CUS/APR/MISC/6089/2022-A/M(I)-O/o Commr-CUS-Nhava Sheva-I

/988206/2023

सीमा शुल्कप्रधान आयुक्त का कार्यालय(एन एस –I)
OFFICE OF THE PR. COMMISSIONER OF CUSTOMS (NS - I),
मूल्यनिरूपण मुख्य (आयात) APPRAISING MAIN (IMPORT),
जवाहरलाल नेहरू सीमाशुल्क भवन, न्हावा शेवा, ता .उरण,JAWAHAR LAL
NEHRU CUSTOM HOUSE, NHAVA- SHEVA,TAL-URAN,
जिला रायगड/ RAIGAD-400707,महाराष्ट्र MAHARASHTRA
(e-mail:appraisingmain.jnchimp@gmail.com; Telephone No.022-27244979)

दिनांक Date:01.02.2023

PUBLIC NOTICE NO. 09 /2023

DIN- 20230278NW000000B7B2

SUB: Import of Medical Devices as per the requirements of the Medical Devices Rules, 2017 –reg.

Attention of the Importers, Customs Brokers and all concerned is invited to the 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 (copy enclosed).

2. The Central Drugs Standard Control Organization, New Delhi, has vide the above-said 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 vide S.O.648 (E) dated 11.02.2020 the definition of a medical device in order to regulate all medical devices (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 phase wise manner. As per the notification, all class A and class B medical devices are under licensing regime w.e.f. 01.10.2022 and class C and class D medical devices will be under licensing w.e.f.01.10.2023. 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 are required to be referred to the concerned Assistant Drug Controller (I) office at the port of import for ensuring the compliance of 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.

(Dipak Kumar Gupta)
Commissioner of Customs
Nhava Sheva-I, JNCH

/988206/2023

Copy to :

1. The Chief Commissioner of Customs, Mumbai Zone- II.
2. All the Commissioner of Customs, Mumbai Zone- II.
3. All Addl./Joint Commissioners of Customs, Mumbai Zone- II.
4. All Deputy/Asst. Commissioners of Customs, Mumbai Zone- II.
5. The DC/EDI for uploading on the JNCH website.
6. BCBA/FIEO for circulation among their members, trade and industry.

No. 29/MISC/03/2022-DC (273)
Government of India
Directorate General of Health Services
Ministry of Health & Family Welfare
Central Drugs Standard Control Organisation
(Medical Devices & Diagnostics Division)

Food and Drugs Administration Bhawan,
Kotla Road, New Delhi-110002.
Date:

To,

The Director General Systems and Data Management
Central Board of Indirect Taxes and Customs
Dept. of Revenue, Ministry of Finance, New Delhi.
E-mail: dg.systems@gov.in, dg.sys@icegate.gov.in

Subject: Import of Medical Devices as per the requirements of the Medical Devices Rules, 2017 – reg.

Sir,

This is with reference to the letter dated 27.12.2022 from Indian Rubber Gloves Manufacturers Association received by this office vide P-2959758 dated 03.01.2023 regarding the subject cited above. (Copy enclosed)

As you are aware that the Ministry of Health & Family Welfare has published the Medical Device Rules 2017 vide G.S.R.78(E) dated 31.01.2017 and are already implemented from 01.01.2018.

In pursuance of sub-clause (iv) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government has published vide S.O.648(E) dated 11.02.2020 the definition of medical devices in order to regulate all medical devices (Copy enclosed). Further, Ministry of Health & Family Welfare has published vide G.S.R. 102(E) dated 11.02.2020 regarding regulation of medical devices in phase wise manner. As per the notification, all class A and class B medical devices are under licensing regime w.e.f 01.10.2022 and class C and class D medical devices will be under licensing w.e.f 01.10.2023.

Further, it is stated that surgical gloves and medical examination gloves falls under the definition of the medical devices and classified under class B (Surgical Gloves) and class A (Medical Examination Gloves).

In this regard, it would be appreciated if you communicate your offices at different ports to forward the bill of entries of the medical devices to the concerned

Assistant Drugs Controller (I) office at the port for ensuring the compliance of the requirements for import the medical devices under the Medical Device Rules 2017.

In case if you need any clarification, you may contact to the concerned Assistant Drugs Controller (I) at the port.

Yours Faithfully,

(Dr. V. G. Somani)
Drugs Controller General (I)

Copy to:

(1) All custom offices at different port
(2) All port offices of CDSCO
(3) PS to Joint Secretary (R)