

STN	Spojky s malým priemerom na kvapaliny a plyny v aplikáciách zdravotnej starostlivosti. Časť 6: Spojky na epidurálne použitie (ISO 80369-6:2016).	STN EN ISO 80369-6 85 5260
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Small bore connectors for liquids and gases in healthcare applications - Part 6: Connectors for neuraxial applications (ISO 80369-6:2016)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

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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)

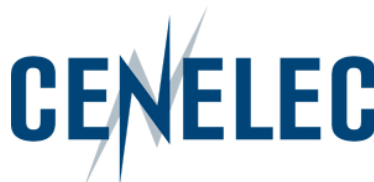
Verbindungsstücke mit kleinem Durchmesser für Flüssigkeiten und Gase in medizinischen Anwendungen - Teil 6: Verbindungsstücke für neuroaxiale Anwendungen (ISO 80369-6:2016, korrigierte Fassung 2016-11-15)

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

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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of an identical text or by endorsement, at the latest by October 2016, and conflicting national standards shall be withdrawn at the latest by October 2016.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 5356-1:2015	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	

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

**Part 6:
Connectors for neuraxial applications**

*Raccords destinés à des applications en contact avec le système
nerveux (neuraxiales) —*

*Partie 6: Raccords destinés à des applications en contact avec le
système nerveux (neuraxiales)*



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ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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.

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.

ISO 80369-6:2016(E)

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](#).

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 brachial 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 80369-6:2016(E)

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*

koniec náhľadu – text ďalej pokračuje v platenej verzii STN