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**Government of Pakistan**
**Ministry of National Health Services, Regulations and Coordination**
**(Drug Regulatory Authority of Pakistan)**
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# NOTIFICATION

Islamabad, the 27th February, 2023.

**S.R.O. 224(I)/2023.**— 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 the approval of the Federal Government, is pleased to direct that the following further amendments shall be made in the Medical Devices Rules, 2017, namely:-

In the aforesaid Rules, 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 enlistment and registration requirements under 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 December, 2023 |
| 2. | Class C medical devices | Till the 31st day of December, 2023 |
| 3. | Class B medical devices | Till the 31st day of December, 2024 |
| 4. | Class A medical device | Till the 31st day of December, 2024 |

Provided that these exemptions shall be applicable only to the establishment licence 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 customs till the validity of exemption period after ensuring the submission of following documents, namely:-

(i) for clearance of class A medical devices 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; 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 classes B, C or D medical devices 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 devices, design examination certificate shall also 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 devices from Pakistan customs, a valid establishment licence 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 Schedules D and E.".

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**AAMAR LATIF,**
*Additional Director (Legal Affairs).*

**The Manager,**
Printing Corporation of Pakistan Press,
Islamabad.