F. No. 29/Misc/03/2022-DC (257)
Central Drugs Standard Control Organisation
Government of India
Ministry of Health and Family Welfare
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FDA Bhawan, New Delhi
Dated the 30th September, 2022

CIRCULAR

Subject: Regulation of all Class A & B Medical Devices under Licensing regime, w.e.f 01.10.2022, as per G.S.R. 102(E) dt 11.02.2020 - Regarding.

The Ministry of Health & Family Welfare (MoHFW) has published 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, which is effective from 01.04 2020.

In order to regulate all the medical devices, MoHFW has published G.S.R. 102 (E) dated 11.02.2020 for regulation of such devices in phase wise manner. As per the said notification the Class A & B medical devices will be under licensing regime from 01.10.2022.

In the meantime, representations from various Associations and Stakeholders have been received by this office, requesting that the business continuity should not be disrupted due to the implementation of licensing regime w.e.f. 01.10.2022 for Class A & B medical devices.

In view of the above, it has been decided that, in case, if an existing importer/manufacturer who is already importing /manufacturing any of Class A or Class B Medical Devices, has submitted application to Central Licensing Authority or State Licensing Authority on or before 30.09.2022, as the case may be, for grant of import /manufacturing licence in respect of the said device(s) under the provisions of MDR, 2017, the said application shall be deemed valid and the importer/manufacturer can continue to import /manufacture the said device(s) up to 6 months from the date of issue of this order or till the time, the Central Licensing Authority or State Licensing Authority, as the case may be, takes a decision on the said application, whichever is earlier.

Digitally Signed by Dr. V G Somani
Date: 30-09-2022 20:41:38
Reason: Approved

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

To
All Stakeholders/Associations.
Copy to:
1. All State Drugs Controllers.
2. All Zonal/Sub-Zonal offices of CDSCO
3. All Port offices.