

**BUREAU OF INDIAN STANDARDS**

**DRAFT FOR COMMENTS ONLY**

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*भारतीय मानक मसौदा*  
**चिकित्सीय उपयोग के लिए इन्फ्यूजन उपकरण**  
**भाग 15 एकल उपयोग के लिए प्रकाश-सुरक्षात्मक इन्फ्यूजन सेट्स**

*Draft Indian Standard*  
**Infusion Equipment for Medical Use**  
**Part 15 Light-Protective Infusion Sets for Single Use**

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)*

Amendment 1 published in 2023 to ISO 8536-15:2022 is given at the end of this publication.

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 8536-1, Infusion equipment for medical use — Part 1: Infusion glass bottles	IS/ISO 8536-1 : 2011, Infusion Equipment for Medical Use Part 1 Infusion Glass Bottles	Identical
ISO 8536-2, Infusion equipment for medical use — Part 2: Closures for infusion bottles	MHD/12/25421, Infusion Equipment for Medical Use Part 2 Closures for Infusion Bottles	Identical
ISO 8536-3, Infusion equipment for medical use — Part 3: Aluminium caps for infusion bottles	MHD/12/25422, Infusion Equipment for Medical Use Part 3 Aluminium Caps for Infusion Bottles	Identical
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 8536-5, Infusion equipment for medical use — Part 5: Burette infusion sets for single use, gravity feed	MHD/12/25423, Infusion Equipment for Medical Use Part 5 Burette Infusion Sets for Single Use Gravity Feed	Identical
ISO 8536-6, Infusion equipment for medical use — Part 6: Freeze drying closures for infusion bottles	MHD/12/25424, Infusion Equipment for Medical Use Part 6 Freeze Drying Closures for Infusion Bottles	Identical
ISO 8536-7, Infusion equipment for medical use — Part 7: Caps made of aluminium-plastics combinations for infusion bottles	MHD/12/25425, Infusion Equipment for Medical Use Part 7 Caps Made of Aluminium-Plastics Combinations for Infusion Bottles	Identical
ISO 8536-8, Infusion equipment for medical use — Part 8: Infusion sets for single use with pressure infusion apparatus	MHD/12/25426, Infusion Equipment for Medical Use Part 8 Infusion Sets for Single Use with Pressure Infusion Apparatus	Identical
ISO 8536-9, Infusion equipment for medical use — Part 9: Fluid lines for single use with pressure infusion equipment	MHD/12/25428, Infusion Equipment for Medical Use Part 9 Fluid Lines for Single Use with Pressure Infusion Equipment	Identical
ISO 8536-10, Infusion equipment for medical use — Part 10: Accessories for fluid lines for single use with pressure infusion equipment	MHD/12/25429, Infusion Equipment for Medical Use Part 10 Accessories for Fluid Lines for Single Use with Pressure Infusion Equipment	Identical

ISO 8536-11, Infusion equipment for medical use — Part 11: Infusion filters for single use with pressure infusion equipment	MHD/12/25430, Equipment for Medical Use Part 11 Infusion Filters for Single Use with Pressure Infusion Equipment	Infusion	Identical
ISO 8536-12, Infusion equipment for medical use — Part 12: Check valves for single use	MHD/12/25431, Equipment for Medical Use Part 12 Check Valves for Single Use	Infusion	Identical
ISO 8536-13, Infusion equipment for medical use — Part 13: Graduated flow regulators for single use with fluid contact	MHD/12/25432, Equipment for Medical Use Part 13 Graduated Flow Regulators for Single Use with Fluid Contact	Infusion	Identical
ISO 8536-14, Infusion equipment for medical use — Part 14: Clamps and flow regulators for transfusion and infusion equipment without fluid contact	MHD/12/25433, Equipment for Medical Use Part 14 Clamps and Flow Regulators for Transfusion and Infusion Equipment without Fluid Contact	Infusion	Identical

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:

<i>International Standard</i>	<i>Title</i>
GB/T 601-2016	Chemical reagent — Preparations of reference titration solutions

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 document specifies the requirements for infusion sets for single use that use light-protective agents in the fluid path materials (henceforth abbreviated as "light-protective infusion sets").

This document also provides guidelines for performance and quality specifications of materials used in light-protective infusion sets.

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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 8536-15:2022 or kindly contact:

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