SLOVENSKI STANDARD
SIST EN ISO 80369-1:2013

01-september-2013

Konektorji z majhnim premerom za tekočine in pline za medicinsko uporabo - 1. del: Splošne zahteve

Small bore connectors for liquids and gases in healthcare applications - Part 1: General requirements

Verbindungsstücke mit kleinem Durchmesser für Flüssigkeiten und Gase in medizinischen Anwendungen - Teil 1: Allgemeine Anforderungen

Joints de petite dimension pour liquides et gaz pour des applications en santé - Partie 1: Exigences générales

Ta slovenski standard je istoveten z: **EN ISO 80369-1:2010**

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment
11.040.20	Transfuzijska, infuzijska in injekcijska oprema	Transfusion, infusion and injection equipment

SIST EN ISO 80369-1:2013 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 80369-1

December 2010

ICS 11.040.10; 11.040.20

Supersedes EN 15546-1:2008

English version

Small bore connectors for liquids and gases in healthcare applications - Part 1: General requirements (ISO 80369-1:2010)

Raccords de petite taille pour liquides et gaz utilisés dans le domaine de la santé - Partie 1: Exigences générales (ISO 80369-1:2010)

Verbindungsstücke mit kleinem Durchmesser für Flüssigkeiten und Gase in medizinischen Anwendungen - Teil 1: Allgemeine Anforderungen (ISO 80369-1:2010)

This European Standard was approved by CEN on 14 December 2010.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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Foreword

This document (EN ISO 80369-1:2010) 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/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 June 2011, and conflicting national standards shall be withdrawn at the latest by June 2011.

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 supersedes EN 15546-1:2008.

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.

Compared to EN 15546-1:2008 the following changes were implemented:

a) Clause 3 "Terms and definitions" has been editorially revised and amended by the terms "accessory", "breathing system", "non-interconnectable", "patient" and "responsible organization". The terms "risk" and "safety" have been cancelled and replaced by a general reference to the appropriate terms given in EN ISO 14971 and IEC 62366;

b) Clause 4 on materials has been amended by a reference to two ASTM standards for tests on conformity;

c) Clause 5 on the requirements has been completely revised and amended by a sub-section on incompatibility;

d) A new Clause 6 on additional applications has been added;

e) Clause 7 (respectively Clause 6 in EN 15546-1) on the assessment of new designs (validation) has been completely revised, more detailed in the structure and amended. Especially the sections on the proposal initiation (7.2) and on the procedure to assess acceptability and non-interconnectable characteristics (7.3) have been stated more detailed;

f) Annex A "Rationale" has been completely revised by providing the reasons for this standard by clauses. In addition the Table A.1 on risk analysis of possible misconnections has been cancelled;

g) A new Annex B "Mechanical tests for verifying non-interconnectable characteristics" has been added;

h) Annex C "Applications" (respectively Clause B in EN 15546-1) has been editorially revised;

i) Annex C "Small bore connectors for vascular systems applications" of EN 15546-1 has been cancelled;

j) A new Annex D "Reference to the Essential Principles" according ISO/TR 16142 has been added;

k) Annex ZA on the relationship to the Medical Device Directive (93/42/EWG) has been aligned;

l) The Bibliography has been updated and amended;

m) A new clause Terminology has been added at the end of the standard;

n) Editorial revision in alignment with the overtaking of the original European Standard into an International Standard.

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, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 80369-1:2010 has been approved by CEN as a EN ISO 80369-1:2010 without any modification.

Annex ZA
(informative)

Relationship between this European Standard 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 Union and the European Free Trade Association to provide a means to conforming to Essential Requirements of the New 576 Approach Directive 93/42/EEC, Council Directive of 14 June 1993 on the approximation of the laws of the Member States concerning medical devices" (Medical Device Directive).

Once this document 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 clauses of this document given in Table ZA.1, within the limits of the scope of this document, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

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

Clause/subclause of this Document	Corresponding Essential Requirement of Directive 93/42/EEC	Qualifying remarks/notes
all	1, 2	
4, 5	7.5, 7.6, 9.1, 12.7.4	
6	6 a, 7.5, 7.6, 9.1, 12.7.4	

WARNING: Other requirements and other EU Directives may be applicable to the products falling within the 585 scope of this International Standard.

INTERNATIONAL STANDARD

ISO 80369-1

First edition
2010-12-15

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

Part 1: General requirements

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

Partie 1: Exigences générales

Reference number
ISO 80369-1:2010(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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 80369-1 was prepared by a Joint Working Group of Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*, IEC/TC 62, *Electrical equipment*, Subcommittee SC D, *Electrical equipment in medical practice* and CEN/CENELEC TC 3/WG 2, *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*

The following parts are under preparation:

— *Part 2: Connectors for breathing systems and driving gases applications*

— *Part 3: Connectors for enteral applications*

— *Part 4: Connectors for urethral and urinary applications*

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

— *Part 6: Connectors for neuraxial applications*

— *Part 7: Connectors for intravascular or hypodermic applications*

