International Standard

ISO 80369-20

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

Part 20: Common test methods

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

Partie 20: Méthodes d'essai communes

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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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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 80369-20:2015), which has been technically revised.

The main changes are as follows:

— clarification that these test methods are also used by the ISO 18250 series;

— major technical revision of the *test methods* described in Annex B “Leakage by pressure decay test method” and Annex D “Subatmospheric-pressure air leakage test method” (replacement of leakage rate by the pressure change as acceptance criterion; definition of three defined mandatory test conditions; more information about this change is included in Annex A);

— introduction of a new attributive *test method* “Air leakage during aspiration” as Annex K;

— editorial revision of the assembling *procedures* of a *connector* under test, affecting all annexes with *test methods*;

— editorial update according to ISO/IEC Directives, Part 2;

— replacement of the terms “male” by “*cone*” and “female” by “*socket*” in the description of a *connector*;

— update of dated normative references;

— definition for *type test* has been updated;

— expansion of the range of environmental test conditions for relative humidity;

— extension of requirements for test reports;

— clarification that all tests are intended to be *type tests*.

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

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 requirements.

— “Should” indicates recommendations.

— “May” indicates permissions.

— “Can” indicates possibility or 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 defined terms used in this document (in italics) is given in Annex M.

Requirements in this document have been broken down so that each requirement is clearly delineated and listed individually. This has been done to support the common practice of automatic tracking of requirements and automatic verification of the requirements of this document.

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

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

Part 20:
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1 Scope

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

This document specifies the common *test methods* to evaluate the performance requirements for *small-bore connectors* specified in the ISO and IEC 80369 series as well as the ISO 18250 series.

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

1) Third edition under preparation. Stage at the time of publication: ISO/FDIS 80369-1:2024. The previous edition is ISO 80369-1:2018.