Doc No: MHD 12 (25440) WC
May 2024

BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

भारतीय मानक मसौदा

स्वास्थ्य देखभाल उत्पादों का कीटाणु-नाशक प्रसंस्करण
भाग 7 चिकित्सा उपकरणों और संयोजन उत्पादों के लिए वैकल्पिक प्रक्रियाएँ

Draft Indian Standard

Aseptic Processing of Health Care Products

Part 7 Alternative Processes for Medical Devices and Combination Products

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

Scope

This part of ISO 13408 specifies requirements and provides guidance on alternative approaches to process simulations for the qualification of the aseptic processing of medical devices and combination products that cannot be terminally sterilized and where the process simulation approach according to ISO 13408-1 cannot be applied.

This part of ISO 13408 describes how risk assessment can be used during the development of an aseptic process to design a process simulation study for medical devices and combination products in those cases where a straightforward substitution of media for product during aseptic processing is not feasible or would not simulate the actual aseptic process.

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 13408-7:2012 or kindly contact:

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