Steriilsed ühekordselt kasutatavad intravaskulaarsed (soonesisesed) kateetrid. Osa 1: Üldnõuded

Sterile, single use intravascular catheters - Part 1: General requirements

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 10555-1:2009 sisaldab Euroopa standardi EN ISO 10555-1:2009 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 10555-1:2009 consists of the English text of the European standard EN ISO 10555-1:2009.
Standard on kinnitatud Eesti Standardikeskuse 31.07.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 31.07.2009 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 13.05.2009.	Date of Availability of the European standard text 13.05.2009.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

ICS 11.040.25

Võtmesõnad: kateetrid, meditsiiniaparatuur, pärast kasutamist hävitatavad vahendid, soontesüsteem, steriilne varustus, teave tarbijale, tehnilised andmed, testimine, tähistus

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10555-1

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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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EUROPEAN COMMITTEE FOR STANDARDIZATION
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EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

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

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.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive …	Qualifying remarks/Notes
4	1, 2, 3, 4, 5	Except I 1. first indent – regarding ergonomics
4.1	6, 7.2, 8.1	
4.2	6, 7.1, 7.5	"*E.R. 7.5 is only partially covered: protection against risks posed by the presence of phthalates and other toxic substances are not specifically addressed*"
4.4	6, 7.3	
4.6	6, 7.6	
4.7	9.1	
5	1, 3, 9.2	Except I 1. first indent – regarding ergonomics
6	3, 13.1, 13.4	
6 a)	13.3 b)	
6 d)	13.3 a)	except 13.3(a) (regarding representative in the Community)
6 e)	13.3 d)	
6 f)	13.3 e)	
6 g)	5	
6 h)	13.3 c)	
6 i)	13.3 m)	
6 j)	13.3 f)	Except 13.3 (f) (second phrase regarding indication of single use consistent across community)
6 k)	13.3 k)	
6 l)	7.3, 13.1, 13.3 i), 13.3 j), 13.3 k), 13.4, 13.6 a), 13.6 b), 13.6 g)	
Annex A	1, 2, 3, 4, 5	Except I 1. first indent – regarding ergonomics

Annex B	1, 2, 3, 4, 5	Except I 1. first indent – regarding ergonomics
Annex C	1, 2, 3, 4, 5, 7.6	Except I 1. first indent – regarding ergonomics
Annex D	1, 2, 3, 4, 5, 7.6	Except I 1. first indent – regarding ergonomics
NOTE	6a	Requirement on clinical evaluation not covered by this standard
NOTE	13.6 (h) – 2nd phrase	Regarding information on known characteristics and technical factors known to manufacturer that could pose a risk if reused is not covered by this standard
NOTE	13.6 (q)	regarding date of issue or latest revision of instructions for use is not covered by this standard

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

Contents

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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.