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

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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

This draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the CEN/BT/TF 123.

If this draft becomes a European Standard, CEN 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.

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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.

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COMITÉ EUROPÉEN DE NORMALISATION
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Foreword

This document (prEN 15546-1:2006) has been prepared by Technical Committee CEN/BT/TF 123 “Small bore connectors for liquids and gases in healthcare applications", the secretariat of which is held by AFNOR.

This document is currently submitted to the CEN Enquiry.

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 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.

Annexes A, B, C and D are informative.

Introduction

In the 1990's 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", 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.

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. 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 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 standard includes general requirements to ensure the prevention of cross-connection between connectors used in different fields of medical application. Subsequent parts of this series include the dimensions and drawings of connectors allocated to specific medical applications.

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, directly or indirectly, 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 of medical devices and accessories for which these connectors are provided. Such requirements are given in particular International or European Standards for specific medical devices and accessories.

Note1: 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 10.

Note 2: Manufacturers are encouraged to incorporate the small bore connectors specified in this series of Standards into medical devices or systems, even if currently not 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 secretariat of CEN/BT/TF 123, so that CEN/BT/TF 123 can consider this feedback during the revision of the relevant part of this series of Standards

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revision of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

ISO 594 / 1	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 1: General requirements
ISO 594 / 2	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock fittings
EN 1707:1996	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)
EN ISO 17664	Information to be provided by the manufacturer for the reprocessing of re-sterilisable medical devices

3 Terms and definitions

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

3.1 Application (specific application)

Medical applications of small bore connectors as listed in annex B (informative).

3.2 Connection

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

3.3 Driving gas

Gas that powers a medical device.

3.4 Harm

Physical injury or damage to the health of people or damage to property or the environment (term taken from ISO 14971: 2000)

3.5 Hazard

Potential source of harm (term taken from ISO 14971: 2000)

3.6 Normal condition

Condition in which all means provided for protection against hazards are intact.

3.7 Normal use

Operation, including routine inspection and adjustments by the operator, and stand-by, according to the instructions for use.

3.8 Operator

Person handling equipment.

3.9 Patient

Human being undergoing a medical, surgical or dental procedure.

3.10 Responsable organisation (user)

Entity accountable for the use and maintenance of an equipment or a system.

NOTE 1 The accountable entity can be a hospital, the operator, or a lay person. In home use applications, the patient, operator and responsible organisation may be one and the same person.

NOTE 2 Education and training is included in "use."

3.11 Risk

Combination of the probability of occurrence of harm and the degree of severity of the harm (term taken from ISO 14971: 2000)

3.12 Safety

Freedom from unacceptable risk (term taken from ISO 14971: 2000)

3.13 Single fault condition

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

3.14 Small bore connector

A connector having a maximum bore diameter of 8,5 mm.

4 Design allocation of small bore connectors

4.1 General

This part 1 of standard is intended to be the guidance and the reference document that leads to the allocation of different small bore connectors to specific applications. The dimensions and drawings of these designs and their allocation to specific medical applications are intended to be given in subsequent parts of this series of Standards.

4.2 Existing designs

Some designs of small bore connectors have already been or are being developed for specific applications, see annex C, e.g. Luer connectors as specified in EN 20594-1 or EN 1707.

4.3 New designs

Standards groups wishing to introduce new designs of small bore connectors should make this request to CEN/CMC according to the procedure set out in clause 7 after which the relevant part of this series of Standards will be amended or revised, in accordance with the CEN procedures.

5 Materials, design and constructions of small bore connectors

Materials and construction used shall be selected with regard to:

a) Compatibility with liquids, gases and other substances with which they will come into contact during use;

b) Non-toxicity;

c) Environmental conditions (e.g. temperature, pressure, humidity, electromagnetic fields) to which they will be exposed;

d) Minimisation of health risks due to substances leached from materials;

e) The recommended reprocessing procedures (e.g. disinfectants, elevated temperatures, radiation) they should be able to withstand.

f) Environmental aspects during normal use and at the time of disposal at the end of the life time.

Compliance with the above shall be confirmed by evidence provided by the manufacturer.

6 Particular small bore connector requirements for specific medical applications

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

Note: An overview of the allocation of small bore connectors to specific medical applications, including some typical examples, is given in annex B (informative).

6.1 Small bore connectors for vascular and specific other medical applications

Small bore connectors intended to be used for connections in vascular applications or with a hypodermic syringe intended for a specific other medical application shall be in accordance with the requirements given in annex C (informative). Small bore connectors for the applications specified in clause 6.2 to 6.6 shall not be connectable with the connectors specified in annex C (informative).

Note: Specific other medical applications for which these connectors are commonly used include, e.g. subcutaneous, intra-muscular and intraperitoneal injections and infiltrations.

6.2 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 part 2 of this Standard.

6.3 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 part 3 of this Standard.

6.4 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 part 4 of this Standard.

6.5 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 part 5 of this Standard.

6.6 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 part 6 of this Standard.

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

7.1 General

To ensure that proposed new small bore connectors are non-interchangeable with the small bore connectors covered by this series of Standards, the procedure shall be as follows :

- Ensure that there are no outstanding intellectual property right issues.
- 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: The three parties involved in the design review and practical tests should originate from three different member bodies. The same party involved in the design review may also carry out the practical tests.

7.2 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 CEN/BT/TF 123 via the Secretariat.

7.3 Consideration of design review and practical test results by CEN/BT/TF 123

- The review of the design review and practical test results shall be assigned to a group within CEN/BT/TF 123 with sufficient technical expertise ;
- 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 CEN/BT/TF 123 giving its conclusions ;
- The results shall be presented and discussed during the next meeting of CEN/BT/TF 123 or circulated by correspondence and a consensus shall be reached as to the suitability of the proposed small bore connector for inclusion in this series of Standards for the application intended ;

Note: Consensus is understood to be absence of major disagreement.

- The proposer shall be informed of the conclusion ;

- If the proposed small bore connector is suitable for inclusion in this series of Standards, the Secretariat of CEN/BT/TF 123 shall initiate the appropriate steps to include the new design by amendment or revision of the relevant part of this series of Standards.

8. Cleaning, disinfection, sterilisation and disposal

8.1 Small bore connectors “not for re-use”

If the small bore connector is specified “not for re-use” the manufacturer shall provide any information necessary for safe disposal of the small bore connector.

8.2 Reusable small bore connectors

If the small bore connector is reusable (indicated by the absence of the “not for re-use” marking) the manufacturer shall provide any information necessary so that the small bore connector can be processed safely and will continue to meet its performance specification.

If small bore connectors are specified to be re-sterilisable, the manufacturer shall provide information in accordance with EN ISO 17664 : 2003.

The manufacturer shall determine if processing in accordance with the provided instructions leads to a degradation that will limit the useful life of the small bore connector. Where such degradation is predicted, the manufacturer shall provide an indication of the number of reprocessing cycles that can normally be tolerated, or some other indication of the end of the small bore connector’s ability to safely fulfil its intended use.