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Sterila intravaskulära katetrar för engångsbruk – Del 1: Allmänna krav (ISO 10555-1:1995 including Amd 1:1999 and Amd 2:2004)

Sterile, single-use intravascular catheters – Part 1: General requirements (ISO 10555-1:1995 including Amd 1:1999 and Amd 2:2004)

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Europastandarden EN ISO 10555-1:2009 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 10555-1:2009.

Denna standard ersätter SS-EN ISO 10555-1, utgåva 1.

The European Standard EN ISO 10555-1:2009 has the status of a Swedish Standard. This document contains the official English version of EN ISO 10555-1:2009.

This standard supersedes the Swedish Standard SS-EN ISO 10555-1, edition 1.

Upplysningar om sakinnehållet i standarden lämnas av SIS, Swedish Standards Institute, telefon 08-555 520 00.
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Information about the content of the standard is available from the Swedish Standards Institute (SIS), tel +46 8 555 520 00.
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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10555-1

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ICS 11.040.25

Supersedes EN ISO 10555-1:1996

English Version

Sterile, single-use intravascular catheters - Part 1: General requirements (ISO 10555-1:1995, including Amd 1:1999 and Amd 2:2004)

Cathéters intravasculaires stériles, non réutilisables - Partie 1: Prescriptions générales (ISO 10555-1:1995, y compris Amd 1:1999 et Amd 2:2004)

Sterile intravaskuläre Katheter zur einmaligen Verwendung -Teil 1: Allgemeine Anforderungen (ISO 10555-1:1995, einschließlich Änderung 1:1999 und Änderung 2:2004)

This European Standard was approved by CEN on 19 April 2009.

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 CEN 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 CEN Management Centre has the same status as the official versions.

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EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN ISO 10555-1:2009: E

Contents

Foreword

The text of ISO 10555-1:1995, including Amd 1:1999 and Amd 2:2004 has been prepared by Technical Committee ISO/TC 84 “Medical devices for injections” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 10555-1:2009 by Technical Committee CEN/TC 205 “Non-active medical devices” the secretariat of which is held by DIN.

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 November 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 10555-1:1996.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EC Directive.

For relationship with EC Directive, see informative Annex ZA, which is an integral part of this document.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 10555-1:1995, including Amd 1:1999 and Amd 2:2004 has been approved by CEN as a EN ISO 10555-1:2009 without any modification.

Sterile, single-use intravascular catheters —

Part 1:
General requirements

1 Scope

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

It does not apply to intravascular catheter accessories, which will be covered by a separate standard.

2 Normative references

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 editions 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 594-1:1986, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements.*

ISO 594-2:1991, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings.*

ISO 7886-1:1993, *Sterile hypodermic syringes for single use — Part 1: Syringes for manual use.*

3 Definitions

For the purposes of this part of ISO 10555, the following definitions apply.

3.1 intravascular catheter: Tubular device, single or multilumen, designed to be partially or totally inserted or implanted into the cardiovascular system for diagnostic and/or therapeutic purposes.

3.2 distal end: End of the catheter inserted furthest into the patient.

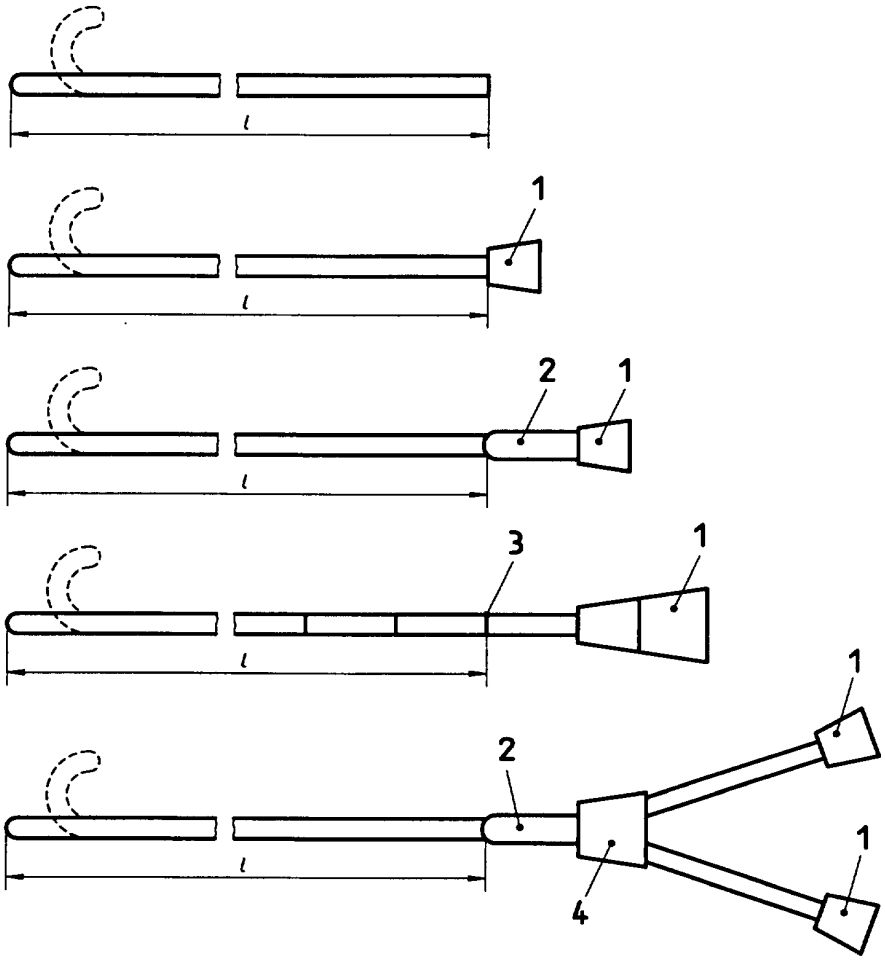
3.3 proximal end; access end: End of the catheter to which connection can be made.

3.4 hub: Connector(s) at the proximal end of the catheter which may either be integral with the catheter or be capable of being securely fitted to the proximal end of the catheter.

3.5 effective length, *l*: Length of the catheter that can be inserted into the body. (See figure 1.)

3.6 outside diameter: Maximum diameter of that part of the catheter that can be inserted into the vessel.

3.7 junction: That portion of the catheter that joins one tube to multiple tubes.



Key

l = effective length

1. catheter hub
2. catheter strain reinforcement
3. length mark
4. junction

Figure 1 — Examples of effective length of catheters

4 Requirements

4.1 General

The catheter shall have been sterilized by a validated method, and shall comply with 4.2 to 4.7 in the sterile condition.

NOTE 1 See ISO 11134, ISO 11135 and ISO 11137 for appropriate methods of sterilization.

4.2 Biocompatibility

The catheter shall be free from biological hazard.

NOTE 2 See ISO 10993-1 for the selection of appropriate test methods.

4.3 Surface

When examined by normal or corrected to normal vision with × 2,5 magnification, the external surface of the effective length of the catheter shall appear free from extraneous matter.

The external surface of the effective length of the catheter, including the distal end, should be free from process and surface defects and should cause minimum trauma to vessels during use.

If the catheter is lubricated, the lubricant should not be visible as drops of fluid on the external surface when the catheter is examined under normal or corrected to normal vision.

4.4 Corrosion resistance

When tested in accordance with the method given in annex A, metallic components of the catheter shall show no signs of corrosion.

4.5 Force at break

When tested in accordance with the method given in annex B, the force at break of each test piece shall be as given in table 1.

4.6 Freedom from leakage

4.6.1 The hub or connection fitting assembly or any other part of the catheter shall not leak liquid when tested in accordance with the method given in annex C.

4.6.2 Air shall not leak into the hub assembly during aspiration when tested in accordance with the method given in annex D.

Table 1 — Force at break of catheter test pieces

Smallest outside diameter of tubular portion of test piece mm	Minimum force at break N
⩾ 0,55 < 0,75	3
⩾ 0,75 < 1,15	5
⩾ 1,15 < 1,85	10
⩾ 1,85	15
NOTE — This part of ISO 10555 does not specify requirements for force at break for tubing of less than 0,55 mm outside diameter.	

4.7 Hubs

If the catheter is supplied with either an integral or a separate hub, it shall be a female hub and shall comply with ISO 594-1 and ISO 594-2.

5 Designation of nominal size

The nominal size of the catheter shall be designated as specified in 5.1 and 5.2.

5.1 Outside diameter

Unless otherwise specified in the International Standard for a particular type of catheter, the outside diameter shall be expressed in millimetres, rounded upwards to the nearest 0,05 mm for outside diameters of less than 2 mm, or to the nearest 0,1 mm for outside diameters of 2 mm and greater.

5.2 Effective length

The effective length shall be expressed in a whole number of millimetres for effective lengths of less than 99 mm and in either a whole number of millimetres or a whole number of centimetres for effective lengths of 99 mm and greater.

6 Information to be supplied by manufacturer

The manufacturer shall supply at least the following information. All dimensions given shall be expressed in SI units of measurement.