SLOVENSKI STANDARD
kSIST FprEN ISO 16061:2009

01-junij-2009

Instrumenti, ki se uporabljajo pri neaktivnih kirurških vsadkih (implantati) - Splošne zahteve (ISO 16061:2008)

Instrumentation for use in association with non-active surgical implants - General requirements (ISO 16061:2008)

Instrumentation à utiliser en association avec les implants chirurgicaux non actifs - Exigences générales (ISO 16061:2008)

Ta slovenski standard je istoveten z: **FprEN ISO 16061**

ICS:

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

kSIST FprEN ISO 16061:2009 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

FINAL DRAFT
FprEN ISO 16061

March 2009

ICS 11.040.40; 11.040.99

Will supersede EN ISO 16061:2008

English Version

Instrumentation for use in association with non-active surgical implants - General requirements (ISO 16061:2008)

Instrumentation à utiliser en association avec les implants chirurgicaux non actifs - Exigences générales (ISO 16061:2008)

This draft European Standard is submitted to CEN members for unique acceptance procedure. It has been drawn up by the Technical Committee CEN/TC 285.

If this draft becomes a European Standard, 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.

This draft European Standard was established by CEN 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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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Contents

Page

Foreword

The text of ISO 16061:2008 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 FprEN ISO 16061:2009 by Technical Committee CEN/TC 285 “Non-active surgical implants” the secretariat of which is held by DIN.

This document is currently submitted to the Unique Acceptance Procedure.

This document will supersede 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.

Endorsement notice

The text of ISO 16061:2008 has been approved by CEN as a FprEN 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

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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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