Catheters - Test methods for kinking of single lumen catheters and medical tubing

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EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN 13868:2002 sisaldab Euroopa standardi EN 13868:2002 ingliskeelset teksti. Käesolev dokument on jõustatud 13.12.2002 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN 13868:2002 consists of the English text of the European standard EN 13868:2002. This document is endorsed on 13.12.2002 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: This Standard specifies test methods for kinking properties for single lumen catheters and medical tubing as they relate to the device ready for clinical use. The purpose of the standard is to ensure uniformity in the evaluation of tubing kink properties	**Scope:** This Standard specifies test methods for kinking properties for single lumen catheters and medical tubing as they relate to the device ready for clinical use. The purpose of the standard is to ensure uniformity in the evaluation of tubing kink properties

ICS 11.040.20

Võtmesõnad: definition, definitions, flexible pipes, flows, general section, kinks, medical equipment, medical products, medical sciences, medicine, properties, safety against buckling, specification (approval), specifications, test methods, testing, tightness, use

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

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English version

Catheters - Test methods for kinking of single lumen catheters and medical tubing

Cathéters - Méthodes d'essai de résistance à la plicature pour cathéters à simple voie et tubes à usage médical

Katheter - Prüfverfahren für die Knickbildung von Kathetern mit Einzellumen und Schläuchen zur medizinischen Anwendung

This European Standard was approved by CEN on 10 May 2002.

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 Management Centre or to any CEN member.

This European Standard exists 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 Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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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 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by February 2003, and conflicting national standards shall be withdrawn at the latest by February 2003.

Annexes A and B are normative.

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, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

Tubes for catheters and for certain other medical uses have to be flexible, but simultaneously they need also to have an appropriate minimum strength. The strength and flexibility allow the tube to be handled easily, so it can be bent around obstacles, for example within the human anatomy. However, not all flexible tubes show the same behaviour during bending. Some tubes can bend considerably without kinking i.e without collapsing and thereby drastically reducing the cross sectional area, while others kink easily. In catheter applications, this reduction of the flow area can cause severe reduction in the flow of fluids.

1 Scope

This European Standard specifies test methods for kinking properties for single lumen catheters and medical tubing, as presented for clinical use, when bent in a single plane. It is recognized that other forces e.g. twisting will influence the behaviour of the product, but no standard test methods are yet available. It is also recognized that such tubing can be used to transport liquids or gases. However, water is used as a standard test medium, as the purpose of this standard is to ensure uniformity in the evaluation of tubing kink properties.

NOTE This method is designed for single-lumen tubing but can also be used for multi-lumen tubing. It should be ensured that the bending is done in the worst case direction, unless this would not present a possible real life situation.

2 Terms and definitions

For the purposes of this European Standard, the following terms and definitions apply.

2.1
kink distance
plate distance at kink in the short term test method

2.2
kink length *L*
length of the tubing loop at kink in the kink test tool in the long term test method

2.3
kink point
total collapse or distinct “knee” when kinking (see Figure A.4)

2.4
plate distance *D*
distance between the two plates of the tensile testing apparatus in the short term test method (see Figure A.3)

2.5
corrected kink distance *C*
plate distance at kink plus correction for grooves, result of the short term test method (see Figure A.3)