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Medical devices — Connectors for reservoir delivery systems for healthcare applications

Part 1: General requirements and common test methods

National foreword

This British Standard is the UK implementation of ISO 18250-1:2018.

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A list of organizations represented on this committee can be obtained on request to its secretary.

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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.

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

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.