ICS 11.040.40 SLOVENSKÁ TECHNICKÁ NORMA Október 2024

STN	**Neaktívne chirurgické implantáty Implantáty kĺbov Špecifické požiadavky na implantáty kolenného kĺbu (ISO 21536: 2023)**	**STN EN ISO 21536** 85 2931

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

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. 09/24

Obsahuje: EN ISO 21536:2024, ISO 21536:2023

Oznámením tejto normy sa ruší
STN EN ISO 21536 (85 2931) zo septembra 2009

139206

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

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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)

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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 document 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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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

For an explanation of the voluntary nature of standards, 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 www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 4, *Bone and joint replacements,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 285, *Non-active surgical implants,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO 21536:2007), which has been technically revised. It also incorporates the Amendment ISO 21536:2007/Amd 1:2014.

The main changes are as follows:

— The scope has been expanded to specify more precisely the knee joint replacement types which are the subject of this document. Also, the scope now clarifies the requirements for implants which have been legally marketed and for which there is a history of sufficient and safe clinical use.

— The number of normative references has been expanded, including the addition of several ASTM standards.

— Several new definitions have been added, including: maximum claimed flexion, mobile-bearing component, mobile-bearing knee joint prosthesis, partial knee joint prosthesis and partial knee joint replacement, posterior stabilized tibial insert, reference implant, sufficient and safe clinical use, tibial insert, total knee joint prosthesis and total knee joint replacement, ultra-high molecular weight polyethylene and UHMWPE, uni-compartmental knee joint replacement and UKR, and worst case.

— The design attributes to be taken into account have been specified in Clause 5. The requirements for the thickness of various knee joint components made from plastic, metal and ceramic have been expanded.

— Several new general requirements have been added in 7.2.1, which specify

a) the circumstances when a test can be omitted,

b) the testing of the worst case,

c) the processes to be followed when no performance requirement has been specified, and

d) the processes to be followed when a performance requirement has been specified but has not been met.

— The number of pre-clinical evaluations (bench tests) to be performed has been greatly increased in 7.2.2. For some of the tests, a performance requirement has been specified. For some of the tests, no performance requirement has been specified and, in these cases, a new requirement has been added, namely the requirement to demonstrate that the performance of the implant under evaluation is the same or better than that of a reference implant. If no reference implant exists, a sequence of alternative options has been specified. These alternative options are also available in the case where there is a performance requirement, which is not met by the implant being tested.

— A new clinical investigation subclause has been added in 7.3, with several requirements which specify the circumstances in which a clinical investigation can be required.

— A new post-market surveillance subclause has been added in 7.4, which references the requirements in ISO 21534:2007, 7.4.

— Several new marking requirements have been specified in 11.4.

— A note has been added in 11.6 which states that in some jurisdictions there is the option to provide the instructions for use in electronic instead of paper format.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

There are three levels of standards dealing with non-active surgical implants. These are as follows, with level 1 being the highest:

— level 1: general requirements for non-active surgical implants and instrumentation used in association with implants;

— level 2: particular requirements for families of non-active surgical implants;

— level 3: specific requirements for types of non-active surgical implant.

This document is a level 3 standard and contains requirements applying specifically to knee joint replacements.

The level 1 standard, ISO 14630, contains requirements that apply to all non-active surgical implants. It also indicates that there are additional requirements in the level 2 and level 3 standards.

The level 2 standards apply to more restricted sets or families of implants such as those designed for use in osteosynthesis, cardiovascular surgery or joint replacement. For joint replacement implants, the level 2 standard is ISO 21534.

To address all requirements, it is recommended that a standard of the lowest available level be consulted first.

INTERNATIONAL STANDARD **ISO 21536:2023(E)**

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

1 Scope

This document specifies requirements for knee-joint replacement implants. Regarding safety, this document specifies requirements for intended performance, design attributes, materials, design evaluation, manufacture, sterilization, packaging, information supplied by the manufacturer and methods of test.

This document applies to both total and partial knee joint replacement implants. It applies to these replacements both with and without the replacement of the patella-femoral joint. It applies to components made of metallic and non-metallic materials.

This document applies to a wide variety of knee replacement implants, but for some specific knee replacement implant types, some considerations, not specifically covered in this document, can be applicable. Further details are given in 7.2.1.2.

The requirements which are specified in this document are not intended to require the re-design or re-testing of implants which have been legally marketed and for which there is a history of sufficient and safe clinical use. For such implants, compliance with this document can be demonstrated by providing evidence of the implant's sufficient and safe clinical use.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 5834-1, *Implants for surgery — Ultra-high-molecular-weight polyethylene — Part 1: Powder form*

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, *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, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 14243-1, *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, *Implants for surgery — Wear of total knee-joint prostheses — Part 2: Methods of measurement*

ISO 14243-3, *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, *Implants for surgery — Wear of total knee prostheses — Part 5: Durability performance of the patellofemoral joint*

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

ISO 14879-1, *Implants for surgery — Total knee-joint prostheses — Part 1: Determination of endurance properties of knee tibial trays*

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

ASTM F648, *Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants*

ASTM F1223, *Standard Test Method for Determination of Total Knee Replacement Constraint*

ASTM F2722, *Standard Practice for Evaluating Mobile Bearing Knee Tibial Baseplate Rotational Stops*

ASTM F2723, *Standard Test Method for Evaluating Mobile Bearing Knee Tibial Baseplate/Bearing Resistance to Dynamic Disassociation*

ASTM F2724, *Standard Test Method for Evaluating Mobile Bearing Knee Dislocation*

ASTM F2777, *Standard Test Method for Evaluating Knee Bearing (Tibial Insert) Endurance and Deformation Under High Flexion*

ASTM F3210, *Standard Test Method for Fatigue Testing of Total Knee Femoral Components under Closing Conditions*

