SLOVENSKI STANDARD
oSIST prEN ISO 80369-7:2019

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Priključki z majhnim premerom za tekočine in pline za uporabo v zdravstvu - 7. del: Priključki s 6 % (Luerjevim) nastavkom za intravaskularno ali podkožno uporabo (ISO/DIS 80369-7:2019)

Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors with 6 % (Luer) taper for intravascular or hypodermic applications (ISO/DIS 80369-7:2019)

Verbindungsstücke mit kleinem Durchmesser für Flüssigkeiten und Gase in medizinischen Anwendungen - Teil 7: Verbindungsstücke mit einem 6 % (Luer) Kegel für intravaskuläre oder hypodermische Anwendungen (ISO/DIS 80369-7:2019)

Raccords de petite taille pour liquides et gaz utilisés dans le domaine de la santé - Partie 7: Raccords à 6 % (Luer) destinés aux applications intravasculaires ou hypodermiques (ISO/DIS 80369-7:2019)

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

Part 7:
Connectors with 6 % (Luer) taper for intravascular or hypodermic applications

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

Partie 7: Raccords à 6 % (Luer) destinés aux applications intravasculaires ou hypodermiques

ICS: 11.040.25

Member bodies are requested to consult relevant national interests in IEC/SC 62D before casting their ballot to the e-Balloting application.

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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 on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT), see the following URL: Foreword — Supplementary information.

The committee responsible for this document is ISO/TC 210, *Quality management and corresponding general aspects for medical devices*, and IEC/SC62D, *Electromedical equipment*. The draft was circulated for voting to the national bodies of both ISO and IEC.

The first edition of ISO 80369-7 cancelled and replaced ISO 594-1:1986 and ISO 594-2:1998, clauses, subclauses, tables, figures, and annexes of which have been consolidated and technically revised.

This second edition of ISO 80369-7 cancels and replaces ISO 80369-7:2016.

This second edition of ISO 80369-7 contains the following major technical revisions to ISO 80369-7:2016.

a) 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 *connector* test and 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.

b) Reference *connectors* made to the previous tolerances still conform to the new tolerances.

This part of ISO 80369 contains the following major technical revisions to ISO 594-1 and ISO 594-2.

c) Some requirement 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 materials* and *rigid materials* have been added.

d) Nominal dimensions have changed to be reference dimensions.

e) The distance from the tip of the *connector* to the bottom of the first complete thread profile of the internal thread, or the *t* dimension has been made a reference dimension due to the difficulty in its measurement. The intent of the dimension is evaluated with the resistance to separation from axial load functional test.

f) The N1 and N2 dimensions of the female *Luer lock connector* with lugs at right angle to axis, variant A have changed to be measured from the open end of the *connector* to better ensure compatibility at the extreme of the design space.

Additional parts on *connectors* for urethral and urinary *applications* and for respiratory *applications* are planned.

Introduction

This part of ISO 80369 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.

ISO 80369-20 contains the common *test methods* to support the performance requirements for *small-bore connectors*.

This part of ISO 80369 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 part of ISO 80369 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 part of ISO 80369, the following print types are used:

— requirements and definitions: Roman type;

— informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;

— terms defined in Clause 3 or as noted: *small capitals.*

In this part of ISO 80369, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this part of ISO 80369 conform to usage described in the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

— “shall” means that conformance with a requirement or a test is mandatory for conformance with this part of ISO 80369;

— “should” means that conformance with a requirement or a test is recommended but is not mandatory for conformance with this part of ISO 80369;

— “may” is used to describe a permission (e.g. a permissible way to achieve conformance with a requirement or test);

— "can" is used to describe a possibility or capability; and

— "must" is used to express an external constraint.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex A.

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

Part 7: Connectors with 6 % (Luer) taper for intravascular or hypodermic applications

1 * Scope

This part of ISO 80369 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 The *Luer connector* was originally designed for use at pressures up to 300 kPa.

This part of ISO 80369 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 part of ISO 80369 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 and applicable portion of ISO 8638 referencing blood compartment ports);

— haemodialysis, haemodiafiltration and haemofiltration equipment *connectors* (ISO 8637);

— infusion system closure piercing *connectors* (ISO 8536-4).

NOTE 2 *Manufacturers* are encouraged to incorporate the *small-bore connectors* specified in this part of ISO 80369 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 3 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 part of ISO 80369.

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

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 and the following apply.

Note 1 to entry For convenience, the sources of all defined terms used in this document are given in Annex J.

3.1
*** *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.*

3.2
*** *Luer slip connector***
Luer connector without a lock

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

3.3
*** *Luer lock connector***
Luer connector that contains a locking mechanism

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

3.4
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, 3.71, modified — replaced "*operator*" with "*user*".]

3.5
***rated* (value)**
term referring to a value assigned by the *manufacturer* for a specified operating condition

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

3.6
rigid material
material with a modulus of elasticity either in flexure or in tension greater than 3 433 MPa

EXAMPLE Metals

3.7
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 part of ISO 80369 conform with the general requirements of ISO 80369-1:2018, unless otherwise indicated in this part of ISO 80369.

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 conditions 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.

Where the design of a *Luer connector* of this part of ISO 80369 relies on dimensions or features of the *medical device* or *accessory* to ensure *non-interconnectable* characteristics, the *non-interconnectable* characteristics shall be *verified*.

Show conformance by applying a computer aided design (CAD) analysis of the dimensions of all of the ISO 80369 series *small bore connectors* and the *small bore connector* under test, in conjunction with physical testing of the *small bore connector* to the dimensions of Annex B where the CAD analysis does not demonstrate the *non-interconnectable* characteristics. When necessary, install the *small-bore connector* on the *medical device* or *accessory* to demonstrate conformance with the *non-interconnectable* characteristics test requirements of ISO 80369-1:2018, Clause 5, and of ISO 80369-1:2018, Annex B.

NOTE 1 *Medical devices* using the *Luer connectors* of this part of ISO 80369 that do not rely on the dimensions or features of the *medical device* or *accessory* to ensure *non-interconnectable* characteristics are presumed to conform with the *non-interconnectable* characteristics test requirements of this part of ISO 80369.

NOTE 2 The summary of *medical devices* and their attributes with *connections* within this *application* is provided in Annex D.

NOTE 3 The summary of the *usability* requirements for *Luer connectors* is provided in Annex E.

NOTE 4 The summary of *Luer connectors* criteria and requirements is provided in Annex F.

NOTE 5 The summary of assessment of the design of *Luer connectors* according to ISO 80369-1:2018, 6.1, is contained in Annex G.

4.2 *Type tests*

Conformance with the requirements of this part of ISO 80369 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,

— Figure B.4 and Table B.4 for a male *Luer lock connector* (L2), with floating or rotatable collar,

— Figure B.5 and Table B.5 for a female *Luer lock connector* (L2),

— Figure B.6 and Table B.6 for a female *Luer lock connector* (L2), with lugs at right angle to axis, variant A,

— Figure B.7 and Table B.7 for a female *Luer lock connector* (L2), with lugs at right angle to axis, variant B, and

— Figure B.8 and Table B.8 for a female *Luer lock connector* (L2), with lugs at right angle to axis, variant C.

Check conformance by confirming the dimensions and tolerances specified in Annex B, as appropriate.

6 Performance requirements

6.1 Fluid leakage

6.1.1 Fluid leakage requirement

Luer connectors shall be evaluated for leakage using either the leakage by pressure decay *test method* or the positive pressure liquid leakage *test method*.

6.1.2 Leakage by pressure decay

Luer connectors evaluated for fluid leakage performance with the leakage by pressure decay *test method* shall not leak by more than 0,005 Pa·m^3/s while being subjected to an applied pressure of between 300 kPa and 330 kPa over a hold period between 15 s and 20 s using air as the medium. *Manufacturers* may use a greater applied pressure.

Check conformance by applying the tests of ISO 80369-20:2015, Annex B, while using the leakage reference *connector* specified in Annex C.

6.1.3 Positive pressure liquid leakage

Luer connectors evaluated for fluid leakage performance with the positive pressure liquid leakage *test method* shall show no signs of leakage, sufficient to form a falling drop of water, over a hold period of 30 s to 35 s while being subjected to an applied pressure of between 300 kPa and 330 kPa. *Manufacturers* may use a greater applied pressure.

Check conformance by applying the tests of ISO 80369-20:2015, Annex C, while using the leakage reference *connector* specified in Annex C.

6.2 Sub-atmospheric pressure air leakage

Luer connectors shall be evaluated for sub-atmospheric pressure air leakage. *Luer connectors* shall not leak by more than 0,005 Pa·m^3/s while being subjected to an applied sub-atmospheric pressure of between 80,0 kPa and 88,0 kPa over a hold period of between 15 s and 20 s. *Manufacturers* may use a greater applied sub-atmospheric pressure.

Check conformance by applying the tests of ISO 80369-20:2015, Annex D, while using the leakage reference *connector* specified in Annex C.

6.3 Stress cracking

Luer connectors shall be evaluated for stress cracking. *Luer connectors* shall meet the requirements of 6.1.1 after being subjected to stresses of ISO 80369-20:2015, Annex E.

Check conformance by applying the tests of ISO 80369-20:2015, Annex E, while using the stress cracking reference *connector* specified in Annex C.

6.4 Resistance to separation from axial load

Luer connectors shall be evaluated for separation from axial load. *Luer connectors* shall not separate from the reference *connector* over a hold period between 10 s and 15 s while being subjected to a disconnection applied axial force between

a) 23 N and 25 N for *Luer slip connectors,* and

b) 32 N and 35 N for *Luer lock connectors*.

Manufacturers may use a greater disconnection applied axial force or a longer hold period.

Check conformance by applying the tests of ISO 80369-20:2015, Annex F, while using the separation from axial load reference *connector* specified in Annex C.

6.5 Resistance to separation from unscrewing

Luer lock connectors shall be evaluated for separation from unscrewing. *Luer lock connectors* shall not separate from the reference *connector* for a hold period between 10 s and 15 s while being subjected to an unscrewing torque of between 0,018 N·m to 0,020 N·m. *Manufacturers* may use a greater applied unscrewing torque or a longer hold period.

Check conformance by applying the tests of ISO 80369-20:2015, Annex G, while using the resistance to separation from unscrewing reference *connector* specified in Annex C.

6.6 Resistance to overriding

Luer lock connectors shall be evaluated for resistance to overriding. *Luer lock connectors* shall not override the threads or lugs of the reference *connector* while being subjected to an applied torque of between 0,15 N·m to 0,17 N·m over a hold period between 5 s and 10 s. *Manufacturers* may use a greater applied torque or a longer hold period.

Check conformance by applying the tests of ISO 80369-20:2015, Annex H, while using the resistance to overriding reference *connector* specified in Annex C.

Annex A
(informative)

Rationale and guidance

A.1 General guidance

This Annex provides a rationale for some requirements of part of ISO 80369 and is intended for those who are familiar with the subject of part of ISO 80369 but who have not participated in its development. An understanding of the rationale underlying these requirements is considered to be essential for their proper use. Furthermore, as clinical practice and technology change, it is believed that a rationale will facilitate any revision of this part of ISO 80369 necessitated by those developments.

A.2 Rationale for particular clauses and subclauses

The clauses and subclauses in this Annex have been numbered to correspond to the numbering of the clauses and subclauses of this part of ISO 80369 to which they refer. The numbering is, therefore, not consecutive.

Clause 1 Scope

The scope includes the fittings described previously in ISO 594-1 and ISO 594-2.

In 2000, a Task Group of the European standards organization CEN proposed a strategy to reduce incidents of accidental misconnection of *patient* therapy lines by the use of a series of *non-interconnectable connectors*, differentiated by design, for use in different medical *applications*. The strategy reserves the use of *Luer connectors* solely for use in *medical devices* used to access the vascular system or for hypodermic applications so that they can achieve their intended function[13].

During the development of this part of ISO 80369, the committee frequently debated how *Luer connector* activated *medical devices* (LADs) should be interpreted. In context of this part of ISO 80369, "LADs" are considered to be a "component" of the *medical device* and are typically a female valve designed to interconnect with male *Luer connector*. The following guidance relates specifically to the LAD (or female valve end) component only and does not include the rest of a *medical device*.

A LAD typically includes a valve that opens and permits access to the fluid conduit when a standard male *Luer connector* is inserted into it. By design, it forms one-half of the *connection* that establishes a fluid conduit with a male *Luer connector*. However, such LADs typically do not conform with this part of ISO 80369. Specifically, they often do not conform to 4.2 regarding materials (since their mating surfaces often include elastomeric materials) nor do they fully conform dimensionally to Clause 5. Thus, a typical LAD is not a *Luer connector*. As such, they are not within the scope of this part of ISO 80369.

The committee, however, felt compelled to provide some guidance on the LAD due to the obvious similarities of intended use with *Luer connectors*. It is advisable that *manufacturers* of LADs utilize the features providing *non-interconnectable* characteristics of this part of ISO 80369, wherever possible, to address the *risk* of misconnections to their *medical devices*. These elements can include the appropriate combinations of the following:

— materials conformance (i.e. ≥700 MPa) for interference features;

— dimensional conformance (i.e. dimensions *H*, *J*, *D*, and *G* from Annex B);

— dimensional and/or CAD analysis showing interference features;

— *non-interconnectable* characteristics testing per ISO 80369-1:2018, Annex B;

— usability testing demonstrating *non-interconnectable* characteristics.

Additionally, the functional performance requirements of Clause 6 should also be considered for the LAD component.

In this way, the LADs can be evaluated for both *non-interconnectable* characteristics and performance characteristics associated with the ISO 80369- series.

The LADs by definition continue to not be considered a "conforming" *Luer connector* (i.e. not conforming with this part of ISO 80369), however they can be considered 'compatible with' a *medical device* utilizing a male *Luer connector* (by way of functional performance).

manufacturers and *responsible organizations* are encouraged to report their experience with the *Luer connectors* specified in this part of ISO 80369 to the Secretariat of ISO/TC 210, so that it can consider this feedback during the revision of the relevant part of the ISO 80369- series.

Definition 3.1 *Luer connector*

Definition 3.2 *Luer slip connector*

Definition 3.3 *Luer lock connector*

For clarity, the new terms *Luer connector*, *Luer slip connector*, and *Luer lock connector* replace conflicting and confusing terms used in ISO 594-1 and ISO 594-2. The new terms align and harmonize this part of ISO 80369 with ISO 80369-1, which does not utilize the legacy terms fitting, conical, or taper. The new terms are equivalent to those now generically used to describe the *small-bore connectors* commonly named after their inventor, 19th century German medical instrument maker Hermann Wülfing Lüer.

Clause 5 Dimensional requirements for *Luer connectors*

Legacy Luer gauges cannot be used to verify the performance of *connectors* that are intended to prevent misconnection because they lack the dimensions for surfaces not intended to form *connections* with *Luer connectors*. Maintenance of production quality (i.e. using gauges) is outside the scope of this part of ISO 80369. The dimensional requirements in Annex B are a more precise description of the design and performance characteristics for both intended *connections* and avoidance of misconnections.

Dimensions and tolerances not previously identified in ISO 594-1 and ISO 594-2 are added to this part of ISO 80369 to reduce the *risk* of misconnections between *medical devices* or between *accessories* for different *applications* with non-*Luer connectors* that are being developed under other parts of the ISO 80369- series. These new requirements were selected to represent the inherent design and dimensions of *Luer connectors* in clinical use at the time this part of ISO 80369 was developed.

Since the configurations of the *connectors* proposed within ISO 80369-7 are *small-bore connectors* with or without a threaded collar, the requirements and parameters from ISO 594-1 and ISO 594-2 have been used where applicable.

The maximum inside diameter at the tip of the male taper (through bore), *Øf*, of 2,900 mm was chosen to describe the majority of *Luer connectors* available to *users* at the time of publication of this part of ISO 80369. The committee considered the clinical needs of high flow rate intravascular *medical devices* and determined that the incremental increase in flow if *Øf* is increased to a theoretical sharp edge of 3,50 mm was not warranted in view of the increased *risk* of misconnection with smaller male *small-bore connectors* in the ISO 80369- series.

Commercially developed glass prefilled syringes routinely mate with *Luer connector* equipped *medical devices* in order to effectively administer the medication stored within the syringe. Examples: disposable needles, needleless ports and other forms of Luer access. Current state-of-technology syringe tip glass forming technology for manufacturing glass-prefilled syringes cannot conform completely to either previous Luer fitting standard, ISO 594 or this part of ISO 80369. Both the previous standard and this part of ISO 80369 have been developed using ground glass, metal and injection moulded technology and plastic resins as the baseline for conformance and capabilities.