



**International
Standard**

ISO 80369-6

**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 pour applications neurales

**Second edition
2025-05**

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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).

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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 “*r2*” of [Figure B.1](#), which is now normative. The figures were updated for clarity.

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- [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.

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