Doc No: MHD 12 (25586) WC
May 2024

(Superseding IS 18319 (Part 1):2023/
ISO 17665-1:2006)

**BUREAU OF INDIAN STANDARDS**

DRAFT FOR COMMENTS ONLY



*भारतीय मानक मसौदा*

# स्वास्थ्य देखभाल उत्पादों का विसंक्रमण — नम गर्मी — चिकित्सा उपकरणों के लिए विसंक्रमण प्रक्रिया के विकास, सत्यापन और नियमित नियंत्रण के लिए आवश्यकताएँ

*Draft Indian Standard*

# Sterilization of Health Care Products — Moist Heat — Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices

ICS 11.080.01

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| Hospital Equipment and Surgical Disposable Products Sectional Committee, MHD 12 | Last date for comments: **07 June 2024** |

NATIONAL FOREWORD

(*Adoption clause will be added later*)

This standard supersedes IS 18319 (Part 1):2023/ISO 17665-1:2006. After publication of this standard, IS 18319 (Part 1):2023/ISO 17665-1:2006 stands withdrawn.

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'
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:

(Superseding IS 18319 (Part 1):2023/
ISO 17665-1:2006)

| *International Standard* | *Corresponding Indian Standard* | *Degree of Equivalence* |
|---|---|---|
| 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 11138-3:2017, Sterilization of health care products — Biological indicators — Part 3: Biological indicators for moist heat sterilization processes | IS/ISO 11138-3 : 2017, Sterilization of Healthcare Products — Biological Indicators Part 3 Biological Indicators for Moist Heat Sterilization Processes | 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 11140-3, Sterilization of health care products — Chemical indicators — Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test | IS/ISO 11140-3 : 2007, Sterilization of Health Care Products — Chemical Indicators Part 3 Class 2 Indicator Systems for Use in the Bowie and Dick-Type Steam Penetration Test | Identical |
| ISO 11140-4, Sterilization of health care products — Chemical indicators — Part 4: Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration | IS/ISO 11140-4 : 2007, Sterilization of Health Care Products — Chemical Indicators Part 4 Class 2 Indicators as an Alternative to the Bowie and Dick-type Test for Detection of Steam Penetration | Identical |
| ISO 11140-5, Sterilization of health care products — Chemical indicators — Part 5: Class 2 indicators for Bowie and Dick-type air removal tests | IS/ISO 11140-5 : 2007, Sterilization of Health Care Products — Chemical Indicators Part 5 Class 2 Indicators for Bowie and Dick-Type Air Removal Tests | Identical |
| ISO 11140-6, Sterilization of health care products — Chemical indicators — Part 6: Type 2 indicators and process challenge | MHD/12/23986, Sterilization of Health Care Products Chemical Indicators Part 6 Type 2 Indicators and Process Challenge Devices for | Identical |

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| devices for use in performance testing of small steam sterilizers | Use in Performance Testing of Small Steam Sterilizers | |
| ISO 11607-1, 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 |

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**Scope**

This document provides requirements for the development, validation and routine control of moist heat sterilization processes for medical devices. It also contains guidance which is intended to explain the requirements set forth in the normative sections. The guidance given is intended to promote good practice related to moist heat sterilization processes according to this document. The application within industrial and health care settings is considered.

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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 17665:2024 or kindly contact:

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