F. No. 29/Misc/03/2023-DC (344) Central Drugs Standard Control Organisation Government of India Ministry of Health and Family Welfare

FDA Bhawan, New Delhi Dated

1 2 OCT 2023

Subject: Clarification on the Regulation of all Class C & D Medical Devices under Licensing regime, w.e.f 01.10.2023, as per G.S.R. 102(E) dt 11.02.2020- Regarding.

In continuation to this office Circular vide No.29/Misc/03/2023-DC(344) dated 12.10.2023 on the Regulation of all Class C & D Medical Devices under Licensing regime, w.e.f 01.10.2023, as per G.S.R. 102(E) dt 11.02.2020.

In this connection, it is to clarify that the said circular is applicable only to the manufacturers/importers who have already filed the application to Central Licensing Authority on or before 30th September 2023.

(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.
- 3. CDSCO- IT Cell for publication on website