

STN	Spojky s malým priemerom na kvapaliny a plyny v aplikáciách zdravotnej starostlivosti Časť 20: Spoločné skúšobné metódy (ISO 80369-20: 2024)	STN EN ISO 80369-20 85 5260
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Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods (ISO 80369-20: 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. 01/25

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English version

Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods (ISO 80369-20:2024)

Raccords de petite taille pour liquides et gaz utilisés dans le domaine de la santé - Partie 20: Méthodes d'essai communes (ISO 80369-20:2024)

Verbindungsstücke mit kleinem Durchmesser für Flüssigkeiten und Gase in medizinischen Anwendungen - Teil 20: Allgemeine Prüfverfahren (ISO 80369-20:2024)

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

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European foreword

This document (EN ISO 80369-20:2024) 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of an identical text or by endorsement, at the latest by May 2025, and conflicting national standards shall be withdrawn at the latest by May 2025.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.

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Endorsement notice

The text of ISO 80369-20:2024 has been approved by CEN-CENELEC as EN ISO 80369-20:2024 without any modification.



International Standard

ISO 80369-20

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

Part 20: Common test methods

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

Partie 20: Méthodes d'essai communes

**Second edition
2024-11**

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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

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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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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 second edition cancels and replaces the first edition (ISO 80369-20:2015), which has been technically revised.

The main changes are as follows:

- clarification that these test methods are also used by the ISO 18250 series;
- major technical revision of the *test methods* described in [Annex B](#) “Leakage by pressure decay test method” and [Annex D](#) “Subatmospheric-pressure air leakage test method” (replacement of leakage rate by the pressure change as acceptance criterion; definition of three defined mandatory test conditions; more information about this change is included in [Annex A](#));
- introduction of a new attributive *test method* “Air leakage during aspiration” as [Annex K](#);
- editorial revision of the assembling *procedures* of a *connector* under test, affecting all annexes with *test methods*;
- editorial update according to ISO/IEC Directives, Part 2;
- replacement of the terms “male” by “*cone*” and “female” by “*socket*” in the description of a *connector*;
- update of dated normative references;
- definition for *type test* has been updated;
- expansion of the range of environmental test conditions for relative humidity;

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- extension of requirements for test reports;
- clarification that all tests are intended to be *type tests*.

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.

ISO 80369-20:2024(en)**Introduction**

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 this document (in italics) is given in [Annex M](#).

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.

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

Part 20: Common test methods

1 Scope

NOTE [Clause A.2](#) contains guidance or rationale for this clause.

This document specifies the common *test methods* to evaluate the performance requirements for *small-bore connectors* specified in the ISO and IEC 80369 series as well as the ISO 18250 series.

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

ISO 80369-1:—¹⁾, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

koniec náhľadu – text ďalej pokračuje v platenej verzii STN