

No.F.4-6/2022-MD (M-50)

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

Islamabad the 21st October, 2022.

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

The applications of following applicants were placed before Medical Device Board (MDB) in its 50th meeting held on 22nd September, 2022 Board deferred these applications being deficient of the information/documents as specified in 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 Paktex Industries, 2.5KM Tatlay Road, Sroyaabad, Kamoke. (ELM-0025) Evaluator AD-I	Pakband Ribbon Gauze BPC 1.25cm x 5m, 1.25cm x 90m, 2.5cm x 5m, 2.5cm x 90m, 1.25cm x 5m with xray detectable thread 1.25cm x 90m with xray detectable thread Class A Shelf Life: 05 Years Rs. 5000/- Codes & Sizes as applied.	Deferred for provision of differential fee of Rs.15,000/
2.	-do- Evaluator AD-I	Pakband Lint Gauze 25gram, 50gram, 75gram, 100gram, 125gram, 150gram, 175gram, 200gram, 250gram, 500gram Class A Shelf Life: 05 Years Rs. 5000/- Codes & Sizes as applied	Deferred for provision of differential fee of Rs.15,000/
3.	M/s Hafiz Pharma Industry, Neelam Cinema Road, Kamoke (ELM-0012) Evaluator AD-I	Surgeon Cotton Gauze Swabs BPC (non-sterile) 15cmx 15cm (8-Ply), 10cm x 10cm (8-ply), 7.5cm x 7.5cm (8-ply) Class A: Shelf Life: 03 Years Old Reg # 044535 Rs.5000/- Codes & Sizes as applied.	Deferred for provision of differential fee of Rs.15,000/
4.	-do- Evaluator AD-I	Surgeon Cotton Gauze Swabs/Sponges USP IV (non- sterile) 15cm x 15cm, 10cm x 10cm, 7.5cm x 7.5cm Class A Shelf Life: 02 Years Rs.5000/-	Deferred for provision of differential fee of Rs.15,000/

Letter of Deferred cases of MDB-50 Meeting (22-09-2022)

5. Evaluator AD-I	Surgeon Absorbent Gauze Roll BPC (non-sterile) 1 x 2.5m, 1 x 10m, 1 x 20m, 1 x 30m, 1 x 40m Class A Shelf Life: 02 Years Rs.5000/- Old Reg # 070084	Deferred for provision of shelf life studies and differential fee of Rs.15,000/
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 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 Tele: 051-9262180