SLOVENSKI STANDARD
SIST EN ISO 15798:2010

01-junij-2010

Nadomešča:
SIST EN ISO 15798:2002
SIST EN ISO 15798:2002/AC:2005

Očesni vsadki (implantati) - Očesni kirurški pripomočki (ISO 15798:2010)

Ophthalmic implants - Ophthalmic viscosurgical devices (ISO 15798:2010)

Ophthalmische Implantate - Viskoelastische Substanzen (ISO 15798:2010)

Implants ophtalmiques - Dispositifs ophtalmiques viscoélastiques (ISO 15798:2010)

Ta slovenski standard je istoveten z: EN ISO 15798:2010

ICS:

11.040.70	Oftalmološka oprema	Ophthalmic equipment

SIST EN ISO 15798:2010 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 15798

February 2010

ICS 11.040.70

Supersedes EN ISO 15798:2001

English Version

Ophthalmic implants - Ophthalmic viscosurgical devices (ISO 15798:2010)

Implants ophtalmiques - Dispositifs ophtalmiques viscoélastiques (ISO 15798:2010)

Ophthalmische Implantate - Viskoelastische Substanzen (ISO 15798:2010)

This European Standard was approved by CEN on 30 January 2010.

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 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 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

Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

This document (EN ISO 15798:2010) 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of an identical text or by endorsement, at the latest by August 2010, and conflicting national standards shall be withdrawn at the latest by August 2010.

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 15798:2001.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 15798:2010 has been approved by CEN as a EN ISO 15798:2010 without any modification.

Annex ZA
(informative)

Relationship between this International Standard and the Essential Requirements of EU Directive 93/42/EEC

This International 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 International Standard given in Table ZA.1 confers, within the limits of the scope of this International 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
4	1, 2, 3	Reference to ISO 14630 for general requirements of non-active implants
5	1, 2, 3, 7.1, 7.2, 8.2, 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
6.1, 6.2	1, 2, 3, 7.1, 7.2, 7.5, 8.2	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
6.3	6, 6a, 7.3	Reference to ISO 14155 for clinical investigation in general
7	1, 2, 7.2, 7.5, 7.6, 8.1, 8.3, 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

Table ZA.1 (continued)

Clause(s)/sub-clause(s) of this International Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
8	1, 3, 4, 5, 8.3	
9	1, 2, 3, 4, 7.1, 9.1	
10	1, 3, 4, 5, 8.3	Reference to ISO 11607-1 and ISO 14630 for packaging requirements
11	2, 8.7, 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.

INTERNATIONAL STANDARD

ISO 15798

Second edition
2010-02-01

Ophthalmic implants — Ophthalmic viscosurgical devices

Implants ophtalmiques — Dispositifs ophtalmiques viscoélastiques

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