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Small-bore connectors for liquids and gases in healthcare applications —

Part 7: Connectors for intravascular or hypodermic applications

Raccords de petite taille pour liquides et gaz utilisés dans le domaine de la santé —

Partie 7: Raccords à 6 % (Luer) destinés aux applications intravasculaires ou hypodermiques

Reference number
ISO 80369-7:2016(E)

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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 on 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.

The committee responsible for this document is ISO/TC 210, *Quality management and corresponding general aspects for medical devices*, and IEC/SC62D, *Electromedical equipment*. The draft was circulated for voting to the national bodies of both ISO and IEC.

This first edition of ISO 80369-7 cancels and replaces ISO 594-1:1986 and ISO 594-2:1998, clauses, subclauses, tables, figures, and annexes of which have been consolidated and technically revised.

This part of ISO 80369 contains the following major technical revisions to ISO 594-1 and ISO 594-2.

a) New terms and definitions have been added to this part of ISO 80369 to more clearly define the various types of LUER CONNECTORS included in the scope of this part of ISO 80369. This part of ISO 80369 more broadly describes the requirements for the CONNECTORS used for intravascular or hypodermic APPLICATIONS, unlike ISO 594-1 and ISO 594-2 that are replaced by this part of ISO 80369, which only described the requirements for the fittings (intended CONNECTION surfaces) of these CONNECTORS. This distinction is important to define here because the previous International Standards do not contain the terms CONNECTOR or CONNECTION and ISO 80369- series does not use the term fitting.

b) Requirements for certain dimensions not previously identified in ISO 594-1 and ISO 594-2 are added to this part of ISO 80369 to reduce the RISK of misconnections between MEDICAL DEVICES or ACCESSORIES for different APPLICATIONS with the SMALL-BORE CONNECTORS that are being developed under other parts of the ISO 80369- series. These new dimensions were selected to represent the current design and dimensions of LUER CONNECTORS in clinical use at the time this part of ISO 80369 was developed. The term "6 % (Luer) taper" used throughout the previous standards has also been clarified to the more commonly used equivalent specified diameters separated by a specified distance on a common axis.

c) Requirements for gauging of LUER CONNECTORS made from SEMI-RIGID MATERIALS using plug and ring test gauges have been replaced by dimensional requirements, which are more precise and essential for reducing the RISK of misconnection with the other CONNECTORS identified in ISO 80369-1.

d) Separate requirements for LUER CONNECTORS made from SEMI-RIGID MATERIALS and RIGID MATERIALS have been eliminated and combined as one common set of dimensions and requirements. This consolidation of requirements was made to further reduce the RISK of misconnection with other SMALL-BORE CONNECTORS.

ISO 80369 consists of the following parts, under the general title *Small-bore connectors for liquids and gases in healthcare applications*:

— *Part 1: General requirements*

— *Part 3: Connectors for enteral applications*

— *Part 5: Connectors for limb cuff inflation applications*

— *Part 6: Connectors for neuraxial applications*

— *Part 7: Connectors with 6 % (Luer) taper for intravascular or hypodermic applications*

— *Part 20: Common test methods*

Additional parts on connectors for urethral and urinary applications and for respiratory applications are planned.

This corrected version of ISO 80369-7:2016 incorporates the following corrections:

— in the Scope, NOTE 1 has been removed and the other notes renumbered accordingly;

— in the second paragraph of 6.6, the reference to the annex has been changed;

— the lower-case greek letter "β" has been changed into a capital greek letter "*B*" in the notes of Tables B.5 and B.6;

— the representation of the angle *B* has been updated in Figure B.7;

— values and angles have been corrected in Figures C.1, C.2, C.3, C.4 and C.6.

Introduction

This part of ISO 80369 was developed because of several incidents, with catastrophic consequences, resulting from inappropriate medication, liquid nutritional formula or air being administered intravenously. Many incidents have been reported leading to international recognition of the importance of these issues and a need has been identified to develop specific CONNECTORS for MEDICAL DEVICES and their ACCESSORIES used to deliver fluids in other APPLICATIONS.

The ISO 80369- series was developed to prevent misconnection between SMALL-BORE CONNECTORS used in different APPLICATIONS. ISO 80369-1 specifies the requirements necessary to verify the designs and dimensions of SMALL-BORE CONNECTORS to ensure that

a) they do not misconnect with other SMALL-BORE CONNECTORS, and

b) they safely and securely connect with their mating half.

ISO 80369-20 contains the common TEST METHODS to support the performance requirements for SMALL-BORE CONNECTORS.

This part of ISO 80369 specifies the design and the dimensions and the drawings of SMALL-BORE CONNECTORS intended to be used as conical fittings with a 6 % (Luer) taper for CONNECTIONS in intravascular or hypodermic APPLICATIONS. Annex D to Annex G describe the methods by which this design has been assessed. Other parts of ISO 80369 include requirements for SMALL-BORE CONNECTORS used in different APPLICATION categories.

CONNECTORS manufactured to the dimensions set out within this part of ISO 80369 are dimensionally incompatible with any of the other CONNECTORS for APPLICATIONS identified in the ISO 80369- series of standards for SMALL-BORE CONNECTORS, except as indicated in Annex G. If fitted to the relevant MEDICAL DEVICES and ACCESSORIES, these CONNECTORS should reduce the RISK of air, non-vascular medication and liquid nutritional formula being delivered through an alternative route, such as intravenously or through an airway device.

In this part of ISO 80369, 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 Clause 3 or as noted: SMALL CAPITALS.

In this part of ISO 80369, 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 part of ISO 80369 conform to usage described in the ISO/IEC Directives, Part 2, Annex H. For the purposes of this part of ISO 80369, the auxiliary verb:

— “shall” means that compliance with a requirement or a test is mandatory for compliance with this part of ISO 80369;

— “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this part of ISO 80369;

— “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.