



# SLOVENSKI STANDARD SIST EN ISO 16671:2015

01-oktober-2015

Nadomešča:  
SIST EN ISO 16671:2004

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**Očesni vsadki (implantati) - Raztopine za izpiranje za očesno kirurgijo (ISO 16671:2015)**

Ophthalmic implants - Irrigating solutions for ophthalmic surgery (ISO 16671:2015)

Ophthalmische Implantate - Spüllösungen für die ophthalmische Chirurgie (ISO 16671:2015)

Implants ophtalmiques - Solutions d'irrigation pour la chirurgie ophtalmique (ISO 16671:2015)

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**Ta slovenski standard je istoveten z: EN ISO 16671:2015**

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**ICS:**

11.040.70	Oftalmološka oprema	Ophthalmic equipment
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EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

**EN ISO 16671**

August 2015

ICS 11.040.70

Supersedes EN ISO 16671:2003

English Version

**Ophthalmic implants - Irrigating solutions for ophthalmic surgery  
(ISO 16671:2015)**

Implants ophtalmiques - Solutions d'irrigation pour la  
chirurgie ophtalmique (ISO 16671:2015)

Ophthalmische Implantate - Spüllösungen für die  
ophthalmische Chirurgie (ISO 16671:2015)

This European Standard was approved by CEN on 7 May 2015.

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-CENELEC 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-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of 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 United Kingdom.

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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**

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## European foreword

This document (EN ISO 16671:2015) has been prepared by Technical Committee ISO/TC 172 “Optics and photonics” in collaboration with Technical Committee CEN/TC 170 “Ophthalmic optics” 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 2016, and conflicting national standards shall be withdrawn at the latest by February 2016.

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 16671:2003.

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.

The following referenced documents are indispensable for the application of this document. For undated references, the latest edition of the referenced document (including any amendments) applies. For dated references, only the edition cited applies. However, for any use of this standard ‘within the meaning of Annex ZA’, the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When an IEC or ISO standard is referred to in the ISO standard text, this shall be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated version of the ISO or IEC standard, as listed below.

**NOTE** The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

**Table — Correlation between normative references and dated EN and ISO standards**

Normative references as listed in Clause 2 of the ISO standard	Equivalent dated standard	
	EN	ISO
ISO 10993-1:2009	EN ISO 10993-1:2009 + AC:2010	ISO 10993-1:2009 + Cor 1:2010
ISO 10993-2:2006	EN ISO 10993-2:2006	ISO 10993-2:2006
ISO 11607-1:2006	EN ISO 11607-1:2009 + A1:2014	ISO 11607-1:2006 + Amd 1:2014
ISO 13408-1:2008 + Amd 1:2013	EN ISO 13408-1:2011 + A1:2013	ISO 13408-1:2008 + Amd 1:2013
ISO 14155:2011	EN ISO 14155:2011 + AC:2011	ISO 14155:2011 + Cor 1:2011
ISO 14630:2012	EN ISO 14630:2012	ISO 14630:2012
ISO 14971:2007	EN ISO 14971:2012	ISO 14971:2007
ISO 15223-1:2012	EN ISO 15223-1:2012	ISO 15223-1:2012
ISO 22442-1:2007	EN ISO 22442-1:2007	ISO 22442-1:2007
EN 1041:2008 + A1:2013	EN 1041:2008 + A1:2013	—

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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 16671:2015 has been approved by CEN as EN ISO 16671:2015 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

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 the Essential Requirements of 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 normative 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.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC, as amended by 2007/47/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining **acceptable risk** must be in compliance with essential requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

NOTE 3 This Annex ZA is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

**Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC**

Clause(s)/subclause(s) of this European Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/notes
5.4.3 & 5.4.6, 7 in respect of EO contamination only.	7.2	
6.3	7.3	
7	7.6	
7	8.1	
5.2, 5.4.3, 6.2.1	8.2	
9, 10 in respect of exposure to environmental elements	8.3	
7 in respect of EO sterilization	8.4	
10	13.1	
10	13.2	
10	13.3 a), b), c), d), e), f), i), j), k), m)	

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10	13.4	
10	13.6 a), b), e), f), g)	

**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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# INTERNATIONAL STANDARD

**ISO**  
**16671**

Second edition  
2015-08-01

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## Ophthalmic implants — Irrigating solutions for ophthalmic surgery

*Implants ophtalmiques — Solutions d'irrigation pour la chirurgie  
ophtalmique*

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Reference number  
ISO 16671:2015(E)

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## ISO 16671:2015(E)

## 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](http://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](http://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](http://www.iso.org/foreword)

The committee responsible for this document is ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This second edition cancels and replaces the first edition (ISO 16671:2003), which has been technically revised.