SLOVENSKI STANDARD
SIST EN ISO 80369-3:2016

01-oktober-2016

Priključki z majhnim premerom za tekočine in pline za uporabo v zdravstvu - 3. del: Priključki za enteralno uporabo (ISO 80369-3:2016)

Small-bore connectors for liquids and gases in healthcare applications - Part 3: Connectors for enteral applications (ISO 80369-3:2016)

Verbindungsstücke mit kleinem Durchmesser für Flüssigkeiten und Gase in medizinischen Anwendungen - Teil 3: Verbindungsstücke für enterale Anwendungen (ISO 80369-3:2016)

Raccords de petite taille pour liquides et gaz utilisés dans le domaine de la santé - Partie 3: Raccords destinés à des applications entérales (ISO 80369-3:2016)

Ta slovenski standard je istoveten z: **EN ISO 80369-3:2016**

ICS:

11.040.25	Injekcijske brizge, igle in katetri	Syringes, needles an catheters

SIST EN ISO 80369-3:2016 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 80369-3

August 2016

ICS 11.040.25

English version

Small-bore connectors for liquids and gases in healthcare applications - Part 3: Connectors for enteral applications (ISO 80369-3:2016)

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Verbindungsstücke mit kleinem Durchmesser für Flüssigkeiten und Gase in medizinischen Anwendungen - Teil 3: Verbindungsstücke für enterale Anwendungen (ISO 80369-3:2016)

This European Standard was approved by CEN on 25 May 2016.

CEN and CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN and CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN and CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN and CENELEC members are the national standards bodies and national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

CEN-CENELEC Management Centre:
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European foreword

This document (EN ISO 80369-3:2016) has been prepared by Technical Committee ISO/TC 210 “Quality management and corresponding general aspects for medical devices” in collaboration with Technical Committee CEN-CENELEC/TC 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 February 2017, and conflicting national standards shall be withdrawn at the latest by February 2017.

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

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive.

For relationship with EU Directive, see informative Annex ZA, which is an integral part of this document.

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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 80369-3:2016 has been approved by CEN as EN ISO 80369-3:2016 without any modification.

The following referenced documents are indispensable for the application of this document. For undated references, the latest edition of the referenced document (including any amendments) applies. For dated references, only the edition cited applies. However, for any use of this standard “within the meaning of Annex ZA”, the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When the ISO or IEC standard is referred to in the ISO text standard, this must be understood as a normative reference to the parallel EN standard or dated ISO standard, as outlined below, including the foreword and the Annexes Z.

NOTE The way in which these references documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

Table — Correlations between normative references and dated EN and ISO/IEC standards

Normative references as listed in Clause 2	Equivalent dated standard	
	EN	ISO/IEC
ISO 5356-1:2004	EN ISO 5356-1:2004	ISO 5356-1:2004
ISO 5356-1:2015	EN ISO 5356-1:2015	ISO 5356-1:2015
ISO 5356-2:2006	EN ISO 5356-2:2007	ISO 5356-2:2006
ISO 5356-2:2012	EN ISO 5356-2:2012	ISO 5356-2:2012
ISO 8185:2007	EN ISO 8185:2009	ISO 8185:2007
EN 13544-2:2002	EN 13544-2:2002	—
EN 13544-2:2002+A1:2009	EN 13544-2:2002+A1:2009	—
ISO 80369-1:2010	EN ISO 80369-1:2010	ISO 80369-1:2010
ISO 80369-6:2016	EN ISO 80369-6:2016	ISO 80369-6:2016
ISO 80369-7:—[a]	EN ISO 80369-7:—[a]	ISO 80369-7:—[a]
ISO 80369-20:2015	EN ISO 80369-20:2015	ISO 80369-20:2015
ASTM D638-10	—	—
ASTM D790-10	—	—

[a] To be published.

Annex ZA
(informative)

Relationship between this document and the Essential Requirements of EU Directive 93/42/EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of Directive 93/42/EEC on Medical Devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative clauses of this standard confers, within the limits of the scope of this standard, a presumption of conformity with the relevant Essential Requirements of that Directive.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC / Directive 90/385/EEC, as amended by 2007/47/EC. This means that risks have to be reduced "as far as possible", "to a minimum", "to the lowest possible level", "minimized" or "removed", according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with essential requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the directive.

NOTE 3 This Annex ZA is based on Normative References according to Table of References, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 — Correspondence between this document and Directive 93/42/EEC

Clause(s)/subclause(s) of this Document	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
6.1	7.5	
4.1, 5, 6.3, 6.4, 6.5, 6.6	9.1	
6.2	12.7.4	
4.1, 5, 6.3, 6.4, 6.5, 6.6	12.8.1	This Essential Requirement is partially covered in that by ensuring that the CONNECTOR does not leak and can only be connected to intended MEDICAL DEVICES or ACCESSORIES it permits a MEDICAL DEVICE to be capable of controlling the flowrate.

WARNING — Other requirements and other EU Directives may be applicable to the products falling within the scope of this document.

For devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC on Machinery, in accordance with Article 3 of Directive 93/42/EEC the following Table ZA.2 details the relevant essential health and safety requirements of Directive 2006/42/EC on Machinery to the extent to which they are more specific than those of Directive 93/42/EEC along with the corresponding clauses of this Document. Table ZA.2, however, does not imply any citation in the OJEU under the machinery directive and thus does not provide presumption of conformity for the machinery directive.

Table ZA.2 — Relevant Essential Health and Safety Requirements (EHSRs) from Directive 2006/42/EC on machinery that are addressed by this document

Clause(s)/subclause(s) of this Document	EHSR of 2006/42/EC	Qualifying remarks/Notes
Clause 4, Clause 5, Clause 6	1.5.4	

INTERNATIONAL STANDARD

ISO 80369-3

First edition
2016-07-01

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

Part 3: Connectors for enteral applications

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

Partie 3: Raccords destinés à des applications entérales

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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/SC 62D, *Electromedical equipment.* The draft was circulated for voting to the national bodies of both ISO and IEC.

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 2: Connectors for breathing systems and driving gases applications*

— *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*

An additional part on connectors for urethral and urinary applications is planned.

Introduction

This part of ISO 80369 was developed because of several incidents, with catastrophic consequences, resulting from firstly, the administration of inappropriate medication into the alimentary canal and secondly, from ENTERAL solutions being administered via incorrect routes, including intravenously and into the airway. Many incidents were reported leading to international recognition of the importance of these issues, and a need was identified to develop specific CONNECTORS for MEDICAL DEVICES and their ACCESSORIES used to deliver feed via the ENTERAL route.

The ISO 80369 series has been developed to prevent misconnection between SMALL-BORE CONNECTORS used in different APPLICATIONS. ISO 80369-1 specifies the requirements necessary to verify the designs 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, the dimensions, and the drawings of SMALL-BORE CONNECTORS intended to be used in ENTERAL 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 for SMALL-BORE CONNECTORS, except as indicated in G.2. If fitted to the relevant MEDICAL DEVICES and ACCESSORIES, these CONNECTORS are to reduce the RISK of medication and liquid nutritional formula intended for ENTERAL administration from being delivered via an alternative route, such as intravenously or via an airway device.

During the development of this International Standard, the committee decided to cover the whole ENTERAL system but to have a separate International Standard for reservoir CONNECTORS. ISO 18250-3 specifies the requirements for ENTERAL reservoir CONNECTORS. This part of ISO 80369 includes the interface dimensions for SMALL-BORE CONNECTORS for access ports and PATIENT interfaces on ENTERAL feeding sets and ENTERAL syringes.

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 International Standard conform to usage described in 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, 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.

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

Part 3: Connectors for enteral applications

1 * Scope

This part of ISO 80369 specifies the dimensions and requirements for the design and functional performance of SMALL-BORE CONNECTORS intended to be used for CONNECTIONS on ENTERAL MEDICAL DEVICES and ACCESSORIES.

NOTE 1 ENTERAL MEDICAL DEVICES include ENTERAL feeding sets, ENTERAL drainage sets, ENTERAL syringes, and PATIENT interface devices including access ports.

This part of ISO 80369 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.

This part of ISO 80369 does not specify requirements for SMALL-BORE CONNECTORS that are used for the following:

— gastric suction-only MEDICAL DEVICES;

— oral-only MEDICAL DEVICES;

EXAMPLE An oral tip syringe that is not intended to connect to another MEDICAL DEVICE. It is intended to administer directly to the PATIENT'S mouth.

— pressurizing and depressurizing the retention mechanism (e.g. balloon) used to hold invasive ENTERAL MEDICAL DEVICES in place;

— MEDICAL DEVICES for rectal drainage, rectal administration of medicines or fluid, and any other rectal access MEDICAL DEVICE;

— gastrointestinal endoscopy equipment;

— skin level gastrostomy MEDICAL DEVICES.

NOTE 2 MANUFACTURERS are encouraged to incorporate the SMALL-BORE CONNECTORS specified in this part of ISO 80369 into ENTERAL MEDICAL DEVICES or ACCESSORIES, even if currently not required by the relevant particular MEDICAL DEVICE standards. It is expected that when the relevant particular MEDICAL DEVICE standards are revised, requirements for SMALL-BORE CONNECTORS, as specified in ISO 80369, will be included.

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 14971:2007, *Medical devices — Application of risk management to medical devices*

ISO 80369-1:2010, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

