SIST

SLOVENSKI STANDARD
SIST EN ISO 16061:2009

01-oktober-2009

Nadomešča:

SIST EN ISO 16061:2009

Instrumenti, ki se uporabljajo pri neaktivnih kirurških vsadkih (implantati) - Splošne zahteve (ISO 16061:2008, popravljena verzija 2009-03-15)

Instrumentation for use in association with non-active surgical implants - General requirements (ISO 16061:2008, Corrected version 2009-03-15)

Instrumente die in Verbindung mit nichtaktiven chirurgischen Implantaten verwendet werden - Allgemeine Anforderungen (ISO 16061:2008, korr. Version 2009-03-15)

Instrumentation à utiliser en association avec les implants chirurgicaux non actifs - Exigences générales (ISO 16061:2008, Version corrigés 2009-03-15)

Ta slovenski standard je istoveten z: **EN ISO 16061:2009**

ICS:

11.040.30	Operacijski instrumenti in materiali	Surgical instruments and materials

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EUROPEAN STANDARD

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English Version

Instrumentation for use in association with non-active surgical implants - General requirements (ISO 16061:2008, Corrected version 2009-03-15)

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This European Standard was approved by CEN on 20 July 2009.

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 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 Management Centre has the same status as the official versions.

CEN members are the national standards bodies of 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 United Kingdom.

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

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Foreword

The text of ISO 16061:2008, corrected version 2009-03-15 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 16061:2009 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 February 2010, and conflicting national standards shall be withdrawn at the latest by February 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 16061:2008.

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 EC Directive 93/42/EEC.

For relationship with EC Directive 93/42/EEC, 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 16061:2008, corrected version 2009-03-15 has been approved by CEN as a EN ISO 16061:2009 without any modification.

Annex ZA
(informative)

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

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 Communities 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 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 — Correspondence between this European Standard and Directive 93/42/EEC

Clause/subclause of this International Standard	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
4	1, 2, 3, 4, 12	
5	1, 2, 3, 4, 5, 7.1, 7.2, 7.3, 7.5, 7.6, 8, 9, 10.1, 12	Part of ER 1 relating to risk of use error is not addressed by this European Standard.
6	1, 2, 7.1	
7	1, 2, 3, 4, 5, 6, 7, 9.1, 9.2, 12	Part of ER 7.1 relating to the results of biophysical or modelling research is not explicitly addressed by this European Standard.
8	1, 2, 3, 4, 5, 7, 9, 12	
9	1, 2, 3, 4, 7, 8.1, 8.3 to 8.7, 13.3. c), 13.6 h)	Part of ER 13.6 h) relating to single use is not addressed by this European Standard.
10	1, 2, 4, 5, 7.2, 7.5, 7.6, 8.3, 8.6, 8.7	
11	13	Part of ER 13.3 a) concerning the information on the authorized representative is not addressed in this European Standard. Part of ER 13.3 f) is only partially addressed: Safety issue is addressed, but not the regulatory requirement (consistency around Europe). Part of ER 13.6 h) relating to single use is not addressed by this European Standard. ER 13.6 q) is not addressed by this European Standard.

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

INTERNATIONAL STANDARD

ISO 16061

Second edition
2008-12-01

Corrected version
2009-03-15

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

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

Reference number
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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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

ISO 16061 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*.

This second edition cancels and replaces the first edition (ISO 16061:2000), which has been technically revised.

In this corrected version of ISO 16061:2008 the normative reference to EN 1041 has been altered:

— in Clause 2 (date deleted);

— in subclause 11.1 (date and reference to 4.3 deleted).

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

1 Scope

This International Standard specifies general requirements for instruments to be used in association with non-active surgical implants. These requirements apply to instruments when they are manufactured and when they are resupplied after refurbishment.

This International Standard also applies to instruments which may be connected to power-driven systems, but does not apply to the power-driven systems themselves.

With regard to safety, this International Standard gives requirements for intended performance, design attributes, selection of materials, design evaluation, manufacture, sterilization, packaging and information to be supplied by the manufacturer.

This International Standard is not applicable to instruments associated with dental implants, transendodontic and transradicular implants and ophthalmic implants.

2 Normative references

The following referenced documents are indispensable for the application 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 11135-1, *Sterilization of health care products — Ethylene oxide — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11137-1, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11137-2, *Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose*

ISO 11137-3, *Sterilization of health care products — Radiation — Part 3: Guidance on dosimetric aspects*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 11607-2, *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes*

ISO 14155-1, *Clinical investigation of medical devices for human subjects — Part 1: General requirements*

ISO 14155-2, *Clinical investigation of medical devices for human subjects — Part 2: Clinical investigation plans*

ISO 14971, *Medical devices — Application of risk management to medical devices*