SLOVENSKI STANDARD
SIST EN ISO 80369-1:2026

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SIST EN ISO 80369-1:2019

Priključki z majhnim premerom za tekočine in pline za uporabo v zdravstvu - 1. del: Splošne zahteve (ISO 80369-1:2025)

Small-bore connectors for liquids and gases in healthcare applications - Part 1: General requirements (ISO 80369-1:2025)

Verbindungsstücke mit kleinem Durchmesser für Flüssigkeiten und Gase in medizinischen Anwendungen - Teil 1: Allgemeine Anforderungen (ISO 80369-1:2025)

Raccords de petite taille pour liquides et gaz utilisés dans le domaine de la santé - Partie 1: Exigences générales (ISO 80369-1:2025)

Ta slovenski standard je istoveten z: **EN ISO 80369-1:2026**

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment
11.040.20	Transfuzijska, infuzijska in injekcijska oprema	Transfusion, infusion and injection equipment

SIST EN ISO 80369-1:2026 **en,fr,de**

EUROPEAN STANDARD

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EUROPÄISCHE NORM

EN ISO 80369-1

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English version

Small-bore connectors for liquids and gases in healthcare applications - Part 1: General requirements (ISO 80369-1:2025)

Raccords de petite taille pour liquides et gaz utilisés dans le domaine de la santé - Partie 1: Exigences générales (ISO 80369-1:2025)

Verbindungsstücke mit kleinem Durchmesser für Flüssigkeiten und Gase in medizinischen Anwendungen - Teil 1: Allgemeine Anforderungen (ISO 80369-1:2025)

This European Standard was approved by CEN on 16 September 2025.

CEN and CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN and CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN and CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN and CENELEC members are the national standards bodies and national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and United Kingdom.

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Ref. No. EN ISO 80369-1:2026 E

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European foreword

This document (EN ISO 80369-1:2026) has been 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 CEN-CENELEC/ JTC 3 “Quality management and corresponding general aspects for medical devices” the secretariat of which is held by NEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by December 2026, and conflicting national standards shall be withdrawn at the latest by December 2026.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN-CENELEC shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 80369-1:2018.

This document has been prepared under a standardization request addressed to CEN and CENELEC by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

For the relationship with EU Legislation, see informative Annex ZA, which is an integral part of this document.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN and CENELEC websites.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 80369-1:2025 has been approved by CEN-CENELEC as EN ISO 80369-1:2026 without any modification.

Annex ZA
(informative)

Relationship between this European standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered

This European standard has been prepared under M/575 to provide one voluntary means of conforming to the General Safety and Performance Requirements of Regulation (EU) 2017/745 of 5 April 2017 concerning medical devices [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up.

Once this standard is cited in the Official Journal of the European Union under that Regulation, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding General Safety and Performance Requirements of that Regulation, and associated EFTA Regulations.

Where a definition in this standard differs from a definition of the same term set out in Regulation (EU) 2017/745, the differences shall be indicated in this Annex ZA. For the purpose of using this standard in support of the requirements set out in Regulation (EU) 2017/745, the definitions set out in this Regulation prevail.

Where the European standard is an adoption of an International Standard, the scope of this standard can differ from the scope of the European Regulation that it supports. As the scope of the applicable regulatory requirements differ from nation to nation and region to region, the standard can only support European regulatory requirements to the extent of the scope of the European regulation for medical devices (EU) 2017/745.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Regulation (EU) 2017/745. This means that risks have to be ‘reduced as far as possible’, ‘reduced to the lowest possible level’, ‘reduced as far as possible and appropriate’, ‘removed or reduced as far as possible’, ‘eliminated or reduced as far as possible’, ’removed or minimized as far as possible’, or ‘minimized’, according to the wording of the corresponding General Safety and Performance Requirement.

NOTE 2 The manufacturer’s policy for determining **acceptable risk** must be in compliance with General Safety and Performance Requirements 1, 2, 3, 4, 5, 8, 9, 10, 11, 14, 16, 17, 18, 19, 20, 21 and 22 of the Regulation.

NOTE 3 When a General Safety and Performance Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 — Correspondence between this European standard and Annex I of Regulation (EU) 2017/745 [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / subclause(s) of this EN	Remarks / Notes
14.1	4, 5	This requirement is partially covered in that intended connections can only be connected to intended medical devices or accessories or medical devices or accessories, where the unintended connection is an acceptable risk, are able to be connected. Such unintended connections are required to be marked with a safety sign and appropriate information for safety placed in the instructions for use. Misconnections between small-bore connectors of this series of standards, which can result in an unacceptable risk, are made impossible by design. But coverage is only provided where the material has a modulus of elasticity greater than 700 MPa. The presumption of conformity is only conferred to small-bore connectors specified in this series of standards – proprietary small-bore connectors are not covered.
14.5	4, 5	This requirement is partially covered as it does not cover manufacture and in that by ensuring that the intended connections do not leak and can only be connected to intended medical devices or accessories. But coverage is only provided where the material has a modulus of elasticity greater than 700 MPa. The presumption of conformity is only conferred to small-bore connectors specified in this series of standards – proprietary small-bore connectors are not covered.
20.4	4, 5	This requirement is partially covered in that intended connections can only be connected to intended medical devices or accessories or medical devices or accessories, where the unintended connection is an acceptable risk, are able to be connected. Misconnections between small-bore connectors of this series of standards, which can result in an unacceptable risk, are made impossible by design. But coverage is only provided where the material has a modulus of elasticity greater than 700 MPa. The presumption of conformity is only conferred to

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / subclause(s) of this EN	Remarks / Notes
		small-bore connectors specified in this series of standards – proprietary small-bore connectors are not covered.
20.5	4, 5	This requirement is partially covered in that misconnections between small-bore connectors of this series of standards, which can result in an unacceptable risk, are made impossible by design or medical devices or accessories, where the unintended connection is an acceptable risk, are able to be connected. Such unintended connections are required to be marked with a safety sign and appropriate information for safety placed in the instructions for use. But coverage is only provided where the material has a modulus of elasticity greater than 700 MPa. The presumption of conformity is only conferred to small-bore connectors specified in this series of standards – proprietary small-bore connectors are not covered.
21.1	4, 5	This requirement is partially covered in that by ensuring that the intended connections do not leak and can only be connected to intended medical devices or accessories. Such connections permit a medical device to be capable of controlling the flowrate. But coverage is only provided where the material has a modulus of elasticity greater than 700 MPa. The presumption of conformity is only conferred to small-bore connectors specified in this series of standards – proprietary small-bore connectors are not covered.

Table ZA.2 — Normative references from Clause 2 of this document and their corresponding European publications

Reference in Clause 2	International Standard Edition	Title	Corresponding European Standard Edition
ISO 14971:2019	ISO 14971:2019	Medical devices — Application of risk management to medical devices	EN ISO 14971:2019 +A11:2021
ISO 20417:2021	ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer	EN ISO 20417:2021
ISO 80369-2:2024	ISO 80369-2:2024	Small-bore connectors for liquids and gases in healthcare applications — Part 2: Connectors for respiratory applications	EN ISO 80369-2:2024
ISO 80369-3:2016 +AMD1:2019	ISO 80369-3:2016 +AMD1:2019	Small-bore connectors for liquids and gases in healthcare applications — Part 3: Connectors for enteral applications	EN ISO 80369-3:2016 +A1:2022
IEC 80369-5:2016	IEC 80369-5:2016	Small-bore connectors for liquids and gases in healthcare applications — Part 5: Connectors for limb cuff inflation applications	EN IEC 80369-5:2016 +AC:2017-02 +AC:2021-06
ISO 80369-6:2016	ISO 80369-6:2016	Small-bore connectors for liquids and gases in healthcare applications — Part 6: Connectors for neural applications	EN ISO 80369-6:2016
ISO 80369-7:2021	ISO 80369-7:2021	Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications	EN ISO 80369-7:2021
IEC 62366-1:2015 +AMD1:2020	IEC 62366-1:2015 +AMD1:2020	Medical devices — Part 1: Application of usability engineering to medical devices	EN IEC 62366-1:2015 +A1:2020 +AC:2015 +AC:2016-09

The documents listed in the Column 1 of Table ZA.2, in whole or in part, are normatively referenced in this document, i.e. are indispensable for its application. The achievement of the presumption of conformity is subject to the application of the edition of Standards as listed in Column 4 or, if no European Standard Edition exists, the International Standard Edition given in Column 2 of Table ZA.2.

WARNING 1 Presumption of conformity stays valid only as long as a reference to this European standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 Other Union legislation may be applicable to the product(s) falling within the scope of this standard.

International Standard

ISO 80369-1

Third edition
2025-10

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

Reference number
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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.

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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);

— 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.