



**SLOVENSKI STANDARD**  
**kSIST prEN ISO 25539-2:2009**

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Cardiovascular implants - Endovascular devices - Part 2: Vascular stents (ISO 25539-2:2008)

Kardiovaskuläre Implantate - Endovaskuläre Implantate - Teil 2: Gefäßstents (ISO 25539-2:2008)

Implants cardiovasculaires - Dispositifs endovasculaires - Partie 2: Stents vasculaires (ISO 25539-2:2008)

**Ta slovenski standard je istoveten z: prEN ISO 25539-2**

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**ICS:**

11.040.40	Implantanti za kirurgijo, protetiko in ortetiko	Implants for surgery, prosthetics and orthotics
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**kSIST prEN ISO 25539-2:2009**

**en**



EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

**FINAL DRAFT**  
**prEN ISO 25539-2**

December 2008

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ICS 11.040.40

Will supersede EN ISO 25539-2:2008

English Version

## Cardiovascular implants - Endovascular devices - Part 2: Vascular stents (ISO 25539-2:2008)

Implants cardiovasculaires - Dispositifs endovasculaires -  
Partie 2: Stents vasculaires (ISO 25539-2:2008)

Kardiovaskuläre Implantate - Endovaskuläre Implantate -  
Teil 2: Gefäßstents (ISO 25539-2:2008)

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.

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**Warning** : This document is not a European Standard. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a European Standard.



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

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## Foreword

The text of ISO 25539-2:2008 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 25539-2:2008 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 25539-2:2008.

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 25539-2:2008 has been approved by CEN as a prEN ISO 25539-2:2008 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, 4, 7.1	
5	1, 2, 3, 4, 5, 7.1, 7.2, 7.3, 7.5, 8, 9.2	
6	1, 2, 7.1, 7.2, 7.3, 7.5, 8.2, 9.2	
7	1, 2, 3, 4, 6, 6a., 7.1, 7.2, 8, 9.2,	
8	1, 2, 3, 5, 7.1, 7.2	
9	1, 2, 3, 7.2, 8.1, 8.3, 8.4	
10	1, 2, 3, 5, 7.2, 8.3, 8.4	
11	1, 2, 8.7, 13.1, 13.3, 13.4, 13.6	<p>Part of 13.3 a relating to the authorised representative is not covered.</p> <p>Part of ER 13.3 f concerning single use is not addressed in this European Standard.</p> <p>13.6 h) concerning single use is not addressed in this European Standard.</p>

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

INTERNATIONAL  
STANDARD

**ISO**  
**25539-2**

First edition  
2008-09-01

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**Cardiovascular implants — Endovascular  
devices —**

Part 2:  
**Vascular stents**

*Implants cardiovasculaires — Dispositifs endovasculaires —  
Partie 2: Endoprothèses vasculaires*



Reference number  
ISO 25539-2:2008(E)

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