SLOVENSKI STANDARD
SIST EN ISO 21536:2009/oprA1:2012

01-maj-2012

Neaktivni kirurški vsadki (implantati) - Sklepne proteze - Posebne zahteve za kolenske proteze (ISO 21536:2007/DAmd 1:2012)

Non-active surgical implants - Joint replacement implants - Specific requirements for knee-joint replacement implants (ISO 21536:2007/DAmd 1:2012)

Nichtaktive chirurgische Implantate - Implantate zum Gelenkersatz - Besondere Anforderungen an Implantate für den Kniegelenkersatz (ISO 21536:2007/DAmd 1:2012)

Implants chirurgicaux non actifs - Implants de remplacement d'articulation - Exigences spécifiques relatives aux implants de remplacement de l'articulation du genou (ISO 21536:2007/DAmd 1:2012)

Ta slovenski standard je istoveten z: **EN ISO 21536:2009/prA1**

ICS:

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

SIST EN ISO 21536:2009/oprA1:2012 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

DRAFT
EN ISO 21536:2009

prA1

March 2012

ICS 11.040.40

English Version

Non-active surgical implants - Joint replacement implants - Specific requirements for knee-joint replacement implants (ISO 21536:2007/DAmd 1:2012)

Implants chirurgicaux non actifs - Implants de remplacement d'articulation - Exigences spécifiques relatives aux implants de remplacement de l'articulation du genou (ISO 21536:2007/DAmd 1:2012)

Nichtaktive chirurgische Implantate - Implantate zum Gelenkersatz - Besondere Anforderungen an Implantate für den Kniegelenkersatz (ISO 21536:2007/DAmd 1:2012)

This draft amendment is submitted to CEN members for parallel enquiry. It has been drawn up by the Technical Committee CEN/TC 285.

This draft amendment A1, if approved, will modify the European Standard EN ISO 21536:2009. If this draft becomes an amendment, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant national standard without any alteration.

This draft amendment 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-CENELEC Management Centre has the same status as the official versions.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

This document EN ISO 21536:2009/prA1:2012 has been prepared by Technical Committee ISO/TC 150 "Implants for surgery" in collaboration with Technical Committee CEN/TC 285 “Non-active surgical implants” the secretariat of which is held by DIN.

This document is currently submitted to the parallel Enquiry.

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 EU Directive.

Endorsement notice

The text of ISO 21536:2007/Damd 1:2012 has been approved by CEN as a EN ISO 21536:2009/prA1:2012 without any modification.

DRAFT AMENDMENT ISO 21536:2007/DAM 1

ISO/TC **150**/SC **4** Secretariat: **BSI**

Voting begins on **2012-03-08** Voting terminates on **2012-08-08**

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Non-active surgical implants — Joint replacement implants — Specific requirements for knee-joint replacement implants

AMENDMENT 1

Implants chirurgicaux non actifs — Implants de remplacement d'articulation — Exigences spécifiques relatives aux implants de remplacement de l'articulation du genou

AMENDEMENT 1

ICS 11.040.40

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO-lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five-month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

Amendment 1 to ISO 21536:2007 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 4, *Bones and joint replacement*.

