AS ISO 80369.7:2026
ISO 80369-7:2021

Australian STANDARD®

STANDARDS Australia

Small-bore connectors for liquids and gases in healthcare applications

Part 7: Connectors for intravascular or hypodermic applications



AS ISO 80369.7:2026

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 80369.7:2026

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 This document may be withdrawn, revised, or superseded at any time.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 727 3

AS ISO 80369.7:2026
ISO 80369-7:2021

Australian Standard®

Small-bore connectors for liquids and gases in healthcare applications

Part 7: Connectors for intravascular or hypodermic applications

First published as AS ISO 80369.7:2026.

© Standards Australia Ltd 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 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.

This document does not specify requirements for the medical devices or accessories that use these connectors. Such requirements are given in particular documents for specific medical devices or accessories.

This document is identical to, and has been reproduced from, ISO 80369-7:2021, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications.*

As this document has been reproduced from an international document, a comma is to be read as a full point when referring to a decimal marker.

Australian or Australian/New Zealand Standards that are identical adoptions of international normative references may be used interchangeably. Refer to the online catalogue for information on specific Standards.

The terms “normative” and “informative” are used in Standards to define the application of the appendices or annexes to which they apply. A “normative” appendix or annex is an integral part of a Standard, whereas an “informative” appendix or annex is only for information and guidance.

© 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 *Luer connectors* 3
4.2 Type tests 3
5 Dimensional requirements for *Luer connectors* **3**
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 Sub-atmospheric pressure air leakage 4
6.3 Stress cracking 4
6.4 Resistance to separation from axial load 5
6.5 Resistance to separation from unscrewing 5
6.6 Resistance to overriding 5
Annex A (informative) **Rationale and guidance** **6**
Annex B (normative) ***Luer connectors*** **10**
Annex C (normative) **Reference *connectors*** **25**
Annex D (informative) **Assessment of *medical devices* and their attributes with *connections* within this *application*** **32**
Annex E (informative) **Summary of the usability requirements for *Luer connectors* for intravascular or hypodermic *applications*** **34**
Annex F (informative) **Summary of *Luer connector* design requirements for intravascular or hypodermic *applications*** **38**
Annex G (informative) **Summary of assessment of the design of the *Luer connector* for intravascular or hypodermic *applications*** **41**
Annex H (informative) **Reference to the essential principles** **44**
Annex I (informative) **Reference to the general safety and performance requirements** **45**
Annex J (informative) **Terminology — Alphabetized index of defined terms** **46**
Bibliography **47**

© 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 of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*, and IEC/SC62D, *Electromedical equipment*, in collaboration with the European Committee for Standardization (CEN) Technical Committee, CEN/CENELEC JTC3/WG 2, *Small-bore connectors*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 80369-7:2016), which has been technically revised.

The main changes compared to the previous edition are as follows:

— Tolerances of several reference *connector* dimensions are increased to facilitate easier manufacturing and certification. Most of the affected tolerances are for features that do not contact the test *connector* and therefore do not affect the test results. The angle tolerance for the bearing side of the threads do contact the *connector* under test but the change in the tolerance is considered likely have minimal to no effect on test outcomes.

— Some requirements for *Luer connectors* have been separated for *semi-rigid materials* and *rigid materials* to better ensure compatibility at the extreme of the design space. Definitions of *semi-rigid material* and *rigid material* have been added.

— The distance from the tip of the *connector* to the bottom of the first complete thread profile of the internal thread (*t* dimension) has been made an *auxiliary dimension* due to the difficulty in its measurement. The functional impact of the dimension is evaluated with the resistance to separation (from axial load) functional test.

— The N1 and N2 dimensions of the female *Luer lock connector* variant A (with lugs at right angle to axis) have been changed to allow measurement from the open end of the *connector*, to better ensure compatibility at the extreme of the design space.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

© Standards Australia Limited 2026

Introduction

This document was developed because of several incidents, with catastrophic consequences, resulting from inappropriate medication, liquid nutritional formula or air being administered intravenously. Many incidents have been reported leading to international recognition of the importance of these issues and a need has been identified to develop specific *connectors* for *medical devices* and their *accessories* used to deliver fluids in other *applications*.

The ISO 80369 series was developed to prevent misconnection between *small-bore connectors* used in different *applications*. ISO 80369-1 specifies the requirements necessary to verify the designs and dimensions 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.

This document specifies the design and the dimensions and the drawings of *small-bore connectors* intended to be used as conical fittings with a 6 % (Luer) taper for *connections* in intravascular or hypodermic *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 document are dimensionally incompatible with any of the other *connectors* for *applications* identified in the ISO 80369 series of documents for *small-bore connectors*, except as indicated in Annex G. If fitted to the relevant *medical devices* and *accessories*, these *connectors* should reduce the *risk* of air, non-vascular medication and liquid nutritional formula being delivered through an alternative route, such as intravenously or through an airway device.

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

In this document, the following verbal forms are used:

— “shall” indicates a requirement;

— “should” means that conformance with a requirement or a test is recommended but is not mandatory for conformance with this document;

— “may” indicates a permission;

— "can" indicates a possibility or a capability.

© Standards Australia Limited 2026

Australian Standard®

Small-bore connectors for liquids and gases in healthcare applications

Part 7: Connectors for intravascular or hypodermic applications

1 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*.

EXAMPLES Hypodermic syringes and needles or intravascular (IV) cannulae with male and female *Luer slip connectors* and *Luer lock connectors*.

NOTE 1 See Annex A.

NOTE 2 The *Luer connector* was originally designed for use at pressures up to 300 kPa.

This document does not specify requirements for the *medical devices* or *accessories* that use these *connectors*. Such requirements are given in particular documents for specific *medical devices* or *accessories*.

This document does not specify requirements for the following *small-bore connectors,* which are specified in other documents:

— haemodialyser, haemodiafilter and haemofilter blood compartment ports (ISO 8637 [5] and applicable portion of ISO 8638 [6] referencing blood compartment ports);

— haemodialysis, haemodiafiltration and haemofiltration equipment *connectors* (ISO 8637 [5]);

— infusion system closure piercing *connectors* (ISO 8536-4 [4]).

NOTE 3 *Manufacturers* are encouraged to incorporate the *small-bore connectors* specified in this document into *medical devices* or *accessories*, even if currently not required by the relevant particular *medical device* documents. It is expected that when the relevant particular *medical device* documents are revised, requirements for *small-bore connectors*, as specified in ISO 80369, will be included.

NOTE 4 ISO 80369-1:2018, Clause 7, specifies alternative methods of conformance with ISO 80369-1:2018, for *small-bore connectors* intended for use with intravascular *applications* or hypodermic *application medical devices* or *accessories*, which do not conform with this document.

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 14971:2019, *Medical devices — Application of risk management to medical devices*

ISO 80369-1:2018, *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*

ISO 80369-20:2015, *Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common test methods*

IEC 62366-1:2015, *Medical devices — Part 1: Application of usability engineering to medical devices*

© Standards Australia Limited 2026