
**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

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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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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](#).

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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