SLOVENSKI STANDARD
SIST EN ISO 16061:2021

01-julij-2021

Nadomešča:
SIST EN ISO 16061:2015

Instrumenti, ki se uporabljajo pri neaktivnih kirurških vsadkih (implantatih) - Splošne zahteve (ISO 16061:2021)

Instruments for use in association with non-active surgical implants - General requirements (ISO 16061:2021)

Instrumente, die in Verbindung mit nichtaktiven chirurgischen Implantaten verwendet werden - Allgemeine Anforderungen (ISO 16061:2021)

Instruments à utiliser en association avec les implants chirurgicaux non actifs - Exigences générales (ISO 16061:2021)

Ta slovenski standard je istoveten z: **EN ISO 16061:2021**

ICS:

11.040.30	Operacijski instrumenti in materiali	Surgical instruments and materials

SIST EN ISO 16061:2021 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 16061

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Supersedes EN ISO 16061:2015

English Version

Instruments for use in association with non-active surgical implants - General requirements (ISO 16061:2021)

Instruments à utiliser en association avec les implants chirurgicaux non actifs - Exigences générales (ISO 16061:2021)

Instrumente, die in Verbindung mit nichtaktiven chirurgischen Implantaten verwendet werden - Allgemeine Anforderungen (ISO 16061:2021)

This European Standard was approved by CEN on 5 January 2021.

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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 16061:2021) 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of an identical text or by endorsement, at the latest by September 2021, and conflicting national standards shall be withdrawn at the latest by September 2021.

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The text of ISO 16061:2021 has been approved by CEN as EN ISO 16061:2021 without any modification.

INTERNATIONAL STANDARD

ISO 16061

Fourth edition
2021-03

Instruments for use in association with non-active surgical implants — General requirements

Instruments à utiliser en association avec les implants chirurgicaux non actifs — Exigences générales

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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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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*, 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 fourth edition cancels and replaces the third edition (ISO 16061:2015), which has been technically revised. The main changes compared to the previous edition are as follows:

— A requirement to include intended purpose has been added in the list of items to be included when establishing the intended performance of the instrument.

— The list of design attributes in Clause 5 has been reorganized and several new attributes have added to the list.

— The selection of materials to be used in the instrument has been based on a risk analysis and the clause now includes a list of the minimum factors to be considered in the risk analysis.

— The requirement for pre-clinical evaluation has been expanded and includes the requirement for testing and biological evaluation of the final instrument.

— A clinical evaluation of the instrument has been added as a requirement in all cases. However, if the pre-clinical evaluation demonstrates the safety and intended performance of the instrument in the conditions of intended use, the results of the pre-clinical evaluation will satisfy the requirement for the clinical evaluation.

— A new requirement for post-market surveillance has been added to Clause 7.

— The requirements in Clause 11 have been reorganized and clarified to reflect current practice and to reference ISO 17664:2017, Clause 6 for instructions for applicable processing step (i.e. cleaning, disinfection, drying, packaging, and sterilization) that need to be carried out by someone other than the manufacturer.

— Annex A has been simplified to provide more consistent guidance on selection of material using a risk-based approach. The stainless-steel grade material characteristic tables have been removed.

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.