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STN	**Očné implantáty** **Vyplachovacie roztoky pre očnú chirurgiu** **(ISO 16671: 2025)**	**STN** **EN ISO 16671** 19 5301

Ophthalmic implants - Irrigating solutions for ophthalmic surgery (ISO 16671:2025)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 08/25

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English Version

Ophthalmic implants - Irrigating solutions for ophthalmic surgery (ISO 16671:2025)

Implants ophtalmiques - Solutions d'irrigation pour la chirurgie ophtalmique (ISO 16671:2025)

Ophthalmische Implantate - Spüllösungen für die ophthalmische Chirurgie (ISO 16671:2025)

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European foreword

This document (EN ISO 16671:2025) 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of an identical text or by endorsement, at the latest by December 2025, and conflicting national standards shall be withdrawn at the latest by December 2025.

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Endorsement notice

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International Standard

ISO 16671

Ophthalmic implants — Irrigating solutions for ophthalmic surgery

Implants ophtalmiques — Solutions d'irrigation pour la chirurgie ophtalmique

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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.

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 document 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 third edition cancels and replaces the second edition (ISO 16671:2015), which has been technically revised. It also incorporates the Amendment ISO 16671:2015/Amd.1:2017.

The main changes are as follows:

— Inclusion of applicable sections from ISO 14630 throughout the document and removal of any reference to that standard. It was further clarified that ophthalmic irrigation solutions (OIS) are not implants 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: Clause 4, Clause 5, Clause 7 and 9.1;

— Clarifications of terms 3.1, 3.2, 3.3 and 3.4;

— Revision of 5.1 for a more accurate description of design attributes;

— Revision of Clause 7 to clarify the risks associated with components of OIS sterilized by ethylene oxide (EO);

— Revision of Clause 8 to clarify that the real time shelf-life testing shall be performed and the accelerated shelf-life testing is optional;

— Revision of Annex E to provide additional clarification regarding the number of test and control eyes enrolled in the study and that use of medication during the study that could possibly impact the study results;

— Annex F was changed from informative to normative and clarified that the same intraocular surgical procedure is performed in the test and control arms and changed the first post-operative intraocular pressure (IOP) measurement from 6 h ± 2 h to 8 h ± 2 h to capture the effect of irrigation solution on IOP and align it with ISO 15798:2022, F.2;

— Inclusion of Annex G;

— The example for patient number calculation is incorporated into Annex H;

— Correction of Formulae H.1 and H.2.

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.

International Standard **ISO 16671:2025(en)**

Ophthalmic implants — Irrigating solutions for ophthalmic surgery

1 Scope

This document defines requirements with regards to safety for the intended performance, design attributes, preclinical and clinical evaluation, sterilization, product packaging, product labelling, and the information supplied by the manufacturer.

This document applies to ophthalmic irrigating solutions (OIS), used during ophthalmic surgery. These solutions do not provide any primary immunological, pharmacological, or metabolic function.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 11135, *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*

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

ISO 15223-1, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements*

ISO 20417, *Medical devices — Information to be supplied by the manufacturer*

ISO 22442-1, *Medical devices utilizing animal tissues and their derivatives — Part 1: Application of risk management*

ISO 22442-2, *Medical devices utilizing animal tissues and their derivatives — Part 2: Controls on sourcing, collection and handling*

ISO 22442-3, *Medical devices utilizing animal tissues and their derivatives — Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents*

European Pharmacopeia (Ph. Eur) 0169, *Water for injections*

United States Pharmacopeia (USP) <1231>, *Water for pharmaceutical purposes*