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GRC BULLETIN

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CDSCO

Regulatory requirements for outsourcing sterilization activity of medical devices by a manufacturer under Medical Device Rules, 2017

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CDSCO NOTIFIES REGULATORY REQUIREMENTS FOR OUTSOURCING STERILIZATION ACTIVITY OF MEDICAL DEVICES BY A MANUFACTURER UNDER MEDICAL DEVICE RULES, 2017

INDUSTRY SPECIFIC

Authority

Drugs Technical Advisory Board (DTAB)
Under the Central Drugs Standard Control Organization (CDSCO)
Ministry of Health & Family Welfare, Government of India

Circular Date

Jun 24, 2025

Circular Number

F. No. DC-DT-13011(11)/1/2025-eoffice
Comp. No. 21508

Effective Date

Jun 24, 2025

Applicability: Applies to medical device manufacturers who hold:

- ***A license in Form MD-3/4 or Form MD-9/10***
  Related to sterilization activities carried out at a sterilization site that already holds:
- ***A valid sterilization license in Form MD-3 or Form MD-9***

Overview:

At its **92nd Meeting held on 24th April 2025**, the Drugs Technical Advisory Board (DTAB) recommended a regulatory relaxation for medical device manufacturers regarding sterilization licensing requirements.

As per the decision formally released via circular on 24th June 2025, **manufacturers licensed under Form MD-3/4 or MD-9/10 are no longer required to obtain a separate loan license for sterilization**, provided that the sterilization activity is carried out at a site already licensed under Form MD-3 or MD-9 for such sterilization processes.

Key Regulatory Requirements:

- **No additional license required**:
  Manufacturers can **outsource sterilization** to licensed third-party sites **without obtaining a separate loan license** for sterilization.
- **Mandatory Documentation**:
  The **manufacturer must submit supporting documentation** regarding sterilization at the time of applying for the manufacturing license.
- **Labeling Requirement**:
  The **label of the medical device must clearly indicate the license number** of the sterilization site used.

Impact and Objective:

This notification aims to:

Simplify the compliance process for manufacturers

Avoid duplication of licensing for sterilization when already performed at a licensed facility

Ensure traceability and safety through clear labeling and documented sterilization processes Support the growth and efficiency of India's **medical device regulatory ecosystem**

SOURCE: Click Here for more details

INDUSTRY SPECIFIC

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