




No.F.4-4/2023-MD (M-56)
Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
Drug Regulatory Authority of Pakistan

Islamabad the 13th March, 2023

Subject:- **ENLISTMENT/REGISTRATION OF MEDICAL DEVICES FOR LOCAL MANUFACTURE – DEFERRED CASES (SUBMISSION OF DEFICIENT INFORMATION/DOCUMENTS THEREOF)**

The applications of following applicants were placed before Medical Device Board (MDB) in its 56th meeting held on 2nd March, 2023 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
I	II	III	IV
1.	M/s General Pharma, Farm Road, 3-KM,G.T. Road Manhes (KotliWagha), Kamoke, District Gujranwala. [ELM No-0038]	Brand Name: Hospitex Safracin Tulle BP Generic /Common Name: Framycetin Sulphate Gauze Dressing Class: C Shelf-life: 3 years Sizes: 5cm x 5cm (Single Sheet) 10cmx10cm (10 pcs pack) 15cmx20cm (10 pcs pack) 15cm x150cm(single roll) Fee Challan No.56916778 Rs.20,000/-	Deferred since as per inspection report the firm would out source sterilization from M/s PARAS which do not have establishment license(Form-3) . The firm applied the product in class-C while it falls in class-D under the MDR 2017.
2.	M/s General Pharma, Farm Road, 3-KM,G.T. Road Manhes (KotliWagha), Kamoke, District Gujranwala. [ELM No-0038]	BrandName: Hospitex Lap Sponges BP Generic/Common Name: Gauze (sterile) Class:C Shelf-life: 3 years Sizes: 22.5cmx22.5cm,4ply 30cmx30cm,4ply 45cmx45cm,4ply Fee Challan No.1934607 Rs.20,000/-	Deferred since as per inspection report the firm would outsource sterilization from M/s PARAS which do not have establishment license(Form-3) 

3.	M/s General Pharma, Farm Road, 3-KM,G.T. Road Manhes (KotliWagha), Kamoke, District Gujranwala. [ELM No-0038]	BrandName: Hospitex Pro Gauze Swab/Sponges USP- IV Generic /Common Name: Gauze Dressing Class: C Shelf-life: 3 years Sizes: 10cm x10cm (8ply,12ply,16ply) 15cmx15cm, (8ply,12ply,16ply) 5cmx5cm, (8ply,12ply,16ply) 7.5cmx7.5cm, (8ply,12ply,16ply) Fee Challan No.0371964898 Rs.20,000/-	Deferred since as per inspection report the firm would outsource sterilization from M/s PARAS which do not have establishment license(Form-3) The firm has to apply separately for sterile & non- sterile.
4.	M/s General Pharma, Farm Road, 3-KM,G.T. Road Manhes (KotliWagha), Kamoke, District Gujranwala. [ELM No-0038]	Brand Name: Hospitex Paraffin Wax Gauze BPC Generic /Common Name: Paraffin Gauze Dressing Class: C Shelf-life: 3 years Sizes: 10cm x10cm Fee Challan No.1934610 Rs.20000/-	Deferred since as per inspection report the firm would outsource sterilization from M/s PARAS which do not have establishment license(Form-3) The firm shall apply separately for sterile & non- sterile.
5.	M/s General Pharma, Farm Road, 3-KM,G.T. Road Manhes (KotliWagha), Kamoke, District Gujranwala. [ELM No-0038]	BrandName: Hospitex Absorbent Gauze BPC Generic /Common Name: Absorbent Gauze Dressing Class: C Shelf-life: 3 years Sizes: 100cmx2.5M,100cmx20M, 100cm x30M, 100cm x 40M Fee Challan No.1998679 Rs.20000/-	Deferred since as per inspection report the firm would out source sterilization from M/s PARAS which do not have establishment license(Form-3). The firm shall apply separately for sterile & non- sterile.
6.	M/s General Pharma, Head Office: Street No. 11, shesh Mehal Road, Kamoke . District Gujranwala. Pakistan	Hospitex X-ray Detectable abdominal Pad BP (Surgical Dressing) Class: B Shelf-life:	Deferred since as per inspection report the firm would out source sterlization from M/s PARAS which do not have establishment license(Form-3)

(ELM-0038)	02 Years	
	Sizes: Fee submitted Rs.20,000/-	

2. It is requested to furnish the requisite information/documents within 20 days after uploading of this letter on official website of DRAP.



(BABAR KHAN)
Additional Director (MDMC)/
Secretary MDB