



SLOVENSKI STANDARD SIST EN ISO 15798:2013

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Nadomešča:
SIST EN ISO 15798:2010

Očesni vsadki (implantati) - Očesni kirurški pripomočki (ISO 15798:2013)

Ophthalmic implants - Ophthalmic viscosurgical devices (ISO 15798:2013)

Ophthalmische Implantate - Viskoelastische Substanzen (ISO 15798:2013)

Implants ophtalmiques - Dispositifs ophtalmiques viscoélastiques (ISO 15798:2013)

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Ta slovenski standard je istoveten z: EN ISO 15798:2013

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ICS:

11.040.70 Oftalmološka oprema Ophthalmic equipment

SIST EN ISO 15798:2013 **en**

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 15798

September 2013

ICS 11.040.70

Supersedes EN ISO 15798:2010

English Version

**Ophthalmic implants - Ophthalmic viscosurgical devices (ISO
15798:2013)**

Implants ophtalmiques - Dispositifs ophtalmiques
viscoélastiques (ISO 15798:2013)

Ophthalmische Implantate - Viskoelastische Substanzen
(ISO 15798:2013)

This European Standard was approved by CEN on 2 April 2013.

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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Foreword

This document (EN ISO 15798:2013) 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 March 2014, and conflicting national standards shall be withdrawn at the latest by March 2014.

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 15798:2010.

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.

For relationship with EU Directive, 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.

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Endorsement notice

The text of ISO 15798:2013 has been approved by CEN as EN ISO 15798:2013 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 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 European Standard and Directive 93/42/EEC

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
5, 6.1, 6.2, 7	7.2	Reference to ISO 14971 for risk assessment. Reference to ISO 22442-1, ISO 22442-2, ISO 22442-3 for material of animal origin. Reference to ISO 10993-1 for testing of biological safety in general. Reference to ISO 10993-9, ISO 10993-16 for toxicokinetics of degradation products. Reference to ISO 17665-1 for sterilization by moist heat. Reference to ISO 11137-1, ISO 11137-2, ISO 11137-3 for sterilization by radiation. Reference to ISO 13408-1 for aseptic processing. Reference to ISO 11135-1 for sterilization with ethylene oxide.
6.2	7.3	
6.1, 6.2, 7	7.5	Reference to ISO 22442-1, ISO 22442-2, ISO 22442-3 for material of animal origin. Reference to ISO 10993-1 for testing of biological safety in general. Reference to ISO 10993-9, ISO 10993-16 for toxicokinetics of degradation products. Reference to ISO 17665-1 for sterilization by moist heat. Reference to ISO 11137-1, ISO 11137-2, ISO 11137-3 for sterilization by radiation. Reference to ISO 13408-1 for aseptic processing. Reference to ISO 11135-1 for sterilization with ethylene oxide.

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
7	7.6	Reference to ISO 17665-1 for sterilization by moist heat. Reference to ISO 11137-1, ISO 11137-2, ISO 11137-3 for sterilization by radiation. Reference to ISO 13408-1 for aseptic processing. Reference to ISO 11135-1 for sterilization with ethylene oxide.
7	8.1	Reference to ISO 17665-1 for sterilization by moist heat. Reference to ISO 11137-1, ISO 11137-2, ISO 11137-3 for sterilization by radiation. Reference to ISO 13408-1 for aseptic processing. Reference to ISO 11135-1 for sterilization with ethylene oxide.
5, 6.1, 6.2	8.2	Reference to ISO 14971 for risk assessment. Reference to ISO 22442-1, ISO 22442-2, ISO 22442-3 for material of animal origin. Reference to ISO 10993-1 for testing of biological safety in general. Reference to ISO 10993-9, ISO 10993-16 for toxicokinetics of degradation products.
7, 8, 10	8.3	Reference to ISO 17665-1 for sterilization by moist heat. Reference to ISO 11137-1, ISO 11137-2, ISO 11137-3 for sterilization by radiation. Reference to ISO 13408-1 for aseptic processing. Reference to ISO 11135-1 for sterilization with ethylene oxide. Reference to ISO 11607-1 and ISO 14630 for packaging requirements.
7	8.4	Reference to ISO 17665-1 for sterilization by moist heat. Reference to ISO 11137-1, ISO 11137-2, ISO 11137-3 for sterilization by radiation. Reference to ISO 13408-1 for aseptic processing. Reference to ISO 11135-1 for sterilization with ethylene oxide.
11	8.7	
9	9.1	
5	9.2	Reference to ISO 14971 for risk assessment. Reference to ISO 22442-1, ISO 22442-2, ISO 22442-3 for material of animal origin.

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EN ISO 15798:2013 (E)

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
11	13	Ophthalmic viscosurgical devices (OVD) containing medicinal substances, or human blood derivatives, have not been considered in the standard, and at present no such products are known. Custom made OVD are not known.

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
15798

Third edition
2013-09-15

**Ophthalmic implants — Ophthalmic
viscosurgical devices**

Implants ophtalmiques — Dispositifs ophtalmiques viscoélastiques

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