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

Part 8: Citrate-based anticoagulant solution for apheresis applications

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

Partie 8: Solution anticoagulante à base de citrate pour les applications d'aphérèse

Reference number
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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: in smaller type.

— Normative text of tables is also in a smaller type.

— TERMS DEFINED IN THIS STANDARD: 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.

For the purposes of this document, the following verbal forms are used:

— "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 series of standards for small-bore CONNECTORS for liquids and gases in healthcare applications (see ISO 80369) it became clear that the risk of MISCONNECTIONS was not limited to the patient access CONNECTORS and that the whole RESERVOIR system needed to be considered. The possible MISCONNECTION between APHERESIS AC RESERVOIR CONNECTORS and spikes was also reviewed. However, as APHERESIS AC 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 MISCONNECTIONS with other devices such as IV bags, and blood pressure cuffs that are likely to be used on the same patient.

This document, therefore, defines the APHERESIS AC RESERVOIR CONNECTORS in geometry, material, and performance to permit them being analyzed (and avoided) by other CONNECTORS intended for non-APHERESIS applications (i.e. the other application parts of the ISO 18250 series).

This document is not a device standard as it specifies only the dimensions of the interfaces for the APHERESIS AC RESERVOIR CONNECTORS used on the disposable tubing sets and solution RESERVOIRS.

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

Part 8: Citrate-based anticoagulant solution for apheresis applications

1 Scope

This document specifies dimensions and requirements for the design and functional performance of APHERESIS ANTICOAGULANT (AC) RESERVOIR CONNECTORS.

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.

The following examples of MEDICAL DEVICES are intended to use the CONNECTORS of this document:

— APHERESIS tubing sets and mating RESERVOIRS containing CITRATE-BASED ANTICOAGULANT solution.

— APHERESIS tubing sets may include, but are not limited to those for use in blood collection, therapeutic applications, and plasma collection.

Some APHERESIS sets are manufactured with a pre-connected RESERVOIR containing CITRATE-BASED ANTICOAGULANT solution. These MEDICAL DEVICES are not intended to use the CONNECTORS of this document.

NOTE Manufacturers are encouraged to incorporate the CONNECTORS specified in this document into APHERESIS 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 APHERESIS AC RESERVOIR CONNECTORS, will be included.

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:—[1)], *Medical devices — 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*

3 Terms and definitions

3.1
ACCESSORY
additional part(s) for use with MEDICAL DEVICE (3.7) in order to:

— achieve the intended use,

1) Under preparation. Stage at the time of publication: ISO/FDIS 18250-1.

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— adapt it to some special use,

— facilitate its use,

— enhance its performance, or

— enable its functions to be integrated with those of other MEDICAL DEVICES (3.7)

[SOURCE: ISO 80369-1:—[2)], definition 3.1]

3.2
APHERESIS
procedure in which blood is drawn from a donor or patient and separated into its components, some of which are retained and the remainder returned by transfusion to the donor or patient

3.3
APHERESIS ANTICOAGULANT RESERVOIR CONNECTOR
APHERESIS AC RESERVOIR CONNECTOR
CONNECTOR (3.6) for CITRATE-BASED ANTICOAGULANT (3.4) solutions for APHERESIS (3.2) applications

3.4
CITRATE-BASED ANTICOAGULANT
citrate, in the form of sodium citrate or acid-citrate-dextrose, added to the blood as it is drawn from the subject's circulation which binds or chelates ionised calcium within the blood, impeding those steps of the coagulation pathway that are dependent on the presence of ionised calcium

3.5
CONNECTION
union or joining of mating halves of a CONNECTOR (3.6)

[SOURCE: ISO 80369-1:—, definition 3.4]

3.6
CONNECTOR
mechanical device, consisting of one of two mating halves and designed to join a conduit to convey liquids or gases

[SOURCE: ISO 80369-1:—, definition 3.5]

3.7
MEDICAL DEVICE
instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of

— diagnosis, prevention, monitoring, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of or compensation for an injury,

— investigation, replacement, modification, or support of the anatomy or of a physiological process,

— supporting or sustaining life,

— control of conception,

— disinfection of MEDICAL DEVICES, or

— providing information for medical purposes by means of in vitro examination of specimens derived from the human body,

2) To be published. Revision of ISO 80369-1:2010.

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and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means

Note 1 to entry: Products which might be considered to be MEDICAL DEVICES in some jurisdictions but not in others include:

— disinfection substances;

— aids for persons with disabilities;

— devices incorporating animal or human tissues;

— devices for in-vitro fertilization or assisted reproduction technologies.

[SOURCE: Based on GHTF/SG1/N071 2012, definition 5.1]

3.8
MISCONNECTION
CONNECTION (3.5) between CONNECTORS (3.6) intended for different APPLICATIONS or from different designs within the same APPLICATION and not intended to connect

3.9
NON-INTERCONNECTABLE
having characteristics which incorporate geometries or other characteristics that prevent different CONNECTORS (3.6) from being connected

3.10
RESERVOIR
fluid container within MEDICAL DEVICE (3.7) or pharmaceutical fields

4 General requirements

4.1 NON-INTERCONNECTABILITY through conformance to ISO 18250-8

Conformance to 4.2, 4.4 and Clause 5 of this document is sufficient to demonstrate conformance to ISO 18250-1 (i.e. NON-INTERCONNECTABILITY with clinical applications other than APHERESIS).

NOTE 1 A summary of the evaluation and residual risks of the NON-INTERCONNECTABLE characteristics of the designs for this document is included in Annex D.

NOTE 2 The NON-INTERCONNECTABLE criteria used in this document deviates from the ISO 18250-1:—, Annex B in that the risk of MISCONNECTIONS between applications that will connect but do not permit transfer of fluids is deemed acceptable.

4.2 *Materials

APHERESIS AC RESERVOIR CONNECTORS shall be made of materials as specified by ISO 18250-1:—, Clause 4.

Compliance shall be checked by applying the tests of ISO 18250-1:—, Clause 4.

4.3 APHERESIS AC RESERVOIR CONNECTOR Descriptions

One pair of connectors are used in the APHERESIS AC RESERVOIR CONNECTOR application. These are:

— The male APHERESIS AC RESERVOIR CONNECTOR. This CONNECTOR shall be on the APHERESIS set.

— The female APHERESIS AC RESERVOIR CONNECTOR. This CONNECTOR shall be on the RESERVOIR.

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