INTERNATIONAL STANDARD

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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

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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.

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.