Doc No: MHD 12 (25449) 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 1 सामान्य आवशयकताएँ

(IS/ISO 10555-1:2013 का दूसरा पुनरीक्षण)

Draft Indian Standard

Intravascular Catheters — Sterile and Single-Use Catheters

Part 1 General Requirements

(*Second Revision of IS/ISO 10555-1:2013*)

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 10555-1:1995 ‘Sterile, single-use intravascular catheters Part 1: General requirements’. The standard was revised in 2018 to align it with the latest version of ISO 10555-1:2013. The second revision of this standard has been undertaken to align it with the latest version of ISO 10555-1:2023. After publication of this standard, IS/ISO 10555-1:2013 stands withdrawn.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 7886-1, Sterile hypodermic syringes for single use — Part 1: Syringes for manual use	IS 10258 (Part 1) : 2022/ISO 7886-1 : 2017, Sterile Hypodermic Syringes for Single Use Part 1 Syringes for Manual Use (*Third Revision*)	Identical
ISO 10993-1, Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process	IS 17932 (Part 1) : 2023, Biological Evaluation of Medical Devices Part 1 Evaluation and Testing within a Risk Management Process (ISO 10993-1 : 2018, MOD)	Modified
ISO 11607-1, Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems	IS/ISO 11607-1 : 2019, Packaging for Terminally Sterilized Medical Devices Part 1 Requirements for Materials, Sterile Barrier Systems and Packaging Systems (*First Revision*)	Identical
ISO 14971, Medical devices — Application of risk management to medical devices	IS/ISO 14971 : 2019, Medical Devices — Application of Risk Management to Medical Devices (*First Revision*)	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 (*Third Revision*)	Identical
IEC 62366-1, Medical devices — Part 1: Application of usability engineering to medical devices	IS 17922 (Part 1) : 2023/ IEC 62366-1: 2015 + AMD 1 : 2020, Medical Devices Part 1: Application of Usability Engineering (*First Revision*)	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:

International Standard	*Title*
ISO 80369-7	Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications

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 for intravascular catheters, supplied sterile and intended for single use, for any application.

This document does not apply 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 10555-1:2023 or kindly contact:

Head
Medical Equipment and Hospital Planning Department
Bureau of Indian Standards
9 Bahadur Shah Zafar Marg
New Delhi-110002
Email: mhd@bis.gov.in
hmhd@bis.gov.in