



Institut luxembourgeois de la normalisation
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ILNAS-EN ISO 11979-7:2024

Ophthalmic implants - Intraocular lenses - Part 7: Clinical investigations of intraocular lenses for the correction of aphakia (ISO 11979-7:2024)

Ophthalmische Implantate -
Intraokularlinsen - Teil 7: Klinische
Prüfungen von Intraokularlinsen für die
Korrektion von Aphakie (ISO

Implants ophtalmiques - Lentilles
intraoculaires - Partie 7: Investigations
cliniques de lentilles intraoculaires pour
la correction de l'aphakie (ISO

01/2024



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Ophthalmic implants - Intraocular lenses - Part 7: Clinical investigations of intraocular lenses for the correction of aphakia (ISO 11979-7:2024)

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Klinische Prüfungen von Intraokularlinsen für die
Korrektion von Aphakie (ISO 11979-7:2024)

This European Standard was approved by CEN on 19 January 2024.

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European foreword

This document (EN ISO 11979-7:2024) 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of an identical text or by endorsement, at the latest by July 2024, and conflicting national standards shall be withdrawn at the latest by July 2024.

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ILNAS-EN ISO 11979-7:2024

**International
Standard**

ISO 11979-7

**Ophthalmic implants — Intraocular
lenses —**

**Part 7:
Clinical investigations of intraocular
lenses for the correction of aphakia**

Implants ophtalmiques — Lentilles intraoculaires —

*Partie 7: Investigations cliniques de lentilles intraoculaires pour
la correction de l'aphakie*

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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 fifth edition cancels and replaces the fourth edition (ISO 11979-7:2018), which has been technically revised. The changes related herein for updating the document to the fifth edition apply to devices that will enter the marketplace after the date of publication of the fifth edition and are not designed or meant to limit any devices currently approved and marketed, nor those devices in the process of approval.

The main changes are as follows:

- development of definitions of non-accommodative posterior chamber “Simultaneous Vision Range” (SVIOL) lenses that include the subtypes of MIOL (Multifocal), EDF (Extended Depth of Focus) and FVR (Full Visual Range) IOLs, and defining each of these IOL types to allow differentiation among the lens types based on clinical and safety performance measures;
- establishment of guidelines for clinical testing of newly defined IOL types as listed above as well as related novel lens types, with alignment of testing methodologies among the lens types;
- ISO 11979-1, ISO 11979-2, ISO 11979-4 and ISO/TR 22979 are under revision and, when published, will be aligned with this edition of ISO 11979-7.

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

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