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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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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.

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