AS ISO 80369.3:2026
ISO 80369-3:2016

Australian STANDARD®

STANDARDS Australia

Small-bore connectors for liquids and gases in healthcare applications

Part 3: Connectors for enteral applications



AS ISO 80369.3:2026

This Australian Standard® was prepared by HE-028, Quality Management and Corresponding General Aspects for Medical Devices. It was approved on behalf of Standards Australia's Standards Development and Accreditation Committee on 28 April 2026.

This Standard was published on 15 May 2026.

The following are represented on Committee HE-028:

AusBiotech
Australian & New Zealand College of Anaesthetists
Australian Dental Industry Association
Australian Digital Health Agency
Australian Healthcare and Hospitals Association
Australian Society of Anaesthetists
Engineers Australia
Federation of Sterilizing Research and Advisory Council of Australia
Joint Accreditation System of Australia & New Zealand
Medical Technology Association of Australia
Queensland Health
Therapeutic Goods Administration (TGA)

This Standard was issued for comment as DR AS ISO 80369.3:2026

Status of this document

Standards Australia publications are periodically reviewed to ensure their ongoing relevance and accuracy. This document may be withdrawn, revised, or superseded at any time. To verify this document's current status, visit:

www.standards.org.au

ISBN: 978 1 76175 730 3

AS ISO 80369.3:2026
ISO 80369-3:2016

Australian Standard®

Small-bore connectors for liquids and gases in healthcare applications

Part 3: Connectors for enteral applications

First published as AS ISO 80369.3:2026.

© ISO 2026 — All rights reserved
© Standards Australia Limited 2026

All rights are reserved. No part of this work may be reproduced or copied in any form or by any means, electronic or mechanical, including photocopying, without the written permission of the publisher, unless otherwise permitted under the Copyright Act 1968 (Cth).

Users must not use the content in this publication in combination with artificial intelligence (AI) tools for any purpose, unless they have the express prior written consent from Standards Australia.

How to read this Standard

This page explains the meaning of the language and structure of this Standard.

Refer to Standards Australia's Standardisation Guide 006 for more details about drafting rules.

Australian and Australian/New Zealand Standards are voluntary unless they are referenced in legislation or called up in contracts.

Requirements

To conform to a Standard, all requirements in the Standard need to be met.

A requirement is any statement in the Standard which uses the word "shall".

Recommendations, permissions and possibilities

The following words are commonly used in Standards, but statements using them do not have to be followed to conform to the Standard:

(a) "should" means that something is recommended.

(b) "may" means that something is permitted.

(c) "can" means that something is possible.

Structure of Standards

A Standard always has the following parts:

(i) The Preface states who developed the Standard, what the Standard is aiming to do, and how it relates to other documents.

(ii) The Scope states what the Standard is about, what it covers and what it does not cover.

(iii) The Normative references clause lists other documents that are referenced in the Standard as part of requirements.

(iv) The Terms and definitions clause defines important terms to help with understanding the Standard.

A Standard may also include other parts, such as the following:

(1) A normative appendix sets additional requirements that need to be conformed to.

(2) An informative appendix provides additional information or guidance. They usually do not contain requirements. If an informative appendix does contain requirements, the Standard will explain when those requirements apply.

(3) A Bibliography lists documents referenced in the Standard but not as part of requirements.

Many Standards include notes. Notes provide recommendations and/or guidance only. They never contain requirements.

Preface

This Standard was prepared by the Standards Australia Committee HE-028, Quality Management and Corresponding General Aspects for Medical Devices.

The objective of this document is to specify 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 AS 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 AS ISO 80369 does not specify requirements for small-bore connectors that are used for the following:

(a) Gastric suction-only medical devices.

(b) 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.

(c) Pressurizing and depressurizing the retention mechanism (e.g. balloon) used to hold invasive enteral medical devices in place.

(d) Medical devices for rectal drainage, rectal administration of medicines or fluid, and any other rectal access medical device.

(e) Gastrointestinal endoscopy equipment.

(f) Skin level gastrostomy medical devices.

NOTE 2 Manufacturers are encouraged to incorporate the small-bore connectors specified in this part of AS ISO 80369 into enteral medical devices or accessories, even if currently not required by the relevant particular medical device standards. It is expected that when the relevant particular medical device standards are revised, requirements for small-bore connectors, as specified in AS ISO 80369, will be included.

This document is identical to, and has been reproduced from, ISO 80369-3:2016, *Small-bore connectors for liquids and gases in healthcare applications — Part 3: Connectors for enteral applications* and its Amendment No. 1 (2019), which has been added at the end of the source text.

© Standards Australia Limited 2026

Contents

Page

Preface ..... **v**
Foreword ..... **vii**
Introduction ..... **viii**
1 * Scope **1**
2 Normative references **1**
3 Terms and definitions **2**
4 General requirements **3**
4.1 General requirements for the ENTERAL APPLICATION 3
4.2 Material used for ENTERAL SMALL-BORE CONNECTORS 3
4.3 TYPE TESTS 3
5 Dimensional requirements for ENTERAL SMALL-BORE CONNECTORS **4**
6 Performance requirements **4**
6.1 Fluid leakage 4
6.1.1 Fluid leakage requirement 4
6.1.2 Leakage by pressure decay 4
6.1.3 Positive pressure liquid leakage 4
6.2 Stress cracking 4
6.3 Resistance to separation from axial load 4
6.4 Resistance to separation from unscrewing 5
6.5 Resistance to overriding 5
6.6 Disconnection by unscrewing 5
Annex A (informative) **Rationale and guidance** **6**
Annex B (normative) **ENTERAL SMALL-BORE CONNECTORS** **10**
Annex C (normative) **Reference CONNECTORS** **15**
Annex D (informative) **Assessment of MEDICAL DEVICES and their attributes with CONNECTIONS within this APPLICATION** **20**
Annex E (informative) **Summary of the usability requirements for SMALL-BORE CONNECTORS for ENTERAL applications** **21**
Annex F (informative) **Summary of SMALL-BORE CONNECTOR criteria and requirements for ENTERAL APPLICATIONS** **26**
Annex G (informative) **Summary of assessment of the design of the CONNECTORS for ENTERAL APPLICATIONS** **29**
Annex H (informative) **Reference to the essential principles** **35**
Annex I (informative) **Terminology — Alphabetized index of defined terms** **37**
Bibliography **38**
AMENDMENT 1 ..... **39**

© Standards Australia Limited 2026

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 210, *Quality management and corresponding general aspects for medical devices*, and IEC/SC 62D, *Electromedical equipment.* The draft was circulated for voting to the national bodies of both ISO and IEC.

ISO 80369 consists of the following parts, under the general title *Small-bore connectors for liquids and gases in healthcare applications*:

— *Part 1: General requirements*

— *Part 2: Connectors for breathing systems and driving gases applications*

— *Part 3: Connectors for enteral applications*

— *Part 5: Connectors for limb cuff inflation applications*

— *Part 6: Connectors for neuraxial applications*

— *Part 7: Connectors with 6 % (Luer) taper for intravascular or hypodermic applications*

— *Part 20: Common test methods*

An additional part on connectors for urethral and urinary applications is planned.

© Standards Australia Limited 2026

Introduction

This part of ISO 80369 was developed because of several incidents, with catastrophic consequences, resulting from firstly, the administration of inappropriate medication into the alimentary canal and secondly, from ENTERAL solutions being administered via incorrect routes, including intravenously and into the airway. Many incidents were reported leading to international recognition of the importance of these issues, and a need was identified to develop specific CONNECTORS for MEDICAL DEVICES and their ACCESSORIES used to deliver feed via the ENTERAL route.

The ISO 80369 series has been developed to prevent misconnection between SMALL-BORE CONNECTORS used in different APPLICATIONS. ISO 80369-1 specifies the requirements necessary to verify the designs of SMALL-BORE CONNECTORS to ensure that

a) they do not misconnect with other SMALL-BORE CONNECTORS, and

b) they safely and securely connect with their mating half.

ISO 80369-20 contains the common TEST METHODS to support the performance requirements for SMALL-BORE CONNECTORS.

This part of ISO 80369 specifies the design, the dimensions, and the drawings of SMALL-BORE CONNECTORS intended to be used in ENTERAL APPLICATIONS. Annex D to Annex G describe the methods by which this design has been assessed. Other parts of ISO 80369 include requirements for SMALL-BORE CONNECTORS used in different APPLICATION categories.

CONNECTORS manufactured to the dimensions set out within this part of ISO 80369 are dimensionally incompatible with any of the other CONNECTORS for APPLICATIONS identified in the ISO 80369 series for SMALL-BORE CONNECTORS, except as indicated in G.2. If fitted to the relevant MEDICAL DEVICES and ACCESSORIES, these CONNECTORS are to reduce the RISK of medication and liquid nutritional formula intended for ENTERAL administration from being delivered via an alternative route, such as intravenously or via an airway device.

During the development of this International Standard, the committee decided to cover the whole ENTERAL system but to have a separate International Standard for reservoir CONNECTORS. ISO 18250-3 specifies the requirements for ENTERAL reservoir CONNECTORS. This part of ISO 80369 includes the interface dimensions for SMALL-BORE CONNECTORS for access ports and PATIENT interfaces on ENTERAL feeding sets and ENTERAL syringes.

In this part of ISO 80369, the following print types are used:

— requirements and definitions: roman type;

— informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;

— terms defined in Clause 3 or as noted: small capitals.

In this part of ISO 80369, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this International Standard conform to usage described in ISO/IEC Directives, Part 2, Annex H. For the purposes of this part of ISO 80369, the auxiliary verb

— “shall” means that compliance with a requirement or a test is mandatory for compliance with this part of ISO 80369,

— “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this part of ISO 80369, and

— “may” is used to describe a permissible way to achieve compliance with a requirement or test.

© Standards Australia Limited 2026

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex A.

© Standards Australia Limited 2026

Australian Standard®

Small-bore connectors for liquids and gases in healthcare applications

Part 3: Connectors for enteral applications

1 * 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.

NOTE 2 MANUFACTURERS are encouraged to incorporate the SMALL-BORE CONNECTORS specified in this part of ISO 80369 into ENTERAL MEDICAL DEVICES or ACCESSORIES, even if currently not required by the relevant particular MEDICAL DEVICE standards. It is expected that when the relevant particular MEDICAL DEVICE standards are revised, requirements for SMALL-BORE CONNECTORS, as specified in ISO 80369, will be included.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 14971:2007, *Medical devices — Application of risk management to medical devices*

ISO 80369-1:2010, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

ISO 80369-6:2016, *Small-bore connectors for liquids and gases in healthcare applications — Part 6: Connectors for neuraxial applications*

© Standards Australia Limited 2026