SLOVENSKI STANDARD
SIST EN ISO 21536:2009

01-julij-2009

Nadomeġļ a:
SIST EN ISO 21536:2008

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

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

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

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

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

ICS:

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

SIST EN ISO 21536:2009 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 21536

May 2009

ICS 11.040.40

Supersedes EN ISO 21536:2007

English Version

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

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

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

This European Standard was approved by CEN on 12 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.

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

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Foreword

The text of ISO 21536:2007 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 EN ISO 21536:2009 by Technical Committee CEN/TC 285 “Non-active surgical implants” 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 21536:2007.

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.

For relationship with EU 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 21536:2007 has been approved by CEN as a EN ISO 21536:2009 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 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, 5, 7.1, 7.2, 9.2	The part of ER 1 relating to the risk of use error is not addressed in this European Standard. The part of ER 7.1 relating to results of biophysical and modelling research is not addressed by this European Standard.
5	1, 2, 3, 4, 5, 6, 7.1, 9.1, 9.2	The part of ER 1 relating to the risk of use error is not addressed in this European Standard. The part of ER 7.1 relating to results of biophysical and modelling research is not addressed by this European Standard.
6	1, 2, 3, 4, 7.1, 7.2, 7.3, 7.4, 8.2, 9.1, 9.2	The part of ER 1 relating to the risk of use error is not addressed in this European Standard. The part of ER 7.1 relating to results of biophysical and modelling research is not addressed by this European Standard. The part of ER 7.4 relating to the regulatory provision for the verification of the medicinal product is not addressed in this European Standard.

7	1, 2, 3, 4, 5, 6, 6a. , 7.1, 7.2, 7.3	The part of ER 1 relating to the risk of use error is not addressed in this European Standard. The part of ER 7.1 relating to results of biophysical and modelling research is not addressed by this European Standard.
8	1, 2, 3, 4, 5, 7.1, 7.2, 7.3	The part of ER 1 relating to the risk of use error is not addressed in this European Standard. The part of ER 7.1 relating to results of biophysical and modelling research is not addressed by this European Standard.
9	3, 8.1, 8.3, 8.4, 8.5, 8.6, 8.7, 13.3	Via ISO 14630 The part of ER 13.3.a concerning the information on the authorized representative is not addressed in this European Standard. The ER 13.3 f is only partly addressed in this European Standard: safety issue of single use.
10	3, 5, 7.2, 8.1, 8.3, 8.4, 8.5, 8.6, 8.7	Via ISO 14630
11	9.1, 13	The part of ER 13.3.a concerning the information on the authorized representative is not addressed in this European Standard. The ER 13.3 f is only partly addressed in this European Standard: safety issue of single use. The part of ER 13.6.h) relating to single use is not addressed in this European Standard. ER 13.6 q is not addressed in this European Standard.
NOTE Clauses 4, 5, 6, 7, 8 and subclause 11.5 supplement and are dependent on the corresponding clauses of ISO 21534.		

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

INTERNATIONAL STANDARD

ISO 21536

Second edition
2007-10-01

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

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

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