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**Priključki z majhnim premerom za tekočine in pline za uporabo v zdravstvu - 7. del:
Priključki za intravaskularno ali podkožno uporabo (ISO 80369-7:2021)**

Small-bore connectors for liquids and gases in healthcare applications - Part 7:
Connectors for intravascular or hypodermic applications (ISO 80369-7:2021)

Steckverbinder mit kleiner Bohrung für Flüssigkeiten und Gase im Gesundheitswesen -
Teil 7: Steckverbinder für intravaskuläre oder subkutane Anwendungen (ISO 80369-
7:2021)

Raccords de petite taille pour liquides et gaz utilisés dans le domaine de la santé - Partie
7: Connecteurs pour les applications intravasculaires ou hypodermiques (ISO 80369-
7:2021)

Ta slovenski standard je istoveten z: EN ISO 80369-7:2021

ICS:

11.040.25	Injekcijske brizge, igle in katetri	Syringes, needles and catheters
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Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications (ISO 80369-7:2021)

Raccords de petite taille pour liquides et gaz utilisés dans le domaine de la santé - Partie 7: Connecteurs pour les applications intravasculaires ou hypodermiques (ISO 80369-7:2021)

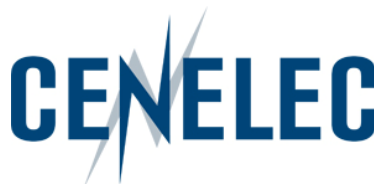
Steckverbinder mit kleiner Bohrung für Flüssigkeiten und Gase im Gesundheitswesen - Teil 7: Steckverbinder für intravaskuläre oder subkutane Anwendungen (ISO 80369-7:2021)

This European Standard was approved by CEN on 29 October 2020.

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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.

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European foreword

This document (EN ISO 80369-7:2021) has been prepared by Technical Committee ISO/TC 210 "Quality management and corresponding general aspects for medical devices" in collaboration with Technical Committee CEN/CLC/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 November 2021, and conflicting national standards shall be withdrawn at the latest by November 2021.

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

This document supersedes EN ISO 80369-7:2017.

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, Turkey and the United Kingdom.

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INTERNATIONAL
STANDARD

ISO
80369-7

Second edition
2021-05

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

**Part 7:
Connectors for intravascular or
hypodermic applications**

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

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*Partie 7: Connecteurs pour les applications intravasculaires ou
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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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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 medical devices*, and IEC/SC62D, *Electromedical equipment*, in collaboration with the European Committee for Standardization (CEN) Technical Committee, CEN/CENELEC JTC3/WG 2, *Small-bore connectors*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 80369-7:2016), which has been technically revised.

The main changes compared to the previous edition are as follows:

- Tolerances of several reference *connector* dimensions are increased to facilitate easier manufacturing and certification. Most of the affected tolerances are for features that do not contact the test *connector* and therefore do not affect the test results. The angle tolerance for the bearing side of the threads do contact the *connector* under test but the change in the tolerance is considered likely have minimal to no effect on test outcomes.
- Some requirements for *Luer connectors* have been separated for *semi-rigid materials* and *rigid materials* to better ensure compatibility at the extreme of the design space. Definitions of *semi-rigid material* and *rigid material* have been added.
- The distance from the tip of the *connector* to the bottom of the first complete thread profile of the internal thread (*t* dimension) has been made an *auxiliary dimension* due to the difficulty in its measurement. The functional impact of the dimension is evaluated with the resistance to separation (from axial load) functional test.
- The N1 and N2 dimensions of the female *Luer lock connector* variant A (with lugs at right angle to axis) have been changed to allow measurement from the open end of the *connector*, to better ensure compatibility at the extreme of the design space.

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.

Introduction

This document was developed because of several incidents, with catastrophic consequences, resulting from inappropriate medication, liquid nutritional formula or air being administered intravenously. Many incidents have been reported leading to international recognition of the importance of these issues and a need has been identified to develop specific *connectors* for *medical devices* and their *accessories* used to deliver fluids in other *applications*.

The ISO 80369 series was developed to prevent misconnection between *small-bore connectors* used in different *applications*. ISO 80369-1 specifies the requirements necessary to verify the designs and dimensions of *small-bore connectors* to ensure that

- a) they do not misconnect with other *small-bore connectors*, and
- b) they safely and securely connect with their mating half.

This document specifies the design and the dimensions and the drawings of *small-bore connectors* intended to be used as conical fittings with a 6 % (Luer) taper for *connections* in intravascular or hypodermic *applications*. [Annex D](#) to [Annex G](#) describe the methods by which this design has been assessed. Other parts of ISO 80369 include requirements for *small-bore connectors* used in different *application* categories.

Connectors manufactured to the dimensions set out within this document are dimensionally incompatible with any of the other *connectors* for *applications* identified in the ISO 80369 series of documents for *small-bore connectors*, except as indicated in [Annex G](#). If fitted to the relevant *medical devices* and *accessories*, these *connectors* should reduce the *risk* of air, non-vascular medication and liquid nutritional formula being delivered through an alternative route, such as intravenously or through an airway device.

In this document, the conjunctive “and” 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” means that conformance with a requirement or a test is recommended but is not mandatory for conformance with this document;
- “may” indicates a permission;
- “can” indicates a possibility or a capability.

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

Part 7: Connectors for intravascular or hypodermic applications

1 Scope

This document specifies dimensions and requirements for the design and functional performance of *small-bore connectors* intended to be used for *connections* in intravascular *applications* or hypodermic *connections* in hypodermic *applications* of *medical devices* and *accessories*.

EXAMPLES Hypodermic syringes and needles or intravascular (IV) cannulae with male and female *Luer slip connectors* and *Luer lock connectors*.

NOTE 1 See [Annex A](#).

NOTE 2 The *Luer connector* was originally designed for use at pressures up to 300 kPa.

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

This document does not specify requirements for the following *small-bore connectors*, which are specified in other documents:

- haemodialyser, haemodiafilter and haemofilter blood compartment ports (ISO 8637 [5] and applicable portion of ISO 8638 [6] referencing blood compartment ports);
- haemodialysis, haemodiafiltration and haemofiltration equipment *connectors* (ISO 8637 [5]);
- infusion system closure piercing *connectors* (ISO 8536-4 [4]).

NOTE 3 *Manufacturers* are encouraged to incorporate the *small-bore connectors* specified in this document into *medical devices* or *accessories*, even if currently not required by the relevant particular *medical device* documents. It is expected that when the relevant particular *medical device* documents are revised, requirements for *small-bore connectors*, as specified in ISO 80369, will be included.

NOTE 4 ISO 80369-1:2018, Clause 7, specifies alternative methods of conformance with ISO 80369-1:2018, for *small-bore connectors* intended for use with intravascular *applications* or hypodermic *application medical devices* or *accessories*, which do not conform with this document.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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 80369-1:2018, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

ISO 80369-6:2016, *Small bore connectors for liquids and gases in healthcare applications — Part 6: Connectors for neuraxial applications*

ISO 80369-7:2021(E)

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

IEC 62366-1:2015, *Medical devices — Part 1: Application of usability engineering to medical devices*

3 Terms and definitions

For the purposes of this document, the terms and definitions specified in ISO 80369-1:2018, ISO 80369-20:2015, ISO 14971:2019, IEC 62366-1:2015 as indicated in [Annex J](#) and the following apply.

NOTE For convenience, the sources of all defined terms used in this document are given in [Annex J](#).

— ISO Online browsing platform: available at <https://www.iso.org/obp>

— IEC Electropedia: available at <http://www.electropedia.org/>

3.1

auxiliary dimension

dimension derived from other dimensions given for information purposes only

[SOURCE: ISO 10209:2012^[2], 4.2]

3.2

Luer connector

small-bore connector that contains a conical mating surface with a 6 % (Luer) taper intended for use in intravascular or hypodermic applications of medical devices and related accessories

Note 1 to entry: A *Luer connector* can be either a *Luer slip connector* or a *Luer lock connector*.

Note 2 to entry: See [Annex A](#).

3.3

Luer slip connector

Luer connector without a lock

Note 1 to entry: The *Luer slip connector* is indicated by the abbreviation L1.

Note 2 to entry: See [Annex A](#).

3.4

Luer lock connector

Luer connector that contains a locking mechanism

Note 1 to entry: The *Luer lock connector* is indicated by the abbreviation L2.

Note 2 to entry: See [Annex A](#).

3.5

normal use

operation, including routine inspection and adjustments by any *user*, and stand-by, according to the instructions for use

Note 1 to entry: *Normal use* should not be confused with *intended use*. While both include the concept of use as intended by the *manufacturer*, *intended use* focuses on the medical purpose while *normal use* incorporates not only the medical purpose, but maintenance, service, transport, etc. as well.

[SOURCE: IEC 60601-1:2005+A1:2012 ^[12], 3.71, modified — replaced “operator” with “user”.]

3.6

rated

<value> term referring to a value assigned by the *manufacturer* for a specified operating condition

[SOURCE: IEC 60601-1:2005 ^[12], 3.97]

3.7***rigid material***

material with a modulus of elasticity either in flexure or in tension greater than 3 433 MPa

EXAMPLE Metals, glass, some fibre-reinforced polymers and high-performance polymers.

3.8***semi-rigid material***

material with a modulus of elasticity either in flexure or in tension, between 700 MPa and 3 433 MPa

EXAMPLE Thermoplastics.

4 General requirements**4.1 General requirements for *Luer connectors***

Luer connectors made in conformance with this document conform with the general requirements of ISO 80369-1:2018, unless otherwise indicated in this document.

In some tolerance combinations, the inside diameter of the fluid lumen of male *Luer connector* may contact the sealing surfaces of the N1 male *connector* (N1), as specified in ISO 80369-6, in *LMC* and thereby these *connectors* mutually fail when evaluating the *non-interconnectable* characteristics tests of ISO 80369-1:2018, Annex B. Additional information is provided in [G.2.2](#).

The reference *connectors* for evaluation of the *non-interconnectable* characteristics are described in [Annex C](#) ([Figures C.1](#), [C.2](#), [C.4](#) and [C.5](#), as appropriate).

Where a *medical device* or *accessory* is designed to provide features of the *Luer connector* of this document, those features shall be included in the *verification* to this document. When necessary, install the *small-bore connector* on the *medical device* or *accessory* to demonstrate conformance with ISO 80369-1:2018, [Annex B](#).

NOTE 1 The summary of *medical devices* and their attributes with *connections* within this *application* is provided in [Annex D](#).

NOTE 2 The summary of the *usability* requirements for *Luer connectors* is provided in [Annex E](#).

NOTE 3 The summary of *Luer connectors* criteria and requirements is provided in [Annex F](#).

NOTE 4 The summary of assessment of the design of *Luer connectors* according to ISO 80369-1:2018, 6.1, is contained in [Annex G](#).

NOTE 5 This document has been prepared to address the relevant essential principles of safety and performance of ISO 16142-1:2016 ^[9] as indicated in [Annex H](#).

NOTE 6 This document has been prepared to address the relevant general safety and performance requirements of European regulation (EU) 2017/745 ^[15] as indicated in [Annex I](#).

4.2 Type tests

Conformance with the requirements of this document shall be determined by *type tests*.

5 Dimensional requirements for *Luer connectors*

Luer connectors shall conform with the dimensions and tolerances as given in

- [Figure B.1](#) and [Table B.1](#) for a male *Luer slip connector* (L1),
- [Figure B.2](#) and [Table B.2](#) for a female *Luer slip connector* (L1),
- [Figure B.3](#) and [Table B.3](#) for a male *Luer lock connector* (L2), with fixed collar,