INTERNATIONAL STANDARD

ISO 11979-5

Third edition
2020-09

Ophthalmic implants — Intraocular lenses —

Part 5: Biocompatibility

Implants ophtalmiques — Lentilles intraoculaires —

Partie 5: Biocompatibilité

Reference number
ISO 11979-5:2020(E)

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Published in Switzerland

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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 11979-5:2006), which has been technically revised.

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

— correction and addition of references throughout the document;

— added more specific guidance on risk-based approach throughout the document;

— added requirement to use state of the art analytical methods;

— update of apparatus lists where applicable;

— clarification of test material in Tables 1 and 2, reference to ISO/TR 22979 when the IOL is a modification of a parent IOL and requirement for a biological evaluation plan added to Clause 4;

— combination and re-writing of physicochemical test methods and their objectives in Table 3 of 5.1;

— added requirement for physical/chemical description and contaminants in 5.2;

— revised order of tests in 6.1 for alignment with ISO 10993 and added subclauses for every test;

— clarification of ratio for material and extraction medium in biological tests in 6.1;

— principle and procedure of exhaustive extraction is explained in more detail (Annex A);

— in hydrolytic stability, products are their own control for spectral transmittance and dioptric power (Annex C);

— removed the allowance of representative test material for photostability testing, added the requirement to measure lens power and image quality (Annex D);

— Annex F change from informative to normative;

— duration of subcutaneously or intramuscularly implantation increased from 4 weeks to 3 months (Annex F);

— duration of ocular implantation test in rabbits reduced from 6 months to 3 months (Annex G).

A list of all parts in the ISO 11979 series can be found on the ISO website.

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