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BSI Standards Publication

Small bore connectors for liquids and gases in healthcare applications

Part 6: Connectors for neuraxial applications

bsi.

National foreword

This British Standard is the UK implementation of EN ISO 80369-6:2016.

The UK participation in its preparation was entrusted by Technical Committee CH/210, Quality management and corresponding general aspects for medical devices, to Subcommittee CH/210/5, Small Bore Connectors for Medical Devices.

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Compliance with a British Standard cannot confer immunity from legal obligations.

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NORME EUROPÉENNE

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English version

Small bore connectors for liquids and gases in healthcare applications - Part 6: Connectors for neuraxial applications (ISO 80369-6:2016, Corrected version 2016-11-15)

Raccords de petite taille pour liquides et gaz utilisés dans le domaine de la santé - Partie 6: Raccords destinés à des applications en contact avec le système nerveux (neuraxiales) (ISO 80369-6:2016, Version corrigée 2016-11-15)

Verbindungsstücke mit kleinem Durchmesser für Flüssigkeiten und Gase in medizinischen Anwendungen - Teil 6: Verbindungsstücke für neuroaxiale Anwendungen (ISO 80369-6:2016, korrigierte Fassung 2016-11-15)

This European Standard was approved by CEN on 20 February 2016.

CEN and CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN and CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN and CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN and CENELEC members are the national standards bodies and national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

CEN-CENELEC Management Centre:
Avenue Marnix 17, B-1000 Brussels

European foreword

This document (EN ISO 80369-6:2016) 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/TC 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 October 2016, and conflicting national standards shall be withdrawn at the latest by October 2016.

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

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive, see informative Annex ZA, which is an integral part of this document.

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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

The following referenced documents are indispensable for the application of this document.

For undated references, the latest edition of the referenced document (including any amendments) applies. For dated references, only the edition cited applies. However, for any use of this standard ‘within the meaning of Annex ZA’, the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When an IEC or ISO standard is referred to in the ISO standard text, this shall be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated version of the ISO or IEC standard, as listed below.

NOTE The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

Table — Correlation between normative references and dated EN and ISO standards

Normative references as listed in Clause 2 of the ISO standard	Equivalent dated standard EN ISO or IEC	
ISO 5356-1:2004	EN 5356-1:2004	ISO 5356-1:2004
ISO 5356-1:2015	EN 5356-1:2015	ISO 5356-1:2015
ISO 5356-2:2006	EN 5356-2:2007	ISO 5356-2:2006
ISO 5356-2:2012	EN 5356-2:2012	ISO 5356-2:2012
ISO 8185:2007	EN 8185:2009	ISO 8185:2007
EN 13544-2:2002	EN 13544-2:2002	—
EN 13544-2:2002+A1:2009	EN 13544-2:2002+A1:2009	—
ISO 80369-1:2010	EN 80369-1:2010	ISO 80369-1:2010
ISO 80369-3:—[1)]	EN 80369-3:— [1)]	ISO 80369-3:— [1)]
ISO 80369-5:— [1)]	EN 80369-5:— [1)]	ISO 80369-5:— [1)]
ISO 80369-7:— [1)]	EN 80369-7:— [1)]	ISO 80369-7:— [1)]
ISO 80369-20:2015	EN 80369-20:— [1)]	ISO 80369-20:2015
ASTM D638-10	—	—
ASTM D790-10	—	—
1 To be published.		

Endorsement notice

The text of ISO 80369-6:2016, Corrected version 2016-11-15 has been approved by CEN as EN ISO 80369-6:2016 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of Directive 93/42/EEC on Medical Devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative clauses of this standard confers, within the limits of the scope of this standard, a presumption of conformity with the relevant Essential Requirements of that Directive.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC / Directive 90/385/EEC, as amended by 2007/47/EC. This means that risks have to be reduced "as far as possible" , "to a minimum", “to the lowest possible level", “minimized" or “removed", according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer’s policy for determining acceptable risk must be in compliance with essential requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the directive.

NOTE 3 This Annex ZA is based on Normative References according to Table of References, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 — Correspondence between this document and Directive 93/42/EEC

Clause(s)/sub-clause(s) of this Document	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
6.2	7.5	
4.1, 5, 6.4, 6.5, 6.6, 6.7	9.1	
6.3	12.7.4	
4.1, 5, 6.2, 6.5, 6.6, 6.7	12.8.1	This Essential Requirement is partially covered in that by ensuring that the CONNECTOR does not leak and can only be connected to intended MEDICAL DEVICES or ACCESSORIES it permits a MEDICAL DEVICE to be capable of controlling the flowrate.

WARNING: Other requirements and other EU Directives may be applicable to the products falling within the scope of this document.

For devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC on Machinery, in accordance with Article 3 of Directive 93/42/EEC the following Table ZA.2 details the relevant essential health and safety requirements of Directive 2006/42/EC on Machinery to the extent to which they are more specific than those of Directive 93/42/EEC along with the corresponding clauses of this Document. Table ZA.2, however, does not imply any citation in the OJEU under the machinery directive and thus does not provide presumption of conformity for the machinery directive.

Table ZA.2 — Relevant Essential Health and Safety Requirements (EHSRs) from Directive 2006/42/EC on machinery that are addressed by this document

Clause(s)/sub-clause(s) of this Document	EHSR of 2006/42/EC	Qualifying remarks/Notes
4, 5, 6	1.5.4	

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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.

ISO 80369 consists of the following parts, under the general title *Small-bore connectors for liquids and gases in healthcare applications*:

— *Part 1: General requirements*

— *Part 3: Connectors for enteral applications*

— *Part 5: Connectors for limb cuff inflation applications*

— *Part 6: Connectors for neuraxial applications*

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

— *Part 20: Common test methods*

An additional part on connectors for urethral and urinary applications is planned.

This corrected version of ISO 80369-6:2016 incorporates the following correction:

— in 6.3, the cross-reference to 6.1.2 has been changed to 6.1.1.

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 neuraxially. 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 drawings of SMALL-BORE CONNECTORS intended to be used in neuraxial 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.

There is international evidence that 'wrong-route' medication errors with neuraxial MEDICAL DEVICES have caused deaths and severe HARM. There are reports of non-epidural medications being administered into the epidural space and local anaesthetic solutions intended for epidural administration being administered by the intravenous route.[1] [9] [14] [15] [19] There is also a report where an anaesthetic agent for intravenous use was administered into the cerebrospinal fluid via an external ventricular drain[11] and earlier reports of antibiotics being inappropriately administered by this route.

In July 2007, the World Health Organization's World Alliance for Patient Safety issued Alert 115 describing four incidents in different countries in which vincristine had been accidentally administered by the intrathecal route instead of intravenous route, as intended.[1] The Alert indicated that, since 1968, this same error had been reported 55 times from a variety of institutional settings.

These incidents occurred despite repeated warnings of the RISK and the introduction of extensive labelling requirements and recommendations, intended to standardize practice and reduce RISKS.

Other health organizations around the world have also issued detailed guidance to minimize the RISK of these 'wrong-route' errors.[9] [15] [20] [21]

Nevertheless, reports of fatal incidents following the administration of vinca alkaloids continue to be reported internationally.[22] In 2009, the Food and Drug Administration in the USA issued a Medical Devices Calendar, which included an example of a case study of a neuraxial misconnection.[12]

CONNECTORS manufactured to the dimensions set out within this International Standard are dimensionally incompatible with any of the other CONNECTORS for APPLICATIONS identified in the ISO 80369 series of standards for SMALL-BORE CONNECTORS, except as indicated in G.2. 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 via an alternative route, such as neuraxially, intravenously, or via an airway device.

In this International Standard, 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 ISO 80369-1 and Clause 3: 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 International Standard conform to usage described in ISO/IEC Directives, Part 2, Annex H. For the purposes of this part of ISO 80369, the auxiliary verb

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

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

— “may” is used to describe a permissible way to achieve compliance with a requirement or test.

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.

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Small bore connectors for liquids and gases in healthcare applications —

Part 6: Connectors for neuraxial applications

1 * Scope

This part of ISO 80369 specifies requirements for SMALL-BORE CONNECTORS intended to be used for CONNECTIONS in neuraxial APPLICATIONS. Neuraxial APPLICATIONS involve the use of MEDICAL DEVICES intended to administer medications to neuraxial sites, wound infiltration anaesthesia delivery, and other regional anaesthesia procedures or to monitor or remove cerebro-spinal fluid for therapeutic or diagnostic purposes.

NOTE 1 Sites for the neuraxial APPLICATION include the spine, intrathecal or subarachnoid space, ventricles of the brain, and the epi-, extra-, or peri-dural space. Neuraxial APPLICATION anaesthetics can be administered regionally affecting a large part of the body, such as a limb, and include plexus blocks, such as the branchial plexus blocks or single nerve blocks. Neuraxial APPLICATION procedures include continuous infusion of wounds with local anaesthetic agents.

NOTE 2 For the purposes of this part of ISO 80369, local anaesthesia injected hypodermically is not considered a neuraxial APPLICATION.

EXAMPLES Intended administration includes intrathecal chemotherapy, local anaesthetics, radiological contrast agents, antibiotics, analgesics.

This part of ISO 80369 specifies dimensions and requirements for the design and functional performance of these SMALL-BORE CONNECTORS intended to be used with MEDICAL DEVICES.

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 International Standards for specific MEDICAL DEVICES or ACCESSORIES.

NOTE 3 MANUFACTURERS are encouraged to incorporate the SMALL-BORE CONNECTORS specified in this part of ISO 80369 into MEDICAL DEVICES, medical systems, or ACCESSORIES, even if currently not required by the relevant particular MEDICAL DEVICE standards. It is expected that when the relevant particular MEDICAL DEVICE standards are revised, requirements for SMALL-BORE CONNECTORS, as specified in this part of ISO 80369, will be included. Furthermore, it is recognized that standards need to be developed for many MEDICAL DEVICES used for neuraxial APPLICATIONS.

NOTE 4 ISO 80369-1:2010, 5.8, specifies alternative methods of compliance with ISO 80369-1:2010, for SMALL-BORE CONNECTORS intended for use with NEURAXIAL APPLICATION MEDICAL DEVICES or ACCESSORIES, which do not comply 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 14971:2007, *Medical devices — Application of risk management to medical devices*

ISO 80369-1:2010, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

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

ASTM D638-10, *Standard test method for tensile properties of plastics*

ASTM D790-10, *Standard test methods for flexural properties of unreinforced and reinforced plastics and electrical insulating materials*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14971:2007, ISO 80369-1:2010, and ISO 80369-20:2015 and the following apply.

NOTE For convenience, the sources of all defined terms used in this document are given in Annex J.

3.1
LOCK CONNECTOR
CONNECTOR with a locking mechanism

3.2
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/Amd1:2012, 3.97, modified replaced 'OPERATOR' with 'USER']

3.3
RATED
<value> term referring to a value assigned by the MANUFACTURER for a specified operating condition

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

3.4
SLIP CONNECTOR
CONNECTOR without a locking mechanism

3.5
USER
person interacting with (i.e. operating or handling) the MEDICAL DEVICE

Note 1 to entry: There can be more than one USER of a MEDICAL DEVICE.

Note 2 to entry: Common USERS include clinicians, PATIENTS, cleaners, maintenance and service personnel.

[SOURCE: IEC 62366-1:2015, 3.24]

3.6
USER PROFILE
summary of the mental, physical and demographic traits of an intended USER GROUP, as well as any special characteristics, such as occupational skills, job requirements and working conditions, which can have a bearing on design decisions

[SOURCE: IEC 62366-1:2015, 3.29]

4 General requirements

4.1 General requirements for the neuraxial APPLICATION

SMALL-BORE CONNECTORS of MEDICAL DEVICES or ACCESSORIES intended for use in neuraxial APPLICATIONS made in compliance with this part of ISO 80369 comply with ISO 80369-1:2010, unless otherwise indicated in this part of ISO 80369.

The inside diameter of the fluid lumen of male LUER CONNECTOR, as specified in ISO 80369-7:—, may contact the sealing surfaces of the N1 male CONNECTOR in LMC conditions when evaluating the NON-INTERCONNECTABLE characteristics tests of ISO 80369-1:2010, Annex B. Additional information is provided in G.2.

The sealing surface of female E1 CONNECTOR, as specified in ISO 80369-3:—, may contact the thread surfaces of the N2 female CONNECTOR in LMC conditions when evaluating the NON-INTERCONNECTABLE characteristics tests of ISO 80369-1:2010, Annex B. Additional information is provided in G.2.

Because the following CONNECTORS are inadequately specified, SMALL-BORE CONNECTORS for use in neuraxial APPLICATIONS should not, but may connect with:

— the cones and sockets of ISO 5356-1:2004, ISO 5356-1:2015, ISO 5356-2:2006 and ISO 5356-2:2012;

— the temperature sensor CONNECTOR and mating ports made in compliance with ISO 8185:2007, Annex DD;

— the nipples of EN 13544-2:2002 and EN 13544-2:2002+Amd1:2009.

The reference CONNECTORS for evaluation of the NON-INTERCONNECTABLE characteristics are described in Annex C.

The test of Annex H shall replace ISO 80369-1:2010, Annex B.

NOTE 1 Annex H describes a deviation to the physical test NON-INTERCONNECTABLE characteristics of ISO 80369-1:2010, Annex B. A rationale for the deviation is provided in Annex A. For neuraxial SMALL-BORE CONNECTORS, Annex H, supersedes ISO 80369-1:2010, Annex B.

Where the design of the SMALL-BORE CONNECTORS 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.

Check compliance by applying the tests of Annex H. Compliance also may be shown 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 per Annex B where the CAD analysis does not demonstrate the NON-INTERCONNECTABLE characteristics. When necessary, the SMALL-BORE CONNECTOR may be installed on the MEDICAL DEVICE or ACCESSORY to demonstrate compliance with the NON-INTERCONNECTABLE requirements of Annex H.

NOTE 2 MEDICAL DEVICES using the SMALL-BORE 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 comply with the NON-INTERCONNECTABLE characteristics of this part of ISO 80369.

NOTE 3 The summary of MEDICAL DEVICES and their attributes with CONNECTIONS within this APPLICATION is provided in Annex D.

NOTE 4 The summary of the usability requirements for CONNECTORS for this APPLICATION is provided in Annex E.

NOTE 5 The summary of criteria and requirements for CONNECTORS for this APPLICATION is provided in Annex F.

NOTE 6 The summary of assessment of the design of CONNECTORS for this APPLICATION according to ISO 80369-1:2010, Clause 7, is contained in Annex G.

4.2 * Material used for SMALL-BORE CONNECTORS

In addition to the requirements of ISO 80369-1:2010, Clause 4, neuraxial SMALL-BORE CONNECTORS shall be made of materials with a nominal modulus of elasticity either in flexure or in tension greater than 950 MPa.

Check compliance by application of the tests of ASTM D638-10 or ASTM D790-10.

4.3 TYPE TESTS

Compliance with the requirements of this part of ISO 80369 shall be determined by TYPE TESTS.

5 Dimensional requirements for neuraxial SMALL-BORE CONNECTORS

Neuraxial SMALL-BORE CONNECTORS shall comply with the dimensions and tolerances as given in

— Figure B.1 and Table B.1 for an N1 male SLIP CONNECTOR.

— Figure B.2 and Table B.2 for an N2 male LOCK CONNECTOR.

— Figure B.3 and Table B.3 for an N2 male LOCK CONNECTOR with rotatable collar.

— Figure B.4 and Table B.4 for an N2 female CONNECTOR with swept threads.

— Figure B.5 and Table B.5 for an N2 female CONNECTOR with lugs.

Check compliance by verifying the relevant dimensions and tolerances specified in Annex B.

6 Performance requirements

6.1 Fluid leakage

6.1.1 Fluid leakage requirement

Neuraxial SMALL-BORE 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

Neuraxial SMALL-BORE 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 or longer hold period.

Check compliance 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

Neuraxial SMALL-BORE 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 or a longer hold period.

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

6.2 Subatmospheric pressure air leakage

Neuraxial SMALL-BORE CONNECTORS shall be evaluated for subatmospheric pressure air leakage. Neuraxial SMALL-BORE CONNECTORS shall not leak by more than 0,005 Pa·m^3/s while being subjected to an applied subatmospheric 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 subatmospheric pressure.

Check compliance by applying the tests of ISO 80369-20:2015, Annex D, while using the stress cracking reference CONNECTOR specified in Annex C.

6.3 Stress cracking

Neuraxial SMALL-BORE CONNECTORS shall be evaluated for stress cracking. Neuraxial SMALL-BORE CONNECTORS shall meet the requirements of 6.1.1 after being subjected to stresses of ISO 80369-20:2015, Annex E.

Check compliance 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

Neuraxial SMALL-BORE CONNECTORS shall be evaluated for separation from axial load. Neuraxial SMALL-BORE 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 a SLIP CONNECTOR, and

b) 32 N and 35 N for a LOCK CONNECTOR.

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

Check compliance 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

LOCK CONNECTORS shall be evaluated for separation from unscrewing. A LOCK CONNECTOR 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 0,0198 N·m to 0,0200 N·m. MANUFACTURERS may use a greater applied unscrewing torque or a longer hold period.

Check compliance by applying the tests of ISO 80369-20:2015, Annex G, while using the separation from axial load reference CONNECTOR specified in Annex C.

6.6 Resistance to overriding

Neuraxial SMALL-BORE CONNECTORS shall be evaluated for resistance to overriding. Neuraxial SMALL-BORE 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 compliance by applying the tests of ISO 80369-20:2015, Annex H, while using the separation from axial load 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 this part of ISO 80369, and is intended for those who are familiar with the subject of this 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 application. 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

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. [8] The strategy reserves the use of LUER CONNECTORS solely for use in MEDICAL DEVICES used to access the vascular system or for hypodermic syringes so that they can achieve their intended function.[7] The CONNECTORS of this part of ISO 80369 are reserved for neuraxial APPLICATIONS.

MANUFACTURERS and RESPONSIBLE ORGANIZATIONS are encouraged to report their experience with the SMALL-BORE 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 this series of International Standards.

4.2 Material used for SMALL-BORE CONNECTORS

The minimum value of the nominal flexural or tensile modulus of 950 MPa was chosen for neuraxial APPLICATIONS predominantly due to current use of polypropylenes for syringe manufacturing. Usability testing, in several cases, demonstrated misconnections with other SMALL-BORE CONNECTORS of the ISO 80369 series when using low modulus materials. It is highly recommended that MANUFACTURERS choose the highest modulus material possible for their MEDICAL DEVICE with preference to be 1 500 MPa or higher wherever possible.

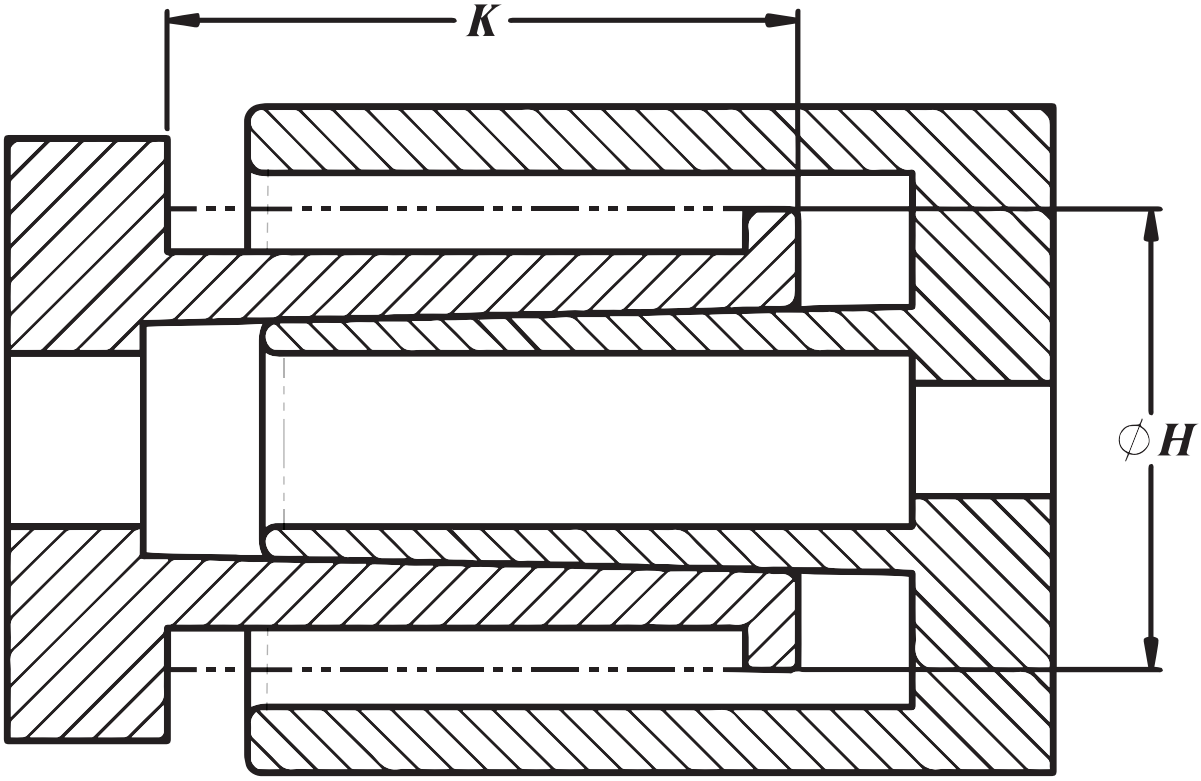
Annex B

Dimension '*K*' and '*k*' are defined to ensure an understanding by MANUFACTURERS of the extent of the CONNECTOR. Failure to comply with these minimum dimensions could result in the inability to properly connect to neuraxial CONNECTORS produced by other MANUFACTURERS. Figure A.1 and Figure A.2 illustrate this concern.

All surface finishes of parts of these CONNECTORS which do not form part of the mating surfaces should be constructed so as to avoid the possibility of any another CONNECTOR, which could be present in the clinical environment, from being able to form a fluid-tight CONNECTION to the CONNECTORS specified within this part of ISO 80369. This ensures that attempts made to connect any other CONNECTOR (not complying with this part of ISO 80369) to one specified within this part of ISO 80369 results in fluid

leakage and the failure to establish a fluid-tight path into the CONNECTORS specified within this part of ISO 80369.

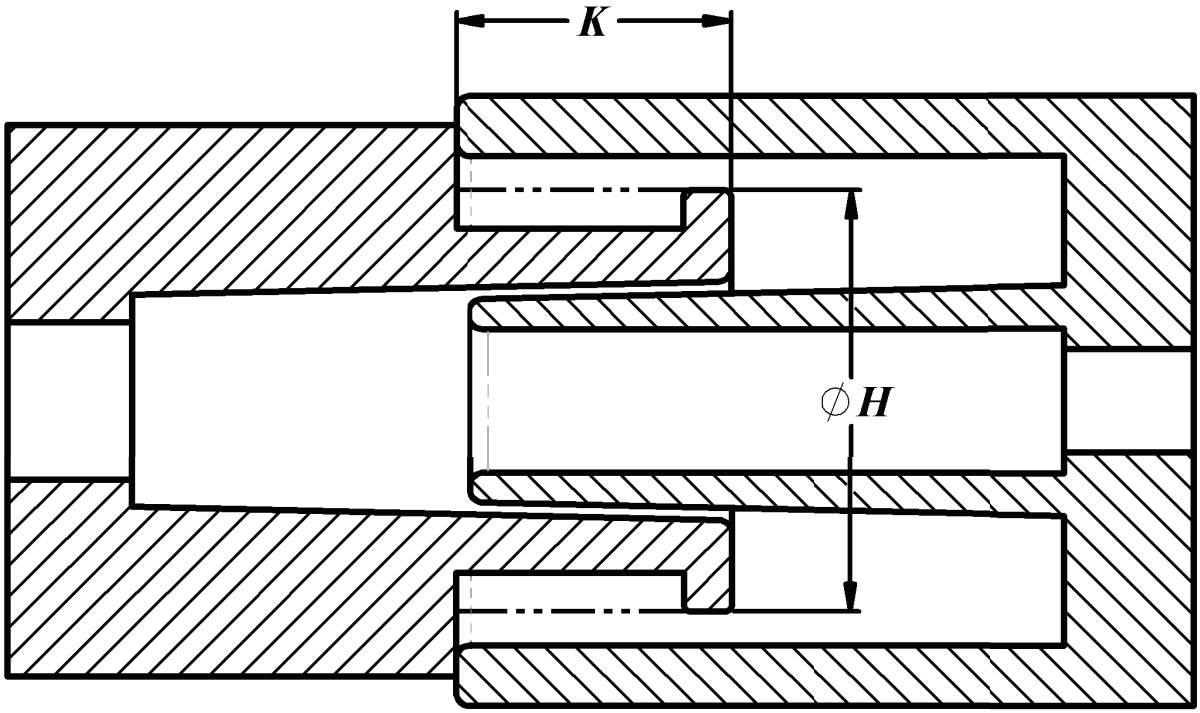
Annex B defines a maximum internal diameter of the male CONNECTOR, to prevent inadvertent male-to-male connectivity between the CONNECTORS defined within this part of ISO 80369 and any other SMALL-BORE CONNECTORS from the ISO 80369 series.



NOTE 1 Table B.4 contains the dimensions for this figure.

NOTE 2 The cones form a seal properly.

Figure A.1 — Extent of the CONNECTOR, compliant with this part of ISO 80369 (K > 8,6 mm)



NOTE 1 Table B.4 contains the dimensions for this figure.

NOTE 2 The cones do not form a seal properly.

Figure A.2 — Extent of the CONNECTOR, not compliant with this part of ISO 80369 (*K* < 8,6 mm)

H.1 Purpose

Several deviations from the physical testing for NON-INTERCONNECTABLE characteristics TEST METHOD of ISO 80369-1:2010, Annex B were developed. These include the following:

a) axial force up to 70 N is changed to 70 N ± 1 N to clarify the requirement;

NOTE If no axial load were applied, this would be less than 70 N and would meet the technical requirements but not the intent of this part of ISO 80369.

b) rotate up to 270° rather than 90°. CONNECTORS employ dual start threads spaced 180° apart. Rotating only 90° allows a false negative since this is less than 180°;

c) the axial separation force is changed to either 0,02 N or the weight of the CONNECTOR to allow for gravity testing if desired;

d) physical NON-INTERCONNECTABLE characteristics are defined as a combination of parts mechanically mating but also leaking at a low-flow rate that a USER might not notice;

Change to disconnection at 2 g or the weight of the CONNECTOR.

The NON-INTERCONNECTABLE characteristics TEST METHOD described in ISO 80369-1:2010, Annex B, poses technical challenges for MANUFACTURERS to perform accurately. According to the original Annex B TEST METHOD, the CONNECTORS are compressed with an axial load of 70 N and a torque of 0,12 N·m for 10 s and then are required disconnection with a force no greater than 0,02 N (2 g). Many MANUFACTURERS and test houses want to use a tensile tester to apply the axial load and the disconnection force with the same instrument. To apply the 70 N axial load, a 100 N load cell is required to handle the 70 N applied load. A typical 100 N load cell has an accuracy of 0,1 %, which means that a 100 N load

cell is only accurate to ±0,1 N. This is not sufficiently accurate to measure a 0,02 N disconnection force. Thus, the same instrument cannot measure both the applied axial load and the disconnection force with the accuracy required to perform the TEST METHOD.

Since using one instrument to apply a 70 N load and detect a 0,02 N separation force is not practical, a gravity detection method is permitted after applying the load and torque. The TEST METHOD was modified such that the CONNECTORS are required to disengage with either 0,02 N or the weight of the CONNECTOR. Most neuraxial components weigh more than 2 g so the acceptance criteria were modified to accommodate the weight of the part. Table A.1 shows representative part weights of common neuraxial components.

Table A.1 — Mass of common neuraxial components

Neuraxial component	Mass g	Equivalent force *N*
Loss of resistance (LOR) device (10 cm^3 barrel only)	4,40	0,044
Spinal needle (25 gauge) and protective sheath but no stylet	1,99	0,02
Epidural Tuohy needle (16 gauge) and protective sheath but no stylet	3,99	0,04
Syringe (20 ml barrel only)	6,70	0,067
Filter 0,2 micron flat in line	5,14	0,051
Catheter CONNECTOR	3,40	0,034

H.5 Test procedure, leakage

The NON-INTERCONNECTABLE characteristics physical TEST METHOD defined in ISO 80369-1:2010, Annex B, sets optimal and desirable goals, which are practically difficult to implement with all SMALL-BORE CONNECTORS. This TEST METHOD utilizes a very high axial load (70 N). Clinicians are highly unlikely to apply such a large force to connect two CONNECTORS when undertaking an injection of a neuraxial nature into a patient, due to the RISK of moving the needle and dislodging the tip from the target space. However, higher forces are possible when connecting MEDICAL DEVICES distant from the PATIENT, such as an administration set to an epidural filter. The 70 N axial load was established based on what a USER could physically apply, not necessarily what a neuraxial USER would likely apply in a clinical setting.

The usability study reported in G.4 demonstrated that a 70 N axial load is excessive for this APPLICATION. The average force at which USERS recognized a misconnection and stopped trying to connect was 26 N. One user did exceed 70 N (86 N). These data indicate that most clinicians would recognize a misconnection well below the axial load levels set by the original TEST METHOD.

During the same usability study, the leak rate of a misconnection was evaluated as to what leak rate the clinicians would recognize that the non-mating parts were leaking. The clinicians all stated that this misconnection would not cause a significant clinical RISK because the high force needed to make the CONNECTION combined with profuse leaking, would provide sufficient clues of a misconnection and they would stop the procedure.

USERS were asked at what leakage rate they would expect to identify a leak and stop delivering medication. The average leakage rate at which clinicians would notice a leak was 6 % and the maximum leakage rate was 25 %. By setting the minimum leak requirement at 75 %, more than 99,9 % of clinicians would recognize a misconnection and stop administering medication. To clarify, clinicians are stating that they would recognize a leak if the leak was 1 % up to 25 % of the total infusate. This is not an indication that fluid passage through the device is acceptable. This study was modelled after misconnection testing conducted by Cook.[11] This study analysed anaesthesiologists' reactions to new non-LUER CONNECTOR neuraxial MEDICAL DEVICES. Of the various misconnections noted in the report, the clinicians discounted the misconnections that leaked significantly. The clinicians stated that between the high force to connect and profuse leaking, the CONNECTION was not a clinical RISK.

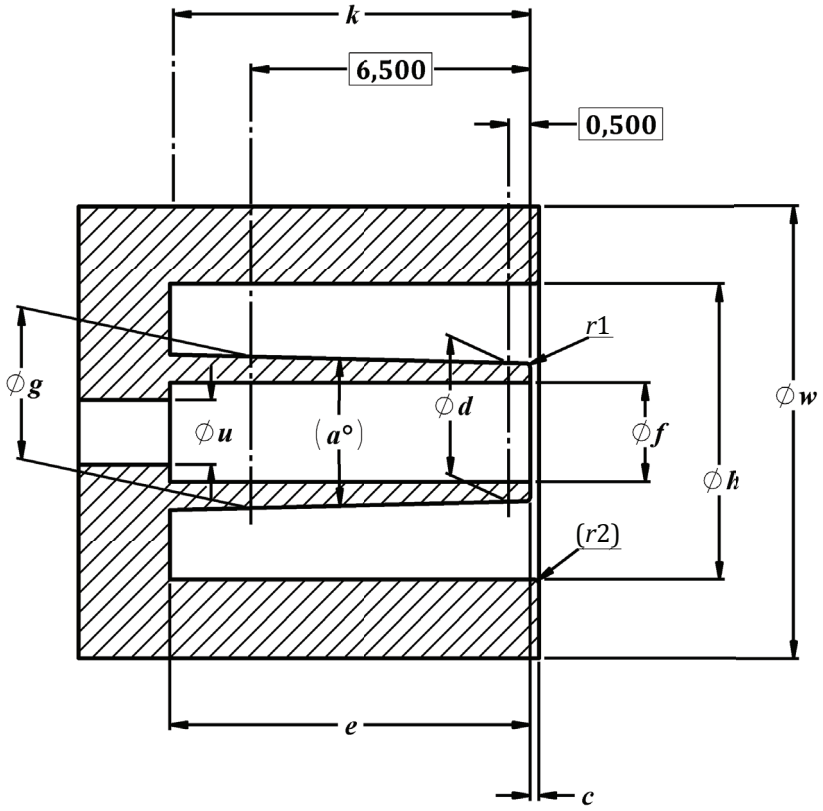
A second experiment was conducted to evaluate if a low flow infusion pump with a flow rate of 4 ml/h could pump fluid through a misconnection and not be noticed by a clinician. Eight 20 gauge epidural

catheters and catheter CONNECTORS were misconnected with a male N2 CONNECTOR, to female L1, as defined in ISO 80369-7. A low flow infusion pump provided a steady, low flow rate of 4 ml/hr. The misconnected joint did not allow any pressure to be generated upstream of the catheter and no fluid was pumped into the catheter; 100 % of low flow fluid leaked from the misconnection. Therefore, even if a misconnection is made and a gross leak is not detected by the clinician, fluid is not erroneously delivered to the PATIENT.

Annex B
(normative)

* SMALL-BORE CONNECTORS for neuraxial APPLICATIONS

Dimensions in millimetres unless otherwise indicated



NOTE Table B.1 contains the dimensions for this figure.

Figure B.1 — Male neuraxial SLIP CONNECTOR (N1)

Table B.1 — Male neuraxial SLIP CONNECTOR dimensions (N1)

Dimensions in millimetres unless otherwise indicated

Male neuraxial SLIP CONNECTOR (N1)				
Reference	Designation	Dimension		
		Minimum	Nominal	Maximum
(*a*)	Angle of the taper (5 % taper nominal) (degrees, reference)	—	(2,86°)	—
c	Recess or protrusion of the tip of the CONNECTOR from the collar[a]	-0,400	0,000	0,400
Ø*d*	Outside diameter at the tip of the male taper at 0,500 (basic dimension) from the tip (small end) of the male taper	3,170	3,210	3,250
e	Length of the male taper [b]	8,130	8,380	8,630
Ø*f*	Inside diameter at the tip of the male taper	—	1,150	2,300
Ø*g*	Outside diameter of the larger end of the male taper at 6,500 (basic dimension) from the tip (small end) of the male taper	3,450	3,510	3,570
Ø*h*	Inside collar diameter[c]	6,750	6,875	7,000
k	Length of CONNECTOR from tip of the male taper[d]	8,000	8,300	—
*r*1	Radius or chamfer at the outside tip of the male taper	0,000	0,100	0,254
*r*2	Radius or chamfer at the inside tip of the male collar (reference)	(0,000)	(0,100)	(0,254)
Ø*u*	Inside diameter of the fluid lumen of the CONNECTOR (optional)	—	1,150	2,300
Ø*w*	Diameter of the smallest cylinder that encompasses the outside surfaces of the external features of the collar[e f]	9,800	10,500	11,500

[a] A positive value indicates protrusion of cone tip outside the collar; a negative value indicates a recess of cone tip inside the collar.

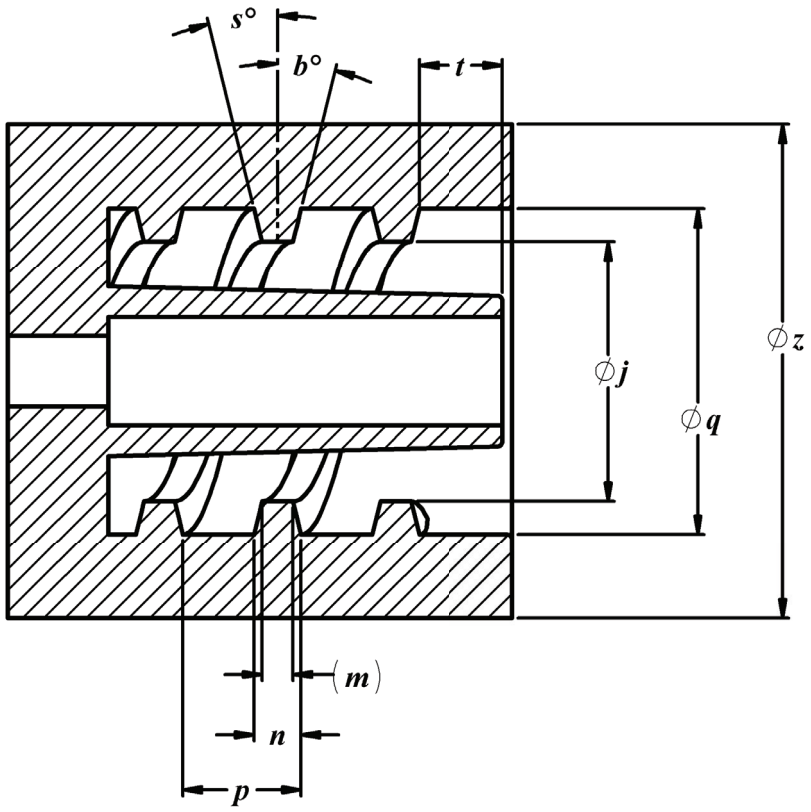
[b] This dimension also defines the internal extent of the CONNECTOR. MEDICAL DEVICE features beyond the CONNECTOR may require evaluation to Annex H, to ensure NON-INTERCONNECTABLE characteristics.

[c] A larger maximum and nominal diameter than Ø*h*, which is equivalent to the diameter Ø*q* of the lock male, if the CONNECTOR is made of materials with a modulus of elasticity either in flexure or in tension greater than of 1 500 MPa.

[d] This dimension also defines the external extent of the CONNECTOR. MEDICAL DEVICE features beyond the CONNECTOR may require evaluation to Annex H, to ensure NON-INTERCONNECTABLE characteristics.

[e] 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 *k*. Either the CONNECTOR or the MEDICAL DEVICE that incorporates this CONNECTOR may achieve this dimension. Alternatively, NON-INTERCONNECTABLE characteristics may be demonstrated using Annex H.

[f] A smaller minimum and nominal diameter than Ø*w*, which is equivalent to the diameter Ø*z* of the lock male, if the connector is made of materials with a modulus of elasticity either in flexure or in tension greater than of 1 500 MPa.



NOTE Table B.2 contains the dimensions for this figure.

Figure B.2 — Male neuraxial LOCK CONNECTOR (N2)

Table B.2 — Male neuraxial LOCK CONNECTOR dimensions (N2)

Dimensions in millimetres unless otherwise indicated

Male neuraxial lock connector (N2)				
Reference	**Designation**	**Dimension**		
		Minimum	**Nominal**	**Maximum**
b	Angle of the internal thread profile on the non-bearing surface against separation (degrees)	11,25°	13,75°	16,25°
Ø*j*	Minor inside thread diameter (diameter at the thread crest)	5,420	5,520	5,620
(*m*)	Width of the thread profile at the crest (reference)	—	(0,651)	—
n	Width of the thread profile at the root	0,890	0,995	1,100
p	Pitch of the double-start, right-hand thread (reference 5 mm lead)	2,373	2,500	2,627
Ø*q*	Major inside thread diameter (diameter at the thread root)	6,750	6,925	7,100
s	Angle of the internal thread profile on the bearing surface against separation (degrees)	11,25°	13,75°	16,25°
t	Distance from the tip of the CONNECTOR to the start at the root of the first complete thread profile of the internal thread	—	1,500	1,800
Ø*z*	Diameter of the smallest cylinder that encompasses the outside surfaces of the external features of the collar[a]	8,850	10,500	11,500

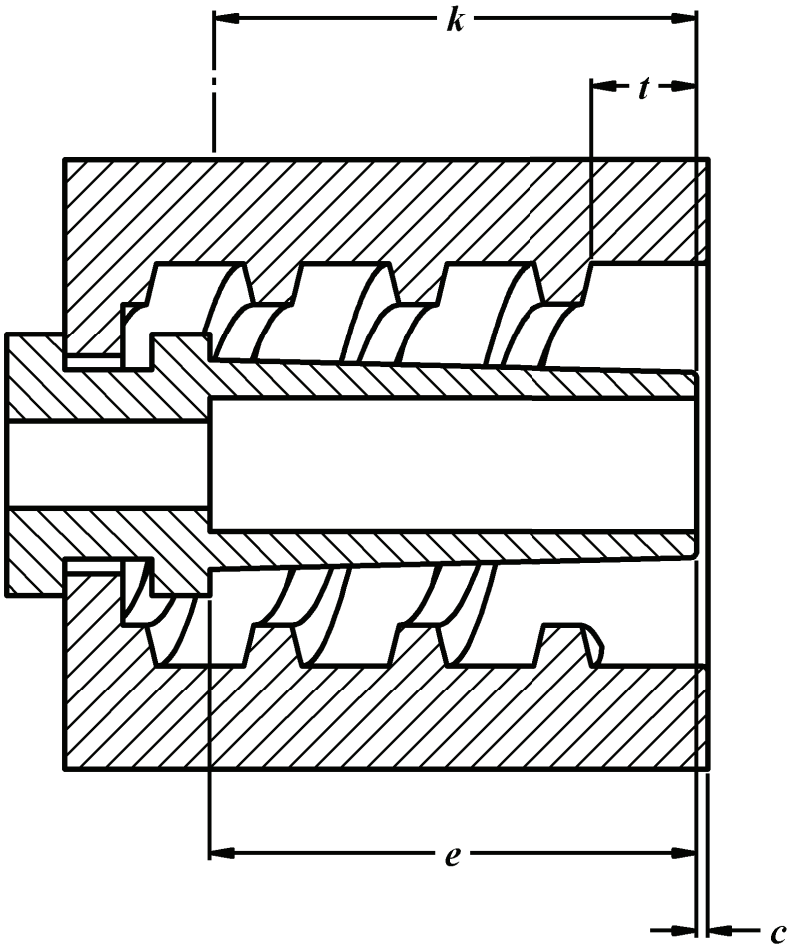
[a] The specified dimensional range shall be maintained for a minimum length of 1 mm from the open end of the collar. Beyond 1 mm, the diameter may be smaller than the specified minimum. The maximum diameter specified shall be maintained for a minimum length of *k*. Either the CONNECTOR or the MEDICAL DEVICE that incorporates this CONNECTOR may achieve this dimension. Alternatively, NON-INTERCONNECTABLE characteristics may be demonstrated using Annex H.

The design and dimensions of the thread profile (*s*, *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 (*s*, *b* and *m*) are not considered important to ensure NON-INTERCONNECTABLE characteristics.

Thread revolution length is not specified, but shall provide clearance for the thread of the female CONNECTOR.

The male neuraxial LOCK CONNECTOR shall include the dimensions and tolerances of the male neuraxial SLIP CONNECTOR as specified in Figure B.1 and Table B.1.



NOTE Table B.3 contains the dimensions for this figure.

Figure B.3 — Male neuraxial LOCK CONNECTOR with rotatable collar (N2)

Table B.3 — Male neuraxial LOCK CONNECTOR with rotatable collar dimensions (N2)

Dimensions in millimetres unless otherwise indicated

Male neuraxial LOCK CONNECTOR with rotatable collar (N2)				
Reference	Designation	Dimension		
		Minimum	Nominal	Maximum
c	Recess of the tip of the CONNECTOR from the collar[a]	−0,400	0,000	0,400
e	Length of the male taper[b]	8,130	8,380	8,630
k	Length of CONNECTOR from tip of the male taper[c,d]	8,000	8,300	—
t	Distance from the tip of the CONNECTOR to the start at the root of the first complete thread profile of the internal thread[c]	—	1,500	1,800
The male neuraxial lock connector shall include the dimensions and tolerances of the male neuraxial connector as specified in Figures B.1 and B.2 and Tables B.1 and B.2.				

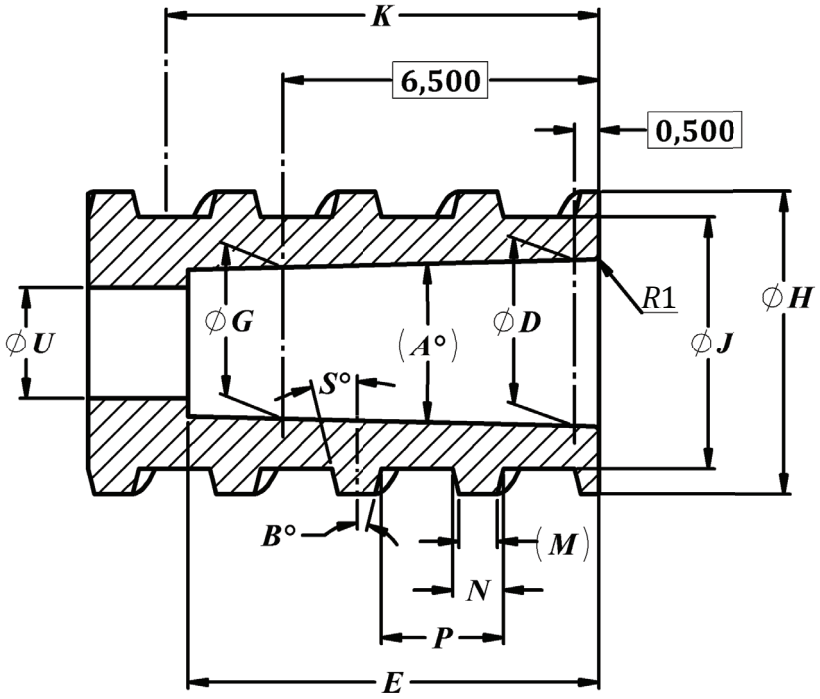
[a] This dimension is when the rotatable collar is positioned fully away from tip of the CONNECTOR. The minimum dimension indicated defines the recess of the tip of the CONNECTOR from the collar and the maximum dimension defines the protrusion of the tip of the CONNECTOR from the collar.

[b] This dimension also defines the internal extent of the CONNECTOR. MEDICAL DEVICE features beyond the CONNECTOR may require evaluation to Annex H, to ensure NON-INTERCONNECTABLE characteristics.

[c] This dimension is when the rotatable collar is positioned fully toward the tip of the CONNECTOR.

[d] This dimension also defines the external extent of the connector. Medical device features beyond the connector may require evaluation to Annex H, to ensure non-interconnectable characteristics.

Dimensions in millimetres unless otherwise indicated



NOTE Table B.4 contains the dimensions for this figure.

Figure B.4 — Female neuraxial LOCK CONNECTOR (N2)

Table B.4 — Female neuraxial LOCK CONNECTOR dimensions (N_2)

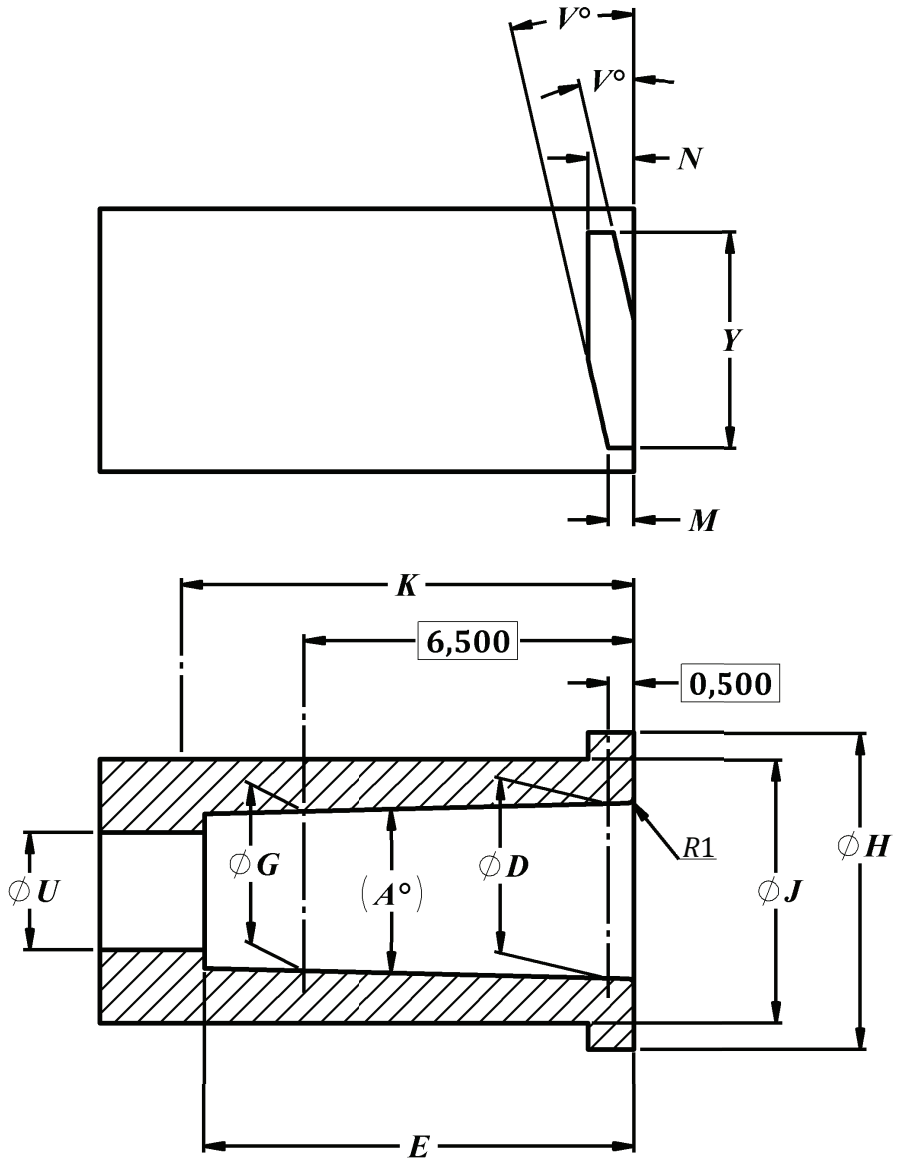
Dimensions in millimetres unless otherwise indicated

Female neuraxial LOCK CONNECTOR (N2)				
Reference	**Designation**	**Dimension**		
		Minimum	**Nominal**	**Maximum**
(*A*)	Angle of the taper (5 % taper nominal) (degrees, reference)	—	(2,86°)	—
B	Angle of the external thread profile on the non-bearing surface against separation (degrees)	11,25°	13,75°	16,25°
ØD	Inside diameter at the open end of the female taper at 0,500 (basic dimension) from the opening (large end) of the female taper	3,400	3,430	3,460
E	Depth of the female taper [a]	8,200	8,450	8,700
ØG	Inside diameter of the smaller end of the female taper at 6,500 (basic dimension) from the opening (large end) of the female taper	3,070	3,130	3,190
ØH	Major outside thread diameter (diameter at the thread crest) for the extent of the thread feature. This defines the diameter of the smallest cylinder of depth *K* that encompasses the outside surfaces of the external features of the CONNECTOR.	6,120	6,220	6,320
ØJ	Minor outside thread diameter (diameter at the thread root)	5,000	5,185	5,370
K	Length of the CONNECTOR [b]	8,600	8,900	—
(*M*)	Width of the thread profile at the crest (reference)	—	(0,787)	—
N	Width of the thread profile at the root at a diameter corresponding to *ØJ* maximum (5,370)	0,890	0,995	1,100
P	Pitch of the double-start, right-hand thread (reference 5 mm lead)	2,373	2,500	2,627
*R*1	Radius or chamfer at the entrance of the female taper	0,000	0,100	0,254
S	Angle of the external thread profile on the bearing surface against separation (degrees)	11,25°	13,75°	16,25°
ØU	Inside diameter of the fluid lumen of the CONNECTOR (optional)	—	1,500	2,300
The design and dimensions of the thread profile (*S*, *B*, *M* and *P*) may vary from those designated provided the CONNECTOR meets the performance requirements of Clause 6.				
The design and dimensions of the thread profile (*S*, *B*, *M* and *P*) are not considered important to ensure NON-INTERCONNECTABLE characteristics.				

[a] This dimension also defines the internal extent of the CONNECTOR. MEDICAL DEVICE features beyond the CONNECTOR may require evaluation to Annex H to ensure NON-INTERCONNECTABLE characteristics.

[b] This dimension also defines the external extent of the CONNECTOR. MEDICAL DEVICE features beyond the CONNECTOR may require evaluation to Annex H to ensure NON-INTERCONNECTABLE characteristics.

Dimensions in millimetres unless otherwise indicated



NOTE Table B.5 contains the dimensions for this figure.

Figure B.5 — Female neuraxial LOCK CONNECTOR with lugs (N2)

Table B.5 — Female neuraxial LOCK CONNECTOR with lugs dimensions (N2)

Dimensions in millimetres unless otherwise indicated

Female neuraxial SLIP CONNECTOR with lugs (N2)				
Reference	**Designation**	**Dimension**		
		Minimum	**Nominal**	**Maximum**
(*A*)	Angle of the taper (5 % taper nominal) (degrees, reference)	—	(2,86°)	—
ØD	Inside diameter at the open end of the female taper at 0,500 (basic dimension) from the opening (large end) of the female taper	3,400	3,430	3,460
E	Depth of the female taper [a]	8,200	8,450	8,700
ØG	Inside diameter of the smaller end of the female taper at 6,500 (basic dimension) from the opening (large end) of the female taper	3,070	3,130	3,190
ØH	Major outside lug diameter (diameter at the lug crest) for the extent of the lug feature. This defines the diameter of the smallest cylinder of depth *K* that encompasses the outside surfaces of the external features of the CONNECTOR.	6,120	6,220	6,320
ØJ	Minor outside lug diameter (diameter at the lug root)	5,000	5,185	5,370
K	Length of the CONNECTOR [b]	8,600	8,900	—
M	Width of the lug profile at the crest	0,400	0,500	0,600
N	Width of the lug profile at the root at a diameter corresponding to *ØJ* maximum (5,370)	0,700	0,900	1,100
*R*1	Radius or chamfer at the entrance of the female taper	0,000	0,100	0,254
ØU	Inside diameter of the fluid lumen of the CONNECTOR (optional)	—	1,500	2,300
V	Angle of the slope of the lug to be measured from a plane parallel with the tip of the CONNECTOR (degrees)	11,0°	13,0°	15,0°
Y	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 5,370	4,100	4,250	4,400
The design and dimensions of the lug profile (*M* and *V*) may vary from those designated provided the CONNECTOR meets the performance requirements of Clause 6. The design and dimensions of the thread profile (*M* and *V*) are not considered important to ensure NON-INTERCONNECTABLE characteristics.				

[a] This dimension also defines the internal extent of the CONNECTOR. MEDICAL DEVICE features beyond the CONNECTOR may require evaluation to Annex H to ensure NON-INTERCONNECTABLE characteristics.

[b] This dimension also defines the external extent of the CONNECTOR. MEDICAL DEVICE features beyond the CONNECTOR may require evaluation to Annex H to ensure NON-INTERCONNECTABLE characteristics.

Annex C
(normative)

Reference CONNECTORS for testing SMALL-BORE CONNECTORS for neuraxial APPLICATIONS

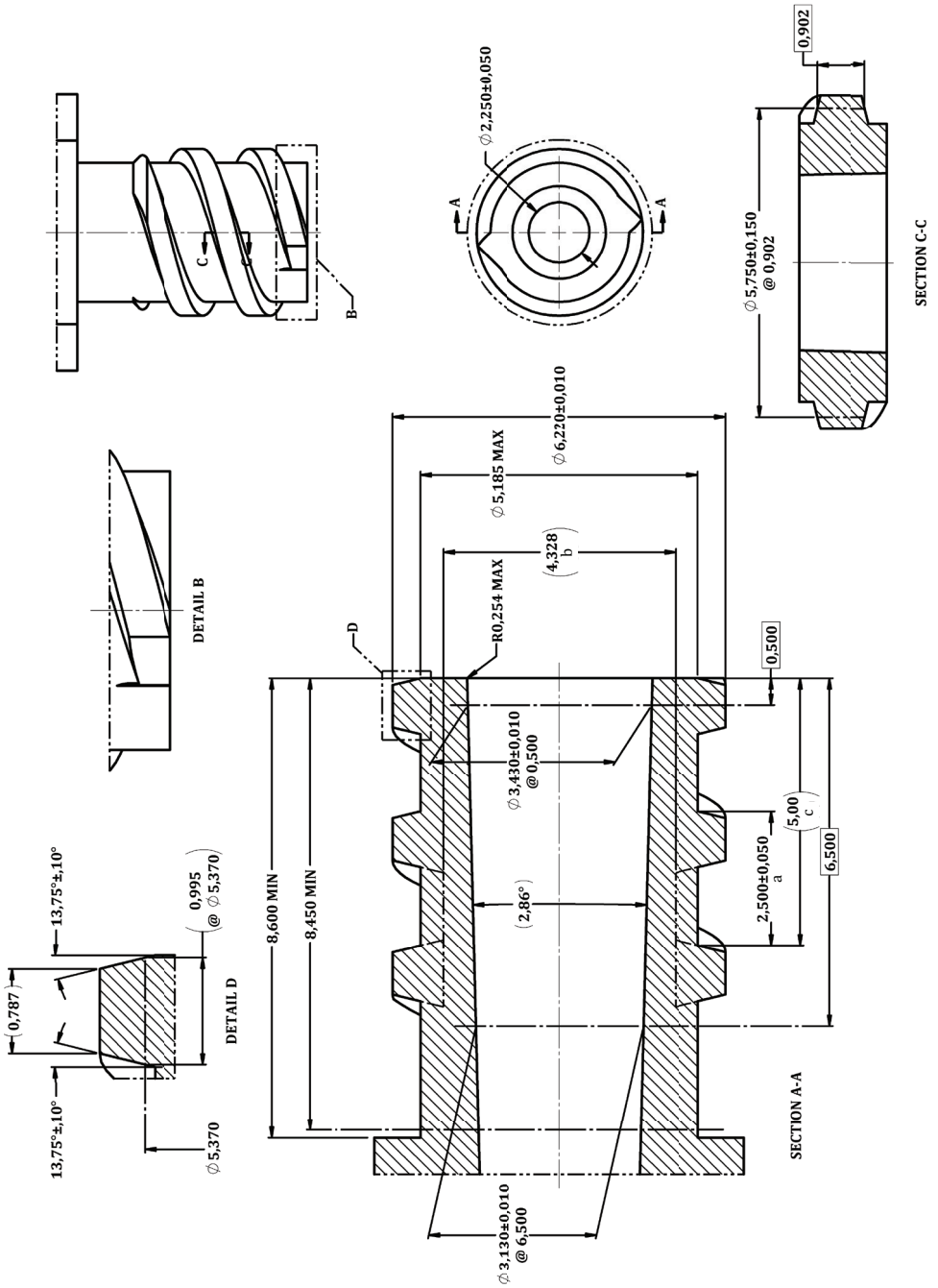
C.1 General requirements for reference CONNECTORS

The reference CONNECTORS shall be manufactured from corrosion-resistant RIGID MATERIALS with a surface roughness value, R_a, not exceeding 0,8 µm on critical surfaces.

The dimensions of these reference CONNECTORS shall be in accordance with those specified in Figure C.1, Figure C.2, Figure C.3, Figure C.4 or Figure C.5, as appropriate.

C.2 Reference CONNECTORS

Dimensions in millimetres unless otherwise indicated



Key

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

b Thread pitch diameter.

c Thread lead.

Figure C.1 — Female reference LOCK CONNECTOR for testing male neuraxial CONNECTORS for leakage, separation from unscrewing, stress cracking and NON-INTERCONNECTABLE characteristics

All outside edges of thread form shall have a radius of 0,20 mm maximum (unless otherwise specified). *R* may be × 45° chamfer.

Dimensions in millimetres unless otherwise indicated

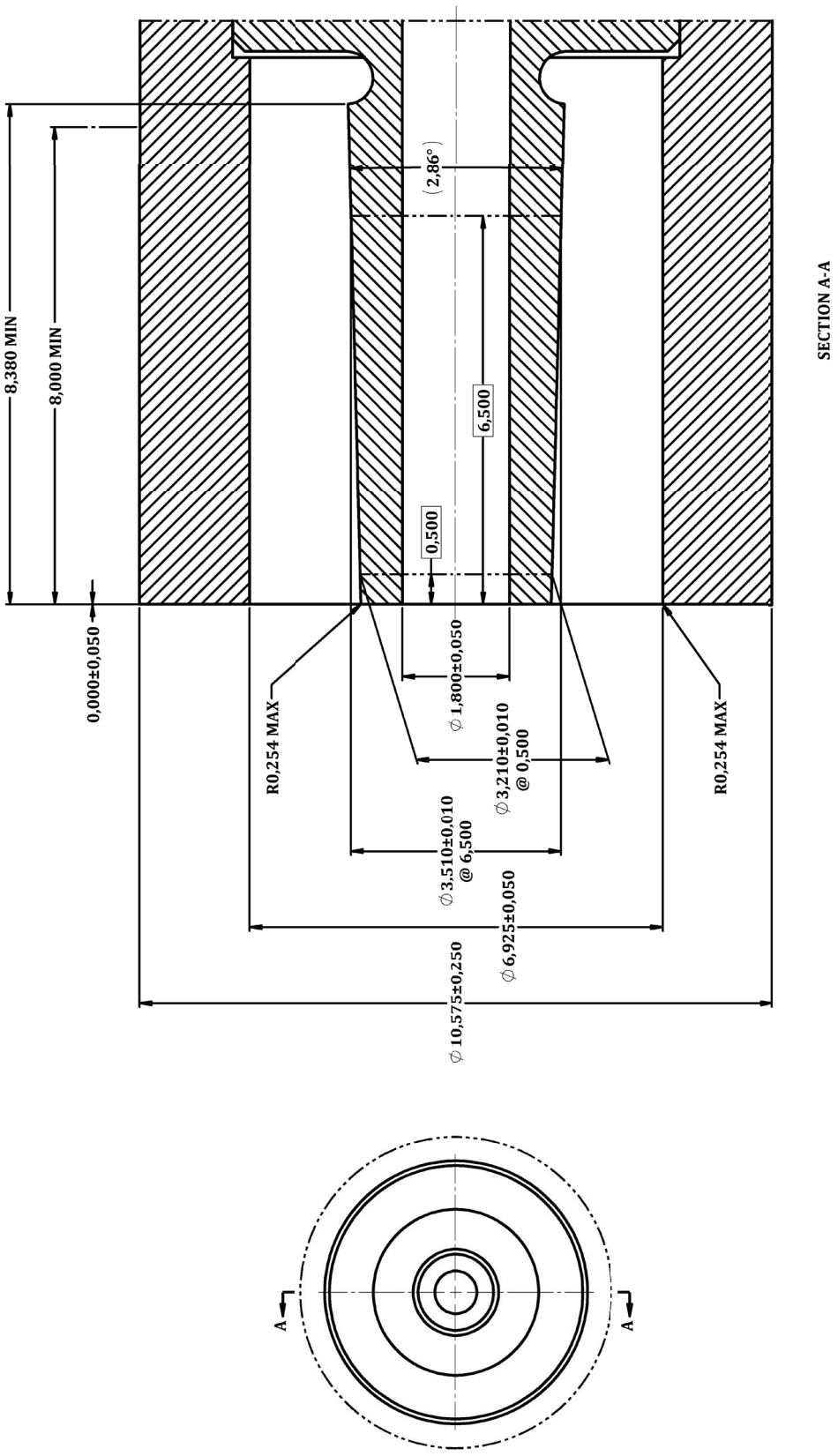


Figure C.2 — Male reference SLIP CONNECTOR for testing female neuraxial CONNECTORS for leakage, stress cracking and NON-INTERCONNECTABLE characteristics

Dimensions in millimetres unless otherwise indicated

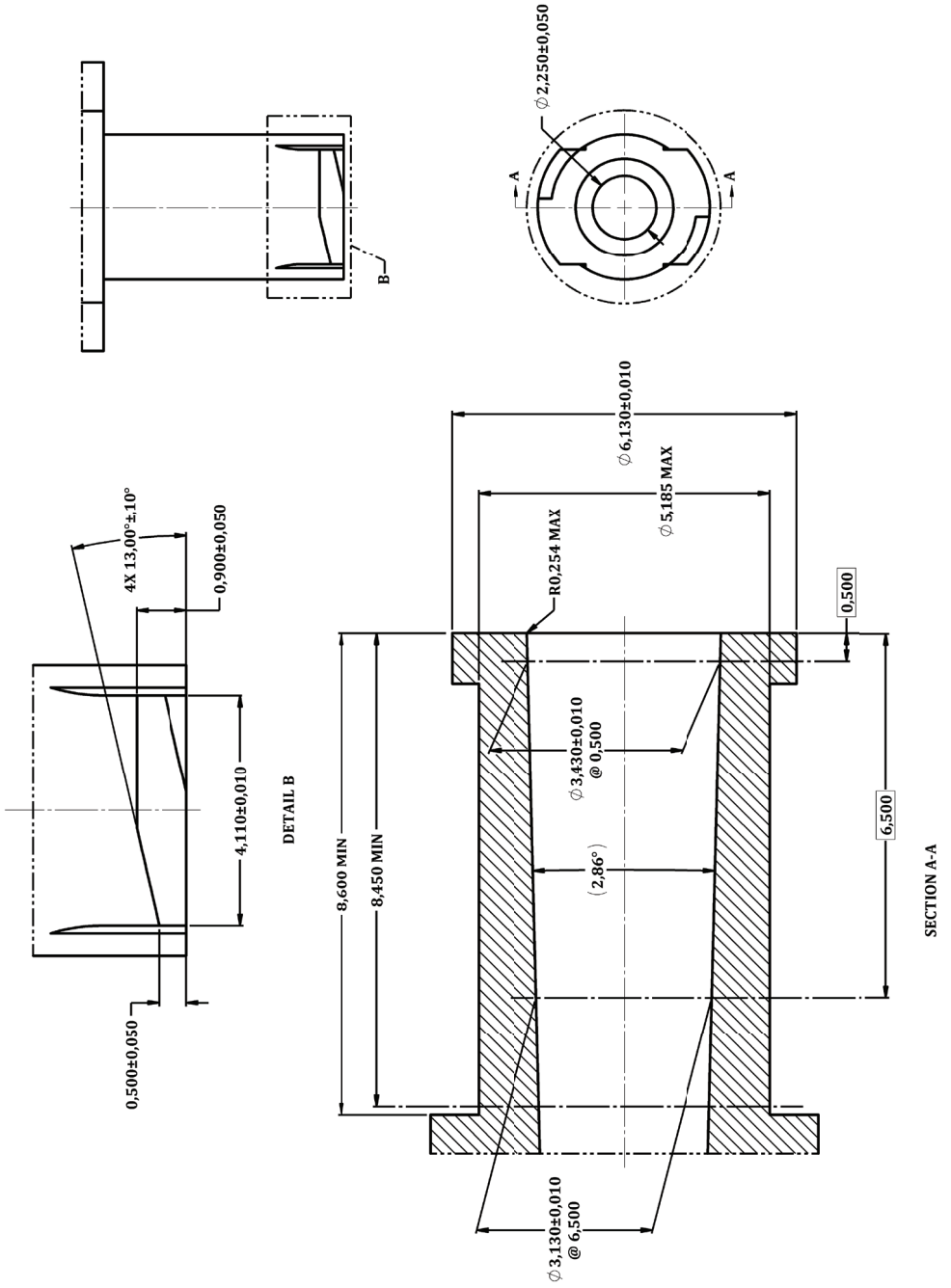
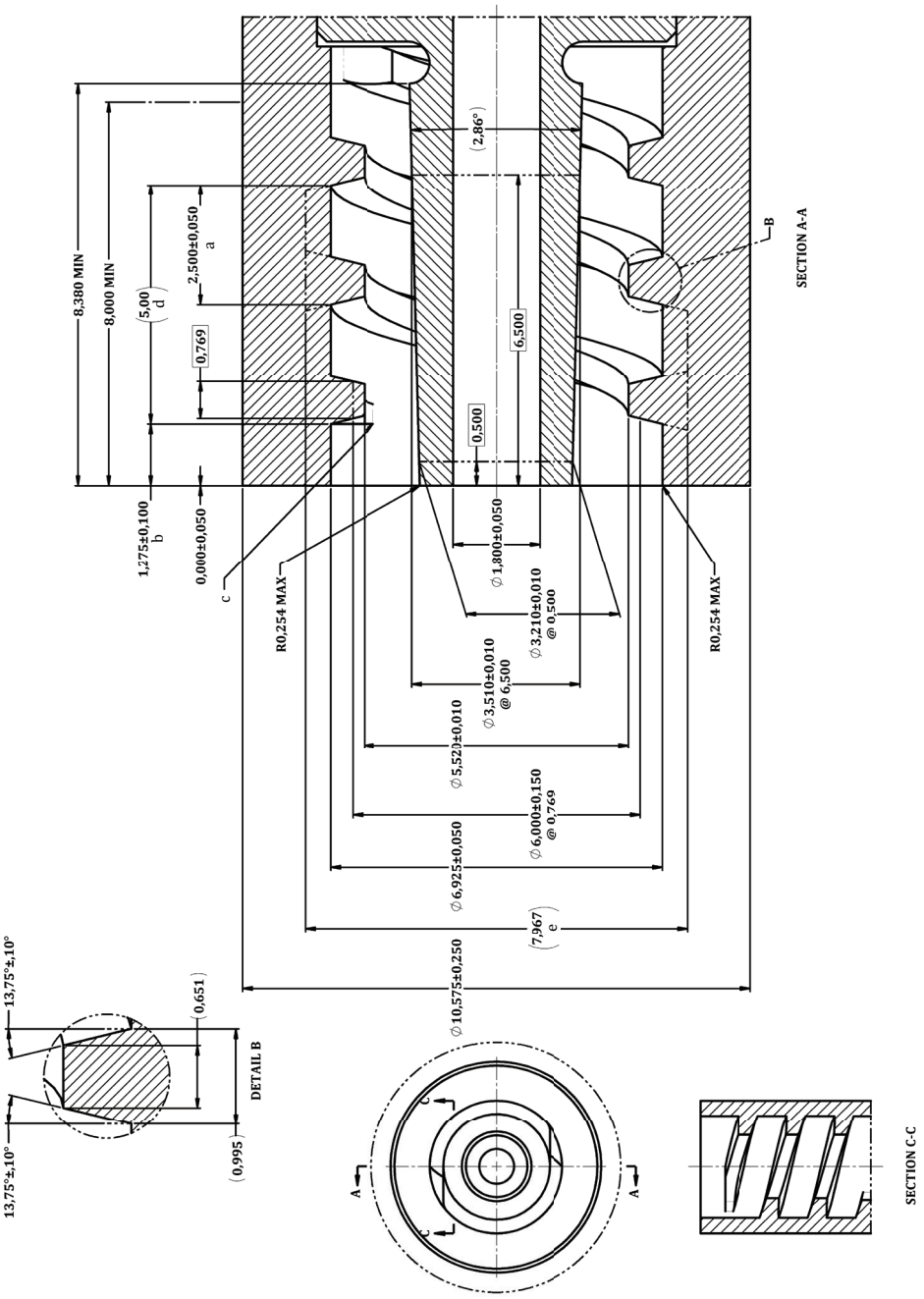


Figure C.3 — Female reference CONNECTOR for testing male neuraxial CONNECTORS for separation from axial load and resistance to overriding

All outside edges of lug shall have a radius of 0,20 mm maximum (unless otherwise specified). *R* may be × 45° chamfer.

Dimensions in millimetres unless otherwise indicated



Key

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

b Measure to flat face on thread at juncture of thread major diameter and thread.

c Circumferential witness line acceptable from machining, but shall maintain dimensional requirements.

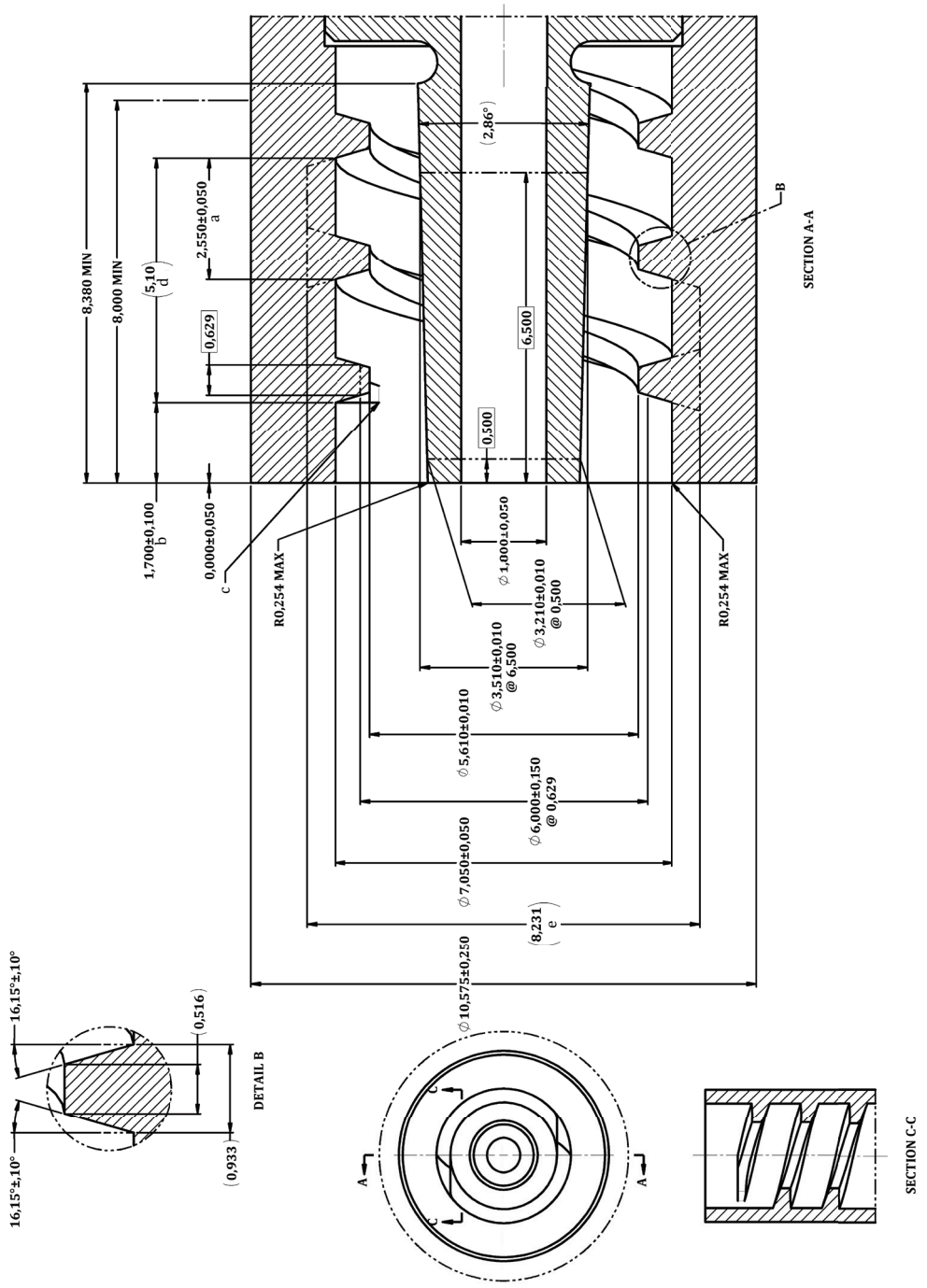
d Thread lead.

e Thread pitch diameter.

Figure C.4 — Male reference LOCK CONNECTOR for testing female neuraxial CONNECTORS for leakage, separation from unscrewing, stress cracking and NON-INTERCONNECTABLE characteristics

All outside edges of thread form shall have a radius of 0,20 mm maximum (unless otherwise specified). *R* may be × 45° chamfer.

Dimensions in millimetres unless otherwise indicated



Key

a Double-start, right-hand thread of 2,550 mm pitch.

b Measure to flat face on thread at juncture of thread major diameter and thread.

c Circumferential witness line acceptable from machining, but shall maintain dimensional requirements.

d Thread lead.

e Thread pitch diameter.

Figure C.5 — Male reference CONNECTOR for testing female neuraxial LOCK CONNECTORS from axial load and resistance to overriding

All outside edges of thread form shall have a radius of 0,20 mm maximum (unless otherwise specified). *R* may be × 45° chamfer.

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 with neuraxial APPLICATIONS. Table D.1 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 to the following groups of subgroups:

a) spinal needle CONNECTIONS;

b) epidural needle CONNECTIONS;

c) regional nerve block needle CONNECTIONS including stimulating needles;

d) neuraxial catheter CONNECTORS;

e) neuraxial bacterial filter CONNECTORS;

f) CONNECTORS on infusion and extension tubing for neuraxial use;

g) neuraxial ACCESSORIES such as stopcocks, manometers, drug draw up devices, extension set;

h) wound infiltration devices with neuraxial CONNECTORS;

i) neuraxial syringe CONNECTORS including loss of resistance (LOR) devices.

Table D.1 — Examples of MEDICAL DEVICES with CONNECTIONS within this APPLICATION and their attributes

Part/component to which the CONNECTOR is applied	Index	Flow administration		Type of fluid		Type of CONNECTION		Functionality		
		Flowrate range ml/h	Bolus	Air	Liquid	CONNEC-TION	Dis-CONNECTION	Locking needed	Slip needed	Flowrate control needed
Spinal needle (bolus)	1	0 to 3 600	yes	yes	yes	yes	yes	yes	no	yes
Epidural/regional nerve block needle (bolus)	2	0 to 3 600	yes	yes	yes	yes	yes	yes	no	yes
Catheter CONNECTOR (bolus)	3	0 to 1 500	yes	no	yes	yes	yes	yes	no	yes
Catheter CONNECTOR (infusion)	4	0 to 1 500	yes	no	yes	yes	yes	yes	no	yes
Filter (infusion)	5	0 to 600	yes	no	yes	yes	yes	yes	no	yes
Filter (bolus)	6	0 to 600	yes	no	yes	yes	yes	yes	no	yes
Infusion line	7	0 to 600	yes	no	yes	yes	yes	yes	no	yes
Wound infiltration	8	0 to 3 600	yes	no	yes	yes	yes	yes	no	yes
Syringe standard	9	0 to 3 600	yes	yes	yes	yes	yes	yes	yes	yes
Syringe, loss of resistance (LOR)	10	0 to 10 000	no	yes	yes	yes	yes	yes	yes	yes

Annex E
(informative)

Summary of the usability requirements for SMALL-BORE CONNECTORS for neuraxial 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 SMALL-BORE CONNECTORS for neuraxial APPLICATIONS are comprised of persons using (i.e. operating or handling) the MEDICAL DEVICE, including but not limited to cleaners, maintainers and installers. 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 as:

   — physicians and nurses who specialize in anaesthesiology, radiology, oncology, paediatrics, surgery or a physician assistant;

   — nurses, *at all levels*;

b) pharmacy or drug delivery USERS responsible for mixing of drugs, filling syringes and reservoirs, storage and dispensing of drugs;

c) non-clinical users such as cleaners, maintainers and installers.

The USER PROFILE is summarized in Table E.1.

Table E.1 — USER PROFILE

	Clinical USERS	**Pharmacy/drug delivery USERS**	**Non-clinical USERS**
USER skills:	Extensive clinical training	Pharmacology	Limited clinical training
PATIENT contact:	Direct PATIENT contact	No PATIENT contact	Direct PATIENT contact

E.2 Use scenarios

Use scenarios for SMALL-BORE CONNECTORS for neuraxial APPLICATIONS can differ by USER group and are comprised of the multitude of sub-APPLICATIONS of the CONNECTORS within different neuraxial sub-specialities.

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

Table E.2 — Use scenarios

Sub-speciality use scenario:	Clinical USERS	Non-clinical USERS	Pharmacy USERS
Intrathecal diagnostics such as CSF pressure measurement and sampling	X		
Therapeutic or diagnostic agent delivery into the intrathecal space	X		X
Epidural bolus injection of anaesthetic agent	X		X
Therapeutic and diagnostic CSF drainage	X		
Continuous epidural infusion of anaesthetic agent	X		X
Peripheral nerve block needle placement and bolus injection of anaesthetic agent	X		X
Peripheral nerve block needle placement and continuous injection of anaesthetic agent	X		X
Home care PATIENT controlled activation doses from infusion pump		X	X
Hospital based PATIENT controlled activation doses from infusion pump	X	X	X

E.3 Use environments

E.3.1 Facilities

SMALL-BORE CONNECTORS for neuraxial APPLICATIONS are used in hospitals, surgery suites, PATIENT rooms, home, labour and delivery suites, intensive care units, doctors' offices, pain clinics, pharmacy, field hospitals, transport systems, infusion clinics, assisted care facilities and emergency medical services.

E.3.2 Use temperatures

The following temperature environments are expected for neuraxial CONNECTORS:

a) ambient temperature, 0°C to +40 °C;

b) body temperature to 42 °C.

E.4 Other attributes

The following usability attributes are expected for neuraxial CONNECTORS:

a) usability under stress (e.g. ignoring labels, attempting force-fit, emergency Caesarean-section);

b) limited dexterity (e.g. gloved hands that might or might not be wet);

c) proximity of other CONNECTOR-bearing equipment (e.g. intravenous infusion lines, gas measurement, etc.);

d) duration, use-life:

   — maximum length of epidural infusion ≤29 d (includes catheter, catheter connector and infusion line);

   — filters, ≤96 h;

— spinal or epidural needles ≤15 min;

— draw up medical devices such as filter needles, filter straws etc.; ≤15 min;

— loss of resistance devices; ≤15 min;

— syringes for short term use; ≤15 min;

— syringes and caps for drug storage to 28 d or longer according to local practice.

E.5 Generic USER needs

The following USER needs are expected for neuraxial CONNECTORS:

a) minimal change to clinical practice;

b) easy to manipulate without the use of tools;

c) ease of assembly/disassembly with fingertip control, especially when fingers are wet or with the use of gloves;

d) does not misconnect to other SMALL-BORE CONNECTORS of the ISO 80369 series not intended for the same APPLICATION in the environment of use;

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

— maximum flowrate 3 600 ml/h;

— pressure in infusion line at maximum flow rate cannot exceed alarm limit on infusion pumps;

i) viscosity of solution

— aqueous (e.g. local anaesthetic agents and additives);

— non-aqueous (e.g. some chemotherapeutic agents);

— contrast medium (up to 30 mPa · s);

j) ability to accommodate catheters through bore of neuraxial CONNECTOR

— catheters as large as 16 gauge;

— ability to accommodate stylets (epidural/spinal) and/or guide wires;

k) Aseptic handling — ability to align and make CONNECTIONS without slipping and inadvertently creating touch contaminations.

Annex F
(informative)

Summary of SMALL-BORE CONNECTOR design requirements for neuraxial APPLICATIONS

Table F.1 is a summary of the design requirements for the SMALL-BORE CONNECTOR for neuraxial APPLICATIONS.

Table F.1 — Neuraxial CONNECTOR — specific design requirements

	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)	330 kPa N/A Yes: 40 kPa	
3	RATED pressure range	minimum maximum	N/A	
4	Is there a need for a leak test?	a) no b) yes Reference for test method	b) Yes same as LUER CONNECTOR	
5	RATED flowrate range	minimum maximum	N/A 3 600 ml/h	
6	Internal diameter range (through bore)	minimum maximum	N/A 2,3 mm	
7	RATED temperature range	minimum maximum	0 °C 40 °C	
8	Minimum range of CONNECTOR mating diameters	minimum maximum	—	Incompatible with LUER CONNECTOR and other SMALL-BORE CONNECTORS of the ISO 80369 series
9	General layout	a) Parallel-sided, O-ring seal b) Parallel-sided, other seal c) Conical d) Other (specify)	c)	Conical, with a male tip smaller diameter than a LUER CONNECTOR
10	Method of keying	a) Collar b) Plug c) Other (specify)	N/A	

Table F.1 *(continued)*

	Criteria		Requirements	Remarks
11	Quick release?	a) No b) Yes i) single-handed operation ii) double-handed operation	a)	
12	Positive locking/unlocking feature?	a) No b) Yes	a) and 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)	Depends on specific MEDICAL DEVICE
15	Need for a syringe in the APPLICATION?	a) No b) Yes	b)	
16	Need for an absence of sharp edges?	a) No b) Yes	b)	
17	Minimum pull-apart force in normal use, when locked Reference for test method	force	35 N Same as LUER CONNECTOR	
18	Constructional materials (excluding seals)	a) RIGID MATERIAL i) metal ii) plastic b) SEMI-RIGID MATERIAL	a) i) ii) b)	
19	Need for use of SEMI-RIGID MATERIAL? CONNECTOR	a) No b) Yes, mating part of (apart from seal)	b)	
20	MRI compatibility?	a) No, with labelling b) No, without labelling c) Yes, with labelling d) Yes, without labelling	d)	
21	Stress-cracking resistance?	a) No b) Yes Specify limits	b)	
22	Externally, how is CONNECTOR to be distinguishable from LUER CONNECTOR?(describe)		CONNECTOR is dimensionally different, but not necessarily visibly distinguishable from the LUER CONNECTOR.	Visual differences are: LUER SLIP CONNECTOR has a collar and the male does not protrude beyond the collar.
23	Proposal for colour-coding?	a) No b) Yes Reference standard	a)	
24	Labelling/Symbols/Marking? (e.g. not for IV)	a) No b) Yes	a)	

Table F.1 *(continued)*

	Criteria		Requirements	Remarks
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)	c)	
28	Decontamination needed?	a) No, single use only b) Yes, cleaning and disinfection indicate method c) Yes, cleaning and sterilization indicate method	a)	
29	How is ISO 80369-2 incompatibility achieved?	a) Dimensional b) Other Indicate method	a)	
30	How is ISO 80369-3 incompatibility achieved?	a) Dimensional b) Other Indicate method	a)	E1 female to N2 female—leaky misconnection; see G.2.2
31	How is ISO 80369-4 incompatibility achieved?	a) Dimensional b) Other Indicate method	not yet defined	
32	How is ISO 80369-5 incompatibility achieved?	a) Dimensional b) Other Indicate method	a)	
33	How is ISO 80369-6 incompatibility achieved?	a) Dimensional b) Other Indicate method	This is the neuraxial CONNECTOR	
34	How is ISO 80369-7 incompatibility achieved?	a) Dimensional b) Other Indicate method	a) b)	Male LUER CONNECTOR to N1 misconnection possible; see G.2.4.

Annex G
(informative)

Summary of assessment of the design of the SMALL BORE CONNECTORS for neuraxial APPLICATIONS

G.1 General

There are no known patents related to the CONNECTOR designs specified in this part of ISO 80369. The CONNECTORS depicted in Annex B use a 5 % taper seal, with mating surface dimensions smaller than the traditional LUER CONNECTOR. This design also incorporates other features to prevent these CONNECTORS from either forming a fluid tight seal or being misconnected with SMALL-BORE CONNECTORS of the ISO 80369 series.

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 using 3D solid model constructs of all tolerances and material conditions (least, nominal and maximum) for all CONNECTORS represented by this series of International Standards. The SMALL-BORE CONNECTORS specified in this part of ISO 80369 have been shown by engineering analysis to be NON-INTERCONNECTABLE with the other specified CONNECTORS the ISO 80369 series with the exception of the following. Five possible connections for accuracy/consistency with the attached Table G.1 and descriptions of those misconnections (G.2.2 to G.2.6) were identified.

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

Neuraxial connector	CONNECTOR of concern	Summary	Reference
N1 male	E1 male	Physical testing according to ISO 80369-1:2010, Annex B, results in no CONNECTION.	G.2.2
N1 male	S1 male	Physical testing according to ISO 80369-1:2010, Annex B, results in no CONNECTION.	G.2.3
N1 male	LUER CONNECTOR male	Misconnection possible	G.2.4
N2 male	LUER SLIP CONNECTOR female	Physical testing according to ISO 80369-1:2010, Annex B, (except using all plastic parts) results in no CONNECTION.	G.2.5
N2 female	E1 female	Physical testing according to Annex H, results in a leaky misconnection.	G.2.6
E1 from ISO 80369-3. S1 from ISO 80369-5. LUER CONNECTOR from ISO 80369-7.			

G.2.2 N1 male to E1 male

Testing was performed according to the TEST METHOD of ISO 80369-1:2010, Annex B. The test demonstrated that the CONNECTORS are NON-INTERCONNECTABLE.

G.2.3 N1 male to S1 male

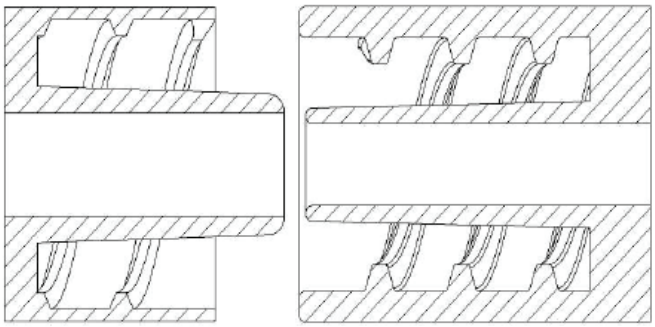
Testing was performed according to the TEST METHOD of ISO 80369-1:2010, Annex B. The test demonstrated that the CONNECTORS are NON-INTERCONNECTABLE.

G.2.4 N1 male to LUER CONNECTOR male

In the engineering analysis, the inside diameter of the fluid lumen of male LUER CONNECTOR, as specified in ISO 80369-7:—, contacts the sealing surfaces of the N1 male CONNECTOR in LMC conditions and thereby these CONNECTORS will mutually fail the NON-INTERCONNECTABLE characteristics tests of ISO 80369-1:2010, Annex B. Figure G.1 illustrates this misconnection.

Testing was performed according to the TEST METHOD of ISO 80369-6:—, Annex H. The CONNECTION did not leak and thereby these CONNECTORS mutually fail this NON-INTERCONNECTABLE characteristics tests. Both of these CONNECTORS are distal to the PATIENT in clinical use in the PATIENT vicinity. In this environment, this misconnection would connect 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 of N1 male to LUER CONNECTOR male misconnection

G.2.5 N2 male to LUER SLIP CONNECTOR female

Testing was performed according to the TEST METHOD of ISO 80369-1:2010, Annex B.

The test demonstrated that the CONNECTORS are NON-INTERCONNECTABLE.

G.2.6 N2 female to E1 female

In the engineering analysis, the sealing surface of female E1 CONNECTOR, as specified in ISO 80369-6, contacts the thread surfaces of the N2 female CONNECTOR in LMC conditions and thereby these CONNECTORS will mutually fail the NON-INTERCONNECTABLE characteristics tests of ISO 80369-1:2010, Annex B.

Testing was performed according to the TEST METHOD of Annex H. Over 75 % of fluid intended to pass through the CONNECTION leaked.

The test demonstrated that the CONNECTORS are acceptable.

It is recommended that MANUFACTURERS use a material with the highest flexural modulus possible for the E1 female CONNECTOR for further RISK CONTROL.

G.3 Summary of the design VERIFICATION

The CONNECTOR design was developed based upon this work and modified to create a design with the highest probability of being NON-INTERCONNECTABLE with the other SMALL-BORE CONNECTORS in this International Standard.

CONNECTORS were moulded from two resins:

a) polypropylene having a nominal modulus of elasticity (tensile) of 960 MPa, and

b) acrylic having a nominal modulus of elasticity (tensile) of 2 300 MPa.

This range of elasticity spans the available common materials most often used in neuraxial APPLICATIONS. These materials meet the requirements of 4.2.

Performance testing was performed according to ISO 80369-20:— as required by Clause 6. The following combinations were tested:

— Male/Female Lock — acrylic;

— Male/Female Slip — acrylic;

— Male/Female Lock — polypropylene;

— Male/Female Slip — polypropylene;

Either 30 or 60 samples were tested.

Conclusion:

The test results indicate the N1 and N2 design is compliant with the performance requirements specified in Clause 6 using the TEST METHODS defined in ISO 80369-20:—.

G.4 Summary of the design validation

G.4.1 Summative usability evaluation

A summative usability evaluation of the design specified in this part of ISO 80369 has been conducted with USERS representing physicians and nurses. Elements of usability standard IEC 62366-1:2015, including D.5.13, were utilized in the development of the protocol.

The usability of the neuraxial CONNECTOR pairs was confirmed with successful results. The following procedures were emulated in the summative usability evaluation:

— spinal anaesthetic;

— lumbar puncture and chemotherapy;

— cerebral spinal fluid (CSF) collection and pressure measurement;

— epidural catheter placement and bolus injection.

No significant usability issues were identified with the neuraxial CONNECTORS during the study.

G.4.2 Usability misconnection evaluation

Following the summative usability evaluation, the same subjects were used to conduct a formative misconnection evaluation. Several anticipated misconnections were also confirmed to exist. These were consistent with prior knowledge as well as with predictions from the CAD analysis results in G.2.1.

G.5 Summary of the design review

The committee reviewed the assessment of the design of the neuraxial CONNECTORS based on the results reported in this Annex. ISO 80369-1:2010, Clause 7, gives the requirements for a CONNECTOR to be included as one of the CONNECTORS specified in ISO 80369-1:2010, Clause 5. Successful completion of requirements requires the combination of a material that is acceptably rigid with the design specified in Annex B.

In summary, the design review concludes there is significant objective engineering, technical and simulated clinical evidence supporting the neuraxial CONNECTOR for the intended neuraxial APPLICATION.

Annex H
(normative)

Mechanical tests for verifying NON-INTERCONNECTABLE characteristics

H.1 * Purpose

ISO 80369-1:2010, Annex B, specifies the TEST METHOD and acceptance criteria to be used to obtain OBJECTIVE EVIDENCE to demonstrate NON-INTERCONNECTABLE characteristics between a SMALL-BORE CONNECTOR being evaluated and other SMALL-BORE CONNECTORS likely to be found in the environment around the PATIENT. This TEST METHOD utilizes physical force testing between the CONNECTOR being evaluated and metal reference CONNECTORS for testing NON-INTERCONNECTABLE characteristics for each of the other SMALL-BORE CONNECTORS specified in this International Standard. This TEST METHOD forcefully attempts to create a CONNECTION and then, should a CONNECTION occur, expects that the SMALL-BORE CONNECTOR being evaluated and the reference CONNECTOR easily disengage from each other.

This part of ISO 80369 modifies that TEST METHOD from ISO 80369-1:2010, Annex B, for neuraxial SMALL-BORE CONNECTORS. Both the detailed methodology of the test and the acceptance criteria are modified.

H.2 Requirement

The neuraxial SMALL-BORE CONNECTOR shall not appear to provide a secure CONNECTION when forcefully assembled to any surface of the components of and shall easily disengage from each SMALL-BORE CONNECTOR of every other APPLICATION category specified in ISO 80369-1:2010 or should a neuraxial CONNECTOR engage, then greater than 75 % of the infusate shall leak from the misconnection between the neuraxial CONNECTOR and the reference SMALL-BORE CONNECTOR.

H.3 TEST METHOD

For the purposes of this test, the CONNECTORS above, other than the neuraxial CONNECTOR being evaluated, shall be made of RIGID MATERIAL using nominal dimensions or may be reference CONNECTORS as specified in other parts of this International Standard.

H.4 Test procedure, physical force

H.4.1 Apparatus

The following items shall be utilized:

a) the male or female CONNECTOR under test;

b) the appropriate reference CONNECTOR;

c) a means to simultaneously apply an axial force of 70 N and a torque of 0,12 N·m.

H.4.2 Procedure

Check compliance with the following test.

a) Condition the CONNECTOR under test at 23 °C ± 2 °C and a relative humidity of 50 % ± 5 % for not less than 1 h.

b) Assemble the SMALL-BORE CONNECTOR to the reference CONNECTOR by applying an axial compressive force of 70 N ± 1 N at a rate of approximately 10 N/s and a simultaneous torque not exceeding 0,12 N·m to a limit of no less than 270° of rotation or whichever comes first.

c) Hold the maximum assembly force and torque for no less than 10 s.

NOTE The requirement from ISO 80369-1:2010 was 70 N and a torque not exceeding 0,12 N·m to a limit of no more than 90° of rotation.

d) Without activation of any latch or disengagement mechanism, apply an axial force of separation to the assembled CONNECTORS to either 0,02 N or the weight of the part.

e) Confirm that the assembled CONNECTORS disengage.

f) If CONNECTORS do not disengage, without disrupting the CONNECTION, perform the CONNECTOR incompatibility test (gross leak at misconnection) of H.5.

H.5 * Test procedure, CONNECTOR incompatibility (gross leakage)

H.5.1 Apparatus

The following items shall be utilized:

a) the male or female CONNECTOR under test;

b) the appropriate reference CONNECTOR;

c) a means to simultaneously apply an axial force of 70 N and a torque of 0,12 N·m;

d) a pressure source;

EXAMPLE A syringe complying with ISO 7886-1.

e) a simulated or actual 22 gauge (0,42 mm inner diameter) × 90 mm spinal needle;

NOTE A length of hypodermic or similar tubing can be used to simulate the spinal needle such that the hypodermic tubing has a maximum inner diameter of 0,43 mm and a length of 90 mm ± 3 mm.

f) a length of tubing able to create a leak proof seal between the CONNECTOR under test and the simulated spinal needle;

g) a weigh pan;

h) a gram scale.

H.5.2 Procedure

Check for CONNECTOR incompatibility with the following test.

a) Assemble the SMALL-BORE CONNECTOR to the reference CONNECTOR by applying an axial compressive force of 70 N ± 1 N at a rate of approximately 10 N/s and a simultaneous torque not exceeding 0,12 N·m to a limit of no less than 270° of rotation or whichever comes first.

b) Hold the maximum assembly force and torque for no less than 10 s.

NOTE If the neuraxial CONNECTOR and reference CONNECTOR are pre-attached for the physical test described in H.4, they do not need to be assembled a second time.

c) Assemble the apparatus as shown in Figure H.1.

d) Prime the CONNECTOR under test, the reference CONNECTOR, connecting tubing and the simulated needle with water by filling the circuit until water drips from the end of the needle.

e) Place a 10 ml syringe on the scale and zero the scale by pressing the tare button.

f) Fill the syringe with 7 ml ± 0,2 ml of water.

g) Weigh the filled syringe on the scale and record this weight as W_1 (syringe water only).

h) Press the filled syringe into the reference CONNECTOR.

i) Confirm that the CONNECTION between the syringe and the reference CONNECTOR does not leak water during the test.

j) Place the weigh pan onto the scale and zero the scale by pressing the tare button.

k) Place the weigh pan under the needle such that water that emerges from the needle will be collected in the weigh pan.

l) Slowly depress the syringe plunger such that the water is fully expelled in 7 s to 15 s.

m) Weigh the pan with water collected from the end of the needle. Record this weight as W_2. This represents the water that did not leak from the misconnected CONNECTORS.

n) Calculate the percentage water leaking, L_w, from the CONNECTION using Formula (H.1).

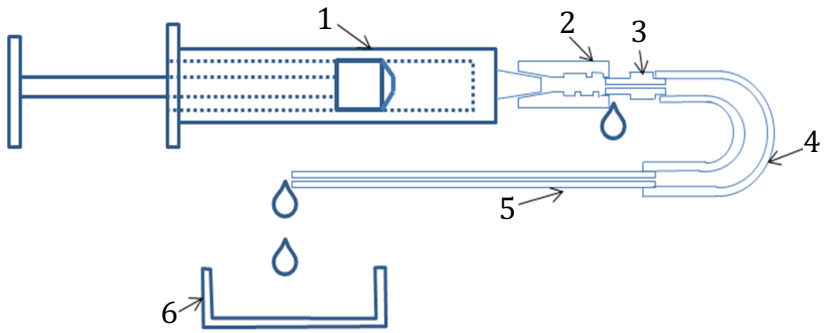
$$L_w = \left(1 - W_2 / W_1\right) \cdot 100\% \quad \text{(H.1)}$$

where

W_1 is the weight measured in step g);

W_2 is the weight measured in step m).

o) Confirm that the percent water leaking from the test CONNECTION exceeds 75 %.



Key

1 pressure source (e.g. syringe)
2 reference CONNECTOR
3 neuraxial CONNECTOR under test
4 tubing
5 twenty-two gauge (0,42 mm inner diameter) × 90 mm long hypodermic tube
6 weigh pan

Figure H.1 — CONNECTOR incompatibility test set up

Annex I
(informative)

Reference to the essential principles

This part of ISO 80369 has been prepared to support the essential principles of safety and performance as intended to be used for CONNECTIONS for neuraxial APPLICATIONS, according to ISO/TR 16142:2006. This part of ISO 80369 is intended to be acceptable for conformity assessment purposes.

Compliance with this this part of ISO 80369 provides one means of demonstrating conformance with the specific essential principles of ISO/TR 16142:2006. Other means are possible. Table I.1 maps the clauses and subclauses of this part of ISO 80369 with the essential principles of ISO/TR 16142:2006.

Table I.1 — Correspondence between this document and the essential principles (1 of 2)

Essential principle of ISO/TR 16142:2006	Corresponding clause(s)/sub-clause(s) of this part of ISO 80369	Qualifying remarks/Notes
A.1	—	Not applicable
A.2	—	Not applicable
A.3	—	Not applicable
A.4	—	Not applicable
A.5	—	Not applicable
A.6	—	Not applicable
A.7.1	—	Not applicable
A.7.2	—	Not applicable
A.7.3	—	Not applicable
A.7.4	—	Not applicable
A.7.5	Clause 4, Clause 5, Clause 6	
A.7.6	Clause 4, Clause 5, Clause 6	
A.8.1	—	Not applicable
A.8.1.1	—	Not applicable
A.8.1.2	—	Not applicable
A.8.2	—	Not applicable
A.8.3	—	Not applicable
A.8.4	—	Not applicable
A.8.5	—	Not applicable
A.8.6	—	Not applicable
A.9.1	Clause 4, Clause 5, Clause 6	
A.9.2	—	Not applicable
A.9.3	—	Not applicable
A.10.1	—	Not applicable
A.10.2	—	Not applicable
A.10.3	—	Not applicable
A.11.1.1	—	Not applicable
A.11.2.1	—	Not applicable
A.11.2.2	—	Not applicable

Table I.1 *(continued)*

Essential principle of ISO/TR 16142:2006	Corresponding clause(s)/sub-clause(s) of this part of ISO 80369	Qualifying remarks/Notes
A.11.3.1	—	Not applicable
A.11.4.1	—	Not applicable
A.11.5.1	—	Not applicable
A.11.5.2	—	Not applicable
A.11.5.3	—	Not applicable
A.12.1	—	Not applicable
A.12.2	—	Not applicable
A.12.3	—	Not applicable
A.12.4	—	Not applicable
A.12.5	—	Not applicable
A.12.6	—	Not applicable
A.12.7.1	—	Not applicable
A.12.7.2	—	Not applicable
A.12.7.3	—	Not applicable
A.12.7.4	Clause 4, Clause 5, Clause 6	
A.12.7.5	—	Not applicable
A.12.8.1	—	Not applicable
A.12.8.2	Clause 4, Clause 5, Clause 6	
A.12.8.3	—	Not applicable
A.13.1	—	Not applicable
A.14.1	—	Not applicable

Annex J
(informative)

Terminology — alphabetized index of defined terms

The ISO online browsing platform (OBP) provides access to terms and definitions.[1)]

Term	Source
ACCESSORY	ISO 80369-1:2010, 3.1
APPLICATION	ISO 80369-1:2010, 3.2
CONNECTION	ISO 80369-1:2010, 3.4
CONNECTOR	ISO 80369-1:2010, 3.5
HARM	ISO 14971:2007, 2.2
INTENDED USE	ISO 14971:2007, 2.5
LOCK CONNECTOR	3.1
LUER CONNECTOR	ISO 80369-7:—, 3.1
LUER SLIP CONNECTOR	ISO 80369-7:—, 3.2
MANUFACTURER	ISO 14971:2007, 2.8
MEDICAL DEVICE	ISO 14971:2007, 2.9
NON-INTERCONNECTABLE	ISO 80369-1:2010, 3.6
NORMAL USE	3.2
PATIENT	ISO 80369-1:2010, 3.7
PROCEDURE	ISO 14971:2007, 2.12
PROCESS	ISO 14971:2007, 2.13
RATED	3.3
RESPONSIBLE ORGANIZATION	ISO 80369-1:2010, 3.8
RIGID MATERIAL	ISO 80369-1:2010, 3.9
RISK	ISO 14971:2007, 2.16
RISK ANALYSIS	ISO 14971:2007, 2.17
RISK ASSESSMENT	ISO 14971:2007, 2.18
RISK MANAGEMENT FILE	ISO 14971:2007, 2.23
RIGID MATERIAL	ISO 80369-1:2010, 3.9
SEMI-RIGID MATERIAL	ISO 80369-1:2010, 3.10
SLIP CONNECTOR	3.4
SMALL-BORE	ISO 80369-1:2010, 3.11
TEST METHOD	ISO 80369-20:2015, 3.1
TYPE TEST	ISO 80369-20:2015, 3.2
USER	3.5
USER PROFILE	3.6
VERIFICATION (VERIFIED)	ISO 14971:2007, 2.28

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2) To be published.

3) To be published.

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6) Revises ISO 5356-1:2004.

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8) Revises ISO 5356-2:2006.

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