

**BUREAU OF INDIAN STANDARDS**

**DRAFT FOR COMMENTS ONLY**

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भारतीय मानक मसौदा  
**चिकित्सीय उपयोग के लिए इन्फ्यूजन उपकरण**  
**भाग 2 इन्फ्यूजन बोतलों के लिए क्लोजर**

*Draft Indian Standard*  
**Infusion Equipment for Medical Use**  
**Part 2 Closures for Infusion Bottles**

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:

<i>International Standard</i>	<i>Corresponding Indian Standard</i>	<i>Degree of Equivalence</i>
ISO 48-4, Rubber, vulcanized or thermoplastic — Determination of	IS 3400 (Part 2/Sec 4) : 2022/ISO 48-4 : 2018, Methods of Test for	Identical

hardness — Part 4: Indentation hardness by durometer method (Shore hardness)	Rubber, Vulcanized or Thermoplastic Part 2 Determination of Hardness Section 4 Indentation Hardness by Durometer Method (Shore Hardness) (Second Revision)	
ISO 3302-1, Rubber — Tolerances for products — Part 1: Dimensional tolerances	IS 16752 : 2018/ISO 3302-1 : 2014, Rubber — Tolerances for Products — Dimensional Tolerances	Identical
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 8536-3, 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 8536-7, 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

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 3302-2	Rubber — Tolerances for products — Part 2: Geometrical tolerances
ISO 8871-1	Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 1: Extractables in aqueous autoclavates
ISO 8871-4	Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 4: Biological requirements and test methods

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 shape, dimensions, material, performance requirements and labelling of closures for infusion bottles as specified in ISO 8536-1.

The dimensional requirements are not applicable to barrier-coated closures.

Closures specified in this document are intended for single use only.

NOTE The potency, purity, stability and safety of a medicinal product during its manufacture and storage can strongly be affected by the nature and performance of the primary packaging.

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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 8536-2:2023 or kindly contact:

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