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BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

भारतीय मानक मसौदा

स्वास्थ्य देखभाल उत्पादों का कीटाणु-नाशक प्रसंस्करण
भाग 4 क्लीन-इन-प्लेस प्रौद्योगिकियों

Draft Indian Standard

Aseptic Processing of Health Care Products

Part 4 Clean-in-Place Technologies

ICS 11.080.01

Hospital Equipment and Surgical Disposable Products Sectional Committee, MHD 12	Last date for comments: **06 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/IEC/IEEE 90003, Software engineering — Guidelines for the	IS/ISO/IEC/IEEE 90003 : 2018, Software Engineering — Guidelines	Identical

application of ISO 9001:2015 to computer software	for the Application of ISO 9001 : 2015 to Computer Software (*Second Revision*)

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

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

This part of ISO 13408 is applicable to processes where cleaning agents are delivered to the internal surfaces of equipment designed to be compatible with CIP, which may come in contact with the product.

This part of ISO 13408 is not applicable to processes where equipment is dismantled and cleaned in a washer.

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 to particular national or regional jurisdictions.

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 13408-4:2005 or kindly contact:

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