Doc No: MHD 12 (25583) WC
May 2024

BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

भारतीय मानक मसौदा

इंट्रावैस्कुलर कैथेटर्स — रोगाणु मुक्त तथा एक बार प्रयोग में आने वाले कैथेटर्स

भाग 4 बैलून डाइलेटेशन कैथेटर्स

(IS/ISO 10555-4:2013 का दूसरा पुनरीक्षण)

Draft Indian Standard

Intravascular Catheters — Sterile and Single-Use Catheters

Part 4 Balloon Dilatation Catheters

(*Second Revision of IS/ISO 10555-4:2013*)

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*)

This standard was first published in 2009 and was identical with ISO 10555-4:1996 'Sterile, single-use intravascular catheters Part 4: Balloon dilatation catheters'. The standard was revised in 2018 to align it with the latest version of ISO 10555-4:2013. The second revision of this standard has been undertaken to align it with the latest version of ISO 10555-4:2023. After publication of this standard, IS/ISO 10555-4:2013 stands withdrawn.

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:

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'
b) 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 10555-1:2023, 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

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 requirements for balloon dilatation catheters supplied sterile and intended for single use.

This document does not specify requirements for vascular stents (see ISO 25539-2).

NOTE Guidance on the selection of balloon materials is given in Annex G.

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 10555-4:2023 or kindly contact:

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