Sites: M/s Fresenius Kabi (Guangzhou) Co., Ltd., No.43 Baoying Street, Free Trade Zone, 510730 Guangzhou, China.	Compoflex® 2F 63ml CPDA-1 PDS-V	Deferred since the product is already registered for M/s Fresenius Kabi Pakistan (Pvt) Ltd., Lahore. The Board decided to call both the firms for personal hearing for the confirmation of valid letter of authorization.
10.	M/s Uniplan Trade International Pvt Ltd, 132/1 Quaid-e-Azam Industrial Estate, Kot Lakhpt Lahore.	Legal Manufacturer M/s. Fresenius Kabi AG, 61346, Bad Homburg Germany. Manufacturing Sites: M/s Fresenius Kabi (Guangzhou) Co., Ltd., No.43 Baoying Street, Free Trade Zone, 510730 Guangzhou, China.	Compoflex® 3F 63ml CPDA-1 PDS-V	Deferred since the product is already registered for M/s Fresenius Kabi Pakistan (Pvt) Ltd., Lahore. The Board decided to call both the firms for personal hearing for the confirmation of valid letter of authorization.

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11.	M/s Uniplan Trade International Pvt Ltd, 132/1 Quaid-e-Azam Industrial Estate, Kot Lakhpt Lahore.	<p>Legal Manufacturer M/s. Fresenius Kabi AG, 61346, Bad Homburg Germany.</p> <p>Manufacturing Sites: M/s Fresenius Kabi (Guangzhou) Co., Ltd., No.43 Baoying Street, Free Trade Zone, 510730 Guangzhou, China.</p>	CompoFlex® 4F 63ml CPDA-1 PDS-V	Deferred since the product is already registered for M/s Fresenius Kabi Pakistan (Pvt) Ltd., Lahore. The Board decided to call both the firms for personal hearing for the confirmation of valid letter of authorization.
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2. In the light of decision of MDB in its 37th meeting wherein Board decided that once the firm has submitted original, valid and notarized/Embassy attested documents at the time of submission of application for registration/enlistment and the same are expired during the processing of application, the firm shall only submit valid and original (where applicable) documents without notarization/Embassy attestation.

3. It is requested to furnish the requisite information/documents mentioned in last column against each within 30 days after uploading of this letter on official website of DRAP.


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