F.No. 29/Misc/03/2020-DC (297)
Central Drugs Standard Control Organisation
Government of India
Ministry of Health and Family Welfare

****

FDA Bhawan, New Delhi
Dated the 28th December, 2020

ORDER

Subject: Regulation of Blood Glucose Monitors, Blood Pressure Monitors, Nebulizers, and Thermometers as Drugs with effect from January 1st, 2021.

Ministry of Health & Family welfare, Government of India has notified the following devices as per S.O. 4671(E) dated December 27, 2019 which will be effective from 01.01.2021.

1. Nebulizer
2. Blood Pressure Monitoring Devices
3. Digital Thermometer; and
4. Glucometer

2. Accordingly, as per the said order the importers/manufacturers are required to take import/manufacturing licence from Central Licencing Authority or State Licencing Authority, as the case may be, for import/manufacture of above devices, w.e.f. 01.01.2021.

3. In the meantime, a representation has been received, requesting to extend implementation of the notification for another 3 to 6 months because a lot of procedural work is to be done such as resolution of queries, audit of facilities by the regulators and notified bodies, as the case may be, testing of products at the requisite testing labs etc.

4. In this regard, it may be pertinent to mention that Rule 97 of Medical Device Rules (MDR) 2017 provides details about applicability of the said rules in respect of various actions/ operations undertaken under Drugs & Cosmetics Rules for the substances and devices referred to in rule 2 of the MDR, 2017 prior to commencement of MDR 2017.

5. In view of the above, it has been decided that in case an existing importer/manufacturer who is already importing /manufacturing any of these devices, has submitted application to Central Licencing Authority or State Licencing Authority, 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 issue of this order or till the time, the Central Licencing Authority or State Licencing Authority, as the case may be, takes a decision on the said application, whichever is earlier.

V.G.Somani

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

To,
All Stakeholders

Copy to:
1. All State Drugs Controllers
2. All Zonal Sub-Zonal & Port Offices of CDSCO