

## Ühekordselt kasutatavad steriilsed uretraalkateetrid (kusicateetrid)

Sterile urethral catheters for single use

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-EN 1616:1999 sisaldab Euroopa standardi EN 1616 :1997 + A1:1999 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 1616:1999 consists of the English text of the European standard EN 1616 :1997 + A1:1999.</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><b>Käsitlusala:</b> Käesolev standard esitab nõuded steriilsetele ühekordselt kasutatavatele ballooniga ja ilma balloonita uretraalkateetritele (kusitikateetritele).</p>	<p><b>Scope:</b></p>
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**ICS** 11.040.20

**Võtmesõnad:** kuseteedekateetrid, meditsiiniaparatuur, mõõtmed, ohutus, pärast kasutamist hävitatavad vahendid, sildiga märgistamine, tehnilised andmed, tõmbetugevus, vooluhulk, ühenduskohad

**English version**

**Sterile urethral catheters for single use**  
(includes Amendment A1 : 1999)

Sondes urinaires stériles non  
réutilisables (amendement A1 : 1999  
inclus)

Sterile Harnblasenkatheter zur  
einmaligen Verwendung (enthält  
Änderung A1 : 1999)

This European Standard was approved by CEN on 1997-01-10 and amendment A1 on 1999-02-13.

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, the Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the 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 to EN 1616 : 1997**

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, and conflicting national standards withdrawn, by August 1997 at the latest.

In accordance with 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, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

### **Foreword to EN 1616 : 1997/A1 : 1999**

This Amendment to EN 1616 : 1997 has been prepared by Technical Committee CEN/TC 205 'Non-active medical devices', the Secretariat of which is held by BSI.

This Amendment shall be given the status of a national standard, either by publication of an identical text or by endorsement, and conflicting national standards withdrawn, by September 1999 at the latest.

In accordance with CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard:

Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

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## 1 Scope

This European Standard specifies requirements for sterile, single-use urethral catheters, with and without balloons.

## 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 provided with medical devices supplied by the manufacturer
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).

## 3 Definitions

For the purposes of this European standard, the following definitions apply.

**3.1 urethral catheter:** Tubular device intended for being introduced into the vesical cavity through the urethra in order to provide drainage and/or flushing of the bladder.