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Ophthalmic implants — Irrigating solutions for ophthalmic surgery

Implants ophtalmiques — Solutions d'irrigation pour la chirurgie ophtalmique

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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 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;

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— Inclusion of Annex G;

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

— Correction of Formulae H.1 and H.2.

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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*

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3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
ophthalmic irrigating solution
OIS
aqueous solution that is used to physiologically stabilize the ocular tissue

Note 1 to entry: It does not provide any primary immunological, pharmacological, or metabolic function.

3.2
primary container
container that is in direct contact with the product

3.3
sterile barrier system
minimum package that prevents ingress of microorganisms and allows aseptic presentation of the product at the point of use

[SOURCE: ISO11139: 2018, 3.272[2]]

Note 1 to entry: For additional details regarding sterile barrier system see ISO 11607-1.

3.4
storage container
part of the packaging intended to protect the device during transport and storage, containing the sterile barrier system

4 Intended performance

This document describes OIS as non-solid medical devices that are physiologically and functionally compatible with the ocular tissues and are used to rinse the surface of the eye, stabilize the ocular surface, and/or manipulate intraocular tissues, spaces, and structures by physiological means.

The manufacturer shall describe and document the functional characteristics of the OIS in terms of its chemical composition and physical properties, the intended surgical applications, the conditions of use and effects upon ocular tissues, with particular regard to safety.

The intended performance shall be determined taking into account published standards, published clinical and scientific literature, validated test results, pre-clinical and clinical evaluation, and clinical investigations.

5 Design attributes

5.1 General

The following subclauses list specific design attributes to be met for the intended performance. Tests described therein are intended to apply when qualifying materials, but not necessarily apply as a routine quality assurance/control programme. A risk assessment shall be performed in accordance with ISO 14971. OIS design attributes shall be documented. Where any of the design attributes are not considered to be relevant, the reason for such shall be documented and justified.

All testing requirements specified below shall be performed with finished, sterilized product, ready for release. Any analytical methods utilized shall be validated.

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