

BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

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भारतीय मानक मसौदा
चिकित्सीय उपयोग के लिए इन्फ्यूजन उपकरण
भाग 13 द्रव संपर्क के साथ एकल उपयोग के लिए क्रमिक प्रवाह रेगुलेटर

Draft Indian Standard

Infusion Equipment for Medical Use

Part 13 Graduated Flow Regulators for Single Use with 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:

- Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'
- 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 8536-4, Infusion equipment for medical use — Part 4: Infusion sets for single use, gravity feed	IS/ISO 8536-4 : 2019, Infusion Equipment for Medical Use Part 4 Infusion Sets for Single Use, Gravity Feed	Identical
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
ISO 80000-4, Quantities and units — Part 4: Mechanics	IS/ISO 80000-4 : 2019, Quantities and Units Part 4 Mechanics (<i>First Revision</i>)	Identical

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, single-use graduated flow regulators used as subcomponents in sterilized infusion sets for single use to control the flow of intravenous infusion solutions with fluid contact under gravity feed conditions.

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 8536-13:2016 or kindly contact:

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