SLOVENSKI STANDARD
SIST EN ISO 80369-2:2024

01-oktober-2024

Priključki z majhnim premerom za tekočine in pline za uporabo v zdravstvu - 2. del: Priključki za respiratorno uporabo (ISO 80369-2:2024)

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

Verbindungsstücke mit kleinem Durchmesser für Flüssigkeiten und Gase in medizinischen Anwendungen - Teil 2: Verbindungsstücke für Atemsysteme und Antriebsgasanwendungen (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)

Ta slovenski standard je istoveten z: **EN ISO 80369-2:2024**

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 80369-2:2024 **en,fr,de**

EUROPEAN STANDARD

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EN ISO 80369-2

August 2024

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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.

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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.

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 Regu- lation (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.

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 Require- ments 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 applica- tions — Part 1: General require-ments	EN ISO 80369-1:2018
ISO 80369-20:2015	ISO 80369-20:2015	Small-bore connectors for liquids and gases in healthcare applica- tions — 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 proper- ties — Part 1: General principles	EN ISO 527-1:2019 ed.3
ISO 178:2019 ed.6	ISO 178:2019 ed.6	Determination of flexural proper- ties	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	----------

ASTM D790-17 See NOTE 2 below	ISO 178:2019 ed.6	Standard Test Methods for Flexur- al 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 deflectometer 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

First edition
2024-07

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

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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).

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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.

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