ILNAS

Institut luxembourgeois de la normalisation
de l'accréditation, de la sécurité et qualité
des produits et services

ILNAS-EN ISO 10555-1:2009

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

05/2009

National Foreword

This European Standard EN ISO 10555-1:2009 was adopted as Luxembourgish Standard ILNAS-EN ISO 10555-1:2009.

Every interested party, which is member of an organization based in Luxembourg, can participate for FREE in the development of Luxembourgish (ILNAS), European (CEN, CENELEC) and International (ISO, IEC) standards:

- Participate in the design of standards
- Foresee future developments
- Participate in technical committee meetings

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 10555-1

May 2009

ICS 11.040.25

Supersedes EN ISO 10555-1:1996

English Version

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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.

CEN members are the national standards bodies of 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 United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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

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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