



International
Standard

ISO 80369-1

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

**Part 1:
General requirements**

*Raccords de petite taille pour liquides et gaz utilisés dans le
domaine de la santé —*

Partie 1: Exigences générales

**Third edition
2025-10**

iTeh Standards
(<https://standards.iteh.ai>)
Document Preview

ISO 80369-1:2025

<https://standards.iteh.ai/catalog/standards/iso/6b7a6a1a-d5ed-46da-b3af-04ee9c95f79c/iso-80369-1-2025>

iTeh Standards
(<https://standards.iteh.ai>)
Document Preview

ISO 80369-1:2025

<https://standards.iteh.ai/catalog/standards/iso/6b7a6a1a-d5ed-46da-b3af-04ee9c95f79c/iso-80369-1-2025>



COPYRIGHT PROTECTED DOCUMENT

© ISO 2025

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

Foreword.....	iv
Introduction.....	vi
1 Scope.....	1
2 Normative references.....	1
3 Terms and definitions.....	2
4 <i>Small-bore connector non-interconnectable requirement</i>	4
5 <i>Small-bore connectors for clinical applications</i>	5
5.1 <i>Small-bore connectors for new clinical applications</i>	5
5.2 <i>Small-bore connectors for respiratory applications</i>	5
5.3 <i>Small-bore connectors for enteral applications</i>	5
5.4 <i>Small-bore connectors for limb cuff inflation applications</i>	6
5.5 <i>Small-bore connectors for neural applications</i>	6
5.6 <i>Small-bore connectors for intravascular and hypodermic applications</i>	6
5.7 <i>Other use cases utilizing an ISO 80369-7 small-bore connector</i>	6
6 <i>Alternative small-bore connectors</i>	7
Annex A (informative) <i>Rationale</i>	9
Annex B (normative) <i>Process for demonstrating non-interconnectable characteristics</i>	15
Annex C (normative) <i>Assessment procedures for small-bore connectors</i>	30
Annex D (informative) <i>Applications of small-bore connectors and the relevant standard</i>	33
Annex E (informative) <i>Design assessment summary</i>	35
Annex F (informative) <i>Reference to the IMDRF essential principles</i>	38
Annex G (informative) <i>Alphabetized index of defined terms</i>	39
Bibliography.....	41

[ISO 80369-1:2025](https://standards.iteh.ai/catalog/standards/iso/6b7a6a1a-d5ed-46da-b3af-04ee9c95f79c/iso-80369-1-2025)

<https://standards.iteh.ai/catalog/standards/iso/6b7a6a1a-d5ed-46da-b3af-04ee9c95f79c/iso-80369-1-2025>

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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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 products with a health purpose including medical devices*, in collaboration with Technical Committee IEC/SC 62D, *Particular medical equipment, software, and systems*, and with the European Committee for Standardization (CEN) Technical Committee CEN/CLC/JTC 3, *Quality management and corresponding general aspects for medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO 80369-1:2018), which has been technically revised.

The main changes are as follows:

- update of normative references;
- update of the document according to ISO/IEC Directives, Part 2;
- addition of *respiratory applications*;
- addition of *interference test part, misconnection* and *unintended connection* definitions;
- deletion of [Clause 4](#) for materials requirements, as those requirements are or will be placed in the individual *connector* parts of the series and normative [Annex B](#) describes the analysis and testing processes for determining *non-interconnectable* characteristics;
- revision of [Annex B](#) by summarising process description and adding figure, editorial changes and adding the dimensional analysis case “potential misconnection”;
- deletion of the original Annex C, replaced with normative reference to parts of ISO 20417;
- addition of [Annex E](#) summarizing the design assessments of the *application* parts of this series of documents;
- replacement of contents of [Annex F](#) by referencing the relevant essential principles and labelling guidance of the International Regulators Forum (IMDRF);

ISO 80369-1:2025(en)

- extension of the use of the ISO 80369-7 *connector* to *medical devices* and *accessories* beyond intravascular and hypodermic *applications* where the *risk* is acceptable.

A list of all parts in the ISO and IEC 80369 series can be found on the ISO website.

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.

iTeh Standards (<https://standards.iteh.ai>) Document Preview

ISO 80369-1:2025

<https://standards.iteh.ai/catalog/standards/iso/6b7a6a1a-d5ed-46da-b3af-04ee9c95f79c/iso-80369-1-2025>

Introduction

In the 1990s, concern grew regarding the proliferation of *medical devices* fitted with *Luer connectors* as specified in the ISO 594 series^[1] and the reports of *patient* death or injury arising from *unintended connections* that resulted in the inappropriate delivery of fluids and gases via incorrect routes. In addition to clinical and workplace protocols and warnings, attention was turned to engineering solutions to reduce the probability of wrong route administration of liquids and gases.

Concerns regarding the use of *Luer connectors* with enteral feeding tubes and gas sampling and gas delivery systems were raised with CEN Bureau Technique (CEN/BT) and the European Commission. In November 1997, the newly created CEN Healthcare Forum (CHeF) steering group set up a Forum Task Group (FTG) to consider the problem.

The FTG produced CEN Report, CEN/CR 13825,^[9] in which they concluded that there is a problem arising from the use of a single *connector* design to several different *applications*. In a coronary care unit, there could be as many as 40 *Luer connectors* on the *medical devices* used with a single *patient* until the use of *connectors* defined in the ISO and IEC 80369 documents started to be established. Therefore, it is not surprising that *unintended connections* were made.

Medical devices have, for many years, followed the established principle of “safety under single fault conditions.” Simply stated, this means that a single fault should not result in an unacceptable *risk*. This principle is embodied in the requirements of numerous *medical device* standards.^[6] Extending this principle to the use of *Luer connectors* (i.e. that an *unintended connection* should not result in an unacceptable *risk* to a *patient*) the FTG recommended that the *Luer connector* should be restricted to *medical devices* intended to be connected to the vascular system or a hypodermic syringe. In addition, the FTG recommended that new designs of *small-bore connectors* should be developed for other *applications*, and these should be *non-interconnectable* with *Luer connectors* and each other.

International medical device regulators forum (IMDRF), GRRP N47:2024,^[10] Essential Principle 5.1.3, addresses this type of problem:

Risk control measures adopted by manufacturers for the design and manufacture of the medical device and IVD medical device should conform to safety principles, taking account of the generally acknowledged state of the art. When risk reduction is required, manufacturers should control risks so that the residual risk associated with each hazard as well as the overall residual risk is judged acceptable. In selecting the most appropriate solutions, manufacturers should, in the following order of priority:

- a) eliminate or appropriately reduce risks through safe design and manufacture;
- b) where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated;
- c) provide information for safety (warnings/precautions/contra-indications) and, where appropriate, training to users.

It is understood that *small-bore connector* systems cannot be designed to overcome all chances of *unintended connections* with the potential for wrong route administration or to eliminate deliberate misuse. With these *application-specific connectors* now available, the *risk* of unintended connections and wrong route administration is greatly reduced thereby improving *patient* safety. Introduction of *medical devices* and *accessories* utilizing these *small-bore connectors* is progressing albeit slowly.

The *risks* associated with *unintended connections* and subsequent wrong route administration of liquids and gases cannot be fully assessed until these *small-bore connectors* are part of a *medical device* or *accessory*. Therefore, the intended *applications* specified are recommendations. It is expected that particular *medical device* standards will reference the *connectors* from the relevant parts of the ISO and IEC 80369 series if considered appropriate.

This document contains the general requirements to reduce *connections* between *small-bore connectors* used in different *applications* as well as specifying those *applications*.

ISO 80369-1:2025(en)

It specifies the general requirements and *test methods* for assessing the *non-interconnectable* characteristics of *small-bore connectors* within the ISO and IEC 80369 series.

The *Luer connector* as originally defined in the withdrawn ISO 594 series has been widely used on many *medical devices* and *accessories* and in a wide range of clinical *applications* for many years. The clinical *applications* that present the highest *risk* to a *patient* from wrong route administration of liquids and gases have been identified and are those included in the *application* parts of the ISO and IEC 80369 series. ISO 80369-7, which replaces the ISO 594 series (i.e. the *Luer connector*), is intended for use with intravascular or hypodermic *applications*.

However, there are currently *medical devices* and *accessories* which incorporate a *Luer connector*, but do not fall into any of the *applications* specified by the ISO and IEC 80369 series. There are also some *medical devices* and *accessories* within the *applications* of the ISO and IEC 80369 series *applications* that incorporate a *Luer connector*. Those that present no unacceptable *risk* to the *patient* from an *unintended connection* to a *medical device* or *accessory* within intravascular or hypodermic *application* are suitable for consideration for the use of the *Luer connector* as specified in ISO 80369-7.

ISO 80369-20 specifies the common *test methods* for assessing the basic performance requirements specified in ISO 80369-2, ISO 80369-3, IEC 80369-5, ISO 80369-6 and ISO 80369-7 for *small-bore connectors*.

ISO 80369-2, ISO 80369-3, IEC 80369-5, ISO 80369-6 and ISO 80369-7 specify the material requirements, dimensional requirements for the interfaces of the *connectors* and the specific performance requirements for assessing the interconnectability of the mating connectors.

The designs and dimensions of *small-bore connectors* specified in ISO 80369-2, ISO 80369-3, IEC 80369-5, ISO 80369-6 and ISO 80369-7 have been successfully assessed according to the requirements of this document (i.e. have been proven to be acceptable with regard to the *risk of misconnection* with the other *connectors* of this series).

The *risks* of changing to these new *small-bore connectors* should be assessed before these *small-bore connectors* are incorporated into *medical devices* as they will when the relevant particular *medical device* standards are revised.

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 requirements.
- “Should” indicates recommendations.
- “May” indicates permissions.
- “Can” indicates possibility or capability.

This document uses italic type to distinguish defined terms from the rest of the text. It is important for the correct understanding of this document that those defined terms are identifiable throughout the text of this document. A list of the defined terms used in italics in this document is given in [Annex G](#).

Requirements in this document have been broken down so that each requirement is clearly delineated and listed individually. This has been done to support the common practice of automatic tracking of requirements and automatic verification of the requirements of this document.

[Annex A](#) contains guidance and rationale on specific subclauses in this document.