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BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

भारतीय मानक मसौदा

स्वास्थ्य देखभाल उत्पादों के एसेप्टिक प्रसंस्करण

भाग 1 सामान्य अपेक्षाएँ

(IS/ISO 13408-1 : 2008 का पहला पुनरीक्षण)

Draft Indian Standard

Aseptic Processing of Health Care Products

Part 1 General Requirements

(*First Revision of IS/ISO 13408-1 : 2008*)

[ICS 11.080.01]

Hospital Equipment and Surgical Disposable Products Sectional Committee, MHD 12	Last date for comments: **05 September 2024**

NATIONAL FOREWORD

(*Adoption clause will be added later*)

This standard was first published in 2022 and was identical with ISO 13408-1 : 2008 'Aseptic processing of health care products — Part 1: General requirements'. The first revision of this standard has been undertaken to align it with the latest version of ISO 13408-1 : 2023. After publication of this standard, IS/ISO 13408-1 : 2008 stands withdrawn.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:

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 13408-2, 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
ISO 13408-6, Aseptic processing of health care products — Part 6: Isolator systems	MHD/12/25439, Aseptic Processing of Health Care Products Part 6 Isolator Systems	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 14644-1:2015	Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration
ISO 14644-2	Cleanrooms and associated controlled environments — Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
ISO 14644-4	Cleanrooms and associated controlled environments — Part 4: Design, construction and start-up
ISO 14644-7	Cleanrooms and associated controlled environments — Part 7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)

Scope

This document specifies the general requirements for, and offers guidance on, processes, programs and procedures for development, validation and routine control of aseptic processing of health care products.

This document includes requirements and guidance relative to the overall topic of aseptic processing.

Specific requirements and guidance on various specialized processes and methods related to sterilizing filtration, lyophilization, clean-in place (CIP) technologies, sterilization in place (SIP) and isolator systems are given in the other parts of the ISO 13408 series.

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 13408-1:2023 or kindly contact:

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