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Health Ministry proposes amendments to Medical Devices Rules, 2017 to promote ease of doing business

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Loan licensing requirements for outsourced sterilising activities removed

The government has introduced major regulatory reforms in the medical devices sector with an aim to promote ease of doing business (EoDB), simplify regulatory processes, enhance transparency, and facilitate timely access to advanced medical technologies in the country.

Towards this objective, the Medical Devices Regulations, 2017 have recently been amended to simplify the regulatory framework governing outsourced sterilisation of medical devices and to expand the list of stringent regulatory jurisdictions recognised to remove diagnostic requirements.

The amendment to Rule 44 of the Medical Devices Regulations, 2017 has been finalised after extensive stakeholder consultations aimed at simplifying regulatory compliances for medical device manufacturers availing outsourced sterilisation facilities.

Under the amended provisions, manufacturers outsourcing sterilisation of products to any other facility having a valid license under the Medical Devices Rules, 2017 will no longer be required to obtain a separate loan license for outsourced sterilisation activity.

The amendment eliminates the need for a separate loan licensing process in such cases, reducing duplication, administrative burden, compliance costs, and associated timelines, especially for manufacturers who do not have in-house sterilisation facilities.

The amended provision also provides for a transition period of six months for implementation of the new labelling requirement.

Further, Rule 63 of the Medical Devices Regulations 2017 has been amended to include the European Union (EU) in the stringent regulatory jurisdictions recognised for relaxation of diagnostic testing requirements for medical devices without prescribing devices.