Kateetrid, v.a intravaskulaarsed (soonesisesed) kateetrid. Üldiste omaduste katsemeetodid

Catheters other than intravascular catheters - Test methods for common properties

EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN 1618:1999 sisaldab Euroopa standardi EN 1618:1997 ingliskeelset teksti. Käesolev dokument on jõustatud 12.12.1999 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN 1618:1999 consists of the English text of the European standard EN 1618:1997. This document is endorsed on 12.12.1999 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 kliiniliseks kasutamiseks valmis olevate vahendite hulka kuuluvate kateetrite üldiste omaduste testimise meetodid. Standardi eesmärk on tagada ühetaolisus kateetrite omaduste hindamisel.	**Scope:**

ICS 11.040.20

Võtmesõnad: hermeetilisus, kateetrid, korrosioonikindlus, meditsiiniaparatuur, mehaaniline tugevus, parameetrid, testimine, vooluhulk

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 1618

February 1997

ICS 11.040.20

Descriptors: Medical equipment, testing, catheters.

English version

Catheters other than intravascular catheters

Test methods for common properties

Cathéters autres que les cathéters intravasculaires – Méthodes d'essai des propriétés communes

Nicht-intravasale Katheter – Prüfverfahren für allgemeine Eigenschaften

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.

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CEN

European Committee for Standardization
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Europäisches Komitee für Normung

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Ref. No. EN 1618:1997 E

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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 has been prepared under a mandate given to CEN by the European Commission and the European Free Trade association, and supports essential requirements of the EU Directive(s).

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.

For relationship with EU Directive(s), see informative annex ZA, which is an integral part of this standard.

Annexes A, B, C, D, E and F form normative parts of this standard. Annex ZA is for information only.

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.

1 Scope

This European Standard specifies test methods for common properties for catheters as they relate to the device ready for clinical use. The purpose of the standard is to ensure uniformity in the evaluation of catheter properties.

This European Standard is not applicable to intravascular catheters.

2 Test methods and results

The test methods are given in annexes A to F and results shall be expressed as e.g.:

"Corrosion test according to EN 1618: No sign of corrosion".

Unless otherwise specified, tolerances on all variables in the test methods shall be ± 10 %.