

**BUREAU OF INDIAN STANDARDS**

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**भारतीय मानक मसौदा**  
**स्वास्थ्य सेवा अनुप्रयोगों में तरल पदार्थ और गैसों के लिए छोटे**  
**बोर कनेक्टर**  
**भाग 3 एंटरल अनुप्रयोगों के लिए कनेक्टर**

***Draft Indian Standard***

**Small-bore connectors for liquids and gases in  
healthcare applications**

**Part 3 Connectors for enteral applications**

ICS 11.040.25

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Hospital Planning Sectional Committee, MHD 14      Last date for comments: **23 August 2024**

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**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 terminologies and 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 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 14971:2007 Medical devices — Application of risk management to medical devices	IS/ISO 14971 : 2019 Medical devices - Application of risk management to medical devices (first revision)	Modified
ISO 80369-1:2010 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	Modified
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 80369-7 Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors with 6% (Luer) taper for intravascular or hypodermic applications	IS/ISO 80369-7 : 2016 Small-Bore Connectors for Liquids and Gases in Healthcare Applications Part 7 Connectors for Intravascular or Hypodermic 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 Small-bore connectors for liquids and gases in healthcare applications Part 20: Common test methods	Identical

The technical committee responsible for the preparation of this standard has reviewed the provisions of the following International Standards and has decided that they are acceptable for use in conjunction with this standard:

<i>International Standard</i>	<i>Title</i>
ASTM D638-10	Standard test method for tensile properties of plastics
ASTM D790-10	Standard test methods for flexural properties of unreinforced and reinforced plastics and electrical insulating materials

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 or analysis, shall be rounded off in accordance with IS 2: 2022 ‘Rules for rounding off numerical values (Second Revision)’.

**Note:** The technical content of the document has not been included as it is identical with the corresponding ISO standard. For details, please refer to ISO 80369-3: 2016 or kindly contact:

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## **SCOPE**

This part of ISO 80369 specifies the dimensions and requirements for the design and functional performance of small-bore connectors intended to be used for connections on enteral medical devices and accessories.

NOTE 1 Enteral medical devices include enteral feeding sets, enteral drainage sets, enteral syringes, and patient interface devices including access ports.

This part of ISO 80369 does not specify the dimensions and requirements for the medical devices or accessories that use these connectors. Such requirements are given in particular International Standards for specific medical devices or accessories.

This part of ISO 80369 does not specify requirements for small-bore connectors that are used for the following:

- gastric suction-only medical devices;
- oral-only medical devices;

EXAMPLE An oral tip syringe that is not intended to connect to another medical device. It is intended to administer directly to the patient's mouth.

- pressurizing and depressurizing the retention mechanism (e.g. balloon) used to hold invasive enteral medical devices in place;
- medical devices for rectal drainage, rectal administration of medicines or fluid, and any other rectal access medical device;
- gastrointestinal endoscopy equipment;
- skin level gastrostomy medical devices.