

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

ICS 11.040.40

National foreword

This British Standard is the UK implementation of EN ISO 21536:2009+A1:2014. It is identical to ISO 21536:2007, incorporating amendment 1:2014. It supersedes BS EN ISO 21536:2009 which is withdrawn.

The UK participation in its preparation was entrusted by Technical Committee CH/150, Implants for surgery to Subcommittee CH/150/4, Surgical Implants - Bone and Joint Replacements.

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 October 2009

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ISBN 978 0 580 92634 1

Amendments/corrigenda issued since publication

Date	Comments
30 April 2014	Implementation of ISO amendment 1:2014 with CEN endorsement A1:2014: New normative reference added to clause 2, subclause 5.4 inserted. Annex ZA amended
31 March 2016	Implementation of CEN Correction Notice 2 July 2014: Table ZA.1 updated

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.

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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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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.

Foreword to amendment A1

This document (EN ISO 21536:2009/A1:2014) has been prepared by Technical Committee ISO/TC 150 "Implants for surgery" in collaboration 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 21536:2009 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by September 2014, and conflicting national standards shall be withdrawn at the latest by September 2014.

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Endorsement notice

The text of ISO 21536:2007/Amd 1:2014 has been approved by CEN as EN ISO 21536:2009/A1:2014 without any modification.

Annex ZA (informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices

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 Union 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.1 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.1 — Correspondence between this European Standard and Directive 93/42/EEC on medical devices

Clause(s)/sub-clause(s) of this European Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
5, 6	7.1, 1st indent	This ER is not covered by these clauses
5.3	7.1, 2nd indent	
7.1	7.1, 3rd indent	
5, 7, 8, 10	7.2	
5, 6, 8, 10	7.3	Clause 10 packaging not covered by this ER
6	7.4	Covered in respect of medicinal products by reference to Clause 6 of EN ISO 14630 from Clause 6 of ISO 21534:2007
5.3, 6, 8	7.5	
5.3, 6, 8	7.6	
5, 6, 8, 9	8.1	
6	8.2	Covered in respect of tissues of animal origin by reference to Clause 6 of EN ISO 14630 from Clause 6 of ISO 21534:2007
9, 10	8.3	Covered in respect of sterilisation and packaging only
9	8.4	
8, 9	8.5	Clauses 8 and 9 do not through their references address the environmental conditions of manufacture
9, 10	8.6	
11	8.7	