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Medical devices — Connectors for reservoir delivery systems for healthcare applications —

Part 1: General requirements and common test methods

Dispositifs médicaux — Connecteurs pour systèmes de livraison de réservoir pour des applications de soins de santé —

Partie 1: Exigences générales et méthodes d'essai courantes

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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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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 medical devices*.

A list of all the parts in the ISO 18250 series can be found on the ISO website. The numbering of the parts follows in parallel the clinical applications listed in ISO 80369-1:2018 where applicable. Other parts are expected to be added in the future for applications not yet covered.

In this document, the following print types are used:

— requirements and definitions: roman type;

— informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;

— compliance checks: *italic type*;

— TERMS DEFINED IN THIS DOCUMENT OR AS NOTED: SMALL CAPITALS.

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.

For the purposes of this document, the following verbal forms are used:

— "shall" indicates that compliance with a requirement or a test is mandatory for compliance with this document,

— "should" indicates that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document, and

— "may" is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex A.

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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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Introduction

During the development of the ISO 80369 series of standards for small-bore CONNECTORS, it became evident that equally important were the CONNECTIONS between MEDICAL DEVICES and fluid RESERVOIRS. It was agreed that such CONNECTORS should be developed in parallel with the small-bore CONNECTORS specified in the ISO 80369 series of standards and comply with analogous safety and interoperability requirements.

ISO 16142-1:2016, Clause 4 addresses this type of problem.

The solutions adopted by the MANUFACTURER for the design and manufacture of the MEDICAL DEVICE should conform to safety principles, taking into account the generally acknowledged state of the art. When risk reduction is required, the manufacturer should control the risks so that the residual risk associated with each hazard is judged acceptable. The manufacturer should apply the following principles in the priority order listed:

a) identify known or foreseeable HAZARDS and estimate the associated RISKS arising from the INTENDED USE and foreseeable misuse;

b) eliminate RISKS as far as reasonably practicable through inherently safe design and manufacture;

c) reduce as far as reasonably practicable the remaining RISKS by taking adequate protection measures, including alarms or information for safety;

d) inform users of any residual RISK.

It was soon realized that many of the RESERVOIRS that contain liquids for administering to PATIENTS for different APPLICATIONS all utilized the same ubiquitous spike as the CONNECTOR between the giving set and the RESERVOIR leading to wrong drug administration. The ISO 18250 series endeavours to provide unique designs for each of the APPLICATIONS specified to reduce the RISK of administering the wrong drug. It is understood that RESERVOIR CONNECTOR systems cannot be designed to overcome all chances of MISCONNECTION or to eliminate deliberate misuse. However, a number of steps that would improve the current situation and lead to greater PATIENT safety can be taken. This will only be achieved through a long-term commitment involving industry, healthcare professionals, MEDICAL DEVICE purchasers and MEDICAL DEVICE regulatory authorities.

The ISO 18250 series specifies the requirements to prevent MISCONNECTION between RESERVOIR CONNECTORS used in different APPLICATIONS. This document specifies the general requirements and TEST METHODS common to all RESERVOIR CONNECTORS in this series. TEST METHODS that are specific to a particular RESERVOIR CONNECTOR will be included in that APPLICATION part. The ISO 18250 series specifies the requirements to prevent MISCONNECTIONS or reduce their occurrence to acceptable levels between RESERVOIR CONNECTORS used in different APPLICATIONS.

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Medical devices — Connectors for reservoir delivery systems for healthcare applications —

Part 1: General requirements and common test methods

1 *Scope

This document specifies general requirements for RESERVOIR CONNECTORS, which convey fluids in healthcare APPLICATIONS. These RESERVOIR CONNECTORS are used in MEDICAL DEVICES or ACCESSORIES intended for use with a PATIENT.

This document also specifies the healthcare fields in which these RESERVOIR CONNECTORS are intended to be used.

These healthcare fields of use include, but are not limited to, APPLICATIONS for

— respiratory,

— enteral,

— neural,

— intravascular,

— citrate-based anticoagulant solution, and

— irrigation.

RESERVOIR CONNECTORS as specified in this document are NON-INTERCONNECTABLE with:

— the RESERVOIR CONNECTORS of every other APPLICATION specified in the ISO 18250 series;

— removable temperature sensor port specified in Annex EE of ISO 80601-2-74:2017;

— the nipples specified in Annex B of ISO 17256[1)];

unless otherwise specified in the ISO 18250 series.

APPLICATION parts of the ISO 18250 series can specify additional CONNECTORS with which RESERVOIR CONNECTORS (as specified in those APPLICATION parts) are to be NON-INTERCONNECTABLE.

This document provides the methodology to assess NON-INTERCONNECTABLE characteristics of RESERVOIR CONNECTORS based on their inherent design and dimensions in order to reduce the RISK of MISCONNECTIONS between MEDICAL DEVICES or between ACCESSORIES for different APPLICATIONS.

This document does not specify requirements for the MEDICAL DEVICES or ACCESSORIES that use these RESERVOIR CONNECTORS. Such requirements are given in particular International Standards for specific MEDICAL DEVICES or ACCESSORIES.

NOTE 1 MANUFACTURERS are encouraged to incorporate the RESERVOIR CONNECTORS specified in the ISO 18250 series into MEDICAL DEVICES, medical systems or ACCESSORIES, even if currently not required by the relevant particular MEDICAL DEVICE standards. It is expected that when the relevant particular MEDICAL DEVICE standards are revised, requirements for RESERVOIR CONNECTORS as specified in the series of standards will be included.

1) Under preparation. Stage at the time of publication: ISO/DIS 17256:2017.

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NOTE 2 The ISO 18250 series does not apply to screw and crown cork caps and necks as they are not CONNECTORS specific for MEDICAL DEVICES. Examples of screw caps and necks are defined in DIN 55525, ASTM D2911/D2911M, DIN 6063-1, DIN 6063-2, DIN 168-1. Examples of crown cork caps and necks are defined in DIN 6094, ISO 12821, EN 14635.

This document also specifies the TEST METHODS to verify the common performance requirements for RESERVOIR CONNECTORS. The performance requirements for these common TEST METHODS are specified in the APPLICATION parts and not in the general part.

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

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

ISO 178, *Plastics — Determination of flexural properties*

ISO 14971:2007, *Medical devices — Application of risk management to medical devices*

ISO 17256[2)], *Anaesthetic and respiratory equipment — Respiratory therapy tubing and connectors*

ISO 18250-3, *Medical devices — Connectors for reservoir delivery systems for healthcare applications — Part 3: Enteral applications*

ISO 18250-6[3)], *Medical devices — Connectors for reservoir delivery systems for healthcare applications — Part 6: Neural applications*

ISO 18250-7[4)], *Medical devices — Connectors for reservoir delivery systems for healthcare applications — Part 7: Intravascular applications*

ISO 18250-8, *Medical devices — Connectors for reservoir delivery systems for healthcare applications — Part 8: Citrate-based anticoagulant solution for apheresis applications*

ISO 80601-2-74:2017, *Medical electrical equipment — Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment*

IEC 62366-1, *Medical devices — Part 1: Application of usability engineering to medical devices*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14971, IEC 62366-1, and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

2) Under preparation. Stage at the time of publication: ISO/DIS 17256:2017.

3) Under preparation. Stage at the time of publication: ISO/DIS 18250-6:2018.

4) Under preparation. Stage at the time of publication: ISO/FDIS 18250-7:2018.

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3.1
ACCESSORY
additional part(s) for use with MEDICAL DEVICE in order to:

— achieve the INTENDED USE,

— adapt it to some special use,

— facilitate its use,

— enhance its performance, or

— enable its functions to be integrated with those of other MEDICAL DEVICES

[SOURCE: IEC 60601-1:2005, definition 3.3, modified — "equipment" has been replaced with MEDICAL DEVICE]

3.2
APPLICATION
specific healthcare field in which a RESERVOIR CONNECTOR is intended to be used

[SOURCE: ISO 80369-1:2018, 3.2, modified — "SMALL-BORE CONNECTOR" has been replaced with "RESERVOIR CONNECTOR"]

Note 1 to entry: Annex K lists RESERVOIR CONNECTOR APPLICATIONS and gives examples of the MEDICAL DEVICES used within that healthcare field.

3.3
CONNECTION
union or joining of mating halves of a CONNECTOR

[SOURCE: ISO 80369-1:2018, 3.3]

3.4
CONNECTOR
mechanical device, consisting of one of two mating halves and designed to join a conduit to convey liquids or gases

[SOURCE: ISO 80369-1:2018, 3.4]

Note 1 to entry: This term refers to both mating halves of the CONNECTION and applies to both the mechanical devices on the RESERVOIR side and PATIENT side.

3.5
MISCONNECTION
CONNECTION between CONNECTORS intended for different APPLICATIONS or from different designs within the same APPLICATION and not intended to connect

3.6
NON-INTERCONNECTABLE
having characteristics which incorporate geometries or other characteristics that prevent different CONNECTORS from making a CONNECTION

[SOURCE: ISO 80369-1:2018, 3.10]

3.7
PATIENT
person undergoing a medical, surgical or dental PROCEDURE

[SOURCE: IEC 60601-1:2005, definition 3.76, modified — "person or animal" has been replaced by "person"]

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3.8
RESERVOIR
fluid container within MEDICAL DEVICE field

3.9
TEST METHOD
PROCEDURE that produces a test result

4 Materials used for RESERVOIR CONNECTORS

4.1 *General

To verify the MISCONNECTION requirements specified in this document, RESERVOIR CONNECTORS shall be made of materials with a modulus of elasticity either in tension or in flexure of at least 700 MPa, unless otherwise specified in specific APPLICATION parts of the ISO 18250 series.

Check compliance in accordance with ISO 527-1 and ISO 527-2 or ISO 178 at (23 ± 2) °C temperature and (50 ± 5) % relative humidity.

Non-rigid materials are allowed in order to provide sealing surfaces or other performance characteristics whereas they do not affect NON-INTERCONNECTABLE characteristics, or unless otherwise specified in specific APPLICATION parts of the ISO 18250 series.

MANUFACTURERS shall demonstrate that, when non-rigid materials are introduced in the design, the NON-INTERCONNECTABLE characteristics are not affected.

NOTE The TEST METHODS listed in Annex L are considered acceptable alternatives to ISO 527-1 and ISO 527-2, and ISO 178.

4.2 Alternative TEST METHODS

MANUFACTURERS may use alternative TEST METHODS to those listed in Annex L if it can be demonstrated that they are technically equivalent to ISO 527-1 and ISO 527-2 or ISO 178 within the typical uncertainty range of the mechanical properties of the plastics used.

In cases of dispute, the TEST METHODS listed in this document shall be identified as the reference TEST METHODS.

Check compliance by inspection of the technical file.

5 *Requirements for RESERVOIR CONNECTORS for specific APPLICATIONS

5.1 *RESERVOIR CONNECTOR incompatibility

RESERVOIR CONNECTORS for APPLICATIONS specified in this document shall be NON-INTERCONNECTABLE with:

— the RESERVOIR CONNECTORS of every other APPLICATION specified in the ISO 18250 series;

— the defined surfaces of nipples of ISO 17256;

— the defined surfaces of temperature sensors and mating ports made in compliance with Annex EE of ISO 80601-2-74:2017;

unless otherwise indicated in this document or the APPLICATION parts of the ISO 18250 series.

Check compliance by confirming that OBJECTIVE EVIDENCE verifies that RISKS have been reduced to acceptable levels for the acceptability criteria specified in Annex B.

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