

BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

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भारतीय मानक मसौदा
चिकित्सीय उपयोग के लिए इन्फ्यूजन उपकरण
भाग 3 इन्फ्यूजन बोतलों के लिए एल्यूमीनियम कैप

Draft Indian Standard
Infusion Equipment for Medical Use
Part 3 Aluminium Caps 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)

Amendment 1 published in 2022 to ISO 8536-3:2009 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 2768-1, General tolerances — Part 1: Tolerances for linear and angular dimensions without individual tolerance indications	IS 2102 (Part 1) : 1993/ISO 2768-1 : 1989, General Tolerances Part 1 Tolerances for Linear and Angular Dimensions without Individual Tolerance Indications (Third Revision)	Identical
ISO 22081, Geometrical product specifications (GPS) — Geometrical tolerancing — General geometrical specifications and general size specifications	IS 17894 : 2022/ISO 22081 : 2021, Geometrical Product Specifications (GPS) — Geometrical Tolerancing — General Geometrical Specifications and General Size Specifications	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

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 8872	Aluminium caps and aluminium/plastic caps for infusion bottles and injection vials — General requirements and test methods

This standard includes modification of cross reference from ISO 2768-2 to ISO 22081. Wherever reference to ISO 2768-2 occurs in the text, ISO 22081 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 specifies aluminium caps for infusion glass bottles which are in accordance with ISO 8536-1.

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 8536-3:2009 or kindly contact:

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