SLOVENSKI STANDARD
kSIST prEN ISO 25539-1:2009

01-marec-2009

Vsadki (implantati) za srce in oǵilje - Znotrajǵilni pripomoļ ki - 1. del: Znotrajǵilne proteze (ISO 25539-1:2003, vkljuļ no z Amd 1:2005)

Cardiovascular implants - Endovascular devices - Part 1: Endovascular prostheses (ISO 25539-1:2003 including Amd 1:2005)

Kardiovaskuläre Implantate - Endovaskuläre Implantate - Teil 1: Endovaskuläre Prothesen (ISO 25539-1:2003, einschließlich Amd 1:2005)

Implants cardiovasculaires - Dispositifs endovasculaires - Partie 1: Prothèses endovasculaires (ISO 25539-1:2003, Amd 1:2005 inclus)

Ta slovenski standard je istoveten z: **prEN ISO 25539-1**

ICS:

11.040.40	Implantanti za kirurgijo, protetiko in ortetiko	Implants for surgery, prosthetics and orthotics

kSIST prEN ISO 25539-1:2009 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

FINAL DRAFT
prEN ISO 25539-1

December 2008

ICS 11.040.40

Will supersede EN ISO 25539-1:2008

English Version

Cardiovascular implants - Endovascular devices - Part 1: Endovascular prostheses (ISO 25539-1:2003 including Amd 1:2005)

Implants cardiovasculaires - Dispositifs endovasculaires - Partie 1: Prothèses endovasculaires (ISO 25539-1:2003, Amd 1:2005 inclus)

Kardiovaskuläre Implantate - Endovaskuläre Implantate - Teil 1: Endovaskuläre Prothesen (ISO 25539-1:2003, einschließlich Amd 1:2005)

This draft European Standard is submitted to CEN members for unique acceptance procedure. It has been drawn up by the Technical Committee CEN/TC 285.

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.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

The text of ISO 25539-1:2003 including Amd 1:2005 has been prepared by Technical Committee ISO/TC 150 “Implants for surgery” of the International Organization for Standardization (ISO) and has been taken over as prEN ISO 25539-1:2008 by Technical Committee CEN/TC 285 “Non-active surgical implants” the secretariat of which is held by DIN.

This document is currently submitted to the Unique Acceptance Procedure.

This document will supersede EN ISO 25539-1:2008.

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.

Endorsement notice

The text of ISO 25539-1:2003 including Amd 1:2005 has been approved by CEN as a prEN ISO 25539-1:2008 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 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 — Correspondence between this European Standard and Directive 93/42/EEC

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4	1 - 2 -3 - 4 - 7.1	
5	1 - 2 - 3 - 4 - 5 - 7.1 - 7.2 - 7.3 - 7.5 - 7.6 - 8 - 9.1 - 9.2	
6	1 - 2 - 7.1 - 7.2 - 7.3 - 7.4 - 7.5 - 7.6 - 8.2 - 9.2	ER 7.4 includes a mandatory consultation of regulatory authorities in relation to medicinal substances that is not addressed in this European Standard.
7	1 - 2 - 3 - 4 - 6 - 6a. - 7.1 - 7.2 - 7.3 - 7.5 - 7.6 - 8 - 9.1 - 9.2	
8	1 - 2 - 3 - 5 - 7.1 - 7.2	
9	1 - 2 - 7.2 - 8.1 - 8.2 - 8.3 - 8.4	
10.1	1 - 2 - 3 - 5 - 7.2 - 7.3 - 7.4 - 7.6 - 8.3 - 8.4	ER 7.4 includes a mandatory consultation of regulatory authorities in relation to medicinal substances that is not addressed in this European Standard.

10.2 - 10.3	1 - 2 - 8.7 - 9.1 - 13	The part of ER 13.3.a concerning the information of the authorized representative is not addressed in this European Standard. Part of ER 13.3 f relating to single use is not addressed in this European Standard. Part of ER 13.6 h) relating to single use is not addressed in this European Standard.

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