VÄIKESE LÄBIMÕÕDUGA ÜHENDUSLIITMIKUD VEDELIKU JA GAASIGA TÖÖTAVATELE MEDITSIINISEADMETELE. OSA 20: ÜLDISED KATSEMEETODID

Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods (ISO 80369-20:2015)

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 80369-20:2015 sisaldab Euroopa standardi EN ISO 80369-20:2015 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 80369-20:2015 consists of the English text of the European standard EN ISO 80369-20:2015.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 20.05.2015.	Date of Availability of the European standard is 20.05.2015.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 80369-20

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English Version

Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods (ISO 80369-20:2015)

Raccords de petite taille pour liquides et gaz utilisés dans le domaine de la santé - Partie 20: Méthodes d'essai communes (ISO 80369-20:2015)

Verbindungsstücke mit kleinem Durchmesser für Flüssigkeiten und Gase in medizinischen Anwendungen - Teil 20: Allgemeine Prüfverfahren (ISO 80369-20:2015)

This European Standard was approved by CEN on 5 March 2015.

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.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN ISO 80369-20:2015 E

Foreword

This document (EN ISO 80369-20:2015) 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 November 2015, and conflicting national standards shall be withdrawn at the latest by November 2015.

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(s).

For relationship with EU Directive(s), 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 80369-20:2015 has been approved by CEN as EN ISO 80369-20:2015 without any modification.

Annex ZA
(informative)

Relationship between this part of EN ISO 80369 and the essential requirements of EU Directive 93/42/EEC

This part of EN ISO 80369 has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means to conforming to essential requirements of the New 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 part of EN ISO 80369 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 confers, within the limits of the scope of this part of EN ISO 80369, a presumption of conformity with the corresponding essential requirements of that directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this part of EN ISO 80369 and Directive 93/42/EEC

Clause(s)/sub-clause(s) of this part of EN ISO 80369	**Essential requirements (ERs) of EU Directive 93/42/EEC**	**Qualifying remarks/notes**
4, Annex B, Annex C	7.5	
4, Annex D	7.6	
4, Annex F, Annex G, Annex H, Annex I	9.1	
4, Annex E	12.7.1	
4	12.7.4	

WARNING Other requirements and other EU Directives might be applicable to the products falling within the scope of this part of EN ISO 80369.

For devices which are also machinery within the meaning of Directive 2006/42/EC on Machinery, Article 2(a), in accordance with Directive 93/42/EEC, Article 3, 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 part of EN ISO 80369. 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)/sub-clause(s) of this part of EN ISO 80369	**EHSR of 2006/42/EC**	**Qualifying remarks/notes**
4	1.5.4	

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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.

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*

The following parts are under preparation:

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

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

Introduction

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 ISO 80369-1 and Clause 3: 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.

The following paragraph is directed to authorities with jurisdiction and is not intended to address clinical implementation.

The attention of Member Bodies and National Committees is drawn to the fact that equipment manufacturers and testing organizations might need a transitional period following publication of a new, amended or revised ISO or IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than three years from the date of publication for equipment newly designed and not earlier than five years from the date of publication for equipment already in production.

This part of ISO 80369 describes the common TEST METHODS for evaluating the performance requirements of the SMALL-BORE CONNECTORS specified in this series.

During the development of the ISO 80369- series, it became evident that many of the TEST METHODS were very similar for each of the APPLICATIONS. It was therefore decided to standardize all the TEST METHODS into a separate part of the series to prevent unnecessary duplication and minor differences. It is also recognized that not all CONNECTORS can be evaluated using each TEST METHOD in this part. The TEST METHODS applicable to each CONNECTOR are specified in the respective part of the ISO 80369- series.