



SLOVENSKI STANDARD SIST EN ISO 16672:2015

01-oktober-2015

Nadomešča:
SIST EN ISO 16672:2003

Očesni vsadki (implantati) - Sredstva za notranjo očesno tamponado (ISO 16672:2015)

Ophthalmic implants - Ocular endotamponades (ISO 16672:2015)

Ophthalmische Implantate - Okulare Endotamponaden (ISO 16672:2015)

Implants ophtalmiques - Produits de tamponnement endoculaires (ISO 16672:2015)

Ta slovenski standard je istoveten z: EN ISO 16672:2015

SIST EN ISO 16672:2015
http://www.sist.si/standards/standards/16672-2015-00-ac29-0abf1f1543ad/sist-en-iso-16672-2015

ICS:

11.040.70 Oftalmološka oprema Ophthalmic equipment

SIST EN ISO 16672:2015 en

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EUROPEAN STANDARD

EN ISO 16672

NORME EUROPÉENNE

EUROPÄISCHE NORM

August 2015

ICS 11.040.70

Supersedes EN ISO 16672:2003

English Version

Ophthalmic implants - Ocular endotamponades (ISO 16672:2015)

Implants ophtalmiques - Produits de tamponnement
endoculaires (ISO 16672:2015)Ophthalmische Implantate - Okulare Endotamponaden (ISO
16672:2015)

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.

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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 16672:2015) 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 16672:2003.

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 16672:2015 has been approved by CEN as EN ISO 16672:2015 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
5.2 & 5.11, 7 in respect of EO contamination only.	7.2	
6.3	7.3	
7	7.6	
7	8.1	
5.2, 6.2.1	8.2	
10, 11 in respect of exposure to environmental elements	8.3	
7 in respect of EO sterilization	8.4	
11	13.1	
11	13.2	
11	13.3 a), b), c), d), e), f), i), j), k), m)	

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11	13.4	
11	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
16672

Second edition
2015-08-01

**Ophthalmic implants — Ocular
endotamponades**

Implants ophtalmiques — Produits de tamponnement endoculaires

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