

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

The European Standard EN 13868:2002 has the status of a British Standard

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National foreword

This British Standard is the official English language version of EN 13868:2002.

The UK participation in its preparation was entrusted to Technical Committee CH/84, Catheters and syringes, which has the responsibility to:

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- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
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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.

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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of an identical text or by endorsement, at the latest by February 2003, and conflicting national standards shall be withdrawn at the latest by February 2003.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)