F. No. 29/Misc/03/2021-DC (28)
Central Drugs Standard Control Organisation
Government of India
Ministry of Health and Family Welfare
****

FDA Bhawan, New Delhi
Dated the 28th September, 2021

To

All the States/UTs Drugs Controllers

Subject: Registration and Labelling requirements of Medical Devices - Regarding.

As you are aware that, Ministry of Health & Family Welfare (MoHFW) has issued notification vide S.O. 648 (E) dated 11.02.2020 specifying all medical devices under sub-clause (iv) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940, as under, which is effective from 01.04 2020. The Ministry has also issued notification G.S.R 102(E) dated 11.02.2020, regarding registration requirements for such medical devices which is effective from 01.04 2020.

As per the notification, from 01.04.2020 till September 2021, such Medical Devices will be under voluntary registration scheme. Thereafter, from October, 2021- Class A & B Medical Devices will be under compulsory registration scheme up to September- 2022 and Class C & D Medical Devices will be under compulsory registration scheme up to September-2023.

Various representations have been received recently from stakeholders informing that complete preparedness of Industry in this regard remains to be achieved, in light of disruption due to COVID-19 pandemic situation.

The representations are under consideration of Ministry of Health and Family welfare, Govt. of India. You are requested to take note of the same with a view to ensure uninterrupted supply of such medical devices and access to the patients till a decision is taken on the representations.

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

Copy to:

1. All Zonal/Sub-Zonal offices of CDSCO
2. All Port offices.
3. All Stakeholders/Associations.