CDSCO Issues Circular in Regard to the Licensing Regime of Class C & D Non-Notified Medical Devices Which are Currently Under Mandatory Registration

On 12th April 2023, the Central Drugs Standards Control Organisation (CDSCO) issued a circular in regard to Licencing Regime of Class C and Class D Non-Notified Medical Devices which are currently under mandatory registration, in accordance with GSR 102 (E) issued on 11th February 2020, under Medical Device Rules 2017, deemed to be effective from 01st October 2023.

The Circular states that the Class C and Class D Non-Notified Medical Devices which are currently under mandatory registration will be under licensing regime deemed to be effective from 01St October 2023, in accordance with the GSR 102(E) issued on 11th February 2020.

It is pertinent to mention that, in accordance with the Medical Devices Rules (MDR) 2017, for the grant of manufacturing license of Class C and Class D Medical Devices, the inspection needs to be carried out within 60 days from the date of application by the Medical Devices Officers (MDO) of Central Licensing Authorities (CLA), to ensure the compliance with Fifth Schedule of MDR 2017.

In order to have a smooth transition from mandatory registration to the licensing regime, the CDSCO has suggested that the manufacturers/importers may apply for the grant of manufacturing/import license with all requisite documents and fees as per MDR 2017, through the www.cdscomdonline.gov.in portal. The application received is to be processed proactively, so that, the license can be issued within the stipulated timeline in order to avoid any disruption of the supply chain of such medical devices and access to the patients.

Official Notification Link Attached Here

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