F. No. 29/Misc/03/2022-DC (94)
Central Drugs Standard Control Organisation
Government of India
Ministry of Health and Family Welfare
****

FDA Bhawan, New Delhi
Dated the April, 2023

CIRCULAR

12 APR 2023

Subject: Licensing regime of Class C & D non-notified medical devices which are currently under mandatory registration, as per GSR 102(E) dated 11.02.2020, under Medical Devices Rules 2017, w.e.f from 01.10.2023 - Regarding.

As you are aware, that the Class C and D non-notified Medical Devices which are currently under mandatory registration, will be under licensing regime w.e.f 01.10.2023, as per GSR 102(E) dated 11.02.2020.

It is pertinent to mention that, as per Medical Devices Rules (MDR) 2017, for grant of manufacturing license of Class C and D medical devices, the inspection needs to be carried out within 60 days from the date of application by the Medical Devices Officers (MDO) of Central Licensing Authority (CLA), to ensure the compliance with Fifth Schedule of MDR 2017.

In order to have smooth transition from mandatory registration to licensing regime, it is suggested that, the manufacturers/importers may apply for grant of manufacturing/import license with all requisite documents and fees as per MDR 2017, through www.cdscomdonline.gov.in portal. The application received will be processed proactively, so that, licensure can be issued within the stipulated time line in order to avoid any disruption of the supply chain of such medical devices and access to the patients.

(Dr Rajeev Singh Raghuvanshi)
Drugs Controller General (I)

To
All Stakeholders/Associations.

Copy to:
1. All Zonal/Sub-Zonal offices of CDSCO
2. All Port offices.