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

Part 6: Neural applications

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

Partie 6: Applications neurales

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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).

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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 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: smaller type;

— TERMS DEFINED IN THIS DOCUMENT: SMALL CAPS;

— *compliance requirements: italic type.*

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.

The verbal forms used in this document conform to usage described in the ISO/IEC Directives, Part 2, Annex H. For the purposes of this document, the auxiliary verb:

— "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;

— "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;

— "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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Introduction

During the development of the ISO 80369 series of standards for small-bore connectors for liquids and gases in healthcare applications it became evident that the risk of misconnections was not limited to the patient access connectors and that the connectors used at the reservoir end of the systems were also a potential high risk for misconnection. For many reasons these reservoir connectors did not fit well within the scope of ISO 80369 so it was decided to develop a separate series of standards specifically for these reservoir connectors. The 18250 series takes into account the risks of misconnections between the reservoir connectors of different applications including the existing standardized IV spike specified in ISO 8536-4 and ISO 1135-4.

NOTE Manufacturers are encouraged to incorporate the connectors specified in this document into medical devices, even if not currently required by the particular device standard. It is expected that when the particular device standards are revised, requirements for connectors with the dimensions, as specified within this document, will be included.

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

Part 6: Neural applications

1 *Scope

This document specifies the connectors recommended for the outlet ports of neural reservoirs and inlet ports of neural giving sets.

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, *Medical devices — Connectors for reservoir delivery systems for healthcare applications — Part 1: General requirements and common test methods*

ISO 80369-6, *Small bore connectors for liquids and gases in healthcare applications — Part 6: Connectors for neuraxial applications*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 18250-1 and ISO 80369-6 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/

4 *Neural reservoir outlet port connector

4.1 The connector at the outlet port of a neural reservoir shall be a male, N2, neuraxial lock connector complying with ISO 80369-6.

4.2 The connector should be non-user-detachable from the reservoir.

5 *Neural giving set inlet port connector

5.1 The connector at the inlet port of a neural giving set shall be a female, N2, neuraxial, lock connector complying with ISO 80369-6.

5.2 The connector should be non-user-detachable from the giving set.

NOTE See Annex A for a rationale.

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