

STN	Neaktívne chirurgické implantáty Implantáty kĺbov Špecifické požiadavky na implantáty bedrového kĺbu (ISO 21535: 2007) Zmena A1	STN EN ISO 21535/A1 85 2937
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Non-active surgical implants - Joint replacement implants - Specific requirements for hip-joint replacement implants (ISO 21535:2007)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 06/17

Obsahuje: EN ISO 21535:2009/A1:2016, ISO 21535:2007/Amd 1:2016

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Úrad pre normalizáciu, metrológiu a skúšobníctvo Slovenskej republiky, 2017
Podľa zákona č. 264/1999 Z. z. o technických požiadavkách na výrobky a o posudzovaní zhody a o zmene a doplnení niektorých zákonov v znení neskorších predpisov sa slovenská technická norma a časti slovenskej technickej normy môžu rozmnožovať alebo rozširovať len so súhlasom slovenského národného normalizačného orgánu.

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 21535:2009/A1

December 2016

ICS 11.040.40

English Version

**Non-active surgical implants - Joint replacement implants -
Specific requirements for hip-joint replacement implants -
Amendment 1 (ISO 21535:2007/Amd 1:2016)**

Implants chirurgicaux non actifs - Implants de
remplacement d'articulation - Exigences spécifiques
relatives aux implants de remplacement de
l'articulation de la hanche - Amendement 1 (ISO
21535:2007/Amd 1:2016)

Nichtaktive chirurgische Implantate - Implantate zum
Gelenkersatz - Besondere Anforderungen an
Implantate für den Hüftgelenkersatz - Änderung 1 (ISO
21535:2007/Amd 1:2016)

This amendment A1 modifies the European Standard EN ISO 21535:2009; it was approved by CEN on 14 October 2016.

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. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This amendment 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-CENELEC 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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European foreword

This document (EN ISO 21535:2009/A1:2016) 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 Amendment to the European Standard EN ISO 21535:2009 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 2017, and conflicting national standards shall be withdrawn at the latest by June 2017.

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 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(s).

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, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 21535:2007/Amd 1:2016 has been approved by CEN as EN ISO 21535:2009/A1:2016 without any modification.

Addition of the new Annex ZB.

Annex ZB (informative)

Correlations between undated normative references and dated EN and ISO standards

The following referenced documents are indispensable for the application of this document. For undated references, the latest edition of the referenced document (including any amendments) applies. For dated references, only the edition cited applies. However, for any use of this standard "within the meaning of Annex ZB", the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When an IEC or ISO standard is referred to in the ISO standard text, this shall be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated version of the ISO or IEC standard, as listed below.

NOTE The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

Table ZB.1 — Correlations between undated normative references and dated EN and ISO standards

Normative references as listed in Clause 2	Equivalent dated standard	
	EN	ISO
ISO 7206-1:2008	—	ISO 7206-1:2008
ISO 7206-2:2011	—	ISO 7206-2:2011
ISO 7206-4:2010	—	ISO 7206-4:2010
ISO 7206-6:2013	—	ISO 7206-6:2013
ISO 7206-10:2003	—	ISO 7206-10:2003
ISO 14630:2012	EN/ISO 14630:2012	ISO 14630:2012
ISO 21534:2007	EN/ISO 21534:2009	ISO 21534:2007

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

AMENDMENT 1

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

AMENDEMENT 1





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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

The committee responsible for this document is ISO/TC 150, *Implants for surgery*, Subcommittee SC 4, *Bone and joint replacements*.

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

AMENDMENT 1

Page 1, Clause 2

Update the normative references with the following:

ISO 7206-1, *Implants for surgery — Partial and total hip joint prostheses — Part 1: Classification and designation of dimensions*

ISO 7206-2, *Implants for surgery — Partial and total hip joint prostheses — Part 2: Articulating surfaces made of metallic, ceramic and plastics materials*

ISO 7206-4, *Implants for surgery — Partial and total hip joint prostheses — Part 4: Determination of endurance properties and performance of stemmed femoral components*

ISO 7206-6, *Implants for surgery — Partial and total hip joint prostheses — Part 6: Endurance properties testing and performance requirements of neck region of stemmed femoral components*

ISO 7206-10, *Implants for surgery — Partial and total hip joint prostheses — Part 10: Determination of resistance to static load of modular femoral heads*

ISO 14242-1, *Implants for surgery — Wear of total hip-joint prostheses — Part 1: Loading and displacement parameters for wear-testing machines and corresponding environmental conditions for test*

ISO 14242-2, *Implants for surgery — Wear of total hip-joint prostheses — Part 2: Methods of measurement*

ISO 14242-3, *Implants for surgery — Wear of total hip-joint prostheses — Part 3: Loading and displacement parameters for orbital bearing type wear testing machines and corresponding environmental conditions for test*

ISO 14630, 2012, *Non-active surgical implants — General requirements*

ISO 21534, 2007, *Non-active surgical implants — Joint replacement implants — Particular requirements*

koniec náhľadu – text ďalej pokračuje v platenej verzii STN