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.