

Institut luxembourgeois de la normalisation de l'accréditation, de la sécurité et qualité des produits et services

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

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National Foreword

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

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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of an identical text or by endorsement, at the latest by July 2024, and conflicting national standards shall be withdrawn at the latest by July 2024.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 11979-7:20 24 International **Standard**

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Part 7:

Clinical investigations of intraocular lenses for the correction of aphakia

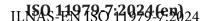
Ophthalmic implants — Intraocular

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Partie 7: Investigations cliniques de lentilles intraoculaires pour a 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.

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