

**BUREAU OF INDIAN STANDARDS**

**DRAFT FOR COMMENTS ONLY**

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*भारतीय मानक मसौदा*

**चिकित्सीय उपयोग के लिए इन्फ्यूजन उपकरण  
भाग 5 एकल उपयोग, ग्रेविटी फ़ीड के लिए ब्यूरेट इन्फ्यूजन सेट**

*Draft Indian Standard*

**Infusion Equipment for Medical Use**

**Part 5 Burette Infusion Sets for Single Use, Gravity Feed**

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
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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 types of single-use, gravity feed burette infusion sets of 50 ml, 100 ml and 150 ml nominal capacity for medical use in order to ensure compatibility of use with containers for infusion solutions and intravenous equipment.

This part of ISO 8536 also provides guidance on specifications relating to the quality and performance of materials used in infusion sets.

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

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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 8536-5:2004 or kindly contact:

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