

Ühekordselt kasutatavad steriilsed dreenkateetrid ja lisaseadmed

Sterile drainage catheters and accessory devices for
single use

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-EN 1617:1999 sisaldab Euroopa standardi EN 1617:1997 ingliskeelset teksti.</p> <p>Käesolev dokument on jõustatud 12.12.1999 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.</p> <p>Standard on kättesaadav Eesti standardiorganisatsioonist.</p>	<p>This Estonian standard EVS-EN 1617:1999 consists of the English text of the European standard EN 1617:1997.</p> <p>This document is endorsed on 12.12.1999 with the notification being published in the official publication of the Estonian national standardisation organisation.</p> <p>The standard is available from Estonian standardisation organisation.</p>
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<p>Käsitlusala: Käesolev standard esitab nõuded steriilsetele ühekordselt kasutatavatele dreenidele, haavadreenerimissüsteemidele ja nende koostisosadele, mis on ette nähtud vedelike kehast väljajuhtimiseks raskusjõu või negatiivse rõhu abil.</p>	<p>Scope:</p>
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ICS 11.040.20

Võtmesõnad: kateetrid, löögikindlus, meditsiiniaparatuur, mehaaniline tugevus, määratlused, pärast kasutamist hävitatavad vahendid, sildiga märgistamine, testimine

ICS 11.040.20

Descriptors: Medical equipment, catheters.

English version

**Sterile drainage catheters and accessory
devices for single use**

Sondes et dispositifs accessoires stériles
de drainage, non réutilisables

Sterile Drainagekatheter und Zubehör zur
einmaligen Verwendung

This European Standard was approved by CEN on 1997-01-10.

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.

CEN members are the national standards bodies of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

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 form normative parts of this standard.

Annex C is given for information only.

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1 Scope

This European Standard specifies requirements for sterile, single use drainage catheters, wound drainage systems and components thereof designed for drainage of fluids to the exterior by means of gravity or negative pressure.

This European Standard does not apply to:

- a) catheters of less than 2 mm outside diameter;
- b) suction catheters for use in the respiratory tract (see prEN 1733);
- c) tracheal catheters (tracheal tubes) (see prEN 1782).

NOTE: Urinary tract catheters are covered in EN 1616.

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 publications referred to applies.

EN 556	Sterilization of medical devices - Requirements for medical devices to be labelled 'Sterile'
EN 980	Information supplied by the manufacturer for 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