SLOVENSKI STANDARD
SIST EN 1615:2001

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Nadomešča:
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Enteralni katetri za hranjenje in kompleti za hranjenje za enkratno uporabo ter njihovi priključki - Načrtovanje in preskušanje

Enteral feeding catheters and enteral giving sets for single use and their connectors - Design and testing

Katheter und Überleitungsgeräte zur enteralen Ernährung und ihre Konnektoren zur einmaligen Verwendung - Ausführung und Prüfung

Sondes et dispositifs de nutrition entérale non réutilisables et leurs raccords - Conception et essais

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This European Standard was approved by CEN on 16 September 2000.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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Foreword

This European Standard has been prepared by Technical Committee CEN/TC 205 "Non-active medical devices", the secretariat of which is held by BSI.

This European Standard replaces EN 1615:1997.

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of an identical text or by endorsement, at the latest by April 2001, and conflicting national standards shall be withdrawn at the latest by April 2001.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

This European Standard specifies requirements for single-use enteral feeding catheters and enteral giving sets and their connector systems.

The requirements for enteral feeding catheters, giving sets and their connections are specified so that, when used in current clinical practice, these devices do not compromise the clinical condition or the safety of patients.

Some general requirements are covered by reference to other European standards listed in the normative references clause. This European Standard contains informative references to other European Standards listed in the Bibliography.

Enteral feeding catheters are intended for human enteral nutrition. They are designed to pass the nutrition solutions through the nose or mouth, or by gastrostomy, jejunostomy or oesophagostomy.

Both enteral giving sets and enteral feeding catheters are often used with enteral nutrition pumps. The performance and connecting system requirements are specified so that both devices and their connections perform safely.

It is important that enteral giving sets should not be able to be connected to parenteral intravascular catheters or any other catheter with a female Luer connector. The requirements for the connecting systems prevent this form of misconnection.

There are many enteral giving sets and enteral feeding catheters on the market which perform satisfactorily. This standard specifies three connectors suitable for enteral giving sets. It has not been found possible or desirable to limit the standard to only one connector. This places the onus on the designers and manufacturers of the enteral feeding catheters to provide connectors on their devices which mate with the connector on the enteral giving set and conform to the appropriate clauses of this standard. The report from the Task Force Group "Luer Fittings" under the auspices of the CEN Health Care Forum has been noted. A revision of the present standard will be undertaken when an appropriate solution has been decided for alternative connector systems for enteral use.

It was not considered necessary to provide a colour code on the enteral giving set, because the connectors specified for the enteral giving set will not fit into a female Luer fitting. Also, many enteral feeding catheters use a colour code on the connector to indicate the diameter of the catheter, and this could cause confusion with any colour suggested for coding the enteral giving set.

1 Scope

This European Standard specifies requirements for the design and testing of single-use enteral feeding catheters, single-use enteral giving sets and their connection systems.

Requirements for radiodetectable enteral feeding catheters are not given in this standard.

> NOTE Enteral feeding catheters intended for insertion through the mouth or nose can be radiodetectable in their entirety or at the tip or by means of intermittent marks. At present there is no generally accepted standard test method for radiodetectability, but research to develop a standard method of test is being considered.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the normative documents indicated below. For undated references, the latest edition of the normative documents referred to applies (including amendments).

EN 550, *Sterilization of medical devices — Validation and routine control of ethylene oxide sterilization.*

EN 552, *Sterilization of medical devices — Validation and routine control of sterilization by irradiation.*

EN 554, *Sterilization of medical devices — Validation and routine control of sterilization by moist heat.*

EN 556+A1, *Sterilization of medical devices — Requirements for terminally-sterilized medical devices to be labelled "Sterile".*

EN 1618:1997, *Catheters other than intravascular catheters — Test methods for common properties.*

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 purposes of this European Standard the following terms and definitions apply.

3.1
enteral giving set
medical device by which nutrient or diet is transferred from a nutrient or diet container to an enteral feeding catheter (see Figure 1)

3.2
enteral feeding catheter
medical device consisting of a flexible tube having one or more eyes and a connector, designed to introduce nutrient or diet into the gastro-intestinal tract

4 Requirements

4.1 Enteral giving set

The enteral giving set shall consist of at least the following:

a) either an integral nutrient container or a means of effecting connection to a nutrient container;

b) flexible tubing;

c) a connector to make a connection with an enteral feeding catheter.

NOTE 1 The enteral giving set can also be provided with other features, e.g. a drip chamber, a pump insert, a means for regulating and/or stopping the flow through the enteral giving set.

NOTE 2 The means of connection between the enteral giving set and the nutrient container (if it is not integral) is preferably a screw fitting or a means different from the piercing pin system used for parenteral administration.

4.1.1 *Tensile properties*

The flexible tubing part of the enteral giving set shall withstand a linear tensile force of 15 N without rupture or cracking when tested in accordance with EN 1618:1997, annex B. Any joints or connections within the enteral giving set shall also withstand a linear tensile force of 15 N.

4.1.2 *Connector on the enteral giving set*

The connector on the enteral giving set shall conform to one of the following requirements:

a) it shall have the dimensions given in either Figure 2 (“Type A”) or Figure 3 (“Type B”);

b) it shall be a female 6% (Luer) connector, slip or lock (“Type C”) conforming to EN 20594-1 or EN 1707;

c) it shall be an alternative connection system (including both an enteral giving set and an enteral feeding catheter) ("Type D") which passes the tests specified in **4.3** and **4.4**, but does not connect with a female 6% (Luer) connector, slip or lock as specified in EN 20594-1 or EN 1707, as appropriate.

NOTE There are a variety of connectors on the market. This standard provides for connectors which provide safe connection to an enteral feeding catheter which has a connector designed to mate with it.

The dimensions of the connector shall not be altered by deformation when connection to an enteral feeding catheter is attempted.

4.1.3 *Liquid leakage test*

4.1.3.1 *Sets designed for use with a pump*

Prior to testing for liquid leakage all the openings shall be sealed. Following this, the set shall be pressurized with water to a minimum pressure equal to or greater than one of the following:

a) the maximum operating pressure of the pump with which it is designed to be used;

b) the pressure value it is able to withstand, as according to the label.

Enteral giving sets shall be tested as described in EN 1618:1997, annex C.

All parts of the enteral giving set distal to the pumping segment shall show no leakage after 2 min.

4.1.3.2 *Gravity sets*

Prior to testing for liquid leakage all the openings shall be sealed. Following this, the set shall be pressurized with water to 20 kPa.

Enteral giving sets shall be tested as described in EN 1618:1997, annex C.

All parts of the enteral giving set shall show no leakage after 30 s.

4.1.4 *Sterility*

If the enteral giving set is to be labelled "Sterile", the device shall be sterilized in accordance with EN 556+A1 and controlled and validated in accordance with EN 550, EN 552 or EN 554.