SLOVENSKI STANDARD
oSIST prEN ISO 80369-6:2023

01-oktober-2023

Priključki z majhnim premerom za tekočine in pline za uporabo v zdravstvu - 6. del: Priključki za nevronsko uporabo (ISO/DIS 80369-6:2023)

Small bore connectors for liquids and gases in healthcare applications - Part 6: Connectors for neural applications (ISO/DIS 80369-6:2023)

Verbindungsstücke mit kleinem Durchmesser für Flüssigkeiten und Gase in medizinischen Anwendungen - Teil 6: Verbindungsstücke für neurale Anwendungen (ISO/DIS 80369-6:2023)

Raccords de petite taille pour liquides et gaz utilisés dans le domaine de la santé - Partie 6: Raccords pour applications neurales (ISO/DIS 80369-6:2023)

Ta slovenski standard je istoveten z: **prEN ISO 80369-6**

ICS:

11.040.25	Injekcijske brizge, igle in katetri	Syringes, needles an catheters

oSIST prEN ISO 80369-6:2023 **en,fr,de**

DRAFT INTERNATIONAL STANDARD

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Small bore connectors for liquids and gases in healthcare applications —

Part 6:
Connectors for neural applications

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)

ICS: 11.040.25

This document is circulated as received from the committee secretariat.

This draft is submitted to a parallel vote in ISO and in IEC.

ISO/CEN PARALLEL PROCESSING

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Contents

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.

A list of all parts in the ISO 80369 series can be found on the ISO website.

This second edition cancels and replaces the first edition (ISO 80369-6:2016), which has been technically revised after a systematic review. The main changes compared to the previous edition are as follows:

— Tolerances of several *connector* dimensions in Annex B were modified. All changes are deemed backwards compatible, except for pitch which is now a performance requirement and r2 of Figure B.1 which is now normative. The figures were updated for clarity.

— Annex C reference connector figures and dimensions were reviewed and modified to increase tolerances. All reference connectors manufactured to the requirements of ISO 80369-6:2016 also conform to the modified figures of this document. The figures were updated for clarity.

— Annex E and Annex F (of the first edition of this document) were removed as the *small-bore* connectors defined in this document have been verified against usability and design requirements.

— Annex G (of the first edition of this document) and all Clause 4 references to non-interconnectability including all residual misconnections / misconnection analysis was moved to Annex E of ISO 80369-1.

— Annex H (of the first edition of this document) was removed as this content is included in Annex B of ISO 80369-1.

93 — Annex J (of the first edition of this document) was converted to an Index of Terms and their
94 Sources and placed after the Bibliography.

95 — Remaining Annexes were re-lettered and re-referenced accordingly.

96 — Editorial updates were made throughout the document. This allows harmonization with other
97 parts of the ISO 80369 series of standards.

98 — As per Clause 8.6 of ISO/IEC Directives Part 2, to ensure inclusive wording the word male was
99 replaced by cone and female replaced by socket throughout the document.

100 — ISO 80369-6 Edition 1 was created and published as neuraxial *applications*. However, many of
101 the *applications* listed in the scope and Annex D are neural *applications* therefore the word
102 neuraxial has been replaced with neural throughout the document.

103 Any feedback or questions on this document should be directed to the user's national standards body. A
104 complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

The *small-bore connectors* specified in this document conform with the *non-interconnectability* requirements of ISO 80369-1.

This document includes design and performance requirements for *small-bore connectors* for the neural *application*.

It is recognised that the *small-bore connectors* specified in this document might not be suitable for some *medical devices* within this application.

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

In this document, the following verbal forms are used:

— “shall” indicates a requirement;

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

— “may” indicates a permission;

— “can” indicates a possibility or a capability.

Small-bore connectors for liquids and gases in healthcare applications — Part 6: Connectors for neural applications

1 Scope

NOTE 1 There is rationale for this requirement in Annex A, A.1.

This document specifies requirements for *small-bore connector*s intended to be used for *connection*s in neural *applications*. Neural *applications* involve the use of *medical devices* intended to administer medications to neural sites, wound infiltration anaesthesia delivery, and other regional anaesthesia procedures or to monitor or remove cerebro-spinal fluid for therapeutic or diagnostic purposes.

NOTE 2 Sites for the neural *application* include the spine, intrathecal or subarachnoid space, ventricles of the brain, and the epi-, extra-, or peri-dural space. Neural *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. Neural *application* procedures include continuous infusion of wounds with local anaesthetic agents.

NOTE 3 For the purposes of this document, local anaesthesia injected hypodermically is not considered a neural *application*.

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

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

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 14971:2019, *Medical devices — Application of risk management to medical devices*

ISO 80369-1:2018, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14971:2019, ISO 80369-1:2018, and ISO 80369-20:2015 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at https://www.iso.org/obp
- IEC Electropedia: available at https://www.electropedia.org

NOTE For convenience, the sources of all defined terms used in this document are given in the Index of Terms and their Sources and are delineated throughout the text in italics.

3.1
auxiliary dimension
dimensions derived from other dimensions given for information purposes only

[SOURCE: ISO 10209:2022, 3.3.2 [23]]

3.2
lock connector
connector with a locking mechanism

3.3
slip connector
connector without a locking mechanism

4 Non-interconnectability requirements

*Small-bore connector*s of *medical devices* or *accessories* intended for use in neural *applications* made in conformance with this document meet the requirements of ISO 80369-1.

NOTE 1 An assessment of *medical devices* and their attributes with *connection*s within this *application* is given in Annex D.

NOTE 2 A summary of assessment of the design of *connector*s for this *application* is given in ISO80369-1, Annex E.

5 Materials requirements

NOTE - There is rationale for this requirement in Annex A, A.5.

The surfaces of neural *small-bore* connectors necessary to ensure *non-interconnectable* characteristics shall be made of materials with a nominal modulus of elasticity either in flexure or in tension greater than 950 MPa. Surfaces, other than those necessary to ensure *non-interconnectable* characteristics, need not comply with this requirement.

Check compliance by applying the tests of ASTM D638, ISO 527, ASTM D790, ISO 178, or for metallic materials the tests of ISO 6892-1.

6 Dimensions and tolerances

Neural *small-bore connector*s shall conform with the dimensions and tolerances given in:

— Figure B.1 and Table B.1 for an N1 cone *slip connector*.

— Figure B.2 and Table B.2 for an N2 cone *lock connector*.

— Figure B.3 and Table B.3 for an N2 cone *lock connector* with rotatable collar.

— Figure B.4 and Table B.4 for an N2 socket *connector* with swept threads.

— Figure B.5 and Table B.5 for an N2 socket *connector* with lugs.

Check conformance by confirming the relevant dimensions specified in Annex B, for the appropriate Figure and Table.

7 Performance requirements

7.1 Positive pressure leakage

Neural *small-bore connector*s shall be evaluated for leakage using either the leakage by pressure decay *test method* or the positive pressure liquid leakage *test method*.

7.1.1 Leakage by pressure decay

Neural *small-bore connector*s evaluated for fluid leakage performance with the leakage by pressure decay *test method* shall not exceed a leakage rate of 0,005 Pa·m³/s while being subjected to an applied pressure of between 300 kPa and 330 kPa over a hold period between 15 s and 20 s using air as the medium.

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

7.1.2 Falling drop positive pressure liquid leakage

Neural *small-bore connector*s evaluated for fluid leakage performance with the positive pressure liquid leakage *test method* shall show no signs of leakage, sufficient to form a falling drop of water, over a hold period of 30 s to 35 s while being subjected to an applied pressure of between 300 kPa and 330 kPa.

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

7.2 Sub-atmospheric pressure air leakage

Neural *small-bore connector*s shall not exceed a leakage rate of 0,005 Pa·m³/s while being subjected to an applied sub-atmospheric pressure of between 80,0 kPa and 88,0 kPa over a hold period of between 15 s and 20 s.

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

7.3 Stress cracking

Neural *small-bore connector*s shall meet the requirements of 7.1 after being subjected to the stresses specified in ISO 80369-20:2015, Annex E.

Check conformance by applying the tests of ISO 80369-20:2015, Annex E, while using the stress cracking reference *connector* specified in Annex C, (Figures C.1, C.2 and C.4, as appropriate).

7.4 Resistance to separation from axial load

Neural *small-bore connector*s 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*.

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

7.5 Resistance to separation from unscrewing

Neural *lock connectors* shall not separate from the reference *connector* for a hold period between 10 s and 15 s while being subjected to an unscrewing torque of between 0,018 N·m to 0,020 N·m.

Check conformance by applying the tests of ISO 80369-20:2015, Annex G, while using the resistance to separation from unscrewing reference *connector* specified in Annex C, (Figures C.1 and C.4, as appropriate). A greater applied unscrewing torque or a longer hold period may be used.

7.6 Resistance to overriding

Neural *small-bore connector*s shall not override the threads or lugs of the reference *connector* while being subjected to an applied torque of between 0,15 N·m to 0,17 N·m over a hold period between 5 s and 10 s.

Check conformance by applying the tests of ISO 80369-20:2015, Annex H, while using the resistance to overriding reference *connector* specified in Annex C, (Figures C.3 and C.5, as appropriate). A greater applied torque or a longer hold period may be used.