SLOVENSKI STANDARD
kSIST prEN ISO 10555-1:2009

01-marec-2009

Sterilni ģilni katetri za enkratno uporabo - 1. del: Sploġne zahteve (ISO 10555-1:1995, vkljuļ no z Amd 1:1999 in Amd 2:2004)

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

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

Ta slovenski standard je istoveten z: **prEN ISO 10555-1**

ICS:

11.040.25	Injekcijske brizge, igle in katetri	Syringes, needles an catheters

kSIST prEN ISO 10555-1:2009 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

FINAL DRAFT
prEN ISO 10555-1

December 2008

ICS 11.040.25

Will supersede 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)

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

This draft European Standard is submitted to CEN members for unique acceptance procedure. It has been drawn up by the Technical Committee CEN/TC 205.

If this draft becomes a European Standard, 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.

This draft European Standard was established by CEN 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
COMITÉ EUROPÉEN DE NORMALISATION
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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 prEN ISO 10555-1:2008 by Technical Committee CEN/TC 205 “Non-active medical devices” the secretariat of which is held by DIN.

This document is currently submitted to the Unique Acceptance Procedure.

This document will supersede 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(s).

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

Endorsement notice

The text of ISO 10555-1:1995, including Amd 1:1999 and Amd 2:2004 has been approved by CEN as a prEN ISO 10555-1:2008 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.