

BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

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भारतीय मानक मसौदा
**इंट्रावैस्कुलर कैथेटर्स — रोगाणु मुक्त तथा एक बार प्रयोग में आने वाले
कैथेटर्स
भाग 7 परिधीय रूप से डाले गए केंद्रीय कैथेटर्स**

Draft Indian Standard

**Intravascular Catheters — Sterile and Single-Use Catheters
Part 7 Peripherally Inserted Central Catheters**

ICS 11.040.25

Hospital Equipment and Surgical Disposable
Products Sectional Committee, MHD 12

Last date for comments: **07 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 10555-1, Intravascular catheters — Sterile and single-use catheters — Part 1: General requirements MHD/12/25449, Intravascular Catheters — Sterile and Single-Use Catheters Part 1 General Requirements (*Second Revision*) Identical

ISO 10555-3, Intravascular catheters — Sterile and single-use catheters — Part 3: Central venous catheters IS/ISO 10555-3 : 2013, Intravascular Catheters — Sterile and Single-Use Catheters Part 3 Central Venous Catheters (*First Revision*) Identical

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 general requirements and test method for peripherally inserted central catheters (PICC), supplied in the sterile condition and intended for single use, for any application.

It is not applicable to intravascular catheter accessories, e.g. those covered by ISO 11070.

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 10555-7:2023 or kindly contact:

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