

BUREAU OF INDIAN STANDARDS

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भारतीय मानक मसौदा
चिकित्सीय उपयोग के लिए इन्फ्यूजन उपकरण
भाग 9 दबाव इन्फ्यूजन उपकरण के साथ एकल उपयोग के लिए द्रव लाइनें

Draft Indian Standard

Infusion Equipment for Medical Use

Part 9 Fluid Lines for Single Use with Pressure Infusion Equipment

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 7000, Graphical symbols for use on equipment — Registered symbols	IS 16450 : 2023/ISO 7000 : 2019, Graphical Symbols for Use on Equipment — Registered Symbols (<i>First Revision</i>)	Identical
ISO 7864, Sterile hypodermic needles for single use — Requirements and test methods	IS 10654 : 2018/ISO 7864 : 2016, Sterile Hypodermic Needles for Single Use — Requirements and Test Methods (<i>Fourth Revision</i>)	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 8536-10, 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, Infusion Equipment for Medical Use Part 11 Infusion Filters for Single Use with Pressure Infusion Equipment	Identical
ISO 10993-4, Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood	IS/ISO 10993-4 : 2017, Biological Evaluation of Medical Devices Part 4 Selection of Tests for Interactions with Blood	Identical
ISO 15223-1, Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	IS 18105 (Part 1) : 2023/ISO 15223-1 : 2021, Medical Devices — Symbols to be Used with Information to be Supplied by the Manufacturer Part 1 General Requirements (<i>Third Revision</i>)	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>
ISO 80369-7	Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications

This standard includes modification of cross reference from ISO 594-2 to ISO 80369-7. Wherever reference to ISO 594-2 occurs in the text, ISO 80369-7 has to be substituted.

This standard also includes modification of cross reference from ISO 8536-4:2010 to ISO 8536-4. Wherever reference to ISO 8536-4:2010 occurs in the text, ISO 8536-4 has to be substituted.

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 applies to sterilized fluid lines for single use for use with pressure infusion equipment up to a maximum of 200 kPa (2 bar).

The following items are covered by this part of ISO 8536:

- a) syringe pump lines (SPL);
- b) connecting lines (CL);
- c) lines with integrated injection cannula (LIC).

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 8536-9:2015 or kindly contact:

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