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Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
Drug Regulatory Authority of Pakistan
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Islamabad, the 10th September, 2021

NOTIFICATION

F.No. 16-4/2019-MD.- In exercise of the powers conferred by the clause (c) of section 7 of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012) and in continuation of earlier notification No.F.16-4/2019-MD dated 29th July, 2021, the Drug Regulatory Authority of Pakistan, is pleased to issue the following guidelines for holders of Drug Manufacturing Licences to manufacture the medical devices under the provisions of the Medical Devices Rules, 2017 aforesaid rules, namely:-

CHAPTER 1

1. Manufacture of Schedule E medical devices and Dialysis Solutions

The DML holders will be allowed to manufacture Schedule E medical devices and Dialysis Solution in the same building as that of pharmaceutical products by following the below mentioned procedure:-

(a) Application of Building Layout Plan:

The applicant will apply to the Division of Licensing for the approval of building lay out. Triplicate copies with duly marked section of medical devices along with the HVAC drawings, personnel and material flow needs to be submitted along with prescribed fee. The building layout plan will be approved by the said Division as per its SOPs for the approval of building layouts.

(b) Application for the grant of Establishment License to Manufacture Medical Devices:

The applicant will apply to the Medical Devices & Medicated Cosmetics (MDMC) Division on FORM 1 along with all the annexures as per the checklist posted on the DRAP official website www.dra.gov.pk under the Division of Medical Devices including the approved building layout and the prescribed fee. The MDMC Division will proceed the application as per the approved SOPs for the grant of License to Manufacture Medical Devices (FORM 3)

(c) Application for the grant of Medical DeviceEnlistment/Registration:

The FORM 3 holder will apply to the MDMC Division on the FORM-6 or FORM-7 (as the case may be) along with all the annexures as per the checklist posted on the DRAP official website www.dra.gov.pk under the MDMC Division and the prescribed fee.

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Additional Director (MD&MC) Secretary MDB
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Government of Pakistan
Islamabad

CHAPTER 2

2. Manufacture of Medical Devices other than Schedule E and Dialysis Solutions

The DML holders intending to manufacture medical devices other than Schedule E and Dialysis Solution will be allowed to manufacture their said medical device on the same plotin separate building by following the below mentioned procedure:-

(a) Application of Building Layout Plan:

The applicant will apply to the MDMC Division for the approval of building lay out. Application shall be submitted on cover letter along with prescribed fee and Triplicate copies of duly marked facilities along with the HVAC drawings (where applicable), personnel and material flow. The building layout plan will be approved by the said Division as per its SOPs for the approval of building layout.

(b) Application for the grant of Establishment License to Manufacture Medical Devices:

The applicant will apply to the MDMC Division on FORM 1 along with all the annexures as per the checklist posted on the DRAP official website www.dra.gov.pk under the Division of MDMC including the approved building layout and the prescribed fee. The MDMC Division will proceed the application as per the approved SOPs for the grant of License to Manufacture Medical Devices (FORM 3)

(c) Application for the grant of Medical DeviceEnlistment/Registration:

The FORM 3 holder will apply to the MDMC Division on the FORM-6 or FORM-7 (as the case may be) along with all the annexures as per the checklist posted on the DRAP official website www.dra.gov.pk under the MDMC Division and the prescribed fee.

3. SITE VERIFICATION:

a) **The documents required to be submitted**

i. Application on cover letter
ii. Prescribed Fee
iii. Land ownership/lease document

b) **Pre-Requisites for site(s) to establish the manufacturing unit to manufacture medical devices**

Sr. #	Classification of Area for establishment of medical devices manufacturing unit:	Requirements of application
01.	Industrial Area.	Exempted from inspection of site verification
02.	Residential Area.	Not allowed for any production activity.
03.	Non-Classified Area. (other than area specified at Sr. # 01 & 02.)	The area will be inspected by the panel/nominated officer of DRAP for site verification

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