

BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

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भारतीय मानक मसौदा
हेल्थकेयर अनुप्रयोगों में तरल पदार्थ और गैसों के लिए छोटे बोर
कनेक्टर्स

भाग 7 इंद्रावैस्कुलर या हाइपोडर्मिक अनुप्रयोगों के लिए कनेक्टर्स

(IS/ISO 80369-7 : 2016 का पहला पुनरीक्षण)

Draft Indian Standard

**Small-Bore Connectors for Liquids and Gases in Healthcare
Applications**

Part 7 Connectors for Intravascular or Hypodermic Applications

(First Revision of IS/ISO 80369-7 : 2016)

[ICS 11.040.25]

Hospital Equipment and Surgical Disposable Products
Sectional Committee, MHD 12

Last date for comments:
05 September 2024

NATIONAL FOREWORD

(Adoption clause will be added later)

This standard was first published in 2019 and was identical with ISO 80369-7 : 2016 ‘Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications’. The first revision of this standard has been undertaken to align it with the latest version of ISO 80369-7 : 2021. After publication of this standard, IS/ISO 80369-7 : 2016 stands withdrawn.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:

- 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 14971:2019, Medical devices — Application of risk management to medical devices	IS/ISO 14971 : 2019, Medical Devices — Application of Risk Management to Medical Devices (<i>First Revision</i>)	Identical
ISO 80369-1:2018, Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements	IS/ISO 80369-1 : 2018, Small-Bore Connectors for Liquids and Gases in Healthcare Applications Part 1 General Requirements	Identical
ISO 80369-6:2016, Small bore connectors for liquids and gases in healthcare applications — Part 6: Connectors for neuraxial applications	IS/ISO 80369-6 : 2016, Small Bore Connectors for Liquids and Gases in Healthcare Applications Part 6 Connectors for Neuraxial Applications	Identical
ISO 80369-20:2015, Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common test methods	IS 17964 (Part 20) : 2023/ISO 80369-20 : 2015, Small-Bore Connectors for Liquids and Gases in Healthcare Applications Part 20 Common Test Methods	Identical
IEC 62366-1:2015, 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 (<i>First Revision</i>)	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 dimensions and requirements for the design and functional performance of small-bore connectors intended to be used for connections in intravascular applications or hypodermic connections in hypodermic applications of medical devices and accessories.

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 80369-7:2021 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