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

Islamabad, the 30th April, 2021.

NOTIFICATION

S.R.O. 526 **(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 make the following amendments in the Medical Devices Rules, 2017, namely:—

In the aforesaid Rules,—

(I) for rule 52, the following shall be substituted, namely;-

"52. Exemption from operation of the rules,— (1) The medical devices specified in column (2) of the Table below shall, in terms of section 36 of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012) and from commencement of these rules, be exempted from the operation of these rules for a period as specified in column (3) thereof, namely:-

TABLE

Sr.	Class of medical device	Exemption period
(1)	(2)	(3)
1	Class D medical devices	Till the 31st day of March, 2022
2	Class C medical devices	Till the 30th day of June, 2022
3	Class B medical devices	Till the 30th day of September, 2022
4	Class A medical devices	Till the 31st day of December, 2022

Provided that the exemptions shall be applicable only to the establishment license holders either as importer or local manufacturer under these rules:

Provided further that the imported consignments of the devices and raw materials of above mentioned licensed importers and manufacturers may be released by Pakistan Custom till the validity of exemption period after ensuring the submission of following documents, namely:-

(i) for clearance of class A medical device from Pakistan Customs, it is mandatory for importer to submit notarized ISO 13485 and notarized letter of authorization from manufacturer abroad along with any of the following document, namely:-

(a) notarized free sale certificate from country of origin; or

(b) notarized declaration of conformity from manufacturer abroad; or

(c) notarized production or full quality assurance certificate (CE-marking certificate) from conformity assessment body CAB);

(ii) for clearance of class B, C or D medical device from Pakistan Customs, it is mandatory for importer to submit notarized ISO 13485 and notarized letter of authorization from manufacturer abroad along with any of the following documents, namely:-

(a) notarized free sale certificate from country of origin along with declaration of conformity, full quality assurance certificate (CE-marking certificate) from CAB. However, for class D medical device, design examination certificate shall be mandatory; or

(b) notarized free sale certificate from any of the reference countries i.e., USA, Japan, Australia, Canada, Austria, Belgium, Denmark, France, Germany, Ireland, Italy, Netherlands, Norway, Spain, Sweden, Switzerland, United Kingdom; or

(c) notarized free sale certificate from country of origin along with WHO prequalification status; and

(iii) for clearance of raw materials for local manufacturing of medical device from Pakistan Customs, a valid establishment license to manufacture medical devices locally issued under these rules.

(2) The exemptions in sub-rule (1) shall not be applicable to the life-saving or life-sustaining medical devices specified in Schedule-D and Schedule-E."; and

(II) after Schedule-D, the following new Schedule shall be inserted, namely;-

"SCHEDULE E
[see rule 52]

LIST OF MEDICAL DEVICES WHICH WERE PREVIOUSLY DEFINED OR DECLARED AS DRUGS UNDER THE DRUGS ACT, 1976

1. Auto-disable and disposable syringe;
2. Cannula;
3. Disposable sets for collection or transfusion of blood or giving any infusion;
4. Catheter;
5. Butterfly needle;
6. Stent;
7. Abortive and contraceptive device;

8. Surgical ligature;
9. Suture;
10. Bandage; and
11. Absorbent cotton.".

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