INTERNATIONAL STANDARD

**ISO 18250-3**

First edition
2018-06

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

## Part 3: Enteral applications

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

*Partie 3: Applications entérales*

Reference number
ISO 18250-3:2018(E)

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

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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 on 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 WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword — Supplementary information.

This document was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*.

A list of all parts in the ISO 18250 series can be found on the ISO website.

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.

— TERMS DEFINED IN THIS STANDARD 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.

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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# Introduction

During the development of the Standard for ENTERAL SMALL-BORE CONNECTORS (ISO 80369-3:2016) it became clear that the RISK of MISCONNECTIONS was not limited to the PATIENT access CONNECTORS and that the whole ENTERAL system needed to be considered. The possible MISCONNECTION between ENTERAL RESERVOIR CONNECTORS and spikes was also reviewed. However as ENTERAL RESERVOIR CONNECTORS are not exactly within the definition of SMALL-BORE CONNECTORS it was decided to develop this separate Standard for these CONNECTORS, taking into account the RISKS of MISCONNECTION with other MEDICAL DEVICES such as intravascular (also referred as "IV") bags.

Two different designs of CONNECTORS have been included to reflect the varying types of feed RESERVOIRS in current use.

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

# Part 3:
# Enteral applications

## 1 *Scope

This document specifies dimensions and requirements for the design and functional performance of CONNECTORS intended to be used on ENTERAL RESERVOIRS.

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

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

This document does not apply to screw and crown cork caps and necks as they are not CONNECTORS specific for MEDICAL DEVICES. They rather belong to the food and beverage packaging domain despite often ENTERAL giving sets are required to connect with them.

NOTE 2 Examples of screw caps and necks are defined in DIN 55525:1988, ASTM D2911-94 (reapproved 2001), DIN 6063-1:2004, DIN 6063-2:2004, DIN 168-1:1998. Examples of crown cork caps and necks are defined in DIN 6094-1:1998, ISO 12821:2013, EN 14635:2010.

## 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 18250-1, *Connectors for reservoir delivery systems for healthcare applications — Part 1: General requirements and common test methods*

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

ASTM D638-10, *Standard test method for tensile properties of plastics*

ASTM D790-10, *Standard test methods for flexural properties of unreinforced and reinforced plastics and electrical insulating materials*

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 18250-1 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/

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**3.1**
**enteral**
used for administration or removal of fluid (liquid or gas) to or from the gastrointestinal tract

[SOURCE: ISO 80369-3:2016, 3.1]

**3.2**
**normal use**
operation, including routine inspection and adjustments by any USER, and stand-by, according to the instructions for use

Note 1 to entry: NORMAL USE should not be confused with INTENDED USE. While both include the concept of use as intended by the MANUFACTURER, INTENDED USE focuses on the medical purpose while NORMAL USE incorporates not only the medical purpose, but maintenance, service, transport, etc. as well.

[SOURCE: IEC 60601-1:2005+A1:2012, 3.71, modified – The word 'OPERATOR' has been replaced with 'USER'.]

**3.3**
**rated (value)**
term referring to a value assigned by the MANUFACTURER for a specified operating condition

[SOURCE: IEC 60601-1:2005+A1:2012, 3.97]

**3.4**
**rigid material**
material with a modulus of elasticity either in flexure or in tension greater than 35 000 kg/cm$^2$ (3 433 MPa)

**3.5**
**semi-rigid material**
material with a modulus of elastic either in flexure or in tension, between 7 138 kg/cm$^2$ and 35 000 kg/cm$^2$ (700 MPa and 3 433 MPa)

# 4 General requirements

## 4.1 NON-INTERCONNECTABLE characteristics

Where the design of the CONNECTOR of this document relies on dimensions or features of the MEDICAL DEVICE or ACCESSORY to ensure NON-INTERCONNECTABLE characteristics, the MANUFACTURER shall verify the NON-INTERCONNECTABLE characteristics. When necessary, the CONNECTOR may be installed on the MEDICAL DEVICE or ACCESSORY to demonstrate compliance with NON-INTERCONNECTABLE characteristics.

NOTE 1 The summary of MEDICAL DEVICES and their attributes with CONNECTIONS within this APPLICATION is provided in Annex D.

NOTE 2 The summary of the usability requirements for ENTERAL RESERVOIR CONNECTORS is provided in Annex E.

NOTE 3 The summary of ENTERAL RESERVOIR CONNECTORS criteria and requirements is provided in Annex F.

NOTE 4 The summary of assessment of the design of ENTERAL RESERVOIR CONNECTORS is contained in Annex G.

## 4.2 *Materials

ENTERAL RESERVOIR CONNECTORS of MEDICAL DEVICES or ACCESSORIES shall be made of materials with a modulus of elasticity either in flexure or in tension greater than 700 MPa.


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