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English version

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

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of an identical text or by endorsement, at the latest by November 2021, and conflicting national standards shall be withdrawn at the latest by November 2021.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.

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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.

Endorsement notice

The text of ISO 80369-7:2021 has been approved by CEN as EN ISO 80369-7:2021 without any modification.

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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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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 “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” 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.

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 80369-20:2015, *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[7], 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,

— 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, for the appropriate figure and table.

NOTE See Annex A.

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 exceed a leakage rate of 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.

Check conformance by applying the tests of ISO 80369-20:2015, Annex B, while using the leakage reference *connector* specified in Annex C (Figures C.1, C.2, C.4 and C.5, as appropriate). A greater applied pressure may be used.

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.

Check conformance by applying the tests of ISO 80369-20:2015, Annex C, while using the leakage reference *connector* specified in Annex C (Figures C.1, C.2, C.4 and C.5, as appropriate). A greater applied pressure may be used.

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.

Check conformance by applying the tests of ISO 80369-20:2015, Annex D, while using the leakage reference *connector* specified in Annex C (Figures C.1, C.2, C.4 and C.5, as appropriate). A greater applied sub-atmospheric pressure may be used.

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 (Figures C.1, C.2, C.4 and C.5, as appropriate).

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*.

Check conformance by applying the tests of ISO 80369-20:2015, Annex F, while using the resistance to separation from axial load reference *connector* specified in Annex C (Figures C.2, C.3, C.5 and C.6, as appropriate). A greater disconnection applied axial force or a longer hold period may be used.

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.

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 (Figures C.1 and C.4, as appropriate). A greater applied unscrewing torque or a longer hold period may be used.

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.

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 (Figures C.3 and C.6, as appropriate). A greater applied torque or a longer hold period may be used.

Annex A
(informative)

Rationale and guidance

A.1 General guidance

This annex provides a rationale for some requirements of this document and is intended for those who are familiar with the subject of this document 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 document 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 document 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 [14].

During the development of this document, the committees frequently debated how *Luer connector* activated *medical devices* (LADs) should be interpreted. In context of this document, "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 document. Specifically, they often are made of materials that are softer than *semi-rigid 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 document.

The committees, 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 document, 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 document), 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 document 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 3.2 *Luer connector*

Definition 3.3 *Luer slip connector*

Definition 3.4 *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 document 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 document. 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 document 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 document was developed.

Since the configurations of the *connectors* proposed within this document 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 document. The committees 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 [8] 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 document. Both the previous standard and this document have been developed using ground glass, metal and injection moulded technology and plastic resins as the baseline for conformance and capabilities.

The minimum inside diameter at the tip of the male taper (through bore), *Øf*, is not defined to accommodate the very small bore of glass syringes.

The committees acknowledge the differences in the manufacturing methodologies and the need for expanded tolerances in the glass forming manufacturing *process*. The baseline specifications of the tapered tip need to remain similar. However, to accommodate the glass forming manufacturing *process*, there needs to be expanded dimensional tolerances. While these tolerances are outside of the range of this document with respect to some of the dimensions, a glass formed tip does successfully mate with the injection moulded female *Luer connectors*. Refer to ISO 11040-4 [8] for a listing of those critical dimensions, their expanded corresponding tolerances and functional *test methods* that accommodate the formed tip manufacturing *process*.

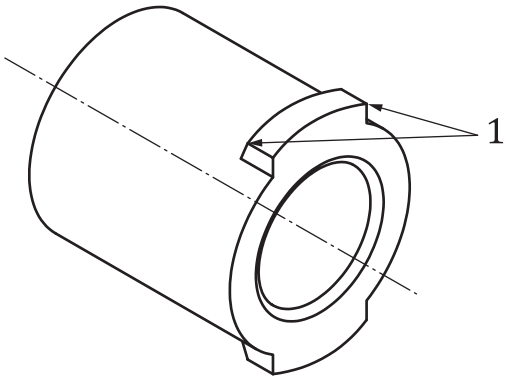
A dimensional analysis of the female *Luer lock connector* (L2), variant A thread form was conducted during the development of this document to ensure both

— proper connection to other male *Luer connectors,* and

— prevention of misconnection to the other *connectors* of the ISO 80369 series.

The analysis demonstrated that in certain instances the thread form detailed in Figure B.6 and Table B.6 could, if taken to certain extremes, collide with non-sealing features of the mating male *Luer connector* (i.e. Figure B.3 and Figure B.4) prior to a fluid tight seal being achieved. Specifically, the diagonal distance between the corners of the right-angle thread of the female *Luer lock connector* of Figure B.6 could bind between adjacent threads of the mating male *Luer connector*. Figure A.1 and Figure A.2 illustrate this possible interference. This can be worsened by the allowable variations in thread profile, thread pitch and thread lead, of the features of the mating male *Luer connector*. This situation is unchanged from the legacy ISO 594-2, the same magnitude of interference was possible with conforming *connectors*.

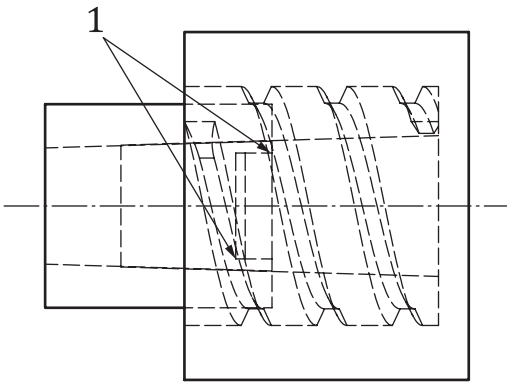
Due to the proliferation of existing *Luer connectors* and general lack of data indicating a problem in use, the committees determined that the same level of interference would be permitted by this document (i.e. the permissible design is unchanged).



Key

1 corners that can interfere

Figure A.1 — Lug corners that can interfere



Key

1 area of potential interfere

Figure A.2 — Area of potential interference

The analysis also demonstrated that in certain instances the taper surfaces of male and female *Luer lock connectors* made from *semi-rigid materials*, if taken to certain extremes, might not engage deep enough to allow the threads to engage properly. In these instances, the resulting *connection* is only equal to a *Luer slip connector* and does not benefit from the additional retention of the locking threads. This potential is mitigated by the deformability of the *semi-rigid materials* from which most *connectors* are made that allow the tapers to engage further as they deform as they are connected. There is a general lack of data indicating a problem in actual use. For these reasons the dimensions have not been changed to eliminate this potential, but a newly recommended (informative) minimum value for the *ØD* and *ØG* dimensions has been added. Conforming with this recommendation reduces the likelihood of this possibility. All *connectors* are still required to conform with the resistance to separation from axial load functional test of 6.4.

The distance from the tip of the *connector* to the bottom of the first complete thread profile of the internal thread, the *t* dimension, is also essential for an effective locking *connection*. It has also been noted that there is a general lack of data indicating there is a problem even when many of the current male *Luer lock connectors* on the market made from *semi-rigid materials* do not meet the ideal maximum dimension of 3,200 mm. For this reason, combined with the difficulty in measuring this feature, the recommended dimension for *connectors* made from *semi-rigid materials* has changed and have been made an *auxiliary dimension*. All *connectors* are still required to conform with the resistance to separation from axial load functional test of 6.4.

In addition, due to the commercial evolution of existing *Luer connectors*, a *connector* conforming with ISO 594-2:1988, Figure 3, Variant A (female *Luer connector* with thread lug at right angle) was elusive to locate for testing purposes. Most participating *manufacturers*, who offer a "lug" version of threads, offer a version that has one side at a right angle with the other inclined at pitch "*p*", thus these are a hybrid between the traditional ISO 594-2:1988, Figure 3, Variant A and ISO 594-2:1988, Figure 4. Since the diameters provide the features that ensure the *non-interconnectable* characteristics are maintained, the committees decided to permit these hybrid thread lugs with the inclusion of features *N*1 and *N*2 (width of the thread lug at the root of the leading and trailing ends, respectively).

NOTE The same level of interference as described above (with threads at right angles) is possible within the tolerances specified. Each *manufacturer* is encouraged to check the performance of their design to ensure the *risk* of leakage is minimized.

Annex B
(normative)

Luer connectors

Dimensions in millimetres unless otherwise indicated

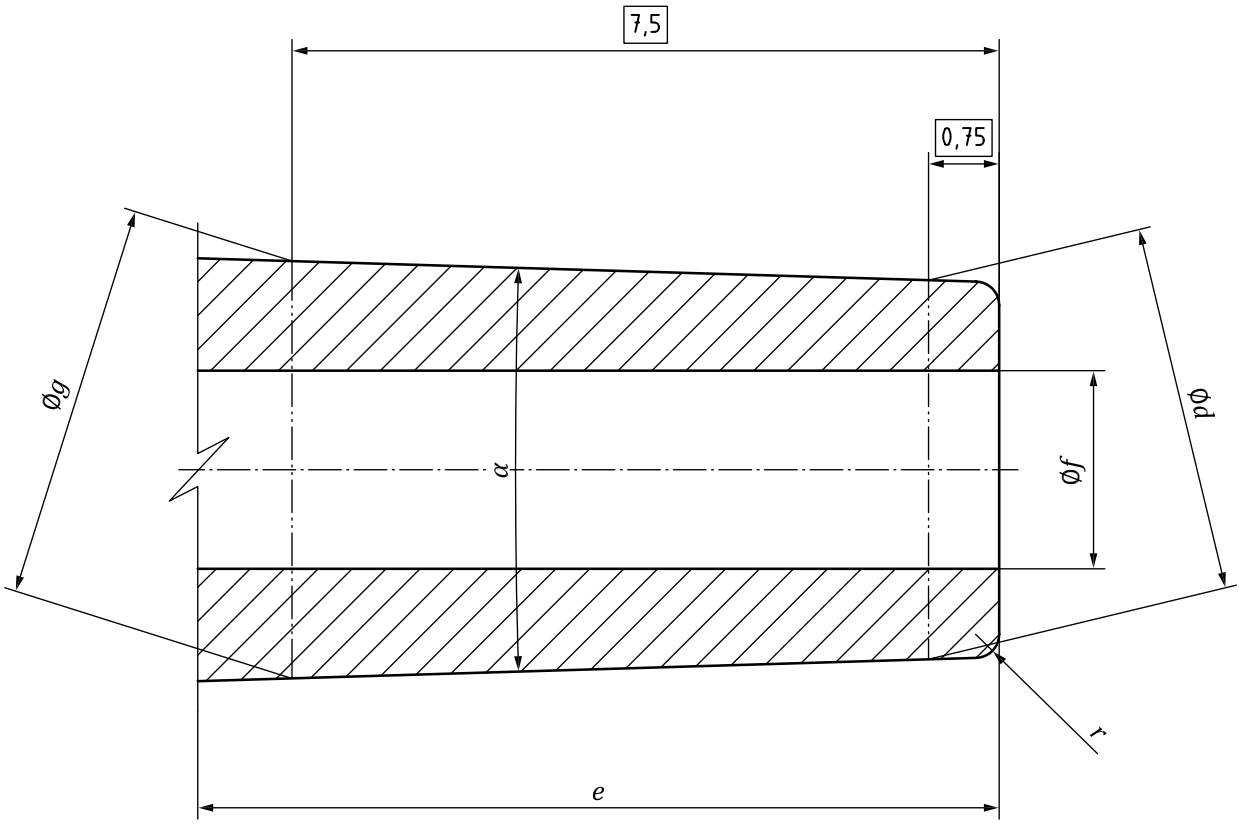


Table B.1 contains the dimensions for this figure.

Figure B.1 — Male *Luer slip connector* (L1)

Table B.1 — Male *Luer slip connector* dimensions (L1)

Dimensions in millimetres unless otherwise indicated
Auxiliary dimensions are in parenthesis

Male *Luer slip connector* (L1)				
Reference	**Designation**	**Dimension**		
		Minimum	***Nominal***	**Maximum**
α	Angle of the taper (6 % taper *nominal*) (degrees, *auxiliary dimension*)	—	(3,44°)	—
[a] This dimension also defines the extent of the *connector*.				

Table B.1 *(continued)*

Male *Luer slip connector* (L1)				
Reference	**Designation**	**Dimension**		
		Minimum	***Nominal***	**Maximum**
Ød	For *rigid material:* Outside diameter at the tip of the male taper at 0,750 (basic dimension) from the tip (small end) of the male taper	3,970	—	4,035
	For *semi-rigid material:* Outside diameter at the tip of the male taper at 0,750 (basic dimension) from the tip (small end) of the male taper	3,970	—	4,072
e	Length of the male taper[a]	7,500	—	10,500
Øf	Inside diameter at the tip of the male taper	—	—	2,900
Øg	For *rigid material:* Outside diameter of the larger end of the male taper at 7,500 (basic dimension) from the tip (small end) of the male taper	4,375	—	4,440
	For *semi-rigid material:* Outside diameter of the larger end of the male taper at 7,500 (basic dimension) from the tip (small end) of the male taper	4,375	—	4,477
r	Radius or chamfer at the outside tip of the male taper	0,000	—	0,500

[a] This dimension also defines the extent of the *connector*.

Dimensions in millimetres unless otherwise indicated

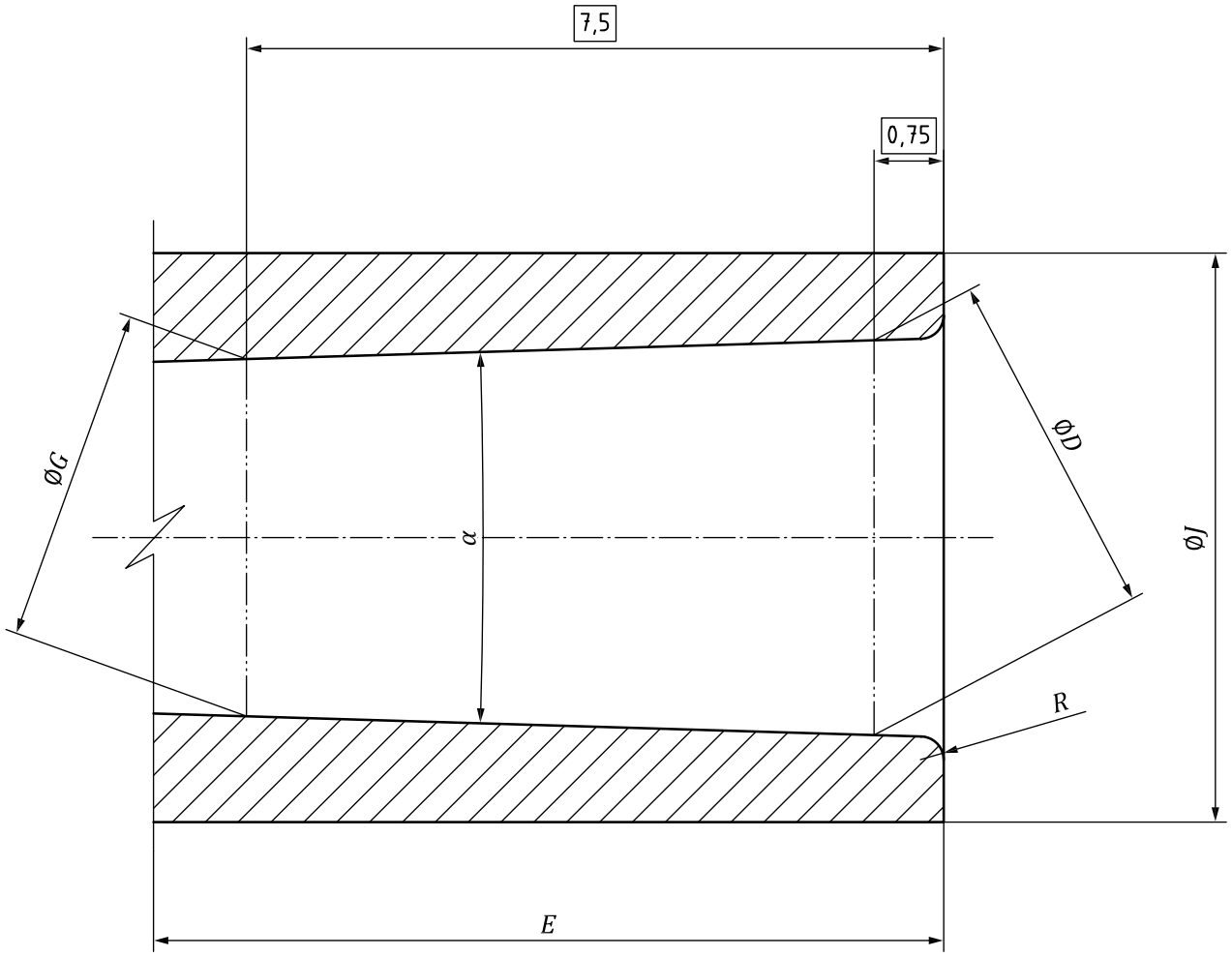


Table B.2 contains the dimensions for this figure.

Figure B.2 — Female *Luer slip* connector (L1)

Table B.2 — Female *Luer slip connector* dimensions (L1)

Dimensions in millimetres unless otherwise indicated
Auxiliary dimensions are in parenthesis

Female *Luer slip connector* (L1)				
Reference	**Designation**	**Dimension**		
		Minimum	***Nominal***	**Maximum**
α	Angle of the taper (6 % taper *nominal*) (degrees, *auxiliary dimension*)	—	(3,44°)	—

[a] This dimension also defines the extent of the *connector*.

[b] It is recommended that *connectors* made from *semi-rigid materials* should consider 4,225 as the minimum value for *ØD* and 3,820 as the minimum value for *ØG* to ensure thread engagement with all male *Luer lock connectors*. See Annex A, Clause 5.

Table B.2 *(continued)*

Female *Luer slip connector* (L1)				
Reference	**Designation**	**Dimension**		
		Minimum	***Nominal***	**Maximum**
ØD	For *rigid material:* Inside diameter at the open end of the female taper at 0,750 (basic dimension) from the opening (large end) of the female taper	4,225	—	4,270
	For *semi-rigid material:* Inside diameter at the open end of the female taper at 0,750 (basic dimension) from the opening (large end) of the female taper	4,198[b]	—	4,298
E	Depth of the female taper[a]	7,500	—	10,500
ØG	For *rigid material:* Inside diameter of the smaller end of the female taper at 7,500 (basic dimension) from the opening (large end) of the female taper	3,820	—	3,865
	For *semi-rigid material:* Inside diameter of the smaller end of the female taper at 7,500 (basic dimension) from the opening (large end) of the female taper	3,793[b]	—	3,893
ØJ	Outside diameter of the female *Luer slip connector* of the smallest cylinder that encompasses the outside surfaces of external features of the *connector*. This diameter shall not be increased above the maximum for a distance from the hub face of 5,5 mm.	6,000	—	6,730
R	Radius or chamfer at the entrance of the female taper	—	—	0,500

[a] This dimension also defines the extent of the *connector*.

[b] It is recommended that *connectors* made from *semi-rigid materials* should consider 4,225 as the minimum value for *ØD* and 3,820 as the minimum value for *ØG* to ensure thread engagement with all male *Luer lock connectors*. See Annex A, Clause 5.

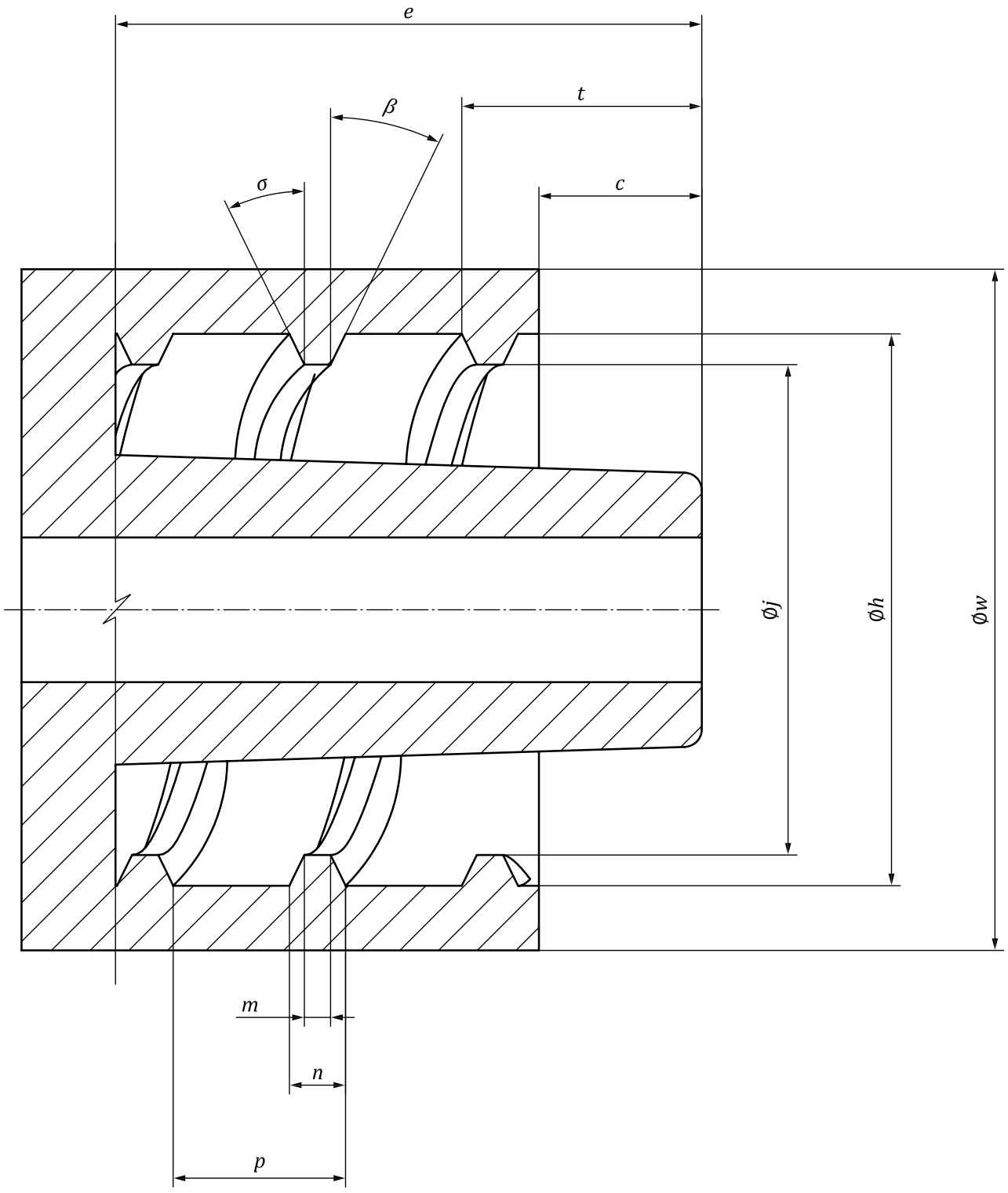


Table B.3 contains the dimensions for this figure.

Figure B.3 — Male *Luer lock connector* (L2), with fixed collar

Table B.3 — Male *Luer lock connector* with fixed collar dimensions (L2)

Dimensions in millimetres unless otherwise indicated
Auxiliary dimensions are in parenthesis

Male *Luer lock connector* (L2) with fixed collar				
Reference	**Designation**	**Dimension**		
		Minimum	***Nominal***	**Maximum**
β	Angle of internal thread profile on the non-bearing surface against separation (degrees)	25,0°	—	—
c	Projection of the tip of the *connector* from the thread collar	2,100	—	—
e	Length of the male taper [a]	7,500	—	10,500
Ø*h*	Major inside thread diameter (diameter at the thread root)	7,900	—	8,100
Ø*j*	Minor inside thread diameter (diameter at the thread crest)	6,800	—	7,200
m	Width of the thread profile at the crest	0,300	—	—
n	Width of the thread profile at the root	—	—	1,000
p	*Nominal* pitch of the double-start, right-hand thread (*auxiliary dimension*) (5 mm lead)	—	(2,500)	—
σ	Angle of internal thread profile on the bearing surface against separation (degrees)	25,0°	—	30,0°
t	For *rigid material:* Distance from the tip of the *connector* to the bottom of the first complete thread profile of the internal thread (*auxiliary dimension*)	—	—	(3,200)
	For *semi-rigid material:* Distance from the tip of the *connector* to the bottom of the first complete thread profile of the internal thread (*auxiliary dimension*)	—	—	(3,650)[c]
Ø*w*	Diameter of the smallest cylinder that encompasses the outside surfaces of the external features of the collar [b]	8,800	—	11,500

The design and dimensions of the thread profile (*σ*, *β* and *m*) may vary from those designated provided the *connector* meets the performance requirements of Clause 6.

NOTE 1 The design and dimensions of the thread profile (*σ*, *β* and *m*) are not considered important to ensure *non-interconnectable* characteristics.

NOTE 2 The dimension *t* is essential for an effective Luer lock connection but is very difficult to measure therefore the effectiveness of this feature is assessed with the resistance to separation from axial load functional test of 6.4.

The length of the thread is not specified but shall provide clearance for the thread of the female *connector*.

The male *Luer lock connector* shall include the dimensions and tolerances of the male *Luer slip connector* as specified in Figure B.1 and Table B.1 except as indicated in this table.

[a] This dimension also defines the extent of the *connector*.

[b] The specified dimensional range shall be maintained for a minimum length of 1 mm from the open end of the collar. Beyond 1 mm, the diameter may be smaller than the specified minimum. The maximum diameter specified shall be maintained for a minimum length of *e*. This dimension may be achieved by either the *connector* or the *medical device* which incorporates this *connector*. Alternatively, *non-interconnectable* characteristics may be demonstrated using ISO 80369-1:2018, Annex B.

[c] It is recommended that *connectors* made from *semi-rigid materials* should consider 3,200 as the maximum value for *t* to ensure thread engagement with all female *Luer lock connectors*. See Annex A, Clause 5.

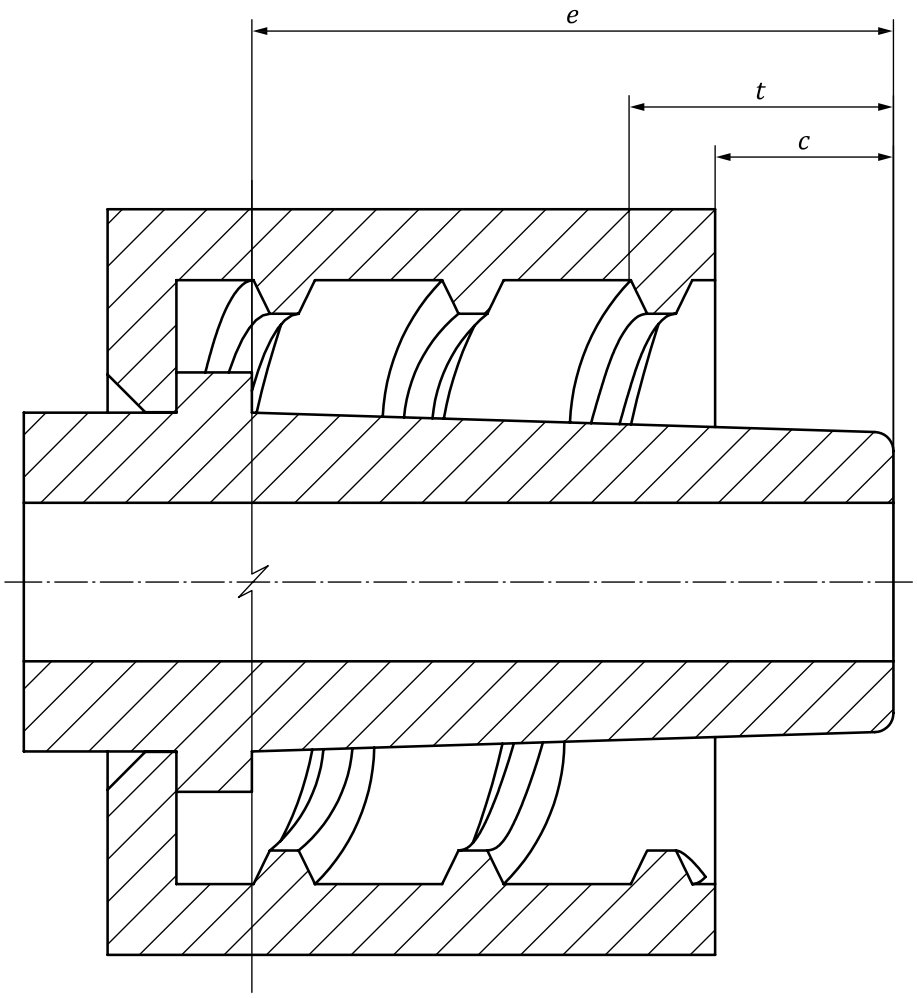


Table B.4 contains the dimensions for this figure.

Figure B.4 — Male *Luer lock connector* (L2), with rotatable collar

Table B.4 — Male *Luer lock connector* (L2), with a rotatable collar dimensions

Dimensions in millimetres unless otherwise indicated
Auxiliary dimensions are in parenthesis

Male *Luer lock connector* (L2), with a rotatable collar				
Reference	**Designation**	**Dimension**		
		Minimum	***Nominal***	**Maximum**
c[a]	Projection of the tip of the *connector* from the thread collar	2,100	—	—
e	Length of the male taper [b]	7,500	—	10,500

The male *Luer lock connector* with rotatable collar shall include the dimensions and tolerances of the male *Luer lock connector* as specified in Figure B.3 and Table B.3 except as indicated in this table.

NOTE The dimension *t* is essential for an effective locking *connection* but is very difficult to measure. Therefore the effectiveness of this feature is assessed with the resistance to separation from axial load functional test of 6.4.

[a] This dimension is when the floating or rotatable collar is positioned fully toward tip of the *connector*.

[b] This dimension also defines the extent of the *connector*.

[c] It is recommended that *connectors* made from *semi-rigid materials* should consider 3,200 as the maximum value for *t* to ensure thread engagement with all female *Luer lock connectors*. See Annex A, Clause 5.

Table B.4 *(continued)*

Male *Luer lock connector* (L2), with a rotatable collar				
Reference	**Designation**	**Dimension**		
		Minimum	***Nominal***	**Maximum**
t[a]	For *rigid material:* Distance from the tip of the *connector* to the bottom of the first complete thread profile of the internal thread (*auxiliary dimension*)	—	—	(3,200)
	For *semi-rigid material:* Distance from the tip of the *connector* to the bottom of the first complete thread profile of the internal thread (*auxiliary dimension*)	—	—	(3,650)[c]
The male *Luer lock connector* with rotatable collar shall include the dimensions and tolerances of the male *Luer lock connector* as specified in Figure B.3 and Table B.3 except as indicated in this table.				
NOTE The dimension t is essential for an effective locking *connection* but is very difficult to measure. Therefore the effectiveness of this feature is assessed with the resistance to separation from axial load functional test of 6.4.				
[a] This dimension is when the floating or rotatable collar is positioned fully toward tip of the *connector*.				
[b] This dimension also defines the extent of the *connector*.				
[c] It is recommended that *connectors* made from *semi-rigid materials* should consider 3,200 as the maximum value for t to ensure thread engagement with all female *Luer lock connectors*. See Annex A, Clause 5.				

Dimensions in millimetres unless otherwise indicated

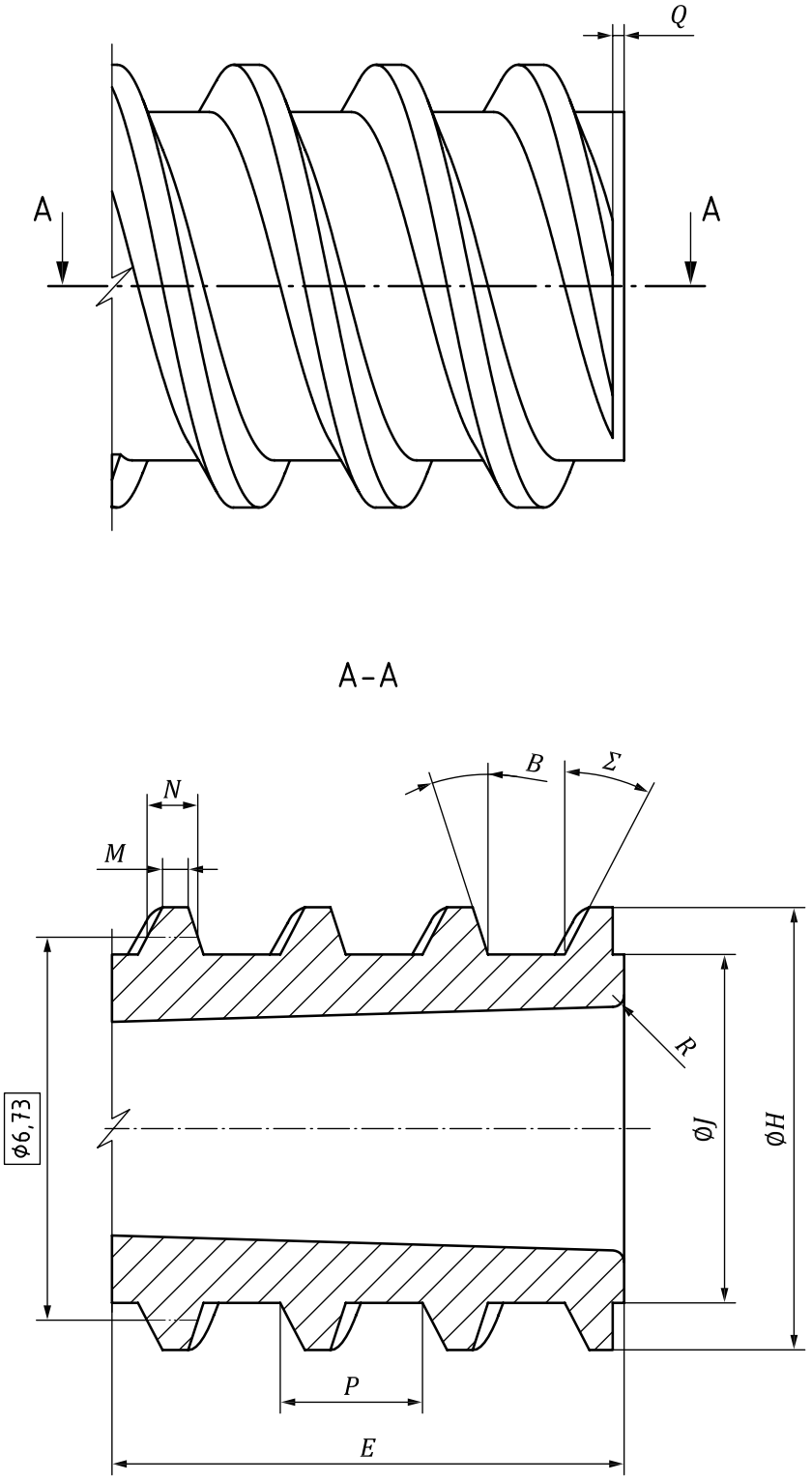


Table B.5 contains the dimensions for this figure. This design and the associated dimensions shall apply to any female *Luer lock connector* that has threads in a plane inclined to the axis of the *connector*. There are no dimensional restrictions on thread length. Figure B.6, Figure B.7 and Figure B.8 apply to designs utilizing lugs that are at a right angle to axis of the *connector*.

Figure B.5 — Female *Luer lock connector* (L2)

Table B.5 — Female *Luer lock connector* dimensions (L2)

Dimensions in millimetres unless otherwise indicated
Auxiliary dimensions are in parenthesis

Female *Luer lock connector* (L2)				
Reference	**Designation**	**Dimension**		
		Minimum	***Nominal***	**Maximum**
B	Angle of the external thread profile on the non-bearing surface against separation (degrees)	0,0°	—	—
E	Depth of the female taper [a]	7,500	—	10,500
ØH	Major outside thread diameter (diameter at thread crest) for the extent of the thread feature. This defines the diameter of the smallest cylinder of depth 5,5 mm from the face of the *connector* that encompasses the outside surfaces of the external features of the *connector.* This diameter shall not be increased above the maximum for a distance from the hub face of 5,5 mm.	7,730	—	7,830
ØJ	Minor outside thread diameter (diameter at the thread root) This diameter shall not be increased above the maximum for a distance from the hub face of 5,5 mm.	5,515	—	6,730
M	Width of the thread profile at the crest	0,300	—	—
N	Width of the thread profile at the root at a diameter corresponding to *ØJ* max (6,730)	—	—	1,200
P	*Nominal* pitch of the double-start, right-hand thread (*auxiliary dimension*) (5 mm lead)	—	(2,500)	—
Q	Distance from the face of the *connector* to the base of the thread at the non-load bearing side	—	—	0,300
R	Radius or chamfer at the entrance of the female taper	—	—	0,500
Σ	Angle of external thread profile on the bearing surface against separation (degrees)	25,0°	—	30,0°

The design and dimensions of the thread profile (*Σ*, *B* and *M*) may vary from those designated provided the *connector* meets the performance requirements of Clause 6.

NOTE The design and dimensions of the thread profile (*Σ*, *B, M* and *P*) are not considered important to ensure *non-interconnectable* characteristics.

The female *Luer lock connector* shall include the dimensions and tolerances of the female *Luer slip connector* as specified in Figure B.2 and Table B.2 except as indicated in this table.

[a] This dimension also defines the extent of the *connector*.

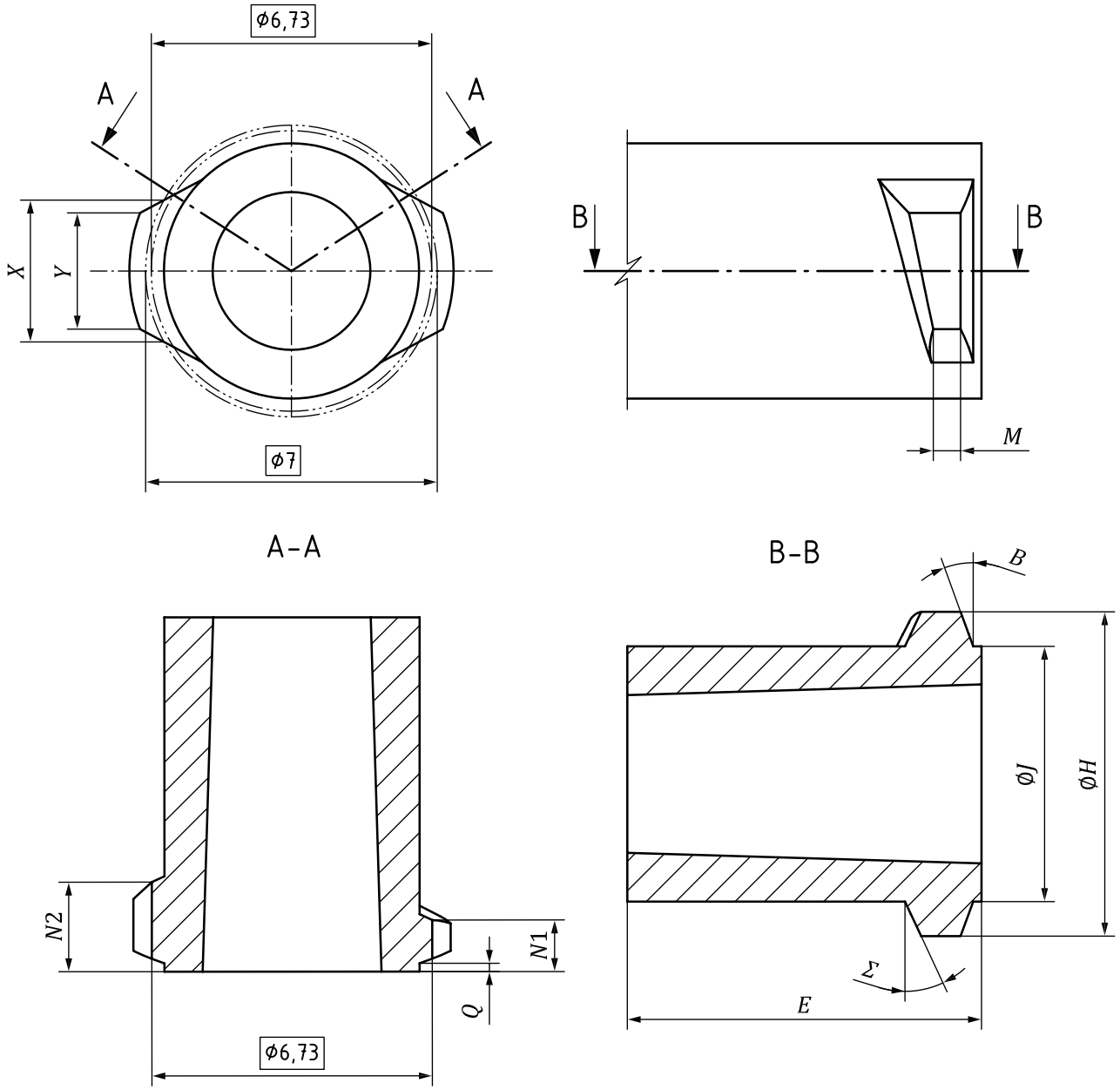


Table B.6 contains the dimensions for this figure.

Figure B.6 — Female *Luer lock connector* with lugs at right angle to axis (L2), variant A

Table B.6 — Female *Luer lock connector* dimensions (L2), variant A

Dimensions in millimetres unless otherwise indicated
Auxiliary dimensions are in parenthesis

Female *Luer lock connector* (L2), variant A				
Reference	**Designation**	**Dimension**		
		Minimum	***Nominal***	**Maximum**
B	Angle of the external lug profile on the non-bearing surface against separation (degrees)	0,0°	—	—
E	Depth of the female taper [a]	7,500	—	10,500
ØH	Major outside lug diameter (diameter at the lug crest)	7,730	—	7,830
ØJ	Minor outside lug diameter (diameter at the lug root) This diameter shall not be increased above the maximum for a distance from the hub face of 5,5 mm.	5,515	—	6,730
M	Width of the lug profile at the crest	0,300	—	—
N1	Distance from the face of the *connector* to the leading end of the lug as it is screwed into the male *connector* at a diameter corresponding to 6,730.	—	—	1,200
*N*2	Distance from the face of the *connector* to the trailing end of the lug as it is screwed into the male *connector* at a diameter corresponding to 6,730.	—	—	2,070
Q	Distance from the face of the *connector* to the base of the lug	—	—	0,300
Σ	Angle of external lug profile on the bearing surface against separation (degrees)	25,0°	—	30,0°
X	Chord length at the base of the lug in a plane at a right angle to the axis of the *connector*, to be measured on a chord of a circle, the diameter of which is 7,000	—	—	3,500
Y	Chord length at the extremity of the lug in a plane at a right angle to the axis of the *connector*	2,710	—	—

The design and dimensions of the thread profile (*Σ*, *B* and *M*) may vary from those designated provided the *connector* meets the performance requirements of Clause 6.

NOTE The design and dimensions of the thread profile (*Σ*, *B* and *M*) are not considered important to ensure *non-interconnectable* characteristics.

The female *Luer lock connector* with external lugs shall include the dimensions and tolerances of the female *Luer slip connector* as specified in Figure B.2 and Table B.2 except as indicated in this table.

Y shall not be greater than *X*.

[a] This dimension also defines the extent of the *connector*.

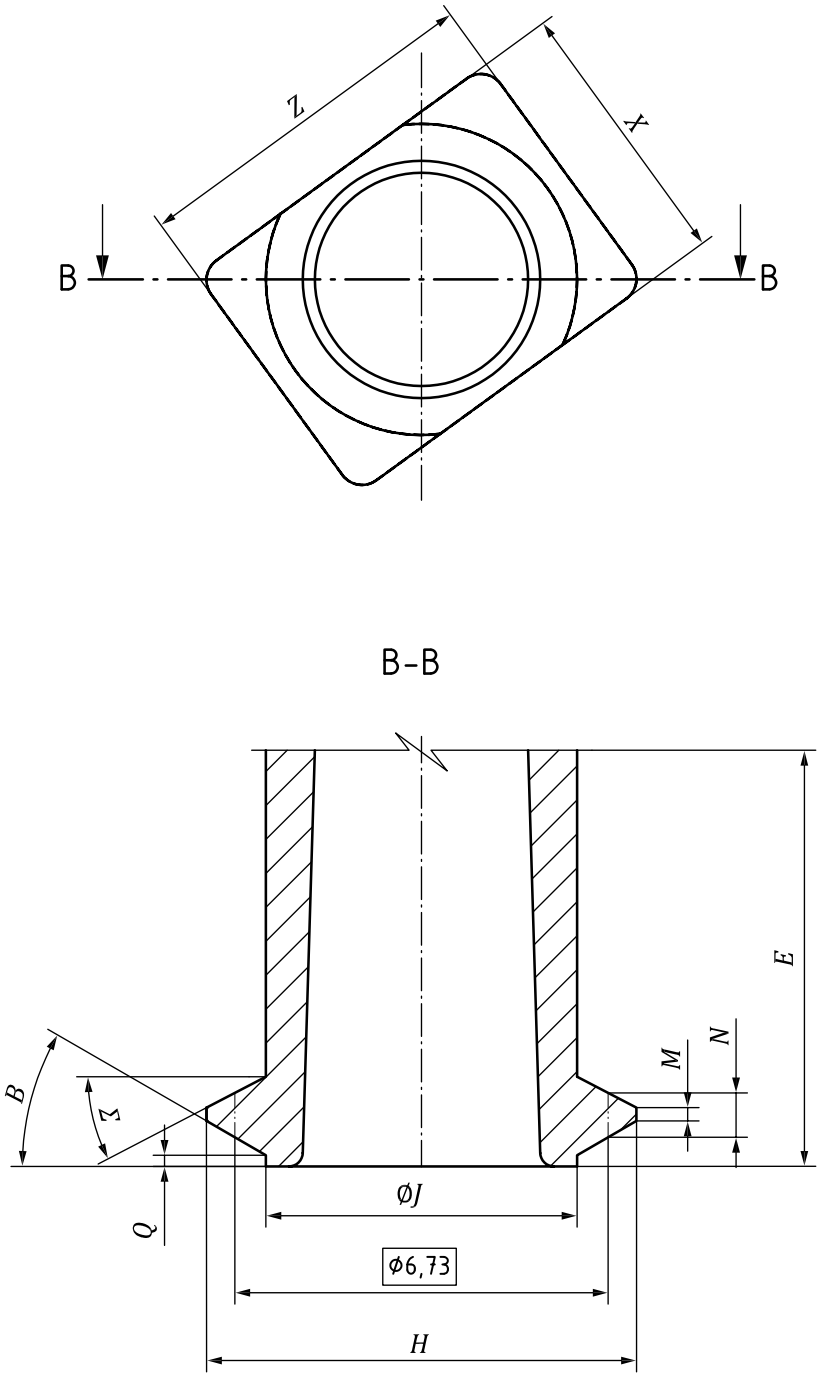


Table B.7 contains the dimensions for this figure. This variant is only intended for use in the design of *rigid material connectors*.

Figure B.7 — Female *Luer lock connector* with lugs at right angle to axis (L2), variant B

Table B.7 — Female *Luer lock connector* dimensions (L2), variant B

Dimensions in millimetres unless otherwise indicated
Auxiliary dimensions are in parenthesis

Female *Luer lock connector* (L2), variant B				
Reference	**Designation**	**Dimension**		
		Minimum	***Nominal***	**Maximum**
B	Angle of the external lug profile on the non-bearing surface against separation (degrees)	0,0°	—	—
E	Depth of the female taper [a]	7,500	—	10,500
H	Major outside lug diagonal (diagonal at the lug crest)	7,700	—	7,800
ØJ	Minor outside lug diameter (diameter at the lug root) This diameter shall not be increased above the maximum for a distance from the hub face of 5,5 mm.	5,515	—	5,700
M	Width of the lug profile at the crest	—	—	0,270
N	Width of the lug profile at a diameter corresponding to 6,730	—	—	1,300
Q	Distance from the face of the *connector* to the base of the lug	—	—	0,300
Σ	Angle of the external lug profile on the bearing surface against separation (degrees)	25,0°	—	30,0°
X	Chord length at the base of the lug in a plane at a right angle to the axis of the *connector*, to be measured on a chord of a circle, the diameter of which is 7,000	—	—	5,000
Z	Width across the lugs in a plane at a right angle to axis of the *connector*	6,400	—	6,500

The design and dimensions of the thread profile (*Σ*, *B* and *M*) may vary from those designated provided the *connector* meets the performance requirements of Clause 6.

The female *Luer lock connector* with external lugs shall include the dimensions and tolerances of the female *Luer slip connector* as specified in Figure B.2 and Table B.2 except as indicated in this table.

[a] This dimension also defines the extent of the *connector*.

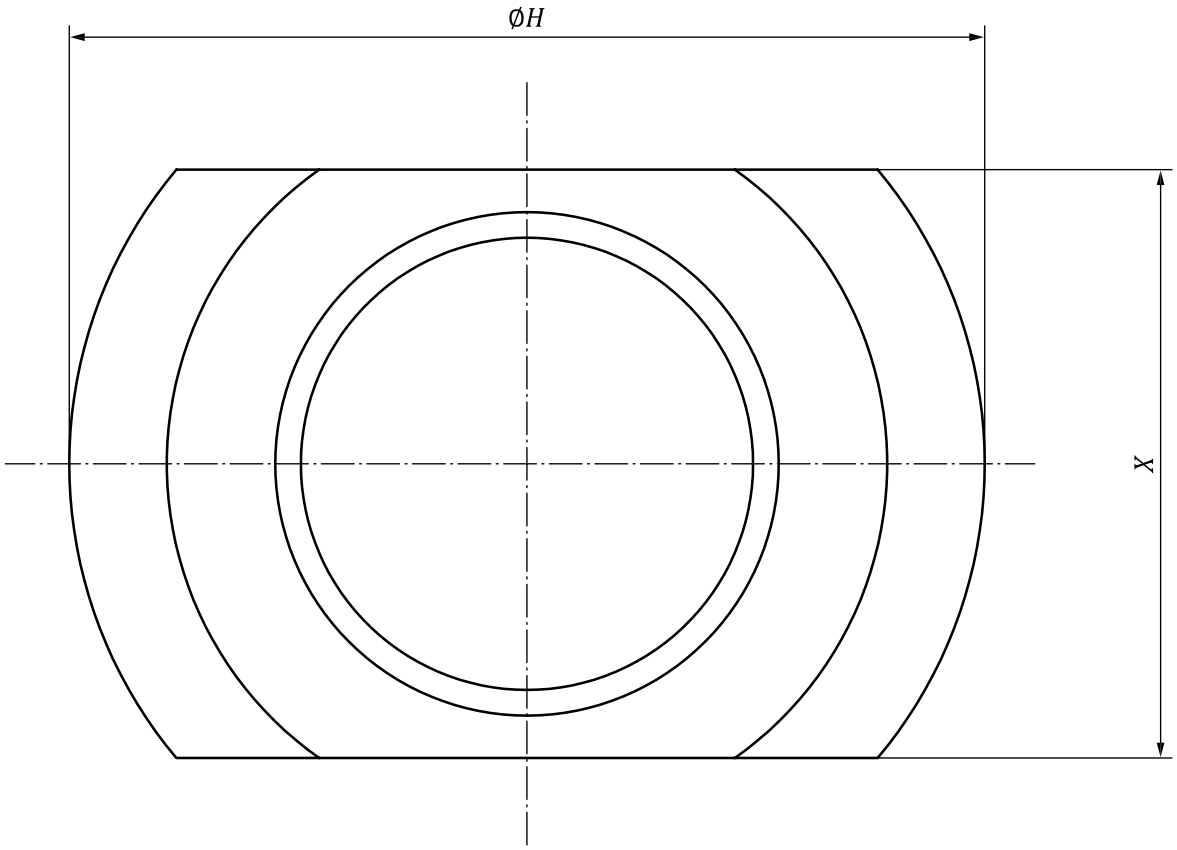


Table B.8 contains the dimensions for this figure. This variant is only intended for use in the design of *rigid material connectors*.

Figure B.8 — Female *Luer lock connector* with lugs at right angle to axis (L2), variant C

Table B.8 — Female *Luer lock connector* dimensions (L2), variant C

Dimensions in millimetres unless otherwise indicated
Auxiliary dimensions are in parenthesis

Female *Luer lock connector* (L2) with external threads				
Reference	**Designation**	**Dimension**		
		Minimum	***Nominal***	**Maximum**
ØH	Major outside lug diameter (diameter at the lug crest)	7,700	—	7,800
X	Chord length at the base of the lug in a plane at a right angle to the axis of the *connector*, to be measured on a chord of a circle, the diameter of which is 7,000	—	—	5,000
The female *Luer lock connector* with external lugs shall include the dimensions and tolerances of the female *Luer slip connector* as specified in Figure B.2 and Table B.2 as well as Section B-B of Figure B.7 and Table B.7 except as indicated in this table.				

Annex C
(normative)

Reference *connectors*

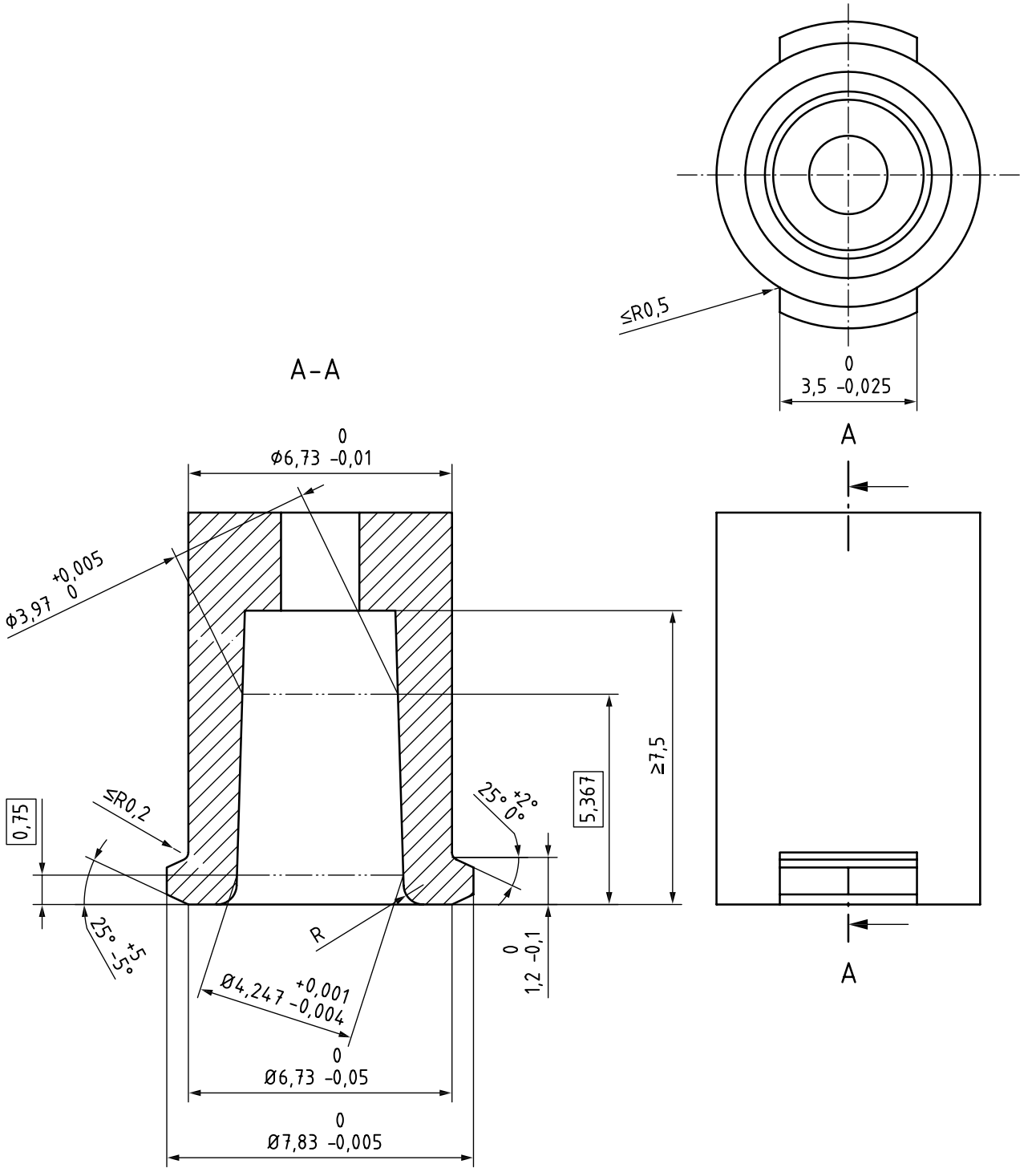
C.1 General requirements for reference *connectors*

Reference *connectors* shall be manufactured from corrosion-resistant *rigid materials* with a surface roughness value, R_a,[3] not exceeding 0,8 µm on critical surfaces.

NOTE Reference *connectors* made to the tolerances of Annex C of ISO 80369-7:2016 are considered to conform to the following figures.

C.2 Reference *connectors*

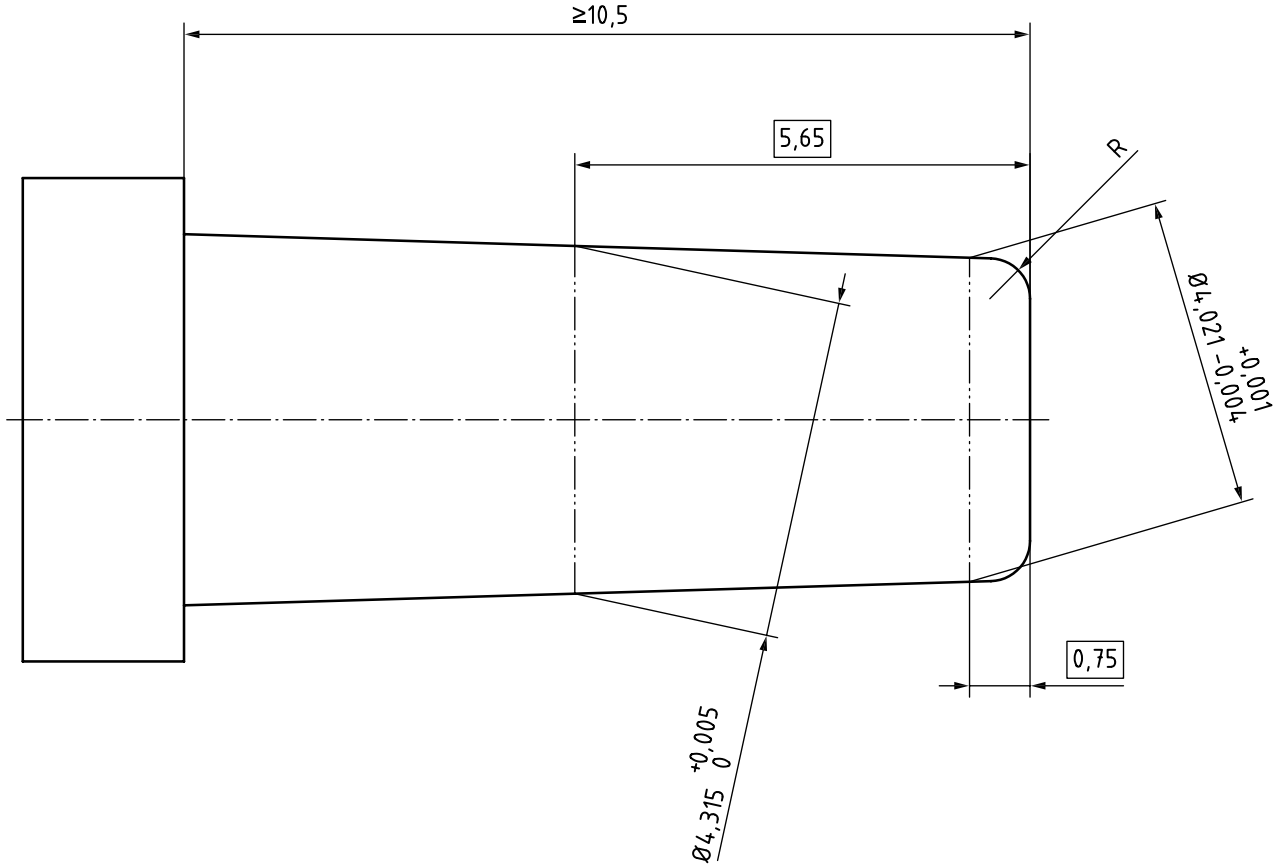
Dimensions in millimetres unless otherwise indicated



In Figure C.1, all outside edges of lug or thread form shall have a radius between 0,15 mm and 0,20 mm (unless otherwise specified). R is a radius or chamfer not to exceed 0,5 mm.

Figure C.1 — Female reference *Luer lock connector* for testing male *Luer connectors* for leakage, separation from unscrewing, stress cracking and *non-interconnectable* characteristics

Dimensions in millimetres unless otherwise indicated



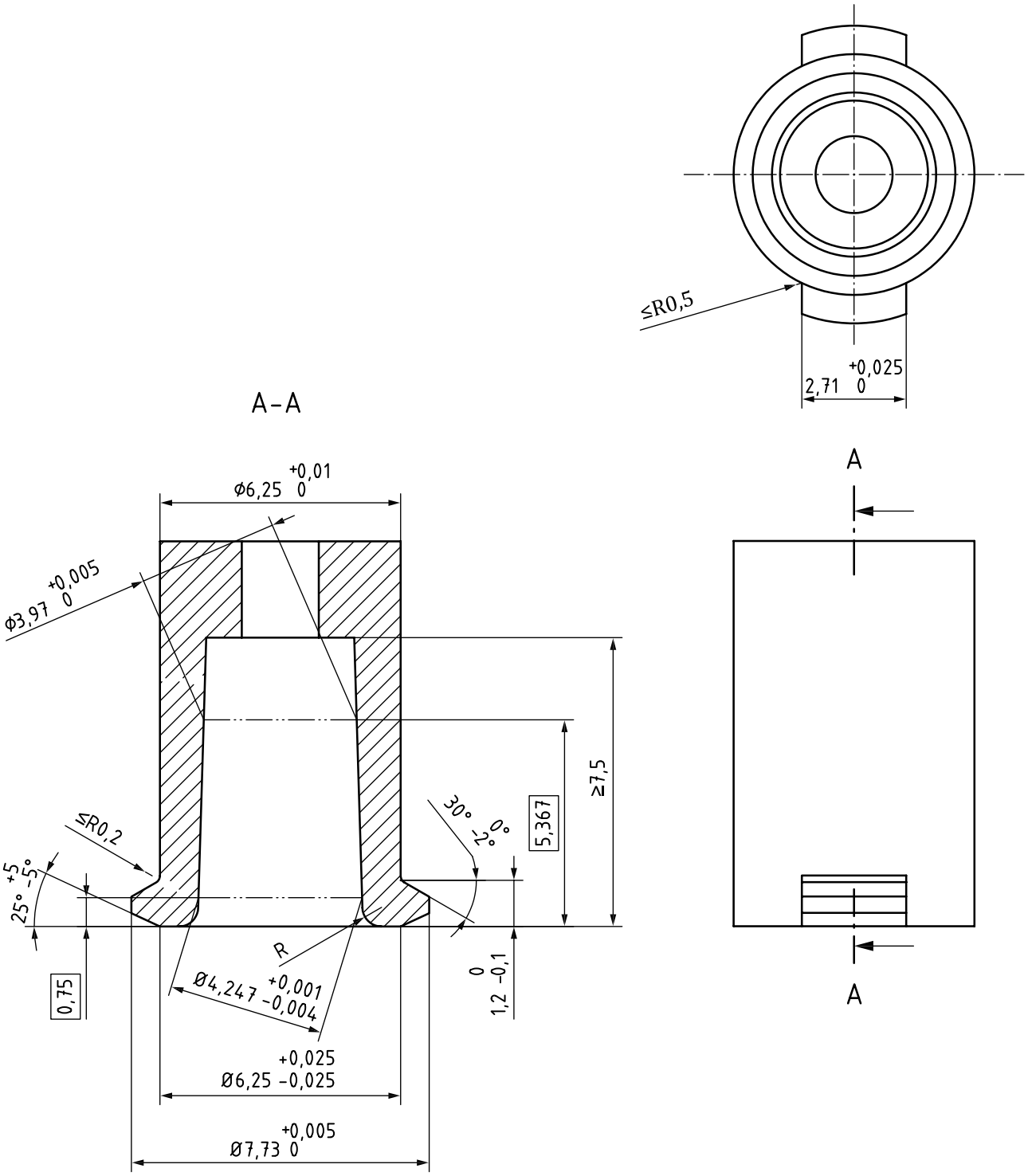
R is a radius or chamfer not to exceed 0,5 mm

The minimum length of the male taper of 10,5 mm is required for testing *non-interconnectable* characteristics. A minimum length of the male taper of 7,5 mm may be used for the performance tests of Clause 6.

NOTE Cone taper (0,06:1).

Figure C.2 — Male reference *Luer slip connector* for testing female *Luer connectors* for leakage, separation from axial load, stress cracking and *non-interconnectable* characteristics

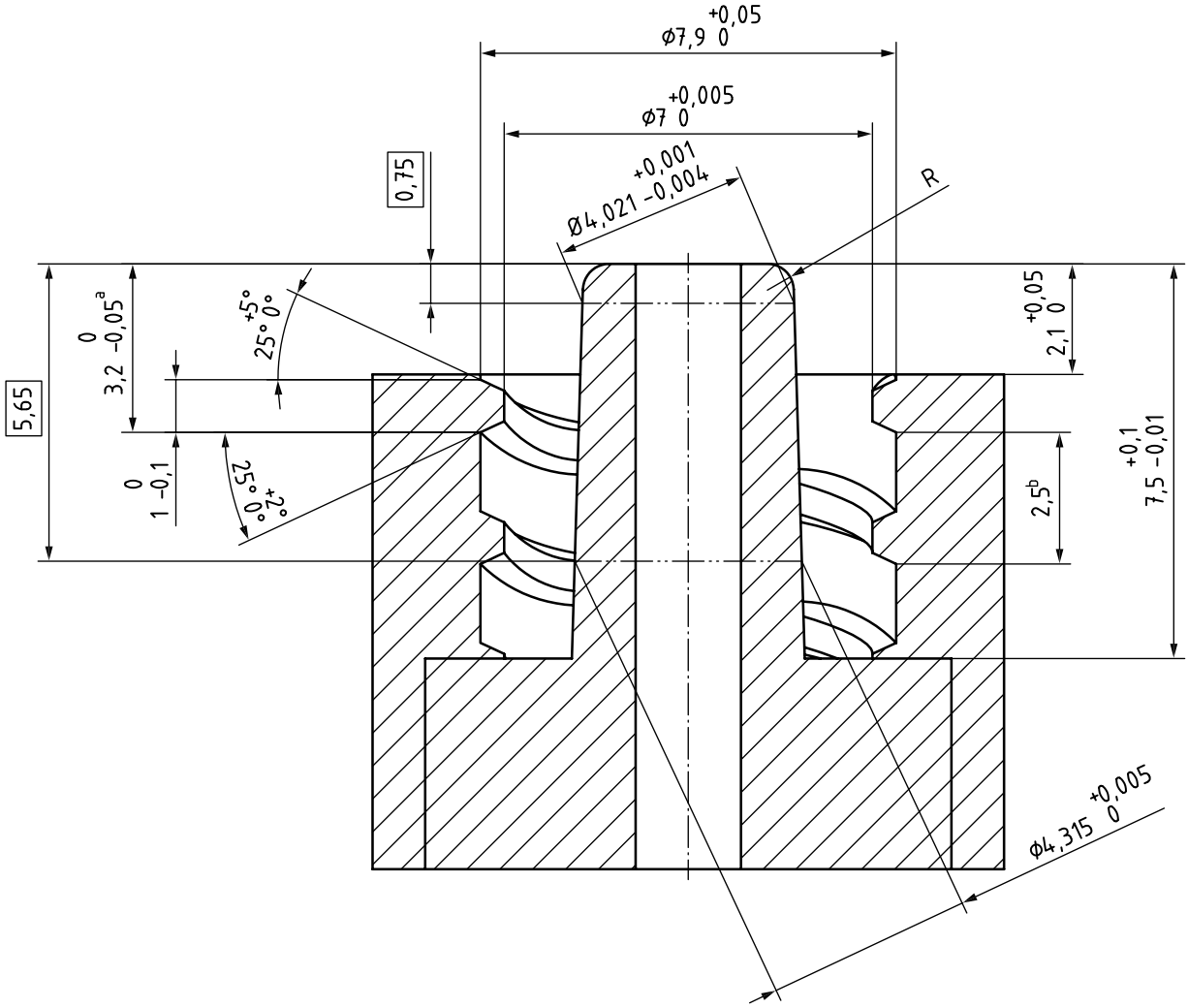
Dimensions in millimetres unless otherwise indicated



In Figure C.3, all outside edges of lug or thread form shall have a radius between 0,15 mm and 0,20 mm (unless otherwise specified). R is a radius or chamfer not to exceed 0,5 mm.

Figure C.3 — Female reference *Luer lock connector* for testing male *Luer lock connector* for separation from axial load and resistance to overriding

Dimensions in millimetres unless otherwise indicated



Key

a Maximum distance from tip of male *Luer lock connector* to the first complete profile of the internal thread (see Table B.3, dimension *t*).

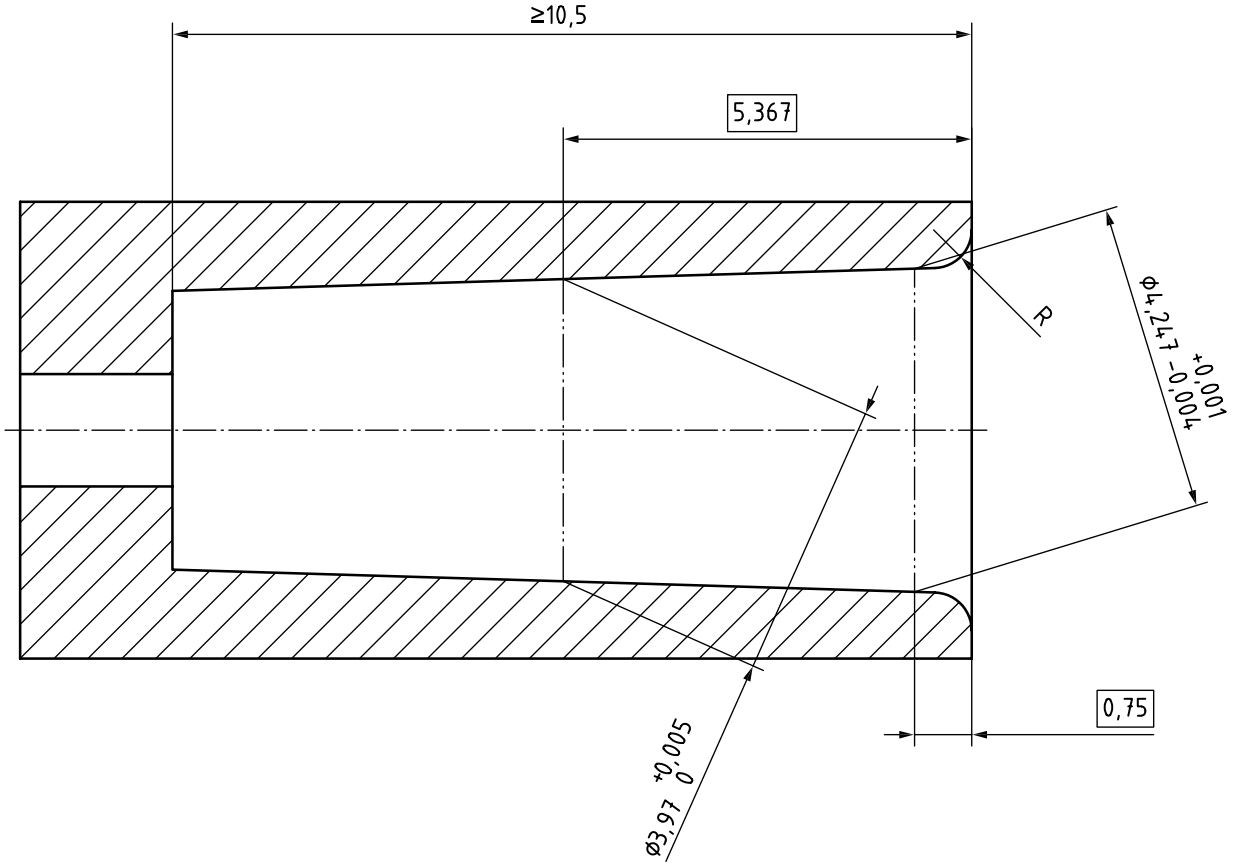
b Double-start, right-hand thread of 2,5 mm pitch.

R is a radius or chamfer not to exceed 0,5 mm.

NOTE This reference *connector* cannot be used for the test of *non-interconnectable* characteristics against its collar outside diameter because its corresponding defined range (Øw) is wide and one single reference *connector* is not representative.

Figure C.4 — Male reference *Luer lock connector* for testing female *Luer connectors* for leakage, separation from unscrewing, stress cracking and *non-interconnectable* characteristics

Dimensions in millimetres unless otherwise indicated



R is a radius or chamfer not to exceed 0,5 mm.

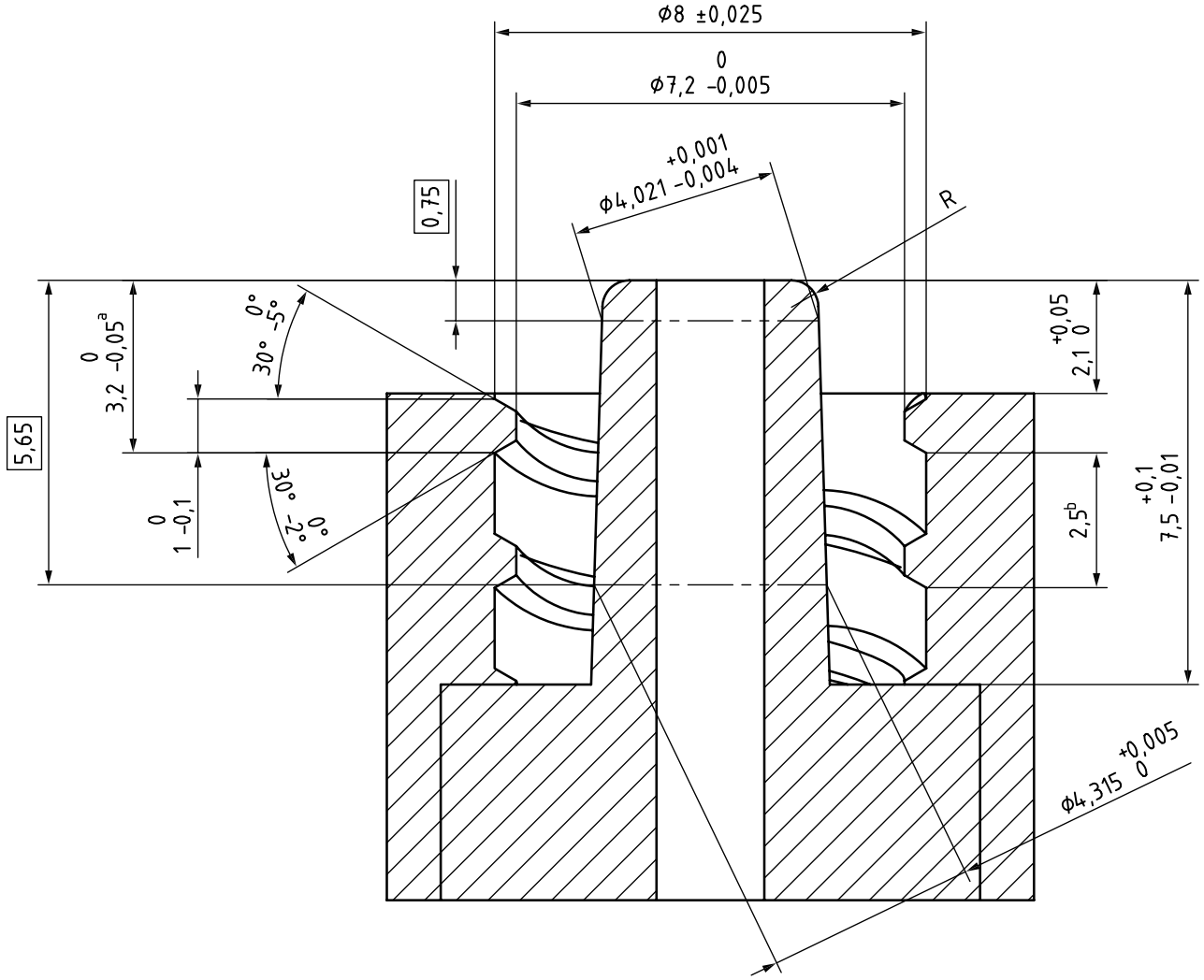
The minimum length of the male taper of 10,5 mm is required for testing *non-interconnectable* characteristics. A minimum length of the male taper of 7,5 mm can be used for the performance tests of Clause 6.

NOTE 1 Cone taper (0,06:1).

NOTE 2 This reference *connector* cannot be used for the test of *non-interconnectable* characteristics against its collar outside diameter because its corresponding defined range (ØJ) is wide and one single reference *connector* is not representative.

Figure C.5 — Female reference *Luer slip connector* for testing male *Luer connectors* for leakage, separation from axial load, stress cracking and *non-interconnectable* characteristics

Dimensions in millimetres unless otherwise indicated



Key

a Maximum distance from tip of male *Luer lock connector* to the first complete profile of the internal thread (see Table B.3, dimension *t*).

b Double-start, right-hand thread of 2,5 mm pitch.

R is a radius or chamfer not to exceed 0,5 mm.

Figure C.6 — Male reference *connector* for testing female *Luer lock connector* for separation from axial load and resistance to overriding

Annex D
(informative)

Assessment of *medical devices* and their attributes with *connections* within this *application*

Table D.1 contains examples of *medical devices* and *accessories* within intravascular or hypodermic *applications*. The table contains an assessment by the working group of the important attributes of *medical devices* and *accessories* as they relate to the intended *connection*. Each *connection* is assessed according to the following index or subgroups:

a) syringe *connections;*

b) needle *connections;*

c) IV tubing set *connections;*

d) IV tubing set port *connections;*

e) retention mechanism (e.g. balloon) *connections* used to hold invasive *medical devices* in place*;*

f) IV catheter *connections;*

g) IV catheter port *connections;*

h) stopcock *connections;*

i) adaptor *connections;* and

j) medication compounding adaptor *connections.*

Table D.1 — Examples of *medical devices* with *connections* within this *application* and their attributes

Part/component to which the *connector* is applied	Index	Flowrate range ml/min	Type of fluid		Type of *connection*		Therapy disruption	*patient* haemorrhage from fluid loss	Disrupted sample collection	Infection control	Functionality		
			Air	Liquid	Connection	Dis-*connection*					Locking needed	Slip needed	Flowrate control needed
Syringe	1	0 to 1 200	yes	yes	yes	yes	yes	no	yes	yes	yes	yes	yes
Needle	2	0 to 1 200	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
IV tubing set	3	0 to 1 200	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
IV tubing set port	4	0 to 1 200	yes	yes	yes	yes	yes	yes	no	yes	yes	yes	yes
Retention mechanism (e.g. balloon) *connections* used to hold invasive *medical devices* in place	5	0 to 1 200	yes	yes	yes	yes	yes	no	no	no	yes	yes	yes
IV catheter	6	0 to 1 200	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
IV catheter port	7	0 to 1 200	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
Stopcock	8	0 to 1 200	yes	yes	yes	yes	yes	yes	no	yes	yes	yes	yes
Adaptor	9	0 to 1 200	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
Medication compounding adaptor	10	0 to 1 200	yes	yes	yes	yes	yes	no	no	yes	yes	yes	yes

Annex E
(informative)

Summary of the usability requirements for *Luer connectors* for intravascular or hypodermic *applications*

E.1 *User profile*

The *user profile* is a summary of the mental, physical and demographic traits of an intended *user* population, as well as any special characteristics that can have a bearing on design decisions, such as occupational skills and job requirements.

Users of *Luer connectors* for intravascular or hypodermic *applications* are comprised of the clinical, laboratory, or non-clinical persons using, i.e. operating or handling, the *medical device*, including, but not limited to, cleaners, maintainers and installers, *patients*, or other laypersons. *Users* are expected to perform an intended action in an *intended use* of a *medical device*, *accessory*, *process* or service in accordance with the specifications, instructions and information provided by the *manufacturer*.

Users include the following:

a) clinical *users*, such as

   1) physicians who specialize in anaesthesiology, neuro-radiology, paediatrics, oncology, haematology/nursing, emergency room, medicine, interventional radiology, or as a physician assistant,

   2) nurses, at all levels, including Certified Registered Nurse Anaesthetist (CRNA) etc.,

   3) emergency medical technicians, and

   4) homecare providers, visiting nurses, relatives;

b) non-clinical *users*, such as cleaners, maintainers and installers; and

c) *in vitro* diagnostics laboratory and pharmacy *users*, responsible for mixing of drugs, filling syringes and reservoirs, storage and dispensing of drugs.

The *user profile* is summarized in Table E.1.

Table E.1 — *User profile*

	Patients* as *users	**Clinical *users***	**Non-clinical *users***	***In vitro* diagnostic laboratory and pharmacy *users***
***User* skills:**	No training	Extensive clinical training	Limited clinical training	Bioengineers, central processing
***Patient* contact:**	Direct *patient* contact	Direct *patient* contact	Direct *patient* contact	No *patient* contact

E.2 Use scenarios

Use scenarios for *Luer connectors* for intravascular or hypodermic *applications* can differ by *user* group, and are comprised of the multitude of sub-*applications* of the *connectors* within different sub-specialities.

A summary of use scenarios by *user* group is summarized in Table E.2.

Table E.2 — Use scenarios

Subspeciality use scenario	***Patients* as *users***	**Clinical *users***	**Non-clinical *users***	***In vitro* diagnostic laboratory and pharmacy *users***
1. Parenteral				
— Chemo	X	X	X	X
— Insulin, subcutaneous	X	X	X	—
— Infusion, IV catheter placements	—	X	X	X
— Medication preparation	X	X	X	X
— Injections	X	X	X	X
— Parenteral nutrition, including TPN (Total parenteral nutrition)	X	X	X	X
2. Extracorporeal				
— Dialysis	—	—	—	—
— Peritoneal Dialysis	X	X	X	X
— Haemodialysis	X	X	X	—
— ECMO (extracorporeal membrane oxygenation)	—	X	—	—
— Invasive pressure monitoring	—	X	—	—
— ICP Intracranial pressure	—	X	—	—
— IABP Intra-aortic balloon pump	—	X	—	—
— VAD Ventricular assist device	—	X	—	—
— Cardio-pulmonary bypass	—	X	—	—
— Cardiac catheters	—	X	—	—
— Rapid infusers	—	X	—	—
— Radiological marker pressure infusers	—	X	—	X
3. Irrigation				
— Wound care	X	X	X	—
— Aspiration	X	X	X	—
— Sample collection	X	X	X	—
4. Retention mechanism (e.g. balloon) (both gas or liquids)				
— Foley catheters	X	X	X	—
— Rectal catheters	X	X	X	—
— PEGs (percutaneous endoscopic gastrosto-my)	X	X	X	—
— Tracheal tubes	—	X	—	—
— Laryngeal Mask Airways	—	X	—	—
— Tracheostomy tubes	X	X	X	—
5. Ports				
— Subdermal	X	X	X	X
— Pain management	X	X	X	X
— Gastric Lapbands	X	X	X	—
— Implant inflation	—	X	X	—
6. Blood				
— Sample collection	X	X	X	X

Table E.2 *(continued)*

Subspeciality use scenario	***Patients* as *users***	**Clinical *users***	**Non-clinical *users***	***In vitro* diagnostic laboratory and pharmacy *users***
— Transfusion	X	X	X	—
— Donation/Phlebotomy	X	X	X	—
7. Medication preparation				
— Add-mixture	X	X	X	X
— Compounding	X	X	X	X
8. Other				
— Thermodilution catheters	—	X	—	—

E.3 Use environments

E.3.1 Facilities

Facilities include: hospitals, surgery suites, *patient* rooms, home, labour and delivery, intensive care units, doctors' offices, pain clinics, pharmacy, field hospitals, transport systems, infusion clinics, home assisted care, emergency medical services.

E.3.2 Use temperature

The following temperature environments are expected for *Luer connectors*:

a) ambient temperature, −40 °C to +60 °C (for field use in emergency medical services);

b) body temperature, to 42 °C;

c) hypothermia treatment, 10 °C (for therapeutic cooling of spinal cord injuries);

d) hypo/normo/hyperthermia treatments, 10 °C to 43 °C (for ECMO treatments).

E.4 Other attributes

The following other attributes are expected for *Luer connectors*:

a) usability under stress (ignoring labels, attempting force-fit);

b) proximity of liquids, use of gloves;

c) proximity of other *connector*-bearing equipment (e.g. sphygmomanometers, gas measurement).

E.5 Generic *user* needs

The following *user* needs attributes are expected for *Luer connectors*:

a) minimal pan-healthcare *user* training on the use of *connectors*;

b) easy to manipulate without the use of tools;

c) ease of assembly/disassembly with finger-tip control, especially in wet environment or with the use of gloves;

d) does not misconnect to other *small-bore connectors* not intended for the same purpose in the environment of use (ISO 80369-1);

e) does not leak under *normal use*;

f) security/integrity of *connection,* cannot unintentionally self-disconnect;

g) low dead space;

h) ease of fluid passage

   1) rate limiting factors;

   2) maximum flowrate

      i) cardiovascular equipment, diluted blood: 4 l/min, at 300 kPa with a dynamic viscosity of 6,89 mPa/s to prevent haemolysis,

      ii) dialysis equipment, blood: 600 ml/min at 400 mmHg below atmospheric pressure, and

      iii) IV pump, aqueous solutions: 1 200 ml/min at 300 mmHg pressure;

   3) Viscosity of solutions

      i) aqueous,

      ii) chemotherapy,

      iii) steroids, and

      iv) hyperbaric local anaesthetics;

i) needle-through-needle techniques, needle stylets (guide wires, peripheral catheters, etc.);

   NOTE Lumen diameter requirements are *medical device* specific and can require a *medical device*-specific *risk assessment* to provide for different capabilities.

j) compatible with disinfection, decontamination, sterilization, reprocessing environments;

k) *Luer slip connectors* are required to address several *user* needs, such as

   1) need to align the syringe with the 3-way stopcock,

   2) need to prevent movement of needle orientation during *connection*,

   3) cognitive distinction between *Luer slip connectors* and *Luer lock connectors* to prevent a misperception that the *Luer slip connector* is locked,

   4) lightweight and unobtrusive needle hub,

   5) little additional cost (making/purchasing), and

   6) consider the need for visible fluid paths in specific *medical devices*.

Annex F
(informative)

Summary of *Luer connector* design requirements for intravascular or hypodermic *applications*

Table F.1 is a summary of the design requirements for *Luer connectors* for intravascular or hypodermic *applications*.

Table F.1 — *Luer connector* specific design requirements for intravascular or hypodermic *applications*

	Criteria		Requirements	Remarks
1	**Fluid type**	a) Liquid b) Gas c) Both	c)	—
2	**Operating pressure range**	maximum pressure minimum pressure sub-atmospheric? (yes/no)	300 kPa Yes, 80 kPa	—
3	***Rated* pressure range**	minimum maximum	See Item 2	—
4	**Is there a need for a leak test?**	a) No b) Yes Reference for *test method*	b)	—
5	***Rated* flowrate range**	minimum maximum	0 ml/min 1 200 ml/min	—
6	**Internal diameter range (through bore)**	minimum maximum	0 mm 2,9 mm	—
7	***Rated* temperature range**	minimum maximum	−40 °C 60 °C	—
8	**Minimum range of *connector* mating diameters**	minimum maximum	—	Not compatible with other new *small-bore connectors*
9	**General layout**	a) Parallel-sided, O-ring seal b) Parallel-sided, other seal c) Conical d) Other (specify)	c) d)	—
10	**Method of keying**	a) Collar b) Plug c) Other (specify)	none	—
11	**Quick release?**	a) No b) Yes i) single-handed operation ii) double-handed operation	a)	—
12	**Positive locking/locking feature?**	a) No b) Yes	b)	—
13	**Need for visual indication of locking status?**	a) No b) Yes	a)	—
14	**Need for indication of evidence of tampering?**	a) No b) Yes	a)	—
15	**Need for a syringe in the *application*?**	a) No b) Yes	b)	—

Table F.1 *(continued)*

	Criteria		Requirements	Remarks
16	**Need for an absence of sharp edges?**	a) No b) Yes	b)	—
17	**Minimum axial force in *normal use*, to remain attached**	force Reference for *test method*	23 N *Luer slip connector* 32 N *Luer lock connector* ISO 594-1 ISO 594-2	—
18	**Constructional materials (excluding seals)**	a) *Rigid material* i) metal ii) glass iii) some plastic b) *Semi-rigid material* i) most plastic	a) Modulus > 3 433 MPa b) 700 MPa < Modulus < 3 433 MPa	—
19	**Need for use of *semi-rigid material*?**	a) No b) Yes, mating part of *connector* (apart from seal)	a) or b)	—
20	**MRI compatibility?**	a) No, with labelling b) No, without labelling c) Yes, with labelling d) Yes, without labelling	b) or d)	—
21	**Stress-cracking resistance?**	a) No b) Yes Specify limits	b)	—
22	**Externally, how is *connector* to be distinguishable from *Luer connector*?** (describe)		Not applicable	This is the *Luer connector*
23	**Proposal for colour-coding?**	a) No b) Yes Reference standard	a)	—
24	**Labelling/Symbols/Marking?**	a) No (e.g. not for IV) b) Yes	a)	—
25	**Other method for indicating *intended use*?**	a) No b) Yes Indicate method	a)	—
26	**Biocompatibility considered?**	a) No b) Yes	b)	—
27	**Reuse variants**	a) Multiple *patient* use b) Single *patient* use c) Single use d) Non-reusable (indicate method of auto-disabling)	a) b) or c)	—
28	**Decontamination needed?**	a) No, single use only b) Yes, cleaning and disinfection; indicate method c) Yes, cleaning and sterilization; indicate method	a) b) or e.g. isopropyl alcohol c)	—
29	**How is** ISO 80369-2 **incompatibility achieved?**	a) Dimensional b) Other Indicate method	a)	—

Table F.1 *(continued)*

	Criteria		Requirements	Remarks
30	**How is** ISO 80369-3 **incompatibility achieved?**	a) Dimensional b) Other Indicate method	a)	—
31	**How is** IEC 80369-5 **incompatibility achieved?**	a) Dimensional b) Other Indicate method	a)	—
32	**How is** ISO 80369-6 **incompatibility achieved?**	a) Dimensional b) Other Indicate method	a) b)	N1 male misconnection possible; see G.2.2.
33	**How is** ISO 80369-7 **incompatibility achieved?** (ISO 594-1 and ISO 594-2)	a) Dimensional b) Other Indicate method	This is a *Luer connector.*	—

Annex G
(informative)

Summary of assessment of the design of the *Luer connector* for intravascular or hypodermic *applications*

G.1 General

Connectors that conform with this document were designed and manufactured under the same essential design and dimensional requirements as those that conform with the previous edition of this document as well as withdrawn standards [3] [4].

Connectors represented by these documents have been successfully manufactured as components to *medical devices* for over 100 years.

G.2 Summary of the engineering analysis of the design

G.2.1 Non-interconnectable analysis

A three-dimensional computer aided design (CAD) engineering analysis has been performed using computational analysis and 3D solid model constructs of all tolerances and material conditions (*least material condition*, *nominal* and *maximum material condition*) for all *connectors* represented by the ISO 80369 series [10][11][13]. The *small-bore connectors* specified in this document have been shown by engineering analysis to be *non-interconnectable* with the other specified *connectors* of the ISO 80369 series with the exception of the following. Table G.1 summarizes the potential misconnections.

A technical report is planned to describe the *process* for the CAD engineering analysis more completely.

Table G.1 — Summary of possible misconnection from CAD analysis

Luer connector	***Connector* of concern**	**Summary**	**Reference**
male	N1[a] male	Misconnection possible	G.2.2
female slip	E1[b] female	Physical testing according ISO 80369-1:2018, Annex B, (except using all plastic parts) results in no *connection*	G.2.3
female slip	N2[a] male	Physical testing according ISO 80369-1:2018, Annex B, (except using all plastic parts) results in no *connection*	G.2.4

[a] N1 and N2 from ISO 80369-6:2016.

[b] E1 from ISO 80369-3:2016 [11].

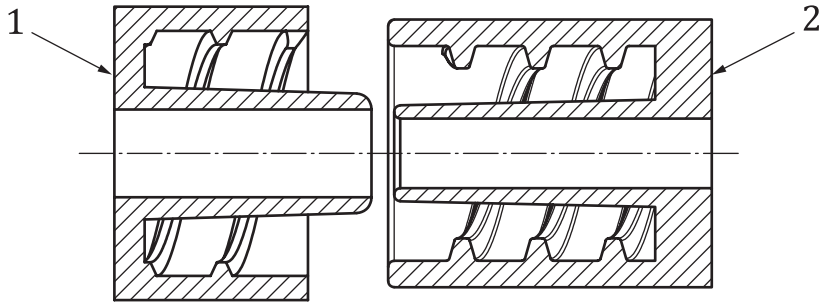
G.2.2 *Luer connector* male to N1 male

In the engineering analysis, the inside diameter of the fluid lumen of male *Luer connector* contacts the sealing surfaces of the N1 male *connector*, as specified in ISO 80369-6:2016, in *LMC* and thereby these *connectors* will mutually fail the *non-interconnectable* characteristics tests of ISO 80369-1:2018, Annex B. Figure G.1 illustrates this misconnection.

Testing was performed according to the *test method* of ISO 80369-6:2016, Annex H. The *connection* did not leak and thereby these *connectors* mutually fail this *non-interconnectable* characteristics test. Both of these *connectors* are distal to the *patient* in clinical use in the *patient* vicinity. In this environment, this misconnection would permit the *connection* an infusion source to an infusion source, which is not

hazardous to the *patient*. In the pharmacy, this misconnection could allow cross filling of vascular and neuraxial medications.

This misconnection is judged to be an acceptable *risk*.



Key

1 male *Luer connector*

2 male N1

Figure G.1 — Illustration *Luer connector* male to N1 male misconnection

G.2.3 *Luer slip connector* female to E1 female

Testing was performed according to the *test method* of ISO 80369-1:2018, Annex B, while substituting *connectors* of *least material condition* (*LMC*) and worst-case flexural modulus material (700 MPa to 720 MPa) for both the reference *Luer slip connector* female and the E1 *connector* being evaluated. The committees consider this modification of the *test method* to be more conservative.

The test demonstrated that the *connectors* are *non-interconnectable.*

G.2.4 *Luer slip connector* female to N2 male lock

Testing was performed according to the *test method* of ISO 80369-1:2018, Annex B.

The test demonstrated that the *connectors* are *non-interconnectable.*

G.3 Summary of the design *verification*

See G.1 and G.2.

Because of the long and successful history of widespread clinical use, the committees concluded that it was unnecessary to evaluate further these *connector* systems according to *processes* and *procedures* of ISO 80369-1:2018, Clause 7. That notwithstanding, performance testing was conducted on test articles that were available in the marketplace at the time and included components made from the following materials.

Luer connectors from two softer polymers are

— *connectors* made from two polypropylenes (PP) having a *nominal* modulus of elasticity (tensile) of 700 MPa, and 950 MPa.

Luer connectors from three harder polymers are

— *connectors* made from styrene acrylonitrile (SAN) having a *nominal* modulus of elasticity (tensile) of 3 800 MPa,

— *connectors* made from acrylonitrile butadiene styrene (ABS) having a *nominal* modulus of elasticity (tensile) of 2 400 MPa, and

— *connectors* made from polycarbonate (PC) having a *nominal* modulus of elasticity (tensile) of 2 344 MPa.

Luer connectors from two metals are

— *connectors* made from brass and stainless steel.

This range of modulus spans the available common materials most often used in intravascular and hypodermic *applications* and meets the requirements of Clause 4 of ISO 80369-1:2018.

Performance testing was conducted according to ISO 80369-20:2015 as required by Clause 6 using 60 samples per test group.

Conclusion:

The performance test results indicate that *Luer connector* design conforms with the performance requirements as specified in Clause 6 using the *test methods* defined in ISO 80369-20:2015.

G.4 Summary of the design validation

See G.1 and G.2.

The *Luer connector* of this document is generally the same design as the current *connector* design of ISO 594.

The current *connector* design has been in use for IV *connections* in clinical settings since 1930. The intended use of the ISO 594 Luer for intravenous and hypodermic *connections* is the same intended use as the *Luer connectors* of this document.

The *small-bore connectors* as defined in ISO 80369-6 have been tested in a human factors study (as described in ISO 80369-6:2016, G.4), which demonstrated that the misconnection potential between the male *Luer connector* and male N1 *connector* of ISO 80369-6 has been reduced to as low as reasonable practicable.

These studies, along with the CAD validation activities (G.2), ensure that the misconnection potential of a *Luer connector* to all the *connectors* specified in this series of documents has been reduced to acceptable levels, as is reasonably practicable, with the design of the *Luer connector* specified in this document.

Additionally, as clinical uses of the *Luer connectors* specified in this document are the same as previously specified for ISO 594 *connectors*, no further usability studies were deemed necessary.

G.5 Summary of the design review

Luer connectors, which conform to this document, also conform to the previous Luer documents, ISO 594-1[1] and ISO 594-2[2].

The committees reviewed the assessment of the design of the *Luer connectors* based on the results reported in this Annex.

In summary, the design review concludes there is significant objective engineering, technical and clinical evidence supporting the *Luer connector* for the intended *application*.

Annex H
(informative)

Reference to the essential principles

This document has been prepared to support the essential principles of safety and performance of *small-bore connectors* intended to be used for *connections* in intravascular or hypodermic *applications* of *medical devices* and related *accessories* according to ISO 16142-1:2016[9]. This document is intended to be acceptable for conformity assessment purposes.

Conformance with this document provides one means of demonstrating conformance with the specific essential principles of ISO 16142-1:2016[9]. Other means are possible. Table H.1 maps the clauses and subclauses of this document with the essential principles of ISO 16142-1:2016.

Table H.1 — Correspondence between this document and the essential principles

Essential principle of ISO 16142-1:2016 [9]	Corresponding clause(s)/ subclause(s) of this document	Qualifying remarks/ Notes
8.5	Clause 4, Clause 5, Clause 6	This essential principle is partially covered by ensuring that the *connector* does not leak and can only be connected to intended *medical devices* or *accessories.*
12.1	Clause 4, Clause 5, Clause 6	—
17.4	Clause 4, Clause 5, Clause 6	—
17.5	Clause 4, Clause 5, Clause 6	—

Annex I
(informative)

Reference to the general safety and performance requirements

This document has been prepared to support the general safety and performance requirements of regulation (EU) 2017/745[15] This document is intended to be acceptable for conformity assessment purposes.

Conformance with this document provides one means of demonstrating conformance with the specific general safety and performance requirements (GSPR) of regulation (EU) 2017/745. Other means are possible. Table I.1 maps the clauses and subclauses of this document with the general safety and performance requirements of regulation (EU) 2017/745.

NOTE When a general safety and performance requirement does not appear in Table I.1, it means that it is not addressed by this document.

Table I.1 — Correspondence between this document and the general safety and performance requirements

General safety and performance requirements (GSPR) of regulation (EU) 2017/745, Annex I[15]	Corresponding clause(s)/subclause(s) of this document	Qualifying remarks/Notes
10.5	Clause 4, Clause 5, Clause 6	This GSPR is partially covered by ensuring that the *connector* does not leak and can only be connected to intended *medical devices* or *accessories.*
14.1	Clause 4, Clause 5, Clause 6	—
20.4	Clause 4, Clause 5, Clause 6	—
20.5	Clause 4, Clause 5, Clause 6	—

For devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC[16] on Machinery, in accordance with Article 1 Element 12 of regulation (EU) 2017/745[15] the following Table I.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 those of regulation (EU) 2017/745 along with the corresponding clauses of this document.

Table I.2 — Correspondence between this document and relevant essential health and safety requirements from Directive 2006/42/EC on machinery

EHSR of 2006/42/EC [16]	Corresponding clause(s)/subclause(s) of this document	Qualifying remarks/Notes
1.5.4	Clause 4, Clause 5, Clause 6	

Annex J
(informative)

Terminology — Alphabetized index of defined terms

Term	Source
accessory	ISO 80369-1:2018, 3.1
application	ISO 80369-1:2018, 3.2
auxiliary dimension	3.1
connection	ISO 80369-1:2018, 3.3
connector	ISO 80369-1:2018, 3.4
intended use	ISO 14971:2019, 3.6
least material condition (*LMC*)	ISO 80369-1:2018, 3.6
Luer connector	3.2
Luer slip connector	3.3
Luer lock connector	3.4
manufacturer	ISO 14971:2019, 3.9
maximum material condition (*MMC*)	ISO 80369-1:2018, 3.7
medical device	ISO 14971:2019, 3.10
nominal	ISO 80369-1:2018, 3.8
non-interconnectable	ISO 80369-1:2018, 3.10
normal use	3.5
patient	ISO 80369-1:2018, 3.11
procedure	ISO 14971:2019, 3.13
process	ISO 14971:2019, 3.14
rated	3.6
responsible organization	ISO 80369-1:2018, 3.12
rigid material	3.7
risk	ISO 14971:2019, 3.18
risk assessment	ISO 14971:2019, 3.20
semi-rigid material	3.8
small-bore	ISO 80369-1:2018, 3.13
test method	ISO 80369-20:2015, 3.1
type test	ISO 80369-20:2015, 3.2
user	IEC 62366-1:2015, 3.24
user profile	IEC 62366-1:2015, 3.29
verification (verified)	ISO 14971:2019, 3.31

Bibliography

[1] ISO 594-1:1986,[1)] *Luer conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements*

[2] ISO 594-2:1998,[2)] *Luer conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: Lock fittings*

[3] ISO 4287, *Geometrical Product Specifications (GPS) — Surface texture: Profile method — Terms, definitions and surface texture parameters*

[4] ISO 8536-4, *Infusion equipment for medical use — Part 4: Infusion sets for single use, gravity feed*

[5] ISO 8637 (series), *Extracorporeal systems for blood purification*

[6] ISO 8638, *Cardiovascular implants and extracorporeal systems — Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters*

[7] ISO 10209:2012, *Technical product documentation — Vocabulary — Terms relating to technical drawings, product definition and related documentation*

[8] ISO 11040-4, *Prefilled syringes — Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling*

[9] ISO 16142-1:2016, *Medical devices — Recognized essential principles of safety and performance of medical devices — Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards*

[10] ISO 80369-2:—,[3)] *Small-bore connectors for liquids and gases in healthcare applications — Part 2: Connectors for breathing systems and driving gases applications*

[11] ISO 80369-3:2016+AMD1:2019, *Small-bore connectors for liquids and gases in healthcare applications — Part 3: Connectors for enteral applications*

[12] IEC 60601-1:2005+AMD1:2012, *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*

[13] IEC 80369-5, *Small-bore connectors for liquids and gases in healthcare applications – Part 5: Connectors for limb cuff inflation applications*

[14] CEN/CR 13825, *Luer connectors — A report to CEN CHeF from the CEN forum task group "Luer fittings"*

[15] (EU) 2017/745, (2017) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices. OJ L 117, *Official Journal of the European Union*, pp. 1-175

[16] (EC) 2006/42, (2006) Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery. OJ L 157, Official Journal of the European Union, pp. 24-86

1) Withdrawn.

2) Withdrawn.

3) Under prepara