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**GOVERNMENT OF PAKISTAN**
**Ministry of National Health Services, Regulations and Coordination**
**(Drug Regulatory Authority of Pakistan)**
*****

Islamabad, the 22nd November, 2021.

**NOTIFICATION**

**S.R.O.**1500 **(I)/2021.**— In exercise of the powers conferred by section 23 of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012), the Drug Regulatory Authority of Pakistan, with approval of the Federal Government, is pleased to direct that the following amendments shall be made in the Medical Devices Rules, 2017, namely:—

In the aforesaid Rules,—

(a) in rule 6, in sub-rule (1).—

(i) for clause (c), the following shall be substituted, namely;-

"(c) the manufacturing shall be conducted under the active supervision of competent technical staff, who shall be in-charge of production, a whole-time employee of the manufacturer and having relevant qualification and experience as deemed appropriate by the MDB;"; and

(ii) for clause (e), the following shall be substituted, namely:-

"(e) the in-charge of quality control shall be a whole-time employee of the manufacturer and shall possess relevant qualification and experience as deemed appropriate by the MDB;"; and

(b) in rule 63, in sub-rule (3), expression after the words "omit any", the words "Form or" shall be inserted.

[No. F.10-1/2020-MD]

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