

SLOVENSKI STANDARD SIST EN ISO 11979-4:2009

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Ophthalmic implants - Intraocular lenses - Part 4: Labelling and information (ISO 11979-4:2008)

Ophthalmische Implantate Intrackularlinsen Teil 4: Etikettierung und Information (ISO 11979-4:2008)

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Implants ophtalmiques - Lentilles intraoculaires 97 Partie 4: Étiquetage et informations (ISO 11979-4:2008) https://standards.iteh.ai/catalog/standards/sist/61aa4880-200e-48b1-8ea2-160413f75329/sist-en-iso-11979-4-2009

Ta slovenski standard je istoveten z: EN ISO 11979-4:2008

ICS:

11.040.70 Oftalmološka oprema Ophthalmic equipment

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EUROPEAN STANDARD NORME EUROPÉENNE EUROPÄISCHE NORM

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English Version

Ophthalmic implants - Intraocular lenses - Part 4: Labelling and information (ISO 11979-4:2008)

Implants ophtalmiques - Lentilles intraoculaires - Partie 4: Étiquetage et informations (ISO 11979-4:2008)

Ophthalmische Implantate - Intraokularlinsen - Teil 4: Etikettierung und Information (ISO 11979-4:2008)

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EUROPEAN COMMITTEE FOR STANDARDIZATION COMITÉ EUROPÉEN DE NORMALISATION EUROPÄISCHES KOMITEE FÜR NORMUNG

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EN ISO 11979-4:2008 (E)

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EN ISO 11979-4:2008 (E)

Foreword

This document (EN ISO 11979-4:2008) has been prepared by Technical Committee ISO/TC 172 "Optics and optical instruments" 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of an identical text or by endorsement, at the latest by June 2009, and conflicting national standards shall be withdrawn at the latest by June 2009.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 11979-4:2000.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

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(stan Endorsement notice)

The text of ISO 11979-4:2008 has been approved by CEN as a EN ISO 11979-4:2008 without any modification.

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INTERNATIONAL STANDARD

ISO 11979-4

Second edition 2008-12-01

Ophthalmic implants — Intraocular lenses —

Part 4: Labelling and information

Implants ophtalmiques — Lentilles intraoculaires —

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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ISO 11979-4 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This second edition cancels and replaces the first edition (ISO 11979-4:2000), which has been technically revised.

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ISO 11979 consists of the following parts, under the general title *Ophthalmic implants* — *Intraocular lenses*:

- Part 1: Vocabularys://standards.iteh.ai/catalog/standards/sist/61aa4880-200e-48b1-8ea2-160413f75329/sist-en-iso-11979-4-2009
- Part 2: Optical properties and test methods
- Part 3: Mechanical properties and test methods
- Part 4: Labelling and information
- Part 5: Biocompatibility
- Part 6: Shelf-life and transport stability
- Part 7: Clinical investigations
- Part 8: Fundamental requirements
- Part 9: Multifocal intraocular lenses
- Part 10: Phakic intraocular lenses