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Australian STANDARD®

STANDARDS Australia

Small-bore connectors for liquids and gases in healthcare applications

Part 2: Connectors for respiratory applications



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- AusBiotech
- Australian & New Zealand College of Anaesthetists
- Australian Dental Industry Association
- Australian Digital Health Agency
- Australian Healthcare and Hospitals Association
- Australian Society of Anaesthetists
- Engineers Australia
- Federation of Sterilizing Research and Advisory Council of Australia
- Joint Accreditation System of Australia & New Zealand
- Medical Technology Association of Australia
- Queensland Health
- Therapeutic Goods Administration (TGA)

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Requirements

To conform to a Standard, all requirements in the Standard need to be met.

A requirement is any statement in the Standard which uses the word "shall".

Recommendations, permissions and possibilities

The following words are commonly used in Standards, but statements using them do not have to be followed to conform to the Standard:

(a) "should" means that something is recommended.

(b) "may" means that something is permitted.

(c) "can" means that something is possible.

Structure of Standards

A Standard always has the following parts:

(i) The Preface states who developed the Standard, what the Standard is aiming to do, and how it relates to other documents.

(ii) The Scope states what the Standard is about, what it covers and what it does not cover.

(iii) The Normative references clause lists other documents that are referenced in the Standard as part of requirements.

(iv) The Terms and definitions clause defines important terms to help with understanding the Standard.

A Standard may also include other parts, such as the following:

(1) A normative appendix sets additional requirements that need to be conformed to.

(2) An informative appendix provides additional information or guidance. They usually do not contain requirements. If an informative appendix does contain requirements, the Standard will explain when those requirements apply.

(3) A Bibliography lists documents referenced in the Standard but not as part of requirements.

Many Standards include notes. Notes provide recommendations and/or guidance only. They never contain requirements.

Preface

This Standard was prepared by the Standards Australia Committee HE-028, Quality Management and Corresponding General Aspects for Medical Devices.

The objective of this document is to specify the design and dimensions for two small-bore connectors intended to be used for connections in respiratory applications of medical devices and accessories. One connector (R1) is intended for use on medical devices and accessories subjected to pressures up to 15 kPa (e.g. a breathing system). The other connector (R2) is intended for use on medical devices and accessories subjected to higher pressures between 15 kPa and 600 kPa (e.g. oxygen therapy tubing).

NOTE 1 The pressure is related to pressure available at the source to which the medical device is connected.

NOTE 2 The intended application does not preclude the use of other connectors on medical devices or accessories within this application.

NOTE 3 Requirements for alternative connectors for this intended application are specified in ISO 80369-1.

This document does not specify requirements for the medical devices or accessories that use these connectors. Such requirements are given in device-specific standards.

NOTE 4 If a device-specific standard does not exist, the performance and material requirements specified in ISO 80369-1 can be used as guidance.

This document is identical to, and has been reproduced from, ISO 80369-2:2024, *Small-bore connectors for liquids and gases in healthcare applications — Part 2: Connectors for respiratory applications*.

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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).

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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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).

A list of all parts in the ISO 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.

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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Introduction

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.

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Australian Standard®

Small-bore connectors for liquids and gases in healthcare applications

Part 2: Connectors for respiratory applications

1 Scope

This document specifies the design and dimensions for two *small-bore connectors* intended to be used for *connections* in respiratory *applications* of *medical devices* and *accessories*. One *connector* (R1) is intended for use on *medical devices* and *accessories* subjected to pressures up to 15 kPa (e.g. a *breathing system*). The other *connector* (R2) is intended for use on *medical devices* and *accessories* subjected to higher pressures between 15 kPa and 600 kPa (e.g. oxygen therapy tubing).

NOTE 1 The pressure is related to pressure available at the source to which the *medical device* is connected.

NOTE 2 The intended *application* does not preclude the use of other *connectors* on *medical devices* or *accessories* within this *application*.

NOTE 3 Requirements for alternative connectors for this intended application are specified in ISO 80369-1.

This document does not specify requirements for the *medical devices* or *accessories* that use these *connectors*. Such requirements are given in device-specific standards.

NOTE 4 If a device-specific standard does not exist, the performance and material requirements specified in ISO 80369-1 can be used as guidance.

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 (all parts), *Determination of tensile properties*

ISO 6892-1:2019, *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 80369-1:2018, *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 80369-20:2015, *Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common test methods*

ASTM D638-22, *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*

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