TECHNICAL REPORT

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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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Contents

Page

Foreword ... iv

1 Scope ... 1

2 Normative references ... 1

3 Terms and definitions ... 1

4 Monofocal lenses ... 1
4.1 General ... 1
4.2 Modification levels (categories) ... 1
4.3 Clinical investigation with multiple IOL models ... 2
4.4 Mechanical data analysis ... 2

5 Multifocal lenses ... 2
5.1 General ... 2
5.2 Addition of a parent multifocal optic to a parent monofocal model ... 3
5.3 Modification of the optical design geometry of a parent multifocal optic ... 3

Annex A (informative) **Examples of modifications to a parent IOL model** ... 4

Annex B (informative) **Mechanical data analysis** ... 7

Bibliography ... 19

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.

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In exceptional circumstances, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example), it may decide by a simple majority vote of its participating members to publish a Technical Report. A Technical Report is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

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

ISO/TR 22979 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

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.