EESTI STANDARD EVS-EN 1615:2001

Ühekordselt kasutatavad steriilsed enteraalseks toitmiseks ettenähtud kateetrid ja manustusseadmed ja nende ühendused. Konstruktsioon ja katsetamine

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

EESTI STANDARDIKESKUS

EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN 1615:2001 sisaldab Euroopa standardi EN 1615:2000 ingliskeelset teksti. Käesolev dokument on jõustatud 09.03.2001 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN 1615:2001 consists of the English text of the European standard EN 1615:2000. This document is endorsed on 09.03.2001 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: Käesolev standard esitab nõuded steriilsetele ühekordselt kasutatavatele enteraalseks toitmiseks ettenähtud kateetritele, enteraalse manustamise seadmetele ja nende ühendussüsteemidele.	**Scope:**

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English version

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

Design and testing

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

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

This European Standard was approved by CEN on 2000-09-16.

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.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

The European Standards exist in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

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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

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Contents

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).*