SLOVENSKI STANDARD
SIST EN ISO 21536:2024

01-september-2024

Neaktivni kirurški vsadki (implantati) - Sklepne proteze - Posebne zahteve za kolenske proteze (ISO 21536:2023)

Non-active surgical implants - Joint replacement implants - Specific requirements for knee-joint replacement implants (ISO 21536:2023)

Nichtaktive chirurgische Implantate - Implantate zum Gelenkersatz - Spezielle Anforderungen an Implantate für den Kniegelenkersatz (ISO 21536:2023)

Implants chirurgicaux non actifs - Implants de remplacement d'articulation - Exigences spécifiques relatives aux implants de remplacement de l'articulation du genou (ISO 21536:2023)

Ta slovenski standard je istoveten z: **EN ISO 21536:2024**

ICS:

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

SIST EN ISO 21536:2024 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 21536

July 2024

ICS 11.040.40

Supersedes EN ISO 21536:2009 EN ISO 21536:2009/A1:2014

English Version

Non-active surgical implants - Joint replacement implants - Specific requirements for knee-joint replacement implants (ISO 21536:2023)

Implants chirurgicaux non actifs - Implants de remplacement d'articulation - Exigences spécifiques relatives aux implants de remplacement de l'articulation du genou (ISO 21536:2023)

Nichtaktive chirurgische Implantate - Implantate zum Gelenkersatz - Spezielle Anforderungen an Implantate für den Kniegelenkersatz (ISO 21536:2023)

This European Standard was approved by CEN on 4 June 2023.

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-CENELEC 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-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and United Kingdom.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Contents

Page

European foreword

This document (EN ISO 21536:2024) 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 January 2025, and conflicting national standards shall be withdrawn at the latest by January 2025.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 21536:2009, EN ISO 21536:2009/A1:2014.

This document has been prepared under a standardization request addressed to CEN by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

For the relationship with EU Legislation, see informative Annex ZA, which is an integral part of this document.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 21536:2023 has been approved by CEN as EN ISO 21536:2024 without any modification.

Annex ZA
(informative)

Relationship between this European standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered

This European Standard has been prepared under a Commission's standardization request "M/575" to provide one voluntary means of conforming to the General Safety and Performance Requirements of Regulation (EU) 2017/745 of 5 April 2017 concerning medical devices [OJ L 117].

Once this standard is cited in the Official Journal of the European Union under that Regulation, compliance with the normative clauses of this standard given in Table ZA.1 and application of the edition of the normatively referenced standards as given in Table ZA.2 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding General Safety and Performance Requirements of that Regulation, and associated EFTA regulations.

Where a definition in this standard differs from a definition of the same term set out in Regulation (EU) 2017/745, the differences shall be indicated in this Annex Z. For the purpose of using this standard in support of the requirements set out in Regulation (EU) 2017/745, the definitions set out in this Regulation prevail.

Where the European standard is an adoption of an International Standard, the scope of this standard can differ from the scope of the European Regulation that it supports. As the scope of the applicable regulatory requirements differ from nation to nation and region to region, the standard can only support European regulatory requirements to the extent of the scope of the European regulation for medical devices (EU) 2017/745).

For application of this European standard under Regulation (EU) 2017/745,

1 it is clarified that the third paragraph of the scope and the related subclause 7.2.1.2 are solely intended to point out that additional testing not specified in this document can be required to ensure the safety and efficacy of implants for which failure modes exist which were unknown at the time of drafting of this document;

2 it is clarified that the fourth paragraph of the scope and related language in the first paragraphs of Clauses 4, 5, 6 and 7 are intended to avoid unnecessary re-design or re-testing of implants which are currently legally marketed in the European Union;

3 it is recognized that the normatively referenced ISO 7207-2:2011+Amd 1:2016+Amd 2:2020 itself includes a reference to the withdrawn ISO 4288:1996 which has been replaced by ISO 21920-3:2021 and for application of this European standard under Regulation (EU) 2017/745 ISO 21920-3:2021 shall be used instead of ISO 4288:1996;

4 it is recognized that the normatively referenced ISO 10993-1 includes a dated reference to ISO 14971:2007 which is outdated and for application of this European standard under Regulation (EU) 2017/745 the most recent European version EN ISO 14971:2019 + A11:2021 shall be used;

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Regulation (EU) 2017/745. This means that risks have to be 'reduced as far as possible', 'reduced to the lowest possible level', 'reduced as far as possible and appropriate', 'removed or reduced as far as possible', 'eliminated or reduced as far as possible', 'removed or minimized as far as possible', or 'minimized', according to the wording of the corresponding General Safety and Performance Requirement.

NOTE 2 The manufacturer's policy for determining **acceptable risk** must be in compliance with General Safety and Performance Requirements 1, 2, 3, 4, 5, 8, 9, 10, 11, 14, 16, 17, 18, 19, 20, 21 and 22 of the Regulation.

NOTE 3 When a General Safety and Performance Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 — Correspondence between this European standard and Annex I of Regulation (EU) 2017/745 [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
10.1 (c)	7.2.2.4 7.2.2.5 7.2.2.6 7.2.2.7 7.2.2.9 7.2.2.10 7.2.2.12 7.2.2.13 and 7.2.2.14	10.1 (c) is covered as follows: The durability of the patellofemoral joint is covered by 7.2.2.4. The attachment of the tibial insert to the tibial tray is covered by 7.2.2.5. The attachment of the patella insert to the patellar tray is covered by 7.2.2.6. The resistance to dynamic disassociation of mobile-bearing knee components from the tibial tray is covered by 7.2.2.7. The dislocation of mobile-bearing knees is covered by 7.2.2.9. The static and fatigue strength of modular connections is covered by 7.2.2.10. The patellofemoral resistance to lateral subluxation is covered by 7.2.2.12. The tibio-femoral and the patella-femoral contact area and pressure are covered by 7.2.2.13 and 7.2.2.14.
10.1 (f)	7.2.2 (all subclauses)	10.1 (f) is covered with the exception of "ductility" by 7.2.2 (all subclauses).
10.1 (g)	5.2.2 and 5.2.3	10.1 (g) is covered with respect to the surface finish by 5.2.2 and 5.2.3.

10.4.1 1st paragraph	7.2.2.2 and 7.2.2.3	10.4.1 is covered with respect to wear of the bearings of knee implants by 7.2.2.2 and 7.2.2.3 which require that the bearings of knee joints shall undergo wear testing and the wear shall be the same or less than the wear of a reference implant.
23.2 (b)	11.2	23.2 (b) is covered with respect to product type and dimensions by 11.2.
23.4 (s)	11.5	23.4 (s) is covered with respect to the information for the patient by 11.5.

Table ZA.2 — Applicable Standards to confer presumption of conformity as described in this Annex ZA

Column 1 Reference in Clause 2	Column 2 International Standard Edition	Column 3 Title	Column 4 Corresponding European Standard Edition
ISO 5834-1	ISO 5834-1:2019	Implants for surgery — Ultra-high-molecular-weight polyethylene — Part 1: Powder form	-
ISO 7207-1:2007	ISO 7207-1:2007	Implants for surgery — Components for partial and total knee joint prostheses — Part 1: Classification, definitions and designation of dimensions	-
ISO 7207-2	ISO 7207-2:2011 and ISO 7207-2:2011/Amd 1:2016 and ISO 7207-2:2011/Amd 2:2020	Implants for surgery — Components for partial and total knee joint prostheses — Part 2: Articulating surfaces made of metal, ceramic and plastics materials	-
ISO 10993-1	ISO 10993-1:2018	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process	EN ISO 10993-1:2020
ISO 14243-1	ISO 14243-1:2009 and ISO 14243-1:2009/Amd 1:2020	Implants for surgery — Wear of total knee-joint prostheses — Part 1: Loading and displacement parameters for wear-testing machines with load control and	-

		corresponding environmental conditions for test	
ISO 14243-2	ISO 14243-2:2016	Implants for surgery — Wear of total knee-joint prostheses — Part 2: Methods of measurement	-
ISO 14243-3	ISO 14243-3:2014 and ISO 14243-3:2014/Amd 1:2020	Implants for surgery — Wear of total knee-joint prostheses — Part 3: Loading and displacement parameters for wear-testing machines with displacement control and corresponding environmental conditions for test	-
ISO 14243-5	ISO 14243-5:2019	Implants for surgery — Wear of total knee prostheses — Part 5: Durability performance of the patellofemoral joint	-
ISO 14630	ISO 14630:2012	Non-active surgical implants — General requirements	EN ISO 14630:2012
ISO 14879-1	ISO 14879-1:2020	Implants for surgery — Total knee-joint prostheses — Part 1: Determination of endurance properties of knee tibial trays	-
ISO 21534:2007	ISO 21534:2007	Non-active surgical implants — Joint replacement implants — Particular requirements	EN ISO 21534:2009

The documents listed in the Column 1 of Table ZA.2, in whole or in part, are normatively referenced in this document, i.e. are indispensable for its application. The achievement of the presumption of conformity is subject to the application of the edition of Standards as listed in Column 4 or, if no European Standard Edition exists, the International Standard Edition given in Column 2 of Table ZA.2.

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the product(s) falling within the scope of this standard.

INTERNATIONAL STANDARD

ISO 21536

Third edition
2023-07

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

Reference number
ISO 21536:2023(E)