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PRESS RELEASE

The Medical Devices Rules, 2017, were made to control and regulate the import, manufacture and sale of Medical Devices and it has come into effect from 01.01.2018.

As per the Medical Devices Rules, 2017, after the completion of a transition period of 30 months from 11.02.2020 (the date of notification), now it has become mandatory to take licences for most of the commonly used Medical Devices from 11.08.2022.

Class A and Class B medical devices include commonly used items like face masks, digital thermometer, surgical gloves, PPE kit, hospital bed, patient gown, contact lens disinfecting solution, contact lens, Acupuncture kit, patient weight scale, rocking infant bed, teething device, forehead temperature strip, sterilizer, stretcher, forceps, icebag to reduce pain, treadmill, electric massager, finger/thumb prosthesis, arm sling, etc.

The complete list of Class A and Class B medical devices is available as a public notice in the CDSCO website for reference.

Hence it is mandated that all the manufacturers of class A and Class B medical devices in this State should apply for obtaining manufacturing licence through CDSCO's online portal .

It is also mandated that all the dealers (wholesalers and retailers) in this State selling such Class A and Class B medical devices should have Drugs sale licences.

With effect from 11.08.2022, manufacturing of Class A and Class B medical devices without a valid licence is a violation of Medical Devices Rules, 2017.

Further, with effect from 11.08.2022, selling of Class A and Class B medical devices without a valid sale licence is also a violation of Medical Devices Rules, 2017.

Similarly, selling of Class A and Class B medical devices, which have been manufactured without a valid manufacturing licence is a violation of Medical Devices Rules, 2017.

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