

<div>STN</div>	<div>Spojky s malým priemerom na kvapaliny a plyny v aplikáciách zdravotnej starostlivosti Časť 2: Spojky na respiračné aplikácie (ISO 80369-2: 2024)</div>	<div>STN EN ISO 80369-2</div> <div>85 5260</div>
----------------	---	--

Small-bore connectors for liquids and gases in healthcare applications - Part 2: Connectors for respiratory applications (ISO 80369-2:2024)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 11/24

Obsahuje: EN ISO 80369-2:2024, ISO 80369-2:2024

139399

EUROPEAN STANDARD

EN ISO 80369-2

NORME EUROPÉENNE

EUROPÄISCHE NORM

August 2024

ICS 11.040.20; 11.040.10

English version

Small-bore connectors for liquids and gases in healthcare applications - Part 2: Connectors for respiratory applications (ISO 80369-2:2024)

Raccords de petite taille pour liquides et gaz utilisés dans le domaine de la santé - Partie 2: Raccords destinés à des applications respiratoires (ISO 80369-2:2024)

Verbindungsstücke mit kleinem Durchmesser für Flüssigkeiten und Gase in medizinischen Anwendungen - Teil 2: Verbindungsstücke für respiratorische Anwendungen (ISO 80369-2:2024)

This European Standard was approved by CEN on 3 July 2024.

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.



**CEN-CENELEC Management Centre:
Rue de la Science 23, B-1040 Brussels**

EN ISO 80369-2:2024 (E)

Contents	Page
European foreword.....	3
Annex ZA (informative) Relationship between this European standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered	4

European foreword

This document (EN ISO 80369-2:2024) 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 February 2025, and conflicting national standards shall be withdrawn at the latest by February 2025.

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 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 80369-2:2024 has been approved by CEN-CENELEC as EN ISO 80369-2:2024 without any modification.

EN ISO 80369-2:2024 (E)**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 Z. 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 , 6 , 7	This requirement is partially covered in that intended connections do not leak and can only be connected to intended medical devices or accessories. Misconnections between small-bore connectors of this series of standards, which could result in an unacceptable risk, are made impossible by design.
14.5	4 , 5 , 6 , 7	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.
20.4	4 , 5 , 6 , 7	This requirement is partially covered in that intended connections do not leak and can only be connected to intended medical devices or accessories. Misconnections between small-bore connectors of this series of standards, which could result in an unacceptable risk, are made impossible by design.
20.5	4 , 5 , 6 , 7	This requirement is partially covered in that intended connections can only be connected to intended medical devices or accessories. Misconnections between small-bore connectors of this series of standards, which could result in an unacceptable risk, are made impossible by design.
21.1	4 , 5 , 6 , 7	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.

EN ISO 80369-2:2024 (E)

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.

For devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC on Machinery, in accordance with Article 1(12) of Regulation (EU) 2017/745, the following [Table ZA.2](#) details the relevant Essential Health and Safety Requirements of Directive 2006/42/EC on Machinery to the extent to which they are more specific than the General Safety and Performance Requirements set out in Chapter II of Annex I of Regulation (EU) 2017/745 along with the corresponding clauses of this European Standard. [Table ZA.2](#), however, does not imply any citation in the OJEU under the machinery directive and thus does not provide presumption of conformity for the machinery directive.

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 the Annex Z. 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.

For the case that small-bore connectors are attached to medical devices or accessories which are also machinery as defined in the Machinery Directive 2006/42/EC, the relevant Essential Health and Safety Requirements from Directive 2006/42/EC on machinery are also addressed by this Document (according to article 1, item 12, of Regulation (EU) 2017/745).

Table ZA.2 — Relevant Essential Health and Safety Requirements from Directive 2006/42/EC on machinery that are addressed by this Document (according to article 1, item 12, of Regulation (EU) 2017/745)

Essential Health and Safety Requirements of Directive 2006/42/EC	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
1.5.4	4 , 5 , 6 , 7	This requirement is partially covered in that misconnections between small-bore connectors of this series of standards, which could result in an unacceptable risk, are made impossible by design.

Table ZA.3 — Applicable Standards to confer presumption of conformity as described in this Annex ZA

Column 1 Reference in Clause 2	Column 2 Inter-national Standard Edition	Column 3 Title	Column 4 Corresponding European Standard Edition
ISO 80369-1:2018	ISO 80369-1:2018	Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements	EN ISO 80369-1:2018
ISO 80369-20:2015	ISO 80369-20:2015	Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common test methods	EN ISO 80369-20:2015
ISO 527-1:2019 ed.3	ISO 527-1:2019 ed.3	Determination of tensile properties — Part 1: General principles	EN ISO 527-1:2019 ed.3
ISO 178:2019 ed.6	ISO 178:2019 ed.6	Determination of flexural properties	EN ISO 178:2019
ISO 6892-1:2019 ed.3	ISO 6892-1:2019 ed.3	Metallic materials — Tensile testing — Part 1: Method of test at room temperature	EN ISO 6892-1:2019
ISO 291:2008 ed.4	ISO 291:2008 ed.4	Plastics — Standard atmospheres for conditioning and testing	EN ISO 291:2008
ASTM D638-22 See NOTE 1 below	ISO 527-1:2019 ed.3	Standard Test Method for Tensile Properties of Plastics	----- -----

EN ISO 80369-2:2024 (E)

ASTM D790-17 See NOTE 2 below	ISO 178:2019 ed.6	Standard Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials	----- -----
----------------------------------	-------------------	---	----------------

NOTE 1 Both ISO 527-1 and ASTM D638 specify test methods for the tensile test. Both standards are technically equivalent, but do not provide fully comparable results, since specimen shapes, test speeds and the method of determining results differ in some respects. The results of both standards are sufficiently compatible to differentiate the modulus of elasticity. See also References (15) and (19).

NOTE 2 ISO 178 is very similar to ASTM D790, with some differences:

ISO 178 requires the use of either a deflectionmeter or a conformity adjustment to determine modulus. For ASTM D790, modulus can be calculated by crosshead displacement alone.

Preferred specimen sizes vary, and since the test speed depends on the specimen depth, the test speeds of the standards may differ. The recommended depth of ISO 178 specimens is 4 mm, while the recommended depth of ASTM D790 specimens is 3,2 mm.

For ASTM D790, only one test speed is allowed, while ISO 178 allows a second (faster) test speed after measuring the module. The results of both standards are sufficiently compatible to differentiate the modulus of elasticity. See also References (15) and (19).

The documents listed in the Column 1 of [Table ZA.3](#), 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.3](#).



International Standard

ISO 80369-2

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

Part 2: Connectors for respiratory applications

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

Partie 2: Raccords destinés à des applications respiratoires

**First edition
2024-07**

ISO 80369-2:2024(en)**COPYRIGHT PROTECTED DOCUMENT**

© ISO 2024

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

ISO 80369-2:2024(en)

Contents		Page
Foreword.....		iv
Introduction.....		v
1	Scope.....	1
2	Normative references.....	1
3	Terms and definitions.....	2
4	Non-interconnectability requirements.....	3
5	Material requirements.....	3
6	Dimensions and tolerances.....	3
6.1	R1 <i>small-bore connectors</i>	3
6.2	R2 <i>small-bore connectors</i>	3
7	Performance requirements.....	4
7.1	Leakage by pressure decay.....	4
7.2	Sub-atmospheric pressure air leakage.....	4
7.3	Stress cracking.....	4
7.4	Resistance to separation from axial load.....	4
7.5	Resistance to separation from unscrewing.....	4
7.6	Resistance to overriding.....	5
7.7	Disconnection by unscrewing.....	5
Annex A (informative) Rationale and guidance.....		6
Annex B (normative) <i>Small-bore connectors for respiratory applications</i>		7
Annex C (normative) Reference connectors for testing <i>small-bore connectors</i> for respiratory applications.....		16
Annex D (informative) Assessment of <i>medical devices</i> and their attributes with connections within this application.....		31
Annex E (informative) Summary of the usability requirements for <i>small-bore connectors</i> for respiratory applications.....		37
Annex F (informative) Summary of <i>small-bore connector</i> design requirements for respiratory applications.....		39
Annex G (informative) Summary of assessment of the design of the <i>small-bore connectors</i> for respiratory applications.....		45
Annex H (informative) Reference to the IMDRF essential principles.....		48
Annex I (informative) Terminology — Alphabetized index of defined terms.....		49
Bibliography.....		50

ISO 80369-2:2024(en)**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).

A list of all parts in the ISO 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.

ISO 80369-2:2024(en)**Introduction**

The *small-bore connectors* specified in this document conform with the requirements for *non-interconnectable* characteristics of ISO 80369-1.

This document includes design and performance requirements for *small-bore connectors* for the respiratory *application*.

It is recognised that the *small-bore connectors* specified in this document might not be suitable for some *medical devices* or *accessories* within this *application*.

[Annex A](#) contains guidance or rationale on the requirements in this document.

This document has been prepared to support the essential principles for *medical device* or *accessories* incorporating respiratory *application small-bore connectors* according to the International Medical Device Regulators Forum (IMDRF). See [Annex H](#).

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” indicates a recommendation;
- “may” indicates a permission;
- “can” indicates a possibility or capability; and
- “must” is used to express an external constraint.

NOTE 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 terms in italics is given in [Annex I](#).

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

Part 2: Connectors for respiratory applications

1 Scope

This document specifies the design and dimensions for two *small-bore connectors* intended to be used for *connections* in *respiratory applications* of *medical devices* and *accessories*. One *connector* (R1) is intended for use on *medical devices* and *accessories* subjected to pressures up to 15 kPa (e.g. a *breathing system*). The other *connector* (R2) is intended for use on *medical devices* and *accessories* subjected to higher pressures between 15 kPa and 600 kPa (e.g. oxygen therapy tubing).

NOTE 1 The pressure is related to pressure available at the source to which the *medical device* is connected.

NOTE 2 The intended *application* does not preclude the use of other *connectors* on *medical devices* or *accessories* within this *application*.

NOTE 3 Requirements for alternative connectors for this intended application are specified in ISO 80369-1.

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

NOTE 4 If a device-specific standard does not exist, the performance and material requirements specified in ISO 80369-1 can be used as guidance.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 178, *Plastics — Determination of flexural properties*

ISO 527 (all parts), *Determination of tensile properties*

ISO 6892-1:2019, *Metallic materials — Tensile testing — Part 1: Method of test at room temperature*

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 80369-7:2021, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

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

ASTM D638-22, *Standard Test Method for Tensile Properties of Plastics*

ASTM D790-17, *Standard Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials*

koniec náhľadu – text ďalej pokračuje v platenej verzii STN