Väikese läbimõõduga ühendusliitmikud vedeliku ja gaasiga töötavatele meditsiiniseadmetele. Osa 1: Üldnõuded (ISO 80369-1:2010)

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

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 80369-1:2010 sisaldab Euroopa standardi EN ISO 80369-1:2010 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 80369-1:2010 consists of the English text of the European standard EN ISO 80369-1:2010.
Standard on kinnitatud Eesti Standardikeskuse 31.12.2010 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 31.12.2010 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 15.12.2010.	Date of Availability of the European standard text 15.12.2010.
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EUROPEAN STANDARD

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EN ISO 80369-1

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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.

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Introduction

In the 1990s concern grew regarding the proliferation of MEDICAL DEVICES fitted with Luer CONNECTORS and the reports of PATIENT death or injury arising from misconnections that resulted in the inappropriate delivery of enteral solutions, intrathecal medication or compressed gases.

Concerns regarding the use of Luer CONNECTORS with enteral feeding tubes and gas sampling and gas delivery systems were raised with CEN/BT and the European Commission. In November 1997 the newly created CHeF steering group set up a Forum Task Group (FTG) to consider the problem.

The FTG produced CEN Report CR 13825, in which they concluded that there is a problem arising from the use of a single CONNECTOR design to a number of incompatible APPLICATIONS. In a coronary care unit there are as many as 40 Luer CONNECTORS on the MEDICAL DEVICES used with a single PATIENT. Therefore it is not surprising that misconnections are made.

MEDICAL DEVICES have for many years followed the established principle of "safety under single fault conditions". Simply stated this means that a single fault should not result in an unacceptable RISK. This principle is embodied in the requirements of numerous MEDICAL DEVICE standards. Extending this principle to the application of Luer CONNECTORS, i.e. that misconnection should not result in an unacceptable RISK to a PATIENT, the FTG recommended that the Luer CONNECTOR should be restricted to MEDICAL DEVICES intended to be connected to the vascular system or a hypodermic syringe. In addition, new designs of SMALL-BORE CONNECTORS should be developed for other APPLICATIONS, and these should be NON-INTERCONNECTABLE with Luer CONNECTORS and each other.

ISO/TR 16142:2006 addresses this type of problem in Essential Principle A.1.2:

> The solutions adopted by the manufacturer for the design and construction of the devices should conform to safety principles, taking into account the generally acknowledged state of the art.
>
> In selecting the most appropriate solutions, the manufacturer should apply the following principles in the following order:
>
> — identify hazards and the associated risks arising from the intended use and foreseeable misuse;
>
> — eliminate or reduce risks as far as possible (inherently safe design and construction);

It is understood that SMALL-BORE CONNECTOR systems cannot be designed to overcome all chances of misconnection or to eliminate deliberate misuse. However, a number of steps that would improve the current situation and lead to greater PATIENT safety can be taken. This will only be achieved through a long-term commitment involving industry, healthcare professionals, MEDICAL DEVICE purchasers and MEDICAL DEVICE regulatory authorities.

This is the first edition of ISO 80369-1 and it cancels and replaces EN 15546-1:2008 which has been editorially revised.

Part 1 of this International Standard and its parts are intended to be the reference documents in which the necessary measures and PROCEDURES to prevent misconnection between SMALL-BORE CONNECTORS used in different APPLICATIONS and designs of SMALL-BORE CONNECTORS for APPLICATIONS are listed. The JWG of ISO/TC 210 – IEC 62D and CEN/CENELEC TC 3/WG 2 is developing this series of standards in such a way that ISO 80369-1 includes general requirements to prevent misconnections between SMALL-BORE CONNECTORS used in different APPLICATIONS.

This part 1 of this International Standard contains general requirements to ensure the prevention of misconnection between SMALL-BORE CONNECTORS used in different APPLICATIONS. Subsequent parts of this series of standards are expected to include requirements with regard to the CONNECTORS used in different APPLICATION categories.

In this standard, 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 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS TYPE.

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

— "shall" means that compliance with a requirement or a test is mandatory for compliance with this standard;

— "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

— "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 attention of Member Bodies and National Committees is drawn to the fact that equipment MANUFACTURERS and testing organizations may 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 3 years from the date of publication for equipment newly designed and not earlier than 5 years from the date of publication for equipment already in production.

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

Part 1: General requirements

1 Scope

This part of ISO 80369 specifies general requirements for SMALL-BORE CONNECTORS, which convey liquids or gases in healthcare APPLICATIONS. These SMALL-BORE CONNECTORS are used in MEDICAL DEVICES or ACCESSORIES intended for use with a PATIENT.

This International Standard also specifies the healthcare fields in which these SMALL-BORE CONNECTORS are intended to be used.

These healthcare fields of use include, but are not limited to, APPLICATIONS for:

— BREATHING SYSTEMS and driving gases,

— enteral and gastric,

— urethral and urinary,

— limb cuff inflation,

— neuraxial devices, and

— intravascular or hypodermic.

SMALL-BORE CONNECTORS as specified in this International Standard are NON-INTERCONNECTABLE with:

— the cones and sockets of ISO 5356-1:2004 and ISO 5356-2:2006;

— the temperature sensor CONNECTOR and mating ports specified in Annex DD of ISO 8185:2007; and

— the nipples of EN 13544-2:2002.

This International Standard provides the methodology to assess NON-INTERCONNECTABLE characteristics of SMALL-BORE CONNECTORS based on their inherent design and dimensions in order to reduce the RISK of misconnections between MEDICAL DEVICES or between ACCESSORIES for different APPLICATIONS and to reduce the RISK of misconnections between MEDICAL DEVICES with 6 % Luer CONNECTORS, and all other non-Luer CONNECTORS that will be developed under future parts of this series of standards.

It does not specify requirements for the MEDICAL DEVICES or ACCESSORIES that use these SMALL-BORE CONNECTORS. Such requirements are given in particular International Standards for specific MEDICAL DEVICES or ACCESSORIES.

NOTE 1 It is intended that new designs of SMALL-BORE CONNECTORS will be included in this series of standards after they have been assessed according to the PROCEDURE given in Clause 6.

NOTE 2 MANUFACTURERS are encouraged to incorporate the SMALL-BORE CONNECTORS specified in this series of standards into MEDICAL DEVICES, medical systems 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 the series of standards will be included.

NOTE 3 MANUFACTURERS and RESPONSIBLE ORGANIZATIONS are encouraged to report their experience with the SMALL-BORE CONNECTORS specified in this series of standards to the Secretariat of ISO/TC 210 to consider this feedback during the revision of the relevant part of this series of standards.

2 Normative references

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

ISO 5356-1:2004, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*

ISO 5356-2:2006, *Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors*

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

EN 13544-2:2002, *Respiratory therapy equipment — Part 2: Tubing and connectors*

IEC 62366:2007, *Medical devices — Application of usability engineering to medical devices*

3 Terms and definitions

For the purposes of this document, the terms and definitions specified in ISO 14971:2007, IEC 62366:2007 and the following apply. For convenience, the sources of all defined terms used in this document are given in an index on page 17.

3.1
ACCESSORY
additional part(s) for use with MEDICAL DEVICE in order to:

— achieve the INTENDED USE,

— adapt it to some special use,

— facilitate its use,

— enhance its performance, or

— enable its functions to be integrated with those of other MEDICAL DEVICES

[Modified from IEC 60601-1:2005, definition 3.3]

3.2
APPLICATION
specific healthcare field in which a SMALL-BORE CONNECTOR is intended to be used

NOTE Annex C lists SMALL-BORE CONNECTOR APPLICATIONS.

3.3
BREATHING SYSTEM
inspiratory and expiratory pathways through which gas flows at respiratory pressures and bounded by the port through which fresh gas enters, the PATIENT CONNECTION port and the exhaust port

