



No.F.4-4/2022-MD (M-48)  
Government of Pakistan  
Ministry of National Health Services, Regulations & Coordination  
Drug Regulatory Authority of Pakistan  
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Islamabad the 14<sup>th</sup> July, 2022.

Subject:- **REGISTRATION OF MEDICAL DEVICES FOR LOCAL MANUFACTURE - SUBMISSION OF DEFICIENT INFORMATION/DOCUMENTS.**

The applications of following applicants were placed before the Medical Device Board (MDB) in its 48<sup>th</sup> meeting held on 31<sup>st</sup> May, 2022 and the same have been deferred being deficient of the information / documents as specified in column (5) of the Table below.

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

S.#	Name of Manufacturer	Name of Medical Devices.	Decision
1.	M/s General Pharma, Head Office: Street No. 11, shesh Mehal Road, Kamoke . District Gujranwala. Pakistan (ELM-0038) <b>Evaluator: AD-I</b>	Hospitex X-ray Detectable abdominal Pad BP (Surgical Dressing) Class B Shelf Life: 02 Years Codes & sizes as applied Fee submitted Rs.20,000/-	<b>Deferred.</b> PARAS does not have establishment license as sterilization process is outsourced.  Firm shall submit stability data for claimed shelf life.
2.	-do-	Hospitex Gauze Swabs/Sponges BPC Class A (while the product fall in Class C) Shelf life: 03 Years 5cm x 5cm (1x10) 7.5cm x 7.5cm (1x10) 10cm x 10cm (1x10) Fee submitted Rs.10,000/-	<b>Deferred.</b> PARAS does not have establishment license as sterilization process is outsourced.  Firm shall provide differential fee Rs.10,000/- as product of Class C, Stability data for claimed shelf life and MRP of medical devices.
3.	-do-	Hospitex Tulle (Surgical Dressing) Class C Shelf Life: 03 Years Codes & sizes as applied Fee submitted Rs.20,000/-	<b>Deferred.</b> PARAS does not have establishment license as sterilization process is outsourced.  Firm shall provide stability data for claimed shelf life.
4.	M/s Karim Industries, 1/2 Km, Lahore Raiwind Road, Onside Roohi, Nala Petrol Pump, Raiwind, District Lahore (ELM- 0014) <b>Evaluator: AD-I</b>	Soft Gauze Surgical Gauze Swab BPC Class A Shelf Life: 02 Years 10x10cm 10's Fee submitted Rs.5000/-	<b>Deferred.</b> PARAS does not have establishment license as sterilization process is outsourced.  Firm shall provide Form-A and differential fee of Rs.15,000/-
5.	M/s Kohinoor Industries, 160/B, Small Industries Estate, Sahiwal (ELM-0046) <b>Evaluator: AD-I</b>	Medi Gauze BP-13 Light Class B Shelf life: 03 Years Fee submitted Rs.20,000/-	<b>Deferred.</b> PARAS does not have establishment license as sterilization process is outsourced.  Firm shall provide stability data for claimed shelf life.

(Dr. Ghazanfar Ali Khan)  
Additional Director (MDMC)/  
Secretary MDB  
Tele: 051-9107402