File No. 29/Misc/03/2017-DC (08)
Central Drugs Standard Control Organization
Directorate General of Health Services
Ministry of Health & Family Welfare
Food & Drugs Administration Bhawan,

Kotla Road, New Delhi-110002
Date:

CIRCULAR

09 AUG 2017

To

All the States/UTs Drugs Controller,

Subject: Establishment of facilities for the activities of coating, assembling of components, sterilization etc for devices regulated under the provisions of Drugs and Cosmetic Act,1940 and Rules,1945 thereunder- reg.

It has been brought to the notice of this office that the manufacturers of the Medical Device are facing difficulties while establishing facilities for the activities of coating, assembling of components, sterilization etc for devices.

In this connection, it is clarified that as per clause (f) of Section 3 of Drugs and Cosmetic Act, 1940, the definition of "manufacture" in relation to the drug(devices) includes any process or part of process for making, altering, ornamenting, finishing, packing, labeling, breaking-up or otherwise, treating or adopting any drug with a view to its sale.

The processes like coating, assembling of the components, sterilization of devices etc attracts definition of the "manufacture" under the said Act. Therefore, for such activity, the firm is required to obtain manufacturing license under the provisions of Drugs and Cosmetic Act & Rules made thereunder.

In view of above, you are requested to kindly take appropriate action for grant of license for such activities under your jurisdiction.

(Dr. G.N. Singh)
Drugs Controller General (India)

Copy to:

1. All the Zonal/Sub-Zonal offices of CDSCO.
2. PS to JS(R).
3. Guard file.