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BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

भारतीय मानक मसौदा

स्वास्थ्य देखभाल उत्पादों का कीटाणु-नाशक प्रसंस्करण
भाग 6 आइसोलेटर प्रणालियाँ

Draft Indian Standard

Aseptic Processing of Health Care Products
Part 6 Isolator Systems

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 13408-1:2008, Aseptic processing of health care products — Part 1: General requirements	IS/ISO 13408-1 : 2008, Aseptic Processing of Health Care Products Part 1 General Requirements	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 13408-7, Aseptic processing of health care products — Part 7: Alternative processes for medical devices and combination products	MHD/12/25440, Aseptic Processing of Health Care Products Part 7 Alternative Processes for Medical Devices and Combination Products	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
ISO 11139, Sterilization of health care products — Vocabulary of terms used in sterilization and related equipment and process standards	IS 18240 : 2023/ISO 11139 : 2018, Sterilization of Health Care Products — Vocabulary of Terms Used in Sterilization and Related Equipment and Process Standards	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 14644-1:2015	Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration
ISO 14644-7	Cleanrooms and associated controlled environments — Part 7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)
ISO 18362	Manufacture of cell-based health care products — Control of microbial risks during processing

Scope

This document specifies the requirements for and provides guidance on the specification, selection, qualification, bio-decontamination, validation, operation and control of isolator systems related to aseptic processing of health care products and processing of cell-based health care products.

This document does not specify requirements for restricted access barrier systems (RABS).

This document does not supersede or replace national regulatory requirements such as Good Manufacturing Practices (GMPs) and/or compendia requirements that pertain in particular to national or regional jurisdictions.

This document does not specify requirements for isolators used for sterility testing; however, some of the principles and information in this document could be applicable to this application.

This document does not define biosafety containment requirements.

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 13408-6:2021 or kindly contact:

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