
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)

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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)

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Ta slovenski standard je istoveten z: EN ISO 21535:2007

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English Version

Non-active surgical implants - Joint replacement implants -
Specific requirements for hip-joint replacement implants (ISO
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Nichtaktive chirurgische Implantate - Implantate zum
Gelenkersatz - Besondere Anforderungen an Implantate für
den Hüftgelenkersatz (ISO 21535:2007)

This European Standard was approved by CEN on 16 August 2007.

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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Contents

Page

Foreword.....	3
---------------	---

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Foreword

This document (EN ISO 21535:2007) 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 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of an identical text or by endorsement, at the latest by March 2008, and conflicting national standards shall be withdrawn at the latest by March 2008.

This document supersedes EN 12563:1998.

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(s).

For relationship with EC Directive(s), 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.

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Endorsement notice

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The text of ISO 21535:2007 has been approved by CEN as a EN ISO 21535:2007 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.

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 International Standard and Directive 93/42/EEC

Clause(s)/sub-clause(s) of this International Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4	1, 2, 3, 4, 5, 7.1, 7.2, 9.2	
5	1, 2, 3, 4, 5, 6, 7.1, 9.1, 9.2	
6	1, 2, 3, 4, 7.1, 7.2, 7.3, 7.4, 8.2, 9.1, 9.2	
7	1, 2, 3, 4, 5, 6, 7.1, 7.2, 7.3, 14	
8	1, 2, 3, 4, 5, 7.1, 7.2, 7.3	
9	3, 8.1, 8.3, 8.4, 8.5, 8.6, 8.7, 13.3	Via ISO 14630
10	3, 5, 7.2, 8.1, 8.3, 8.4, 8.5, 8.6, 8.7	Via ISO 14630
11	9.1, 13	
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.

**Non-active surgical implants — Joint
replacement implants — Particular
requirements**

*Implants chirurgicaux non actifs — Implants de remplacement
d'articulation — Exigences particulières*

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Contents

Page

Foreword.....	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions.....	2
4 Intended performance	2
5 Design attributes.....	3
5.1 General.....	3
5.2 Surface finish of metallic or ceramic implants articulating on ultra-high-molecular-weight polyethylene (UHMWPE)	3
5.3 Surface finish of metallic or ceramic partial implants	3
5.4 Surfaces of convex, spherically-conforming metallic or ceramic implants articulating on UHMWPE.....	3
5.5 Surfaces of spherically-conforming metallic or ceramic partial implants.....	3
5.6 Surfaces of concave, spherically-conforming UHMWPE components	3
6 Materials	4
6.1 General.....	4
6.2 Dissimilar metals or alloys	4
7 Design evaluation	4
7.1 General.....	4
7.2 Preclinical evaluation	4
7.3 Clinical investigation	5
7.4 Post market surveillance	5
8 Manufacture and inspection	5
8.1 General.....	5
8.2 Metal surfaces	5
8.3 Plastic surfaces.....	5
8.4 Ceramic surfaces	5
9 Sterilization.....	6
9.1 General.....	6
9.2 Expiry	6
10 Packaging	6
11 Information supplied by the manufacturer	6
11.1 General.....	6
11.2 Labelling of implants for use on one side of the body only.....	6
11.3 Instructions for orientation of implants.....	6
11.4 Markings for orientation of the implants	6
11.5 Placing of markings on implants	6
11.6 Restrictions on use.....	7
11.7 Re-sterilization of zirconia ceramics	7
11.8 Labelling of implants for use with or without bone cement.....	7
Annex A (informative) List of International Standards for materials found acceptable for the manufacture of implants	8
Annex B (informative) List of International Standards for materials found acceptable or not acceptable for articulating surfaces of implants	9

Annex C (informative) List of materials found acceptable or non-acceptable for metallic combinations for non-articulating contacting surfaces of implants 11

Bibliography 12

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 21535:2008
<https://standards.iteh.ai/catalog/standards/sist/265ff83f-c1d2-43d7-977a-0b9cb211f1bc/sist-en-iso-21535-2008>

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.

ISO 21534 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 4, *Bone and joint replacements*.

This second edition cancels and replaces the first edition (ISO 21534:2002), which has been technically revised.

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