Small bore connectors for liquids and gases in healthcare applications - Part 6: Connectors for neural applications (ISO 80369-6:2025)

EESTI STANDARDIMIS- JA AKREDITEERIMISKESKUS
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NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 80369-6:2025 sisaldab Euroopa standardi EN ISO 80369-6:2025 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 80369-6:2025 consists of the English text of the European standard EN ISO 80369-6:2025.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 04.06.2025.	Date of Availability of the European standard is 04.06.2025.
Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.	The standard is available from the Estonian Centre for Standardisation and Accreditation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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Small bore connectors for liquids and gases in healthcare applications - Part 6: Connectors for neural applications (ISO 80369-6:2025)

Raccords de petite taille pour liquides et gaz utilisés dans le domaine de la santé - Partie 6: Raccords pour applications neurales (ISO 80369-6:2025)

Verbindungsstücke mit kleinem Durchmesser für Flüssigkeiten und Gase in medizinischen Anwendungen - Teil 6: Verbindungsstücke für neurale Anwendungen (ISO 80369-6:2025)

This European Standard was approved by CEN on 26 May 2025.

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European foreword

This document (EN ISO 80369-6:2025) has been prepared by Technical Committee ISO/TC 210 "Quality management and corresponding general aspects for products with a health purpose including medical devices" in collaboration with Technical Committee CEN-CENELEC/ JTC 3 “Quality management and corresponding general aspects for medical devices” the secretariat of which is held by NEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by December 2025, and conflicting national standards shall be withdrawn at the latest by December 2025.

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

This document supersedes EN ISO 80369-6:2016.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN and CENELEC websites.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 80369-6:2025 has been approved by CEN-CENELEC as EN ISO 80369-6:2025 without any modification.

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Foreword

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

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document 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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for products with a health purpose including medical devices*, in collaboration with Technical Committee IEC/SC 62D, *Particular medical equipment, software, and systems*, and with the European Committee for Standardization (CEN) Technical Committee CEN/CLC/JTC 3, *Quality management and corresponding general aspects for medical devices,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 80369-6:2016), which has been technically revised.

The main changes are as follows:

— To ensure inclusive wording, the word "male" was replaced by "cone" and "female" replaced by "socket" throughout the document.

— Compared to the first edition of this document, the word "neuraxial" has been replaced with "neural" throughout the document.

— The materials requirements of Clause 5 were updated to include all applicable parts of the ISO 527 series.

— All performance requirements of the first edition of this document utilized ISO 80369-20:2015. This second edition references ISO 80369-20:2024. To retain the backward compatibility with the first edition of this document, two of the ISO 80369-20:2015 *test methods* were migrated into this document as Annex F and Annex G. Several informative passages related to these methods were similarly migrated into Annex A. Performance requirements 7.1.2 and 7.2 now reference the *test methods* of Annex F and Annex G, respectively. All other performance requirements reference the *test methods* of ISO 80369-20:2024.

— Tolerances of several *connector* dimensions in Annex B were modified. All changes are deemed backwards compatible, except for the pitch "*p*" which is now a dimensional requirement only and radius "*r*2" 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 the first edition of this document also conform to the modified figures of this document. The figures were updated for clarity.

— Annexes E and 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, were moved to ISO 80369-1:—,[1] Annex E.

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

— Annex J of the first edition of this document is now Annex H.

— Remaining Annexes were renumbered accordingly.

— The bibliography was revised to cite only documents and standards that are referenced informatively in this document.

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

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

Introduction

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 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 1 Sites for the neural *application* include the spine, intrathecal or subarachnoid space, ventricles of the brain, and the epidural, extradural, or peridural 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 2 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.

It is possible that the *small-bore connectors* specified in this document are not 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.

This document uses italic type to distinguish defined terms from the rest of the text. It is important for the correct understanding of this document that those defined terms are identifiable throughout the text of this document. A list of the terms in italics is given in Annex H.

Annex A contains guidance and rationale for specific clauses and subclauses in this document.

Small bore connectors for liquids and gases in healthcare applications —

Part 6: Connectors for neural applications

1 Scope

NOTE Clause A.2 contains guidance or rationale for this clause.

This document specifies requirements for *small-bore connector*s intended to be used for *connection*s in neural *applications*.

This document does not specify requirements for the *medical devices* or *accessories* that use these *connector*s. Such requirements are given in particular standards 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 178, *Plastics — Determination of flexural properties*

ISO 527-1:2019, *Plastics — Determination of tensile properties — Part 1: General principles*

ISO 527-2:2012, *Plastics — Determination of tensile properties — Part 2: Test conditions for moulding and extrusion plastics*

ISO 527-5:2021, *Plastics — Determination of tensile properties — Part 5: Test conditions for unidirectional fibre-reinforced plastic composites*

ISO 6892-1, *Metallic materials — Tensile testing — Part 1: Method of test at room temperature*

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

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

ISO 80369-7:2021, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

ISO 80369-20:2024, *Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common test methods*

ASTM D638-14, *Standard Test Method for Tensile Properties of Plastics*

ASTM D790-17, *Standard Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials*

1) Third edition under preparation. Stage at the time of publication: ISO/FDIS 80369-1:2025. The previous edition is ISO 80369-1:2018.