INSTRUMENDID KASUTAMISEKS MITTEAKTIIVSETE KIRURGILISTE IMPLANTAATIDEGA. ÜLDNÕUDED.

Instrumentation for use in association with non-active surgical implants - General requirements (ISO 16061:2015)

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 16061:2015 sisaldab Euroopa standardi EN ISO 16061:2015 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 16061:2015 consists of the English text of the European standard EN ISO 16061:2015.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 20.05.2015.	Date of Availability of the European standard is 20.05.2015.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.040.40, 11.040.99

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 16061

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Supersedes EN ISO 16061:2009

English Version

Instrumentation for use in association with non-active surgical implants - General requirements (ISO 16061:2015)

Instrumentation à utiliser en association avec les implants chirurgicaux non actifs - Exigences générales (ISO 16061:2015)

Instrumente die in Verbindung mit nichtaktiven chirurgischen Implantaten verwendet werden - Allgemeine Anforderungen (ISO 16061:2015)

This European Standard was approved by CEN on 12 March 2015.

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Foreword

This document (EN ISO 16061:2015) 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 November 2015, and conflicting national standards shall be withdrawn at the latest by November 2015.

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 16061:2009.

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 EU Directive(s).

For relationship with EU Directive(s), 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, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 16061:2015 has been approved by CEN as EN ISO 16061:2015 without any modification.

Annex ZA
(informative)

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

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 Union 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.1 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.1 — Correspondence between this International Standard and Directive 93/42/EEC

Clause(s)/sub-clause(s) of this International Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
7.3	6a	
6	7.1, 1. indent	
6	7.1, 2. indent	
10.1	7.2	In respect of packaging only
6	7.3	
5 i)	7.5	
5 i)	7.6	
5 b) and 6	8.1	
10.2	8.3	In respect of packaging only
9.1	8.4	
5 b)	8.5	
10.1	8.6	
9.1, 9.2, 10.2 and 11.3 i)	8.7	
11.3 f) and 11.5	9.1	
5 f) and 7.1	9.2, 1. indent	
7.1	9.2, 2. indent	
11.2	10.1	
11.1, 11.4 and 11.5	13.1	
11.1	13.2	
11.2 b)	13.3 (a)	The part of ER 13.3 (a) concerning the information on the manufacturer's authorized representative in the European Community is not addressed in this European Standard
11.2 c)	13.3 (b)	

11.2 e)	13.3 (c)	This European Standard is not applicable to power-driven systems, so ER 13.3 (l) is not applicable.
11.2 c)	13.3 (d)	
11.2 g) and 11.1	13.3 (e)	
11.2 h) 11.7	13.3 (f)	ER: 13.3 (f) is only partially addressed in this European Standard. The safety issue is addressed, but not the regulatory requirement that the manufacturer's indication of single use must be consistent across the European community.
11.2 i)	13.3 (i)	
11.2 j)	13.3 (j)	
11.2 e)	13.3 (m)	
11.2 d) and 11.3 d)	13.4	
113 b), 11.3 c), 11.3 h), 11.3 k), 13.3 n)	13.6 (a)	The part of ER 13.6 (a) concerning the information on the manufacturer's authorized representative in the European Community is not addressed in this European Standard. The part of ER 13.6 (a) concerning the regulatory requirement that the manufacturer's indication of single use must be consistent across the European community is not addressed in this European Standard.
11.3 e)	13.6 (b)	
11.3 f)	13.6 (c)	
11.3 g)	13.6 (d)	
13.3 j)	13.6 (g)	
11.3 k)	13.6 (h)	
11.3 m)	13.6 (i)	
11.3 a)	13.6 (j)	
11.3 k)	13.6 (k)	
11.3 o)	13.6 (l)	
11.3 r)	13.6 (m)	
11.3 q)	13.6 (n)	
11.3 r)	13.6(o)	
11.4	13.6 (p)	
11.3 s)	13.6 (q)	

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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