SLOVENSKI STANDARD
SIST EN 1615:2000

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Sterilni ļ revesni katetri za hranjenje in kompleti za hranjenje za enkratno uporabo

Sterile enteral feeding catheters and giving sets for single use

Sterile Katheter zur enteralen Ernährung und Übertragungsgeräte zur einmaligen Verwendung

Sondes et dispositifs stériles de nutrition entérale non réutilisables

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English version

Sterile enteral feeding catheters and giving sets for single use

Sondes et dispositifs stériles de nutrition entérale non réutilisables

Sterile Katheter zur enteralen Ernährung und Übertragungsgeräte zur einmaligen Verwendung

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CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart,36 B-1050 Brussels

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 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by August 1997, and conflicting national standards shall be withdrawn at the latest by August 1997.

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

Annexes A and B are informative.

Introduction

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

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

General requirements are covered by reference to other European or International Standards listed in the normative references clause.

Enteral feeding catheters are intended for human enteral nutrition and are applied through the nose or mouth, or by gastrostomy, jejunostomy or oesophagostomy.

Enteral feeding catheters are introduced for periods in excess of one day, sometimes in excess of one month, and both giving sets and 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 under these conditions of use.

Working Group 6 of CEN/TC 205, responsible for developing this standard, has found it very important that enteral giving sets should not be able to be connected with parenteral intravascular systems or any other catheter with a female Luer connector. The requirements for the connecting systems prevent this form of misconnection.

1 Scope

This European Standard specifies requirements for sterile single use enteral feeding catheters, enteral giving sets and their connection systems.

This European Standard does not apply to enteral feeding catheters in which the external diameter of the tube is greater than 7 mm or to gastro-intestinal catheters primarily intended for the administration of medication.

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 revisions 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.

EN 556	Sterilization of medical devices - Requirements for medical devices to be labelled 'Sterile'
EN 980	Terminology, symbols and information provided with medical devices - Graphical symbols for medical devices
prEN 1041	Terminology, Symbols and Information provided with Medical Devices - Information supplied by the manufacturer with medical devices
EN 1618 : 1997	Catheters other than intravascular catheters - Test methods for common properties
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 1707	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment - Lock fittings
EN ISO 6009	Hypodermic needles for single use - Colour coding for identification (ISO 6009 : 1992)

3 Definitions

For the purposes of this European Standard the following 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.

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 the following:

a) flexible tubing;

b) a means for effecting connection to a nutrient container;

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

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

4.2 Connector on enteral giving set

The connector on the enteral giving set shall not connect with female 6 % (Luer) conical fittings and female 6 % (Luer) lock conical fittings as specified in EN 20594-1 and EN 1707.

The connector shall be secured so that the dimensions do not alter by deformation when connection to a catheter is attempted.

Examples of connectors that fulfill this requirement are shown in annex A.

4.3 Performance

4.3.1 *Tensile test*

All parts and joints of the enteral giving set and the enteral feeding catheter shall withstand a linear tensile force of 15 N without disconnection, rupture or cracking when tested as described in annex B of EN 1618 : 1997.

4.3.2 *Security of connections*

When tested in accordance with annex F of EN 1618 : 1997, the assembled connector shall not be separated by a force of 15 N.

4.3.3 *Liquid leakage*

When tested as described in annex C of EN 1618 : 1997, all parts and joints of the enteral giving set and the enteral feeding catheter, when sealed at their openings and pressurized with water to a minimum pressure of 150 kPa, or a higher pressure as stated by the manufacturer, shall show no leakage after 2 min.

4.4 Connector on enteral feeding catheter

4.4.1 After simulated use as described in 4.4.2, the assembled connectors shall comply with 4.3.1, 4.3.2 and 4.3.3.

4.4.2 Connect the connector on the enteral feeding catheter to a connector at (32 ± 2) °C for 5 days. Twice each day, disconnect the catheter connection and, after a period not exceeding 2 min, reconnect it.

4.5 Biocompatibility

The device shall be evaluated for biocompatibility, and shall be free from biological hazard.

NOTE: Methods for evaluation for biocompatibility are given in EN 30993.

4.6 Sterility

The device shall comply with EN 556.

4.7 Corrosion test

When tested in accordance with the method given in annex A of EN 1618 : 1997, the test specimen shall not show any evidence of corrosion.

5 Colour code

If present and if coloured, the means for regulating and/or stopping the flow on the enteral giving set shall be coloured medium purple. The colour shall conform with colour sample RAL 840 HR as specified in EN ISO 6009.

NOTE: This colour code is intended to prevent confusion between enteral giving sets and parenteral medical devices, e.g. infusion sets.

6 Symbols and labelling

In addition to the symbols and labelling requirements specified in EN 980 and prEN 1041, the unit container, the multi-unit container and the storage container of enteral feeding catheters and enteral giving sets shall be labelled with the following:

a) the warning "For enteral nutrition only" or equivalent.

b) If intended for use with feeding pumps, the maximum operating pressure in kPa (see 4.3.3).