

I/1082894/2023

आयुक्त (सीमाशुल्क) आयात-II का कार्यालय
 OFFICE OF THE COMMISSIONER OF CUSTOMS (IMPORT - II)
 नवीन सीमाशुल्क भवन, वेलाड ईस्टेट, मुंबई- ४००००१
 New Customs House, Ballard Estate, Mumbai- 400 001

F. No. CUS/APR/MISC/2357/2023-GR.2B(CHEM-3) Date: 21-03-2023
 DIN No. 2023037700000000CC 29

PUBLIC NOTICE NO. 55/2023

**Sub.-:Import of Medical Devices as per the requirements of the
 Medical Devices Rules, 2017 - reg.**

The attention of the Importers, Customs Brokers, and all concerned is invited to Medical Device Rules, 2017 published vide G.S.R. 78(E) dated 31.01.2017 and letter F. No. 29/Misc/03/2022-DC (273) dated 03.01.2023 issued by the Central Drugs Standard Control Organization, New Delhi on the above subject.

2. The Central Drugs Standard Control Organization, New Delhi has vide the above-mentioned letter informed that the Ministry of Health & Family Welfare has published the Medical Device Rules, 2017 vide G.S.R. 78(E) dated 31.01.2017 which is already implemented from 01.01.2018. Further, in pursuance of sub-clause (iv) of clause (b) of Section 3 of the Drug and Cosmetics Act, 1940 (23 of 1940) the Central Government has published S.O. 648(E) dated 11.02.2020 defining medical devices in order to regulate their import etc (copy enclosed). Further, the Ministry of Health & Family Welfare has published G.S.R. 102(E) dated 11.02.2020 regarding the regulation of Medical Devices in a phased manner. As per the said Notification, all Class A and Class B medical devices and Class C and Class D Medical Devices would be covered under licensing regime w.e.f. 01.10.2022 and 01.10.2023 respectively. Surgical Gloves and Medical Examination Gloves fall under the definition of Medical Devices and are classified under Class B and Class A respectively.

3. In this regard, it is brought to the notice of all stakeholders that all the Bills of Entry containing Medical Devices including Surgical and Medical Examination Gloves can only be imported with the following mandatory compliance: -

A. CDSCO license w.e.f 01.04.2023 for Class A (Non-latex medical examination gloves and latex medical examination gloves) and Class B (Latex surgical gloves and Non-latex surgical gloves).

B. CDSCO license w.e.f. 01.10.2023 for Class C and Class D.

C. Compliance of Rule 7(1) of Medical Devices Rules, 2017 -

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(1) The medical device shall conform to the standards laid down by the Bureau of Indian Standards established under section 3 of the Bureau of Indian Standards Act, 1985 (63 of 1985) or as may be notified by the Ministry of Health and Family Welfare in the Central Government, from time to time.

(2) Where no relevant Standard of any medical device has been laid down under sub-rule (1), such device shall conform to the standard laid down by the International Organization for Standardization (ISO) or the International Electro-Technical Commission (IEC), or by any other pharmacopeia standards.

(3) In case of the standards which have not been specified under sub-rule (1) and sub-rule (2), the device shall conform to the validated manufacturer's standards.

D. Compliance with Rule 44 of MDR Rules 2017 before the clearance.

E. All the Bills of Entry containing Medical Devices including Surgical and Medical Examination Gloves are required to be referred to the concerned Assistant Drug Controller (I) Office at the port of import for ensuring compliance with the requirements before clearance of the medical devices under the Medical Device Rule, 2017.

4. Difficulty, if any may also be brought to the notice of the undersigned.
5. Action to be taken in terms of decisions taken in this Public Notice should be considered as a Standing Order for the purpose of officers and staff.

Signed by Meghana Moghe

Date: 21-03-2023 15:11:56

Reason: Approved

(Meghana Moghe),
Joint Commissioner of Customs,
Import-II, NCH, Mumbai.

Copy to: -

1. The Pr. Chief Commissioner of Customs, Mumbai Zone-I,
2. The Commissioner of Customs, Import I, NCH, Mumbai,
3. The Addl. Commissioner of Customs (Docks), Import-I, Mumbai,
4. The Dy. Commissioner of Customs (Docks), Import-I, Mumbai,
5. The Dy. Commissioner of Customs (EDI), Import-I, Mumbai,