Irish Standard
I.S. EN ISO 15798:2013&A1:2017

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

I.S. EN ISO 15798:2013&A1:2017

Incorporating amendments/corrigenda/National Annexes issued since publication:

EN ISO 15798:2013/A1:2017

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National Foreword

I.S. EN ISO 15798:2013&A1:2017 is the adopted Irish version of the European Document EN ISO 15798:2013, Ophthalmic implants - Ophthalmic viscosurgical devices (ISO 15798:2013)

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 15798:2013/A1

October 2017

ICS 11.040.70

English Version

Ophthalmic implants - Ophthalmic viscosurgical devices - Amendment 1 (ISO 15798:2013/Amd 1:2017)

Implants ophtalmiques - Dispositifs ophtalmiques viscoélastiques - Amendement 1 (ISO 15798:2013/Amd 1:2017)

Ophthalmische Implantate - Viskoelastische Substanzen - Änderung 1 (ISO 15798:2013/Amd 1:2017)

This amendment A1 modifies the European Standard EN ISO 15798:2013; it was approved by CEN on 10 October 2017.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant 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 amendment 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, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Contents

Page

European foreword

This document (EN ISO 15798:2013/A1:2017) 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 Amendment to the European Standard EN ISO 15798:2013 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 2018, and conflicting national standards shall be withdrawn at the latest by April 2018.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

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, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 15798:2013/Amd 1:2017 has been approved by CEN as EN ISO 15798:2013/A1:2017 without any modification.

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.

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.

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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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Contents

Page

Foreword

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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.

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.

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.

I.S. EN ISO 15798:2013&A1:2017

INTERNATIONAL STANDARD

ISO 15798

Third edition
2013-09-15

Ophthalmic implants — Ophthalmic viscosurgical devices

Implants ophtalmiques — Dispositifs ophtalmiques viscoélastiques

Reference number
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Contents

Page

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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ISO 15798 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This third edition cancels and replaces the second edition (ISO 15798:2010), which has undergone minor revision to update the normative references and to revise Table 1.

Ophthalmic implants — Ophthalmic viscosurgical devices

1 Scope

This International Standard is applicable to ophthalmic viscosurgical devices (OVDs), a class of non-active surgical implants with viscous and/or viscoelastic properties, intended for use during surgery in the anterior segment of the human eye. OVDs are designed to create and maintain space, to protect intraocular tissues and to manipulate tissues during surgery.

This International Standard specifies requirements with regard to safety for the intended performance, design attributes, preclinical and clinical evaluation, sterilization, product packaging, product labelling and information supplied by the manufacturer of these devices.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 10993-2, *Biological evaluation of medical devices — Part 2: Animal welfare requirements*

ISO 10993-6, *Biological evaluation of medical devices — Part 6: Tests for local effects after implantation*

ISO 10993-9, *Biological evaluation of medical devices — Part 9: Framework for identification and quantification of potential degradation products*

ISO 10993-16, *Biological evaluation of medical devices — Part 16: Toxicokinetic study design for degradation products and leachables*

ISO 11135-1, *Sterilization of health care products — Ethylene oxide — Part 1: Requirements for 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 13408-1, *Aseptic processing of health care products — Part 1: General requirements*

ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 14630, *Non-active surgical implants — General requirements*

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

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*