



GRC BULLETIN JULY - 2025, VOLUME: I

CDSCO

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

Click Here to Read Full Bulletin

#Trusted Compliance Partner

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)/1/2025eoffice Comp. No. 21508

Effective Date

Jun 24, 2025

INDUSTRY SPECIFIC

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

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:

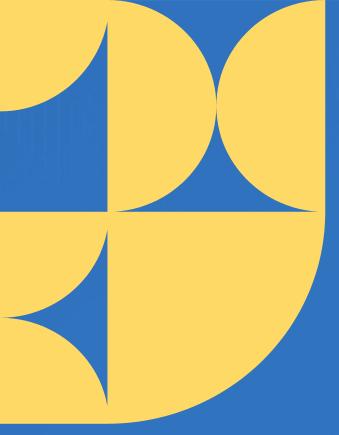
This notification aims to:

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





Head Quarters:

Vasudha, 2nd Floor, No. 2, 38th Main Rd, Rose Garden, JP Nagar Phase 6, J. P. Nagar, Bengaluru, Karnataka 560078

Ph: 080 41673023 Email: info@ricago.com Website: www.ricago.com

Subscribe to the Newsletter:

Subscribe

Disclaimer: This newsletter is prepared by Clonect Solutions Pvt. Ltd. and contains information about the statutory compliance updates for general information only. No claim is made as to warrant or represent that the information contained in this document is correct. Also, it should not be considered as legal or financial advice and under no circumstances Clonect Solutions Pvt. Ltd. shall be held responsible for any kind of damages arising there to.

#Trusted Compliance Partner