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Handläggande organ	Fastställd	Utgåva	Sida
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Sterile, single-use intravascular catheters – Del 2: Angiographic catheters (ISO 10555-2:1996)

The European Standard EN ISO 10555-2:1997 has the status of a Swedish Standard. This document contains the official English version of EN ISO 10555-2:1997.

Swedish Standards corresponding to documents referred to in this Standard are listed in ”Catalogue of Swedish Standards”, issued by SIS. The Catalogue lists, with reference number and year of Swedish approval, International and European Standards approved as Swedish Standards as well as other Swedish Standards.

Sterila intravaskulära katetrar för engångsbruk – Del 2: Angiografikatetrar (ISO 10555-2:1996)

Europastandarden EN ISO 10555-2:1997 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 10555-2: 1997.

Motsvarigheten och aktualiteten i svensk standard till de publikationer som omnämns i denna standard framgår av ”Katalog över svensk standard”, som ges ut av SIS. I katalogen redovisas internationella och europeiska standarder som fastställts som svenska standarder och övriga gällande svenska standarder.

ICS 11.040.20

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Postadress: SIS, Box 6455, 113 82 STOCKHOLM
Telefon: 08 - 610 30 00. *Telefax*: 08 - 30 77 57

Upplysningar om **sakinnehållet** i standarden lämnas av HSS.
Telefon: 08 - 702 49 00. *Telefax*: 08 - 702 49 15
E-post: hss@hss.se
Prisgrupp M

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English version

Sterile, single-use intravascular catheters – Del 2: Angiographic catheters (ISO 10555-2:1996)

Cathéters intravasculaires stériles, non réutilisables – Partie 2: Cathéters angiographiques (ISO 10555-2:1996)

Sterile intravaskuläre Katheter zur einmaligen Verwendung – Teil 2: Angiographiekatheter (ISO 10555-2:1996)

This European Standard was approved by CEN on 1997-06-09. 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
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart 36, B-1050 BRUSSELS

Ref. No. EN ISO 10555-2:1997 E

Foreword

The text of the International Standard from Technical Committee ISO/TC 84 "Medical devices for injections" of the International Organization for Standardization (ISO) has been taken over as a European Standard 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 January 1998, and conflicting national standards shall be withdrawn at the latest by January 1998.

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

Endorsement notice

The text of the International Standard ISO 10555-2:1996 has been approved by CEN as a European Standard without any modification.

NOTE: Normative references to International Standards are listed in annex ZA (normative).

Sterile, single-use intravascular catheters —

Part 2:
Angiographic catheters

1 Scope

This part of ISO 10555 specifies requirements for angiographic catheters supplied in the sterile condition, and intended for single use.

NOTE 1 Attention is drawn to ISO 11070, which specifies requirements for accessory devices for use with intravascular catheters.

2 Normative reference

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 10555. At the time of publication, the edition indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 10555 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 10555-1:1995, *Sterile, single-use intravascular catheters — Part 1: General requirements.*

3 Definitions

For the purposes of this part of ISO 10555, the definitions given in ISO 10555-1 and the following definitions apply.

3.1 angiographic catheter: Intravascular catheter used for the injection or infusion of contrast media and/or fluids and which may be used for pressure measurements and to obtain blood samples.

3.2 distal end configuration: Shape of the catheter which is designed to facilitate its manual manipulation through the cardiovascular system and the placement of the tip in the location chosen for the angiographic procedures.

4 Requirements

4.1 General

Unless otherwise specified in this part of ISO 10555, catheters shall comply with ISO 10555-1.

4.2 Radio-detectability

The catheter shall be radio-detectable.

NOTE 2 At the time of publication of this part of ISO 10555, there is no acceptable, validated test method to determine radio-detectability. An approved test method for producing a value of radio-detectability will be established. Until that time, a manufacturer may label his product "radio-opaque" provided he can support this claim by demonstrating that he has an appropriate method for showing radio-opacity.

4.3 Designation of nominal size

The nominal size of the catheter shall be designated in accordance with ISO 10555-1 and also by the diameter of the largest guidewire that can be used with the catheter. If the inside diameter of the catheter is additionally designated, it shall be expressed in millimetres, rounded down to the nearest 0,1 mm.

4.4 Physical requirements

4.4.1 Tip configuration

In order to minimize trauma to vessels during use, the tip of the distal end should be smooth, rounded, tapered or similarly finished.

4.4.2 Freedom from leakage and damage under high static pressure conditions

When tested as described in annex A, there shall be no liquid leakage from the catheter and no visible signs of damage. There shall be no permanent deformation of the catheter shaft sufficient to prevent the free movement of a ring gauge over the tested portion of the catheter.

4.4.3 Side holes

The design, number and positioning of side holes should be such as to minimize adverse effects on the catheter and trauma to the tissues.

4.5 Information to be supplied by the manufacturer

Information supplied by the manufacturer shall comply with ISO 10555-1 and shall also include the following:

a) nominal size of the catheter, as designated in 4.3;

b) depiction or description of the distal end configuration, if not identifiable through the package;

c) maximum rated injection pressure, expressed in kilopascals (kPa), as determined under dynamic test conditions.

NOTES

3 The time for which the catheter can withstand the maximum rated pressure may also be given.

4 Units of measurement systems other than those specified in this part of ISO 10555 may additionally be used.