
**Ophthalmic implants — Intraocular
lenses — Guidance on assessment of the
need for clinical investigation of
intraocular lens design modifications**

*Implants ophtalmiques — Lentilles intraoculaires — Directives relatives
à l'évaluation de la nécessité d'investigation clinique pour les
modifications de dessin des lentilles intraoculaires*



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Foreword

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Ophthalmic implants — Intraocular lenses — Guidance on assessment of the need for clinical investigation of intraocular lens design modifications

1 Scope

This Technical Report provides guidance on the application of Parts 3, 7 and 9 of the ISO 11979 series of International Standards for intraocular lenses (IOLs). It addresses factors to be considered in a risk analysis of the significance of modifications to anterior and posterior chamber, monofocal and multifocal, intraocular lenses. It also suggests methods of data analysis and interpretation that can be used to determine the need for and the design of a clinical investigation.

2 Normative references

The following referenced documents are indispensable for the application 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*

3 Terms and definitions

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

4 Monofocal lenses

4.1 General

Monofocal IOLs that are modifications of a parent IOL, have different requirements for clinical investigations depending on the magnitude of the modifications. This Technical Report provides considerations for the risk analysis to determine which of the following are needed.

- a) No clinical investigation.
- b) Limited clinical investigation of 100 subjects followed up to and including Form 4, see ISO 11979-7.
- c) Full clinical investigation as defined in ISO 11979-7.

4.2 Modification levels (categories)

4.2.1 Level A modifications

Level A modifications are minor modifications for which all safety and performance questions can be adequately addressed by non-clinical testing. Level A modifications require no clinical investigation.