# Instrumendid kasutamiseks mitteaktiivsete kirurgiliste implantaatidega. Üldnõuded

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

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

| | |
|---|---|
| Käesolev Eesti standard EVS-EN ISO 16061:2010 sisaldab Euroopa standardi EN ISO 16061:2009 ingliskeelset teksti. | This Estonian standard EVS-EN ISO 16061:2010 consists of the English text of the European standard EN ISO 16061:2009. |
| Standard on kinnitatud Eesti Standardikeskuse 30.04.2010 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas. | This standard is ratified with the order of Estonian Centre for Standardisation dated 30.04.2010 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation. |
| Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 05.08.2009. | Date of Availability of the European standard text 05.08.2009. |
| Standard on kättesaadav Eesti standardiorganisatsioonist. | The standard is available from Estonian standardisation organisation. |



**ICS** 11.040.30, 11.040.99

EUROPEAN STANDARD

NORME EUROPÉENNE

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# EN ISO 16061

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ICS 11.040.40; 11.040.99

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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)

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

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

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.

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Ref. No. EN ISO 16061:2009: E

# 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.<br>Part of ER 13.3 f) is only partially addressed: Safety issue is addressed, but not the regulatory requirement (consistency around Europe).<br>Part of ER 13.6 h) relating to single use is not addressed by this European Standard.<br>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.

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# 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*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 17664, *Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices*

ISO 17665-1, *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

EN 556-1, *Sterilization of medical devices — Requirements for medical devices to be designated "STERILE" — Part 1: Requirements for terminally sterilized medical devices*

EN 556-2, *Sterilization of medical devices — Requirements for medical devices to be designated "STERILE" — Part 2: Requirements for aseptically processed medical devices*

EN 1041, *Information supplied by the manufacturer of medical devices*

## 3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

**3.1**
**associated instrument**
**instrument**
non-active medical device intended for use during surgical procedures related to a specific non-active surgical implant

**3.2**
**resupplied instrument**
instrument or set of instruments that has been returned to the manufacturer and has been re-issued

## 4 Intended performance

The intended performance of an instrument shall be described and documented by addressing the following:

a) functional characteristics;

b) intended conditions of use.

NOTE Account should be taken of

— published standards;

— published clinical and scientific literature;

— validated test results.

The extent to which the intended performance of an instrument has been achieved shall be determined (see Clause 7).