BS EN ISO 16061:2015

BSI Standards Publication

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

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National foreword

This British Standard is the UK implementation of EN ISO 16061:2015. It supersedes BS EN ISO 16061:2009 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/150, Implants for surgery.

A list of organizations represented on this committee can be obtained on request to its secretary.

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May 2015

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 16061:2015)

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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COMITÉ EUROPÉEN DE NORMALISATION
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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of an identical text or by endorsement, at the latest by November 2015, and conflicting national standards shall be withdrawn at the latest by November 2015.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.

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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)	

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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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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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT), see the following URL: Foreword — Supplementary information.

The committee responsible for this document is ISO/TC 150, *Implants for surgery*.

This third edition cancels and replaces the second edition (ISO 16061:2008), which has been technically revised.

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INTERNATIONAL STANDARD ISO 16061:2015(E)

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, materials, design evaluation, manufacture, sterilization, packaging, and information 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 documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

ISO 11135, *Sterilization of health-care products — Ethylene oxide — Requirements for the 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, *Clinical investigation of medical devices for human subjects — Good clinical practice*

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

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*

ISO 80000-1, *Quantities and units — Part 1: General*

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