



SLOVENSKI STANDARD
kSIST prEN ISO 21535:2009
01-marec-2009

Neaktivni kirurški vsadki (implantati) - Sklepne proteze - Posebne zahteve za umetni kolk (ISO 21535:2007)

Non-active surgical implants - Joint replacement implants - Specific requirements for hip-joint replacement implants (ISO 21535:2007)

Nichtaktive chirurgische Implantate - Implantate zum Gelenkersatz - Besondere Anforderungen an Implantate für den Hüftgelenkersatz (ISO 21535:2007)

Implants chirurgicaux non actifs - Implants de remplacement d'articulation - Exigences spécifiques relatives aux implants de remplacement de l'articulation de la hanche (ISO 21535:2007)

Ta slovenski standard je istoveten z: prEN ISO 21535

ICS:

11.040.40	Implantanti za kirurgijo, protetiko in ortetiko	Implants for surgery, prosthetics and orthotics
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kSIST prEN ISO 21535:2009

en

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

FINAL DRAFT
prEN ISO 21535

December 2008

ICS 11.040.40

Will supersede EN ISO 21535:2007

English Version

**Non-active surgical implants - Joint replacement implants -
Specific requirements for hip-joint replacement implants (ISO
21535:2007)**

Implants chirurgicaux non actifs - Implants de
remplacement d'articulation - Exigences spécifiques
relatives aux implants de remplacement de l'articulation de
la hanche (ISO 21535:2007)

Nichtaktive chirurgische Implantate - Implantate zum
Gelenkersatz - Besondere Anforderungen an Implantate für
den Hüftgelenkersatz (ISO 21535:2007)

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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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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Foreword

The text of ISO 21535:2007 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 prEN ISO 21535:2008 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 21535:2007.

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.

Endorsement notice

The text of ISO 21535:2007 has been approved by CEN as a prEN ISO 21535:2008 without any modification.

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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	<p>The part of ER 1 relating to the risk of use error is not addressed in this European Standard.</p> <p>The part of ER 7.1 relating to results of biophysical and modelling research is not addressed by this European Standard.</p>
9	3, 8.1, 8.3, 8.4, 8.5, 8.6, 8.7, 13.3	<p>Via ISO 14630</p> <p>The modification of ER 13.3 f is not addressed in this European Standard.</p>
10	3, 5, 7.2, 8.1, 8.3, 8.4, 8.5, 8.6, 8.7	Via ISO 14630
11	9.1, 13	<p>The part of ER 13.3.a concerning the information on the authorized representative is not addressed in this European Standard.</p> <p>ER 13.3 f is only partly addressed in this European Standard: safety issue of single use.</p> <p>ER 13.6 q is not addressed by this International Standard.</p>
<p>NOTE Clauses 4, 5, 6, 7, 8 and subclause 11.5 supplement and are dependent on the corresponding clauses of ISO 21534.</p> <p>https://standards.iteh.ai/catalog/standards/sist/4fd3c608-5bb4-4db6-a8ba-a874ce218b2e/sist-en-iso-21535-2009</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
21535

Second edition
2007-10-01

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

*Implants chirurgicaux non actifs — Implants de remplacement
d'articulation — Exigences spécifiques relatives aux implants de
remplacement de l'articulation de la hanche*

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