# SLOVENSKI STANDARD
# SIST EN ISO 15798:2022

**01-april-2022**

**Nadomešča:**
**SIST EN ISO 15798:2013**
**SIST EN ISO 15798:2013/A1:2017**

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**Očesni vsadki (implantati) - Očesni kirurški pripomočki (ISO 15798:2022)**

Ophthalmic implants - Ophthalmic viscosurgical devices (ISO 15798:2022)

Ophthalmische Implantate - Viskoelastische Substanzen (ISO 15798:2022)

Implants ophtalmiques - Dispositifs ophtalmiques viscoélastiques (ISO 15798:2022)



**Ta slovenski standard je istoveten z:** **EN ISO 15798:2022**



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**ICS:**

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|---|---|---|
| 11.040.70 | Oftalmološka oprema | Ophthalmic equipment |

**SIST EN ISO 15798:2022** **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

# EN ISO 15798

February 2022

ICS 11.040.70

Supersedes EN ISO 15798:2013, EN ISO 15798:2013/A1:2017

English Version

# Ophthalmic implants - Ophthalmic viscosurgical devices (ISO 15798:2022)

Implants ophtalmiques - Dispositifs ophtalmiques viscoélastiques (ISO 15798:2022)

Ophthalmische Implantate - Viskoelastische Substanzen (ISO 15798:2022)

This European Standard was approved by CEN on 17 January 2022.

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

**CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels**

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## European foreword

This document (EN ISO 15798:2022) 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of an identical text or by endorsement, at the latest by August 2022, and conflicting national standards shall be withdrawn at the latest by August 2022.

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.

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## Endorsement notice



The text of ISO 15798:2022 has been approved by CEN as EN ISO 15798:2022 without any modification.

INTERNATIONAL STANDARD

**ISO 15798**

Fourth edition
2022-01

# Ophthalmic implants — Ophthalmic viscosurgical devices

*Implants ophtalmiques — Dispositifs ophtalmiques viscoélastiques*



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# Foreword

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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).

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This document was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 170, *Ophthalmic optics,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).



This fourth edition cancels and replaces the third edition (ISO 15798:2013 and its Amendment, ISO 15798:2013/Amd.1:2017), which has been technically revised.

The main changes compared to the previous edition are as follows:

a) Inclusion of applicable sections from ISO 14630 throughout the document, but removal of any reference to that standard. It was further clarified that ophthalmic viscosurgical devices (OVD) are no implant by their intended use but are likely to share some of the risks related to non-active implants. Therefore, the following clauses and subclauses have been revised: Clauses 4 and 5, 6.1, 6.2.1, Clause 7. A new subclause 5.4 has been added.

b) minor clarifications in Clause 3 (3.3, 3.4) and addition of term *surgical invasive medical device*;

c) clarification in Clause 4 that a recommended removal procedure shall enable removal of the OVD as completely as possible;

d) revised wording in 5.2 to align with defined terminology from Clause 3;

e) revised note in 5.3.2: narrowed recommended measuring range;

f) revised note in 5.3.8: more accurate description of the risk;

g) clarification that control OVD for the intraocular implantation test and the clinical investigation shall be the same in both studies; therefore, the following subclauses have been revised: 6.1, 6.2.5, 6.3.2, and Annex A;

h) revised wording in 6.2.2 of this document to include ISO 15798:2013/Amd.1:2017 and guidance on standard LAL-test;

i) revised wording in 6.2.3 to address the potential risk of interaction of the OVD with fluorescence or radioisotope labelling;

j) revised 6.3 to clarify requirement of a clinical evaluation, clarification of the clinical investigation protocol, revision of the clinical investigation design, and additional standardization for evaluation and reporting of result from the clinical investigation;

k) inclusion of reference to ISO 10993-7 for acceptable levels of ethylene oxide and ethylene chlorohydrin in Clause 7;

l) packaging integrity has been specifically included into the scope of product stability Clause 8; in addition, reference to ISO 14971 has been included into this clause;

m) "Do not use if sterile barrier is breached" has been aligned with the recommended wording from ISO 15223-1 "Do not use if package is damaged"; in addition, molecular mass distribution has been removed from the list of information to be supplied by the manufacturer in Table 1;

n) major revision of Annex A;

o) correction of a typo in the formula for calculating the minimum number of evaluable patients per treatment group in Annex B.

p) Addition of new informative Annex C on analyses of OVD clinical data.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.