



BSI Standards Publication

Ophthalmic implants — Intraocular lenses

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

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National foreword

This British Standard is the UK implementation of EN ISO 11979-7:2024. It is identical to ISO 11979-7:2024. It supersedes BS EN ISO 11979-7:2018, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/172/7, Eye implants.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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Partie 7: Investigations cliniques de lentilles
intraoculaires pour la correction de l'aphakie (ISO
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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of an identical text or by endorsement, at the latest by July 2024, and conflicting national standards shall be withdrawn at the latest by July 2024.

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.

This document supersedes EN ISO 11979-7:2018.

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The text of ISO 11979-7:2024 has been approved by CEN as EN ISO 11979-7:2024 without any modification.

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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 document 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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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.

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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Intraocular lenses (IOLs) are used to correct residual refractive errors in subjects who have aphakia. Such residual refractive errors typically include sphere and astigmatism but may also correct for a lack of accommodation. Different designs of IOLs can be used to correct for specific refractive errors. In the case where an IOL is designed to provide more than one type of refractive correction, that IOL will have to satisfy each of the separate requirements of those correction designs.

This document provides requirements and recommendations for intraocular lens investigations of new IOL models. In the case where an IOL model is a modification of a parent IOL model, a risk analysis can be used in order to determine the appropriate level of testing.

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Ophthalmic implants — Intraocular lenses —

Part 7:

Clinical investigations of intraocular lenses for the correction of aphakia

1 Scope

This document specifies the particular requirements for the clinical investigations of intraocular lenses that are implanted in the eye in order to correct aphakia.

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

ISO 11979-10, *Ophthalmic implants — Intraocular lenses — Part 10: Clinical investigations of intraocular lenses for correction of ametropia in phakic eyes*

ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

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

3 Terms and definitions and abbreviated terms

3.1 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 11979-1 and ISO 14155 apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

3.2 Abbreviated terms

UDVA	uncorrected distance visual acuity
UIVA	uncorrected intermediate visual acuity
UNVA	uncorrected near visual acuity
BSCVA	best spectacle corrected visual acuity
CDVA	corrected distance visual acuity
CS	contrast sensitivity