BSI Standards Publication

Small-bore connectors for liquids and gases in healthcare applications

Part 7: Connectors for intravascular or hypodermic applications

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National foreword

This British Standard is the UK implementation of EN ISO 80369-7:2021. It is identical to ISO 80369-7:2021. It supersedes BS EN ISO 80369-7:2017, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/210, Quality management and corresponding general aspects for medical devices.

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

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Published by BSI Standards Limited 2021

ISBN 978 0 539 06119 2

ICS 11.040.25

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This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 May 2021.

Amendments/corrigenda issued since publication

Date	Text affected

EUROPÄISCHE NORM

May 2021

ICS 11.040.25

Supersedes EN ISO 80369-7:2017

English version

Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications (ISO 80369-7:2021)

Raccords de petite taille pour liquides et gaz utilisés dans le domaine de la santé - Partie 7: Connecteurs pour les applications intravasculaires ou hypodermiques (ISO 80369-7:2021)

Steckverbinder mit kleiner Bohrung für Flüssigkeiten und Gase im Gesundheitswesen - Teil 7: Steckverbinder für intravaskuläre oder subkutane Anwendungen (ISO 80369-7:2021)

This European Standard was approved by CEN on 29 October 2020.

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European foreword

This document (EN ISO 80369-7:2021) has been prepared by Technical Committee ISO/TC 210 "Quality management and corresponding general aspects for medical devices" in collaboration with Technical Committee CEN/CLC/JTC 3 “Quality management and corresponding general aspects for medical devices” the secretariat of which is held by NEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by November 2021, and conflicting national standards shall be withdrawn at the latest by November 2021.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 80369-7:2017.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 80369-7:2021 has been approved by CEN as EN ISO 80369-7:2021 without any modification.

Contents

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*, and IEC/SC62D, *Electromedical equipment*, in collaboration with the European Committee for Standardization (CEN) Technical Committee, CEN/CENELEC JTC3/WG 2, *Small-bore connectors*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 80369-7:2016), which has been technically revised.

The main changes compared to the previous edition are as follows:

— Tolerances of several reference *connector* dimensions are increased to facilitate easier manufacturing and certification. Most of the affected tolerances are for features that do not contact the test *connector* and therefore do not affect the test results. The angle tolerance for the bearing side of the threads do contact the *connector* under test but the change in the tolerance is considered likely have minimal to no effect on test outcomes.

— Some requirements for *Luer connectors* have been separated for *semi-rigid materials* and *rigid materials* to better ensure compatibility at the extreme of the design space. Definitions of *semi-rigid material* and *rigid material* have been added.

— The distance from the tip of the *connector* to the bottom of the first complete thread profile of the internal thread (*t* dimension) has been made an *auxiliary dimension* due to the difficulty in its measurement. The functional impact of the dimension is evaluated with the resistance to separation (from axial load) functional test.

— The N1 and N2 dimensions of the female *Luer lock connector* variant A (with lugs at right angle to axis) have been changed to allow measurement from the open end of the *connector*, to better ensure compatibility at the extreme of the design space.

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

This document 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.

This document 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 document are dimensionally incompatible with any of the other *connectors* for *applications* identified in the ISO 80369 series of documents 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 document, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

In this document, the following verbal forms are used:

— “shall” indicates a requirement;

— “should” means that conformance with a requirement or a test is recommended but is not mandatory for conformance with this document;

— “may” indicates a permission;

— "can" indicates a possibility or a capability.

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

Part 7: Connectors for intravascular or hypodermic applications

1 Scope

This document specifies dimensions and requirements for the design and functional performance of *small-bore connectors* intended to be used for *connections* in intravascular *applications* or hypodermic *connections* in hypodermic *applications* of *medical devices* and *accessories*.

EXAMPLES Hypodermic syringes and needles or intravascular (IV) cannulae with male and female *Luer slip connectors* and *Luer lock connectors*.

NOTE 1 See Annex A.

NOTE 2 The *Luer connector* was originally designed for use at pressures up to 300 kPa.

This document does not specify requirements for the *medical devices* or *accessories* that use these *connectors*. Such requirements are given in particular documents for specific *medical devices* or *accessories*.

This document does not specify requirements for the following *small-bore connectors,* which are specified in other documents:

— haemodialyser, haemodiafilter and haemofilter blood compartment ports (ISO 8637 [5] and applicable portion of ISO 8638 [6] referencing blood compartment ports);

— haemodialysis, haemodiafiltration and haemofiltration equipment *connectors* (ISO 8637 [5]);

— infusion system closure piercing *connectors* (ISO 8536-4 [4]).

NOTE 3 *Manufacturers* are encouraged to incorporate the *small-bore connectors* specified in this document into *medical devices* or *accessories*, even if currently not required by the relevant particular *medical device* documents. It is expected that when the relevant particular *medical device* documents are revised, requirements for *small-bore connectors*, as specified in ISO 80369, will be included.

NOTE 4 ISO 80369-1:2018, Clause 7, specifies alternative methods of conformance with ISO 80369-1:2018, for *small-bore connectors* intended for use with intravascular *applications* or hypodermic *application medical devices* or *accessories*, which do not conform with this document.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 14971:2019, *Medical devices — Application of risk management to medical devices*

ISO 80369-1:2018, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

ISO 80369-6:2016, *Small bore connectors for liquids and gases in healthcare applications — Part 6: Connectors for neuraxial applications*