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BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

भारतीय मानक मसौदा

स्वास्थ्य देखभाल उत्पादों का विसंक्रमण — निम्न तापमान पर वाष्पीकृत हाइड्रोजन पेरॉक्साइड —चिकित्सा उपकरणों के लिए विसंक्रमण प्रक्रिया के विकास, सत्यापन और नियमित नियंत्रण के लिए अपेक्षाएँ

Draft Indian Standard

Sterilization of health care products — Low temperature vaporized hydrogen peroxide — Requirements for the 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: **02 October 2025**

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 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'; and
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 respective 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 (ISO 10993-1 : 2018, MOD)	Modified
ISO 11138-1:2017 Sterilization of health care products — Biological indicators — Part 1: General requirements	IS/ISO 11138-1 : 2017 Sterilization of health care products ― Biological indicators: Part 1 General requirements	Identical
ISO 11140-1 Sterilization of health care products — Chemical indicators — Part 1: General requirements	IS 18446 (Part 1) : 2023 Sterilization of health care products — Chemical indicators: Part 1 General requirements (ISO 11140-1 : 2014, MOD)	Modified
ISO 11607-1:2019 Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems	IS/ISO 11607-1 : 2019 Packaging for terminally sterilized medical devices: Part 1 Requirements for materials, sterile barrier systems and packaging systems (*first revision*)	Identical
ISO 11607-2 Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes	IS/ISO 11607-2 : 2019 Packaging for terminally sterilized medical devices: Part 2 Validation requirements for forming, sealing and assembly processes (*first revision*)	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 11737-2 Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process	IS/ISO 11737-2 : 2019 Sterilization of health care products — Microbiological methods: Part 2 Tests of sterility performed in the definition, validation and maintenance of a sterilization process	Identical

The Committee responsible for the preparation of this standard has reviewed the provisions of the following International Standards referred in this adopted standard and has decided that they are acceptable for use in conjunction with this standard:

International Standard/ Other Publication	*Title*
ISO 10993-17	Biological evaluation of medical devices — Part 17: Establishment of allowable limits for leachable substances

Scope

This document provides requirements for the development, validation and routine monitoring and control of a low temperature sterilization process for medical devices using vaporized hydrogen peroxide (VH2O2) as the sterilizing agent.

This document is intended to be applied by process developers, manufacturers of sterilization equipment, manufacturers of medical devices to be sterilized, organizations performing process validation of VH2O2 sterilization, and organizations responsible for sterilizing medical devices.

NOTE VH2O2 sterilizers can be used in both health care and industrial facilities, and this document acknowledges the similarities and differences between the two applications.

The technical content of the document has not been enclosed as it is identical with the corresponding ISO standard. For details, please refer to ISO 22441:2022 or kindly contact:

Head
Medical Equipment and Hospital Planning Department
Bureau of Indian Standards
9 Bahadur Shah Zafar Marg
New Delhi-110002
Email: mhd@bis.gov.in
hmhd@bis.gov.in