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BUREAU OF INDIAN STANDARDS

DRAFT IN WIDE CIRCULATION FOR COMMENTS ONLY

भारतीय मानक मसौदा

स्वास्थ्य देखभाल उत्पादों का स्टरलाइज़ेशन - जानवरों के ऊतकों और उनके डेरिवेटिव का उपयोग करने वाले एकल-उपयोग चिकित्सा उपकरणों के लिए तरल रासायनिक स्टरलाइज़िंग एजेंट - चिकित्सा उपकरणों के लिए विसंक्रमण प्रक्रिया के लक्षण वर्णन, विकास, सत्यापन और नियमित नियंत्रण के लिए आवश्यकताएँ

Draft Indian Standard

Sterilization of health care products — Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives — Requirements for characterization, development, validation and routine control of a sterilization process for medical devices

[ICS 11.080.01]

Hospital Equipment and Surgical Disposable Products Sectional Committee, MHD 12	Last date for comments: 30 **Nov 2023**

NATIONAL FOREWORD
(*Adoption clause will be added later*)

The text of ISO Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain terminologies and conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.
b) Comma (,) has been used as a decimal marker, while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards, which are to be substituted in their places, are listed below along with their degree of equivalence for the editions indicated:

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 10993-1, Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process	IS 17932 (Part 1) : 2023 Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process	Identical
ISO 10993-17, Biological evaluation of medical devices — Part 17: Establishment of allowable limits for leachable substances	IS/ISO 10993-17 : 2002 Biological Evaluation of Medical Devices Part 17 Establishment of Allowable Limits for Leachable Substances	Identical
ISO 11737-1, Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products	IS/ISO 11737-1 : 2018 Sterilization of health care products Microbiological methods Part 1: Determination of a population of microorganisms on products	Identical
ISO 13408-2 : 2018 Aseptic processing of health care products Part 2 Sterilizing filtration	IS/ISO 13408-2 : 2018 Aseptic processing of health care products Part 2 Sterilizing filtration	Identical

The technical committee responsible for the preparation of this standard has reviewed the provisions of following mentioned International Standards and has decide that they are acceptable for use in conjunction with this standard:

International Standard/ Other Publication	*Title*
ISO 13408-1: 2023	Aseptic processing of health care products Part 1 General requirements
ISO 13408-3:2006	Aseptic processing of health care products — Part 3: Lyophilization
ISO 13408-4:2005	Aseptic processing of health care products — Part 4: Clean-in-place technologies
ISO 13408-5:2006	Aseptic processing of health care products — Part 5: Sterilization in place
ISO 13408-6:2021	Aseptic processing of health care products — Part 6: Isolator systems
ISO 13408-7:2012	Aseptic processing of health care products — Part 7: Alternative processes for medical devices and combination products

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 2022 ‘Rules for rounding off numerical values (Second Revision)’.

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Note: The technical content of the document has not been included as it is identical to the corresponding ISO standard. For details, please refer to ISO 14160:2020 or kindly contact:

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Scope

This document specifies requirements for the characterization of a liquid chemical sterilizing agent and for the development, validation, process control and monitoring of sterilization by liquid chemical sterilizing agents of single-use medical devices comprising, in whole or in part, materials of animal origin.
This document covers the control of risks arising from contamination with bacteria and fungi by application of a liquid chemical sterilization process. Risks associated with other microorganisms can be assessed using other methods (see NOTE 1).
This document is not applicable to material of human origin.
This document does not describe methods for the validation of the inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents (see NOTE 2 and NOTE 3).
This document does not describe methods for validation of the inactivation or elimination of protozoa and parasites.
The requirements for validation and routine control described in this document are only applicable to the defined sterilization process of a medical device, which is performed after the manufacturing process, and do not take account of the lethal effects of other bioburden reduction steps (see NOTE 4).
This document does not specify tests to establish the effects of any chosen sterilization process upon the fitness for use of the medical device (see NOTE 5).
This document does not cover the level of residual sterilizing agent within medical devices (see NOTE 6).
Guidance for the characterization of a liquid chemical sterilizing agent and for the development, validation, process control and monitoring of sterilization by liquid chemical sterilizing agents of single-use medical devices comprising, in whole or in part, materials of animal origin is provided in informative Annex A.

NOTE 1 The prior application of risk management principles to medical devices utilizing animal tissues, as described in ISO 22442-1 is important. ISO 18362 provides information on control of microbial risks during processing of cell-based health-care products.

NOTE 2 Liquid chemical sterilizing agents traditionally employed to sterilize animal tissues in medical devices might not be effective in inactivating the causative agents of TSE such as bovine spongiform encephalopathy (BSE), or scrapie. Satisfactory validation in accordance with this document does not necessarily demonstrate inactivation of infective agents of this type. Risk controls related to sourcing, collection and handling of animal materials are described in ISO 22442-2.

NOTE 3 The validation of the inactivation, elimination, or elimination and inactivation of viruses and TSE agents is described in ISO 22442-3.

NOTE 4 Manufacturing processes for medical devices containing animal tissues frequently include exposure to chemical agents which can significantly reduce the bioburden on the medical device. Following the manufacturing process, a medical device is exposed to a specified sterilization process.

NOTE 5 Such testing is a crucial part of the design and development of a medical device.

NOTE 6 ISO 10993-17 specifies a method to establish allowable limits for residues of sterilizing agents.

NOTE 7 Standards for quality management systems (see ISO 13485) can be used in the control of all stages of manufacture including the sterilization process.