

ISO 80369-2

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

Part 2: Connectors for respiratory applications

Raccords de petite taille pour liquides et gaz utilisés dans le domaine de la santé —

Partie 2: Raccords destinés à des applications respiratoires

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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).

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This corrected version of ISO 80369-2:2024 incorporates the following corrections:

- In [Tables B.1 to B.5](#) and [Table G.1](#), values have been corrected to include commas as the decimal sign.

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

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

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

[Annex A](#) contains guidance or rationale on the requirements in this document.

This document has been prepared to support the essential principles for *medical device* or *accessories* incorporating respiratory *application small-bore connectors* according to the International Medical Device Regulators Forum (IMDRF). See [Annex H](#).

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” indicates a recommendation;
- “may” indicates a permission;
- “can” indicates a possibility or capability; and
- “must” is used to express an external constraint.

NOTE 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 I](#).