Doc No: MHD 12 (25433) WC
May 2024

BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

भारतीय मानक मसौदा

चिकित्सीय उपयोग के लिए इन्फ्यूजन उपकरण
भाग 14 द्रव संपर्क के बिना ट्रांस्फ्यूजन और इन्फ्यूजन उपकरण के लिए क्लैंप और प्रवाह रेगुलेटर

Draft Indian Standard

Infusion Equipment for Medical Use

Part 14 Clamps and Flow Regulators for Transfusion and Infusion Equipment without Fluid Contact

ICS 11.040.20

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 10993-1, Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process	IS 17932 (Part 1) : 2023, Biological Evaluation of Medical Devices Part 1 Evaluation and Testing within a Risk Management Process (ISO 10993-1 : 2018, MOD)	Modified

This standard also makes a reference to the BIS Certification Marking of the product. Details of which is given in National Annex A.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test shall be rounded off in accordance with IS 2: 2022 ‘Rules for rounding off numerical values (*second revision*)’.

NATIONAL ANNEX A
(National Foreword)

A-1 BIS CERTIFICATION MARKING

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act,* 2016 and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.

Scope

This part of ISO 8536 specifies requirements for non-sterile clamps and flow regulators used as a subcomponent to control the flow of intravenous solutions and/or blood components through sterilized infusion and blood transfusion sets and blood bag assemblies without fluid contact.

In some countries, the national pharmacopoeia or other national regulations are legally binding and take precedence over this part of ISO 8536.

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 8536-14:2016 or kindly contact:

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