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BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

भारतीय मानक मसौदा

स्वास्थ्य देखभाल उत्पादों का कीटाणु-नाशक प्रसंस्करण
भाग 5 स्थान पर विसंक्रमण

Draft Indian Standard

Aseptic Processing of Health Care Products

Part 5 Sterilization in Place

ICS 11.080.01

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*)

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:

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 11138-1, Sterilization of health care products — Biological	IS/ISO 11138-1 : 2017, Sterilization of Health Care Products —	Identical

indicators — Part 1: General requirements	Biological Indicators Part 1 General Requirements	
ISO 11138-2, Sterilization of health care products — Biological indicators — Part 2: Biological indicators for ethylene oxide sterilization processes	IS/ISO 11138-2 : 2017, Sterilization of Health Care Products — Biological Indicators Part 2 Biological Indicators for Ethylene Oxide Sterilization Processes	Identical
ISO 11138-3, 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 11138-4, Sterilization of health care products — Biological indicators — Part 4: Biological indicators for dry heat sterilization processes	IS/ISO 11138-4 : 2017, Sterilization of Health Care Products — Biological Indicators Part 4 Biological Indicators for Dry Heat Sterilization Processes	Identical
ISO 11138-5, Sterilization of health care products — Biological indicators — Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes	IS/ISO 11138-5 : 2017, Sterilization of Health Care Products — Biological Indicators Part 5 Biological Indicators for Low-Temperature Steam and Formaldehyde Sterilization Processes	Identical
ISO 11138-7, Sterilization of health care products — Biological indicators — Part 7: Guidance for the selection, use and interpretation of results	IS 18469 (Part 7) : 2023/ISO 11138-7 : 2019, Sterilization of Health Care Products — Biological Indicators Part 7 Guidance for the Selection Use and Interpretation of Results	Identical
ISO 11138-8, Sterilization of health care products — Biological indicators — Part 8: Method for validation of a reduced incubation time for a biological indicator	IS 18469 (Part 8) : 2023/ISO 11138-8 : 2021, Sterilization of Health Care Products — Biological Indicators Part 8 Method for Validation of a Reduced Incubation Time for a Biological Indicator	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	IS/ISO 11140-3 : 2007, Sterilization of Health Care Products —	Identical

indicators — Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test	Chemical Indicators Part 3 Class 2 Indicator Systems for Use in the Bowie and Dick-Type Steam Penetration Test	
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 devices for use in performance testing of small steam sterilizers	MHD/12/23986, Sterilization of Health Care Products Chemical Indicators Part 6 Type 2 Indicators and Process Challenge Devices for Use in Performance Testing of Small Steam Sterilizers	Identical
ISO 13408-4, Aseptic processing of health care products — Part 4: Clean-in-place technologies	MHD/12/25436, Aseptic Processing of Health Care Products Part 4 Clean-in-Place Technologies	Identical
ISO 14937, Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices	IS/ISO 14937 : 2009, Sterilization of Health Care Products — General Requirements for Characterization of a Sterilizing Agent and the Development, Validation and Routine Control of a Sterilization Process for Medical Devices	Identical
ISO 17665-1, Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices	IS 18319 (Part 1) : 2023/ISO 17665-1 : 2006, Sterilization of Health Care Products — Moist Heat Part 1 Requirements for the Development Validation and Routine Control of a Sterilization Process for Medical Devices	Identical
ISO/IEC/IEEE 90003, Software engineering — Guidelines for the application of ISO 9001:2015 to computer software	IS/ISO/IEC/IEEE 90003 : 2018, Software Engineering — Guidelines for the Application of ISO 9001 : 2015 to Computer Software (*Second Revision*)	Identical

The technical committee 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	*Title*
ISO 13408-1	Aseptic processing of health care products — Part 1: General requirements

Scope

1.1 This part of ISO 13408 specifies the general requirements for sterilization in place (SIP) applied to product contact surfaces of the equipment used in the manufacture of sterile health care products by aseptic processing and offers guidance on qualification, validation, operation and control.

NOTE SIP can be achieved by using steam or other gaseous or liquid sterilizing agents. Specific guidance on steam sterilization in place, which is the most common method used, is given in.

1.2 This part of ISO 13408 applies to processes where sterilizing agents are delivered to the internal surfaces of equipment that can come in contact with the product.

1.3 This part of ISO 13408 does not apply to processes where equipment is dismantled and delivered to a sterilizer.

1.4 This part of ISO 13408 does not supersede or replace national regulatory requirements, such as Good Manufacturing Practices (GMPs) and/or compendial requirements that pertain in particular national or regional jurisdictions.

1.5 This part of ISO 13408 does not specify requirements for development, validation and routine control of a process for inactivating the causative agents of spongiform encephalopathies, such as scrapie, bovine spongiform encephalopathy and Creutzfeldt-Jakob disease. Specific recommendations have been produced in particular countries for the processing of materials potentially contaminated with these agents.

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 13408-5:2006 or kindly contact:

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