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Ophthalmic implants - Intraocular lenses - Part 5: Biocompatibility (ISO 11979-5:2020)

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. 04/21

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EUROPEAN STANDARD

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Supersedes EN ISO 11979-5:2006

English Version

Ophthalmic implants - Intraocular lenses - Part 5: Biocompatibility (ISO 11979-5:2020)

Implants ophtalmiques - Lentilles intraoculaires - Partie 5: Biocompatibilité (ISO 11979-5:2020)

Ophthalmische Implantate - Intraokularlinsen - Teil 5: Biokompatibilität (ISO 11979-5:2020)

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Ref. No. EN ISO 11979-5:2020 E

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European foreword

This document (EN ISO 11979-5:2020) 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of an identical text or by endorsement, at the latest by April 2021, and conflicting national standards shall be withdrawn at the latest by April 2021.

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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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
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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 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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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

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);

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— 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.

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.

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Introduction

This document follows the general principles given in ISO 10993-1. ISO 10993-1 describes the principles governing the biological evaluation of medical devices, the definitions of categories based on the nature and duration of contact with the body, and selection of appropriate tests. Other parts of ISO 10993 present biological test methods, tests for ethylene oxide residues, tests for degradation and principles for sample preparation.

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INTERNATIONAL STANDARD **ISO 11979-5:2020(E)**

Ophthalmic implants — Intraocular lenses —

Part 5: Biocompatibility

1 Scope

This document specifies particular requirements for the biocompatibility evaluation of materials for intraocular lenses (IOLs) including the processing conditions to produce them. These requirements include evaluation of physicochemical properties that are relevant to biocompatibility. It also gives guidance on conducting an ocular implantation test.

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 10993-3, *Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity*

ISO 10993-5, *Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity*

ISO 10993-6, *Biological evaluation of medical devices — Part 6: Tests for local effects after implantation*

ISO 10993-10, *Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization*

ISO 10993-12, *Biological evaluation of medical devices — Part 12: Sample preparation and reference materials*

ISO 10993-17, *Biological evaluation of medical devices — Part 17: Establishment of allowable limits for leachable substances*

ISO 11979-1, *Ophthalmic implants — Intraocular lenses — Part 1: Vocabulary*

ISO 11979-2, *Ophthalmic implants — Intraocular lenses — Part 2: Optical properties and test methods*

ISO 11979-3, *Ophthalmic implants — Intraocular lenses — Part 3: Mechanical properties and test methods*

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

ISO 18369-4, *Ophthalmic optics — Contact lenses — Part 4: Physicochemical properties of contact lens materials*

ISO/TS 21726, *Biological evaluation of medical devices — Application of the threshold of toxicological concern (TTC) for assessing biocompatibility of medical device constituents*

ISO/TR 22979, *Ophthalmic implants — Intraocular lenses — Guidance on assessment of the need for clinical investigation of intraocular lens design modifications*

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