SLOVENSKI STANDARD
SIST EN 15546-1:2008

01-julij-2008

Priključ ki z majhnim premerom za tekoļ ine in pline za uporabo v zdravstvu - 1. del: Sploġne 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

Raccords de petite taille pour liquides et gaz dans les applications médicales - Partie 1 : Exigences générales

Ta slovenski standard je istoveten z: **EN 15546-1:2008**

ICS:

11.040.01	Medicinska oprema na splošno	Medical equipment in general

SIST EN 15546-1:2008 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 15546-1

May 2008

ICS 11.040.10

English version

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

Raccords de petite taille pour liquides et gaz dans les applications médicales - Partie 1 : Exigences générales

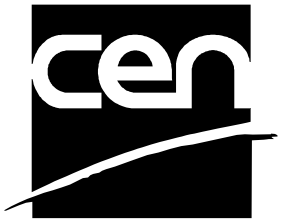
Verbindungsstücke mit kleinem Durchmesser für Flüssigkeiten und Gase in medizinischen Anwendungen - Teil 1: Allgemeine Anforderungen

This European Standard was approved by CEN on 21 March 2008.

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 Management Centre or to any CEN or 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/or CENELEC member into its own language and notified to the CEN Management Centre has the same status as the official versions.

CEN and CENELEC members are the national standards bodies and national electrotechnical committees, respectively, of Austria, Belgium, Bulgaria, 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.



CEN Management Centre:
rue de Stassart, 36 B-1050 Brussels

CENELEC Central Secretariat:
rue de Stassart, 35 B-1050 Brussels

Contents

Page

Foreword

This document (EN 15546-1:2008) has been prepared by CEN/BT/TF 123 "'Small-bore connectors for liquids and gases in healthcare applications", the secretariat of which is held by AFNOR.

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 2008, and conflicting national standards shall be withdrawn at the latest by November 2008.

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.

Following the recommendations given in the CEN Report 13825, Luer connectors - A report to CEN CHeF from the CEN forum task group "Luer fittings", this European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association.

This part 1 of the standard contains general requirements to ensure the prevention of cross-connection between small bore connectors used in different fields of medical applications. It is intended that subsequent parts include the dimensions and drawings of connectors allocated to specific medical applications.

This European Standard supports the essential requirements of the EU Directive(s). For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this 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, 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.

Introduction

In the 1990s concern grew regarding the proliferation of 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 CEN Healthcare Forum (CheF) steering group set up a Forum Task Group (FTG) to consider the problem.

The FTG produced CEN Report “CR 13825:2000" [2], in which they concluded that there is a problem arising from the application of a single connector design to a number of incompatible applications. In a coronary care unit there are as many as 40 connectors on the devices used with a single patient. Therefore, it is not surprising that misconnections are made.

For many years medical devices have followed the established principle of “safety under single fault conditions”. Simply stated, this means that a single fault should not result in a hazard. 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 a patient hazard, the FTG recommended that the Luer connector should be restricted to devices intended to be connected to the vascular system or a hypodermic syringe. In addition, new designs of small bore connector should be developed for non-intravascular applications, and these should be incompatible with Luer connectors and each other.

NOTE Condition in which a single means for reducing a RISK is defective or a single abnormal condition is present.

The Medical Device Directive 93/42/EEC addresses this type of problem in Essential Requirement 1.2. (*solutions adopted for the design and construction of devices must conform to safety principles, taking into account the generally acknowledged state of the art. In seeking the most appropriate solutions, the manufacturer must apply the following principles in the following order:*

eliminate or reduce risk as far as possible (inherently safe design and construction, etc.)

and 9.1 *(if the device is intended for use in combination with other devices or equipment, the whole combination, including the connector system must be safe, etc.*)

CEN/BT/Task Force 123 ‘Small bore connectors for liquids and gases in healthcare applications’ was established to carry forward the recommendations of CR 13825 [2]. It was recognised that small bore connector systems could not be designed to overcome all chances of misconnection or to eliminate deliberate misuse. However, a number of steps could be taken that would improve the current situation and lead to greater patient safety. This will only be achieved through a long-term commitment involving industry, healthcare professionals, device purchasers and medical device regulatory authorities.

This part 1 of European Standard and its parts are intended to be the reference documents in which all designs of small bore connectors for medical applications are listed. CEN/BT/TF 123 has developed this series of Standards in such a way that the standard includes general requirements to ensure the prevention of cross-connection between connectors used in different fields of medical application.

1 Scope

This part of the series of European Standards specifies general requirements for small bore connectors used in specific medical applications to convey liquids or gases to or from a patient or via intermediate systems.

It is intended to be a reference document that can be used as a tool to minimise the risk of misconnections of small bore connectors between different medical applications.

It provides a framework to assess non-interchangeability of small bore connectors based on their inherent design and dimensions.

It does not specify requirements for the medical devices and accessories on which these connectors are provided. Such requirements are given in particular International or European Standards for specific medical devices and accessories.

NOTE 1 It is intended that new designs of small bore connectors should 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 or systems, even if they are not currently required by the particular device standards. It is expected that when the particular device standards are revised, requirements for small bore connectors as specified in the series of Standards will be included.

NOTE 3 Manufacturers and users are encouraged to report their experience with the small bore connectors specified in this series of Standards to the technical committee or task force in charge of the elaboration of the present series of Standards, 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.

prEN 15546-2, Small bore connectors for liquids and gases in healthcare applications - Part 2 - Connectors for respiratory applications

EN 1707, Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment - Lock fittings

EN 20594-1, Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements (ISO 594-1: 1986)

3 Terms and definitions

For the purpose of this series of Standards, the following terms and definitions apply:

3.1
application (specific application)
medical applications of small bore connectors as listed in Annex B (informative)

3.2
connection
means by which at least two engaged small bore connectors convey a gas or liquid from one device to another

3.3
rigid material
material with a modulus of elasticity either in flexure or in tension greater than 7 000 kg/cm² (100,000 psi) at 23 °C and 50 % relative humidity when tested in accordance with ASTM methods D 747 or D 790: Test for stiffness of plastics

3.4
semi-rigid material
material with a modulus of elasticity either in flexure or in tension, between 700 and 7 000 kg/cm² (10,000 and 100,000 psi) at 23 °C and 50 % relative humidity when tested in accordance with ASTM methods D 747 or D 790: Test for stiffness of plastics

3.5
risk
combination of the probability of occurrence of harm and the degree of severity of the harm (term taken from ISO 14971:2007 [3])

3.6
safety
freedom from unacceptable risk (term taken from ISO 14971:2007 [3])

3.7
small bore connector
connector having a maximum bore diameter of 8,5 mm

4 Materials used for small bore connectors

Small bore connectors shall be made of rigid or semi-rigid materials (see definitions in 3.3 and 3.4).

5 Small bore connector requirements for specific medical applications

5.1 General

Small bore connectors for different applications shall not be compatible.

5.2 Small bore connector applications

5.2.1 General

The specific medical applications and requirements of small bore connectors included in this series of Standards or given in other standards shall be as follows:

NOTE An overview of the allocation of small bore connectors, including some typical examples, is given in Annex B (informative).

5.2.2 Small bore connectors for vascular or hypodermic applications
Small bore connectors intended to be used for connections in vascular or hypodermic applications shall be in accordance with EN 1707 and EN 20594-1.

NOTE Specific hypodermic applications include e.g. subcutaneous, intra-muscular and intraperitoneal injections and infiltrations.

5.2.3 Small bore connectors for enteral applications
Small bore connectors intended to be used for connections in enteral applications shall be in accordance with the requirements given in the relevant part of this Standard.

5.2.4 Small bore connectors for respiratory applications
Small bore connectors intended to be used for connections in respiratory applications shall be in accordance with the requirements given in prEN 15546-2.

5.2.5 Small bore connectors for neuraxial applications
Small bore connectors intended to be used for connections in neuraxial applications shall be in accordance with the requirements given in the relevant part of this Standard.

5.2.6 Small bore connectors for urethral / urinary applications
Small bore connectors intended to be used for connections in urethral/urinary applications shall be in accordance with the requirements given in the relevant part of this Standard.

5.2.7 Small bore connector for circumferential cuff inflation system (for limbs) applications
Small bore connectors intended to be used for connections in circumferential cuff inflation system (for limbs) applications shall be in accordance with the requirements given in the relevant part of this Standard.

5.2.8 Alternative connectors
Small bore connectors different from those detailed in this part of Standard shall be presumed to be in compliance with the safety objectives of this standard if it can be demonstrated that an equivalent degree of safety is obtained (i.e. compliance with requirements presumes that risks have been mitigated to acceptable levels) unless objective evidence to the contrary becomes available.

NOTE 1 Objective evidence is usually obtained through post-market surveillance.

Evidence of an equivalent degree of safety shall be provided by the manufacturer.

NOTE 2 Regional or national regulations usually require the provision of evidence to competent authority or a conformity assessment body e.g. notified body in the European Economic Area (EEA) upon request.

6 Procedure to assess proposed new small bore connector for inclusion in this series of Standards

6.1 General

To ensure that new designs of small bore connectors are non-interchangeable with the small bore connectors covered by this series of Standards, or other small bore connectors commonly known to be used in the same patient environment, the procedure shall be as follows:

- Make a paper comparison of the design of the proposed small bore connector with the design details in this series of Standards;
- Produce test samples and carry out practical tests as described below;
- Confirm the results of the design review and practical tests with at least two other parties with sufficient expertise.

NOTE 1 The three parties involved in the design review and practical tests should originate from three different member bodies. The parties involved in the design review may also carry out the practical tests.

NOTE 2 Attention is drawn to the possibility that new designs may be subject to patent rights. CEN cannot be held responsible for identifying any or all such patents rights

6.2 Procedure to be carried out by proposer of new small bore connector to assess the non-interchangeability with existing small bore connectors

- Select at least three parties to carry out the design review and practical tests and ensure that they have sufficient technical expertise;
- Obtain all necessary documentation, including dimension requirements and drawings of small bore connectors already included in this series of Standards, or due to be included by amendment or revision. Compare with dimension requirements and drawings of proposed new small bore connector to ensure theoretical non-interchangeability;
- Produce sufficient test samples and carry out practical tests to ensure non-interchangeability with small bore connectors already included in this series of Standards or due to be included by amendment or revision;
- Prepare reports of three or more design reviews and practical tests and submit them for consideration to the technical committee or task force in charge of the elaboration of the present series of Standards.

6.3 Design review

- A group with sufficient technical expertise within the technical committee or task force in charge of the elaboration of the present series of standards shall be assigned the responsibility of reviewing the design and practical test results;

- The group shall be given a time scale to carry out the review and the proposer notified of this time scale;
- The group shall assess the results and prepare a report to the technical committee or task force in charge of the elaboration of the present series of standards giving its conclusions;
- Results shall be presented and discussed within the technical committee or task force in charge of the elaboration of the present series of standard for deciding whether or not the proposed small bore connector is suitable for inclusion in this series of Standards for the application intended;
- Proposer shall be informed of the conclusion;
- If the proposed small bore connector is suitable for inclusion in this series of Standards, the relevant committee shall initiate the appropriate steps to include the new design by amendment or revision of the relevant part of this series of Standards.

Annex A
(informative)

Rationale for this Standard

Advances in modern medicine have led to a significant rise in the number of medical devices attached to patients. Many of these devices fall into the categories of monitoring devices, diagnostic devices and drug delivery devices.

Such devices perform a variety of similar, but not interchangeable functions. Examples include: intravenous fluid delivery, enteral feeding, respiratory gas sampling, non-invasive blood pressure measurement and the injection of intrathecal medication. Despite the varied nature of the functions performed, many of these devices continue to use a universal system of small bore connectors based on the 6 % Luer tapered connector.

The universal nature of the connectors used, and the proximity of several different connectors around a single patient make accidental misconnections inevitable. The consequences of such misconnections are variable but a significant number are actually or potentially fatal.

Serious and usually fatal misconnections include the intravenous injection of air, the intravenous injection of enteral feeds and the intrathecal injection of vincristine. Less disastrous misconnections such as the enteral administration of intravenous fluids may not directly harm the patient but will lead to a failure of the intended administration.

Introducing a series of non-interchangeable, small bore connectors for medical devices made from rigid or semi-rigid materials will help to reduce the incidence of misconnections and lead to a direct improvement in patient safety. Rigid or semi-rigid materials have been specified to eliminate the possibility of forcing a fit between incompatible connectors made from flexible materials. Any such series must also include the 6 % Luer which should be reserved for connections in vascular applications or with a hypodermic syringe intended for specific other medical applications such as subcutaneous, intra-muscular and intraperitoneal injections and infiltrations.

CEN/BT/TF 123 carried out an extensive risk analysis of possible misconnections that might result when Luer connectors are used in different applications. The results of this analysis are shown in Table A.1

Terms and definitions used in the risk analysis table:

Severity level (SL)	1 = minor injury or discomfort
	2 = reversible injury
	3 = death or irreversible injury
Probability level (PL)	1 = low
	2 = medium
	3 = high
Risk category (RC)	$RC = SL^2 \times PL^2$