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File no. MED/48/2025-eoffice
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Medical Device Division)

FDA Bhawan, Kotla Road,
New Delhi - 110002,
Dated
24 JUN 2025

To,

All the State / Union Territory Drugs Controllers.

Subject: Regulatory requirements for outsourcing sterilization activity of medical devices by a manufacturer under Medical Device Rules, 2017- Reg.

Sir,

Concerns have been raised by the stakeholders from time to time regarding requirement of loan license for outsourcing sterilization activity at the site of another facility having valid license to carry out sterilization process of medical devices under Medical Device Rules, 2017.

The Drugs Consultative Committee (DCC) in its 61st meeting held on 01.06.2023, had deliberated the matter and recommended for constitution of a sub-committee for in-depth examination & suitable recommendation in the matter. The sub-committee constituted for this purpose examined the matter and recommended as under.

1. After detailed deliberation with respect to all the aspects of QMS, the Sub-committee is of the opinion that the requirement of loan license may not be insisted, as the final product is released from the actual manufacturing site and manufacturer is monitoring the entire QC check before release. Such activity may be carried out by the manufacturer by way of mutual third party agreement provided that the facilities shall have license to carry out such sterilization process under MDR-2017.
2. The Sub-committee also emphasized that it is appropriate that the manufacturer in whose premises the sterilization process will be carried out shall have valid license for the sterilization of distinct medical device for which the actual manufacturer is holding the manufacturing license.
3. The Sub-committee also suggested that since the sterilization activity of medical device is critical activity, therefore the manufacturer may include at least the license number of the sterilization site (where the outsourced sterilization activity is carried out) on the device label and accordingly necessary provision may be included in Rule 44 of the MDR-2017 as part of the labelling requirements for such critical activity.

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The recommendation of the sub-committee was placed in 65th Drugs Consultative Committee (DCC) meeting held on 20.12.2024. The DCC agreed with recommendations of the sub-committee subject to inclusion of an appropriate mechanism for submission of documentary evidence to the Licensing Authority in support of such activity prior to obtaining the manufacturing license. The said documentary evidence may include mutual agreement between the manufacturer of the device and the sterilization site, Quality Management System document (Plant Master File, Device Master File, etc) of the manufacturer mentioning the details of such outsourced activity, etc. Further the committee also recommended that since the sterilization activity of medical device is a critical activity, the license number of the sterilization site where the activity is carried out should also be mentioned on label of the device.

The above recommendation of the DCC was placed in the 92nd DTAB meeting held on 24.04.2025 for further consideration. The Board deliberated the matter and agreed to the said recommendations. The relevant portion of MOM is enclosed.

This is for your information & necessary action in the matter.

Yours faithfully

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General of India

To:

1. All Zonal and sub-zonal office of CDSCO
2. All stakeholders of Medical Device Industry through CDSCO website.

डॉ.राजीव सिंह रघुवंशी
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स्वास्थ्य एवम परिवार कल्याण मंत्रालय
भारत सरकार
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नई दिल्ली–110002

सत्यमेव जयते

Dr. Rajeev Singh Raghuvanshi
Drugs Controller General (India)
Central Drugs Standard Control Organisation
Ministry of Health & Family Welfare
Government of India
FDA Bhawan, Kotla Road
New Delhi-110002 (India)

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

Dated: 28 APR 2025

To

All Members of DTAB

Subject: Minutes of the 92nd meeting of the Drugs Technical Advisory Board (DTAB) held on 24.04.2025 through Hybrid mode.

Sir/Madam,

92nd meeting of Drugs Technical Advisory Board was held on 24.04.2025 through Hybrid mode.

The minutes of the 92nd meeting of Drugs Technical Advisory Board duly approved by the Chairman, is annexed for your information please.

Yours faithfully,

Dr. Rajeev Singh Raghuvanshi
Drugs Controller General (India)
Member Secretary (DTAB)

Encl: Minutes of meeting

Copy to:

1. PPS to DGHS, MoHFW, Nirman Bhawan, New Delhi
2. PS to JS(R), MoHFW, Nirman Bhawan, New Delhi

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PART-B (Related to Medical Devices)

Agenda No. 20

Consideration of the proposal for no requirement of loan license application for sterilization purpose by a manufacturer, who has license in Form MD-3/4 or in Form MD-9/10, at the sterilization site having valid license for sterilization in Form MD-3 or Form MD-9

The Board was apprised about the DCC sub-committee report and DTAB agreed with the recommendation of the sub-committee subject to inclusion of an appropriate mechanism for submission of documentary evidence to the Licencing Authority in support of proper sterilization of product, at the time of seeking manufacturing licence subject to the condition that the license number of the sterilization site should be mentioned on label of the device.