

Govt notifies rules for medical devices

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The Union government notified the Medical Devices Rules on Tuesday as Medical Devices (Amendment) Rules, 2022. The Rules made provisions for all class A medical device manufacturers to register themselves through an identified online portal established for the purpose.

Class A medical devices are those with low-to-moder-

ate risk to the patient or user (like surgical dressings). All class A and class B manufacturers are required to transition to the licensing regime by October 1.

Several manufacturers are awaiting audits from the government licensing authorities. Online registration with self declaration would make this transition process easier.

The manufacturer has to give an undertaking stating that the proposed device is

class A medical device — non-sterile and/or non-measuring. This was a long-standing demand from the medical devices industry.

“An undertaking (is needed) from the manufacturer stating that the proposed device is class A medical device (non-sterile and/or non-measuring), according to First Schedule of the said rules,” the notification read.

The manufacturer will have to self-certify that the

product is conforming to the essential principles checklist of safety and performance of such devices, the government said in the notification. It added that the manufacturer shall self-certify to comply with the standards prescribed in the Medical Devices Rules, 2017. After furnishing the information on the “Online System for Medical Devices” established for the purpose, registration number will be generated.