SLOVENSKI STANDARD
oSIST prEN ISO 80369-1:2009

01-november-2009

Priključ ki z majhnim premerom za tekoče ine in pline za uporabo v zdravstvu - 1. del: Splošne zahteve (ISO/DIS 80369-1:2009)

Small bore connectors for liquids and gases in healthcare applications - Part 1: General requirements (ISO/DIS 80369-1:2009)

Verbindungsstücke mit kleinem Durchmesser für Flüssigkeiten und Gase in medizinischen Anwendungen - Teil 1: Allgemeine Anforderungen (ISO/DIS 80369-1:2009)

Joints de petite dimension pour liquides et gaz pour des applications en santé - Partie 1: Exigences générales (ISO/DIS 80369-1:2009)

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

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

oSIST prEN ISO 80369-1:2009 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

DRAFT
prEN ISO 80369-1

June 2009

ICS 11.040.10; 11.040.20

Will supersede EN 15546-1:2008

English version

Small bore connectors for liquids and gases in healthcare applications - Part 1: General requirements (ISO/DIS 80369-1:2009)

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Verbindungsstücke mit kleinem Durchmesser für Flüssigkeiten und Gase in medizinischen Anwendungen - Teil 1: Allgemeine Anforderungen (ISO/DIS 80369-1:2009)

This draft European Standard is submitted to CEN members for parallel enquiry. It has been drawn up by the Technical Committee CEN/CLC/TC 3.

If this draft becomes a European Standard, 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.

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

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Warning : This document is not a European Standard. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a European Standard.

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Foreword

This document (prEN ISO 80369-1:2009) 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 document is currently submitted to the parallel Enquiry.

This document will supersede 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 EC Directive(s).

Endorsement notice

The text of ISO/DIS 80369-1:2009 has been approved by CEN as a prEN ISO 80369-1:2009 without any modification.

DRAFT INTERNATIONAL STANDARD ISO/DIS 80369-1

ISO/TC **210** Secretariat: **ANSI**

Voting begins on **2009-06-18** Voting terminates on **2009-11-18**

Small bore connectors for liquids and gases in healthcare applications —

Part 1:
General requirements

Joints de petite dimension pour liquides et gaz pour des applications en santé —

Partie 1: Exigences générales

ICS 11.040.10; 11.040.20

This draft is submitted to a parallel enquiry in ISO and a CDV vote in the IEC.

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO-lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five-month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

In accordance with the provisions of Council Resolution 15/1993 this document is circulated in the English language only.

Conformément aux dispositions de la Résolution du Conseil 15/1993, ce document est distribué en version anglaise seulement.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.

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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/IEC 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 TC3/WG 2, *Small-bore connectors*.

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

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 for respiratory use*

— *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*

In this standard, the following print types are used:

— Requirements and definitions: roman type.

— *Test specifications: italic 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: bolded roman 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.

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 incompatible 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.

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 TC3/WG 2 is developing this series of standards in such a way that ISO 80369-1 include 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.