File No.29/Misc/03/2022- DC (94)
Government of India
Director General of Health Services
Central Drugs Standard Control Organisation

Date:11 July 2022

NOTICE

In pursuance of notification No. G.S.R. 102(E) dated 11.02.2020, all non-notified medical devices of Class A & Class B categories are scheduled to enter licensing regime with effect from 01.10.2022

A transition period of 30 months had been provided for Class A & Class B medical devices from date of implementation of G.S.R. 102(E) i.e., 01.04.2020 for the transition to licensing regime. During that period the manufacturers were required to register their products on the portal (https://cdscomdonline.gov.in/NewMedDev/Homepage) established for the purpose by CDSCO and to affix the registration number on the label of such registered medical devices.

Of late, it has come to the notice of this office that some other entities are issuing quality certificates to the manufacturers at their own level, which is becoming a source of confusion for manufacturers vis-a-vis the prescribed regulatory pathway for obtaining the licensure for such medical devices under Medical Devices Rules (MDR), 2017. **In this regard, it is hereby clarified that such quality certificates issued by other entities shall not be a replacement of licensure to be granted under MDR, 2017 by the competent Licensing Authority. All manufacturers shall have to comply with the licensing requirement and obtain the license as per MDR, 2017, as the said rules do not recognize any such certificates which are not mentioned in it or part of it.**

Further, it is again advised that all manufacturers shall apply for obtaining manufacturing license for Class A & Class B medical devices through CDSCO's on-line portal so that the manufacturing license can be granted by respective State Licensing Authorities after review of the applications and audit (as the case may be) as per stipulated time specified in MDR, 2017 in order to avoid further delay.

In this regard this office has proactively taken up the issue vide notice No. 29/Misc/03/2022-DC (94) dated 25.04.2022, requesting all State Licensing Authorities (SLAs) to dispose of the applications received by them as per MDR, 2017 in time to avoid the disruption of the supply of such devices to the patients.

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

To,

1. All SLAs
2. All Associations
3. CDSCO Website
4. Quality Council of India
5. Department of Pharmaceuticals