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The medical device importer must obtain an import license from the Central Drugs Standard Control Organisation (CDSCO). In the year 2020, the Ministry of Health and Family Welfare (MoHFW) issued a notification stating all the medical devices mentioned under sub-clause 4 of clause b of section 3 of the Drugs and Cosmetics Act, 1940, have to be regulated.

For this, the MoHFW released guidelines dated 11.02.2020. The guidelines mentioned that the regulation of medical devices should be carried out in a phased manner. The notification had given a deadline of 01.10.2022 to Class A and Class B medical devices; post this date, all devices shall come under the licensing regime i.e. 1st of October 2022.

Numerous stakeholders and associations requested the government that the licensing regime should not be implemented from 01.10.2022 for business continuity. The licensing of class A and B medical devices at the moment would disrupt the business flow, resulting in heavy losses.

CDSCO took cognizance of the abovementioned concerns and decided that in case there are any importer or manufacturer who is currently importing or manufacturing Class A or Class B medical device and has submitted the application for the same either to the Central Licensing Authority (CLA) or State Licensing Authority (SLA) on or before the 30th of September 2022 as per the provisions of the Medical Device Rules 2017, then that application shall be held valid for a period of six months. During this period, the manufacturer or the importer shall be allowed to import or manufacture the medical devices six months from the date of issue of the current notification or till the time the Central licensing authority or the State licensing authority takes a decision on the application (whichever is earlier).

For official notification click here.

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