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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 conception des lentilles intraoculaires

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Contents

Page

Foreword ... **iv**

1 Scope ... **1**

2 Normative references ... **1**

3 Terms and definitions ... **1**

4 Modifications to parent models ... **1**
4.1 General ... 1
4.2 Modification levels ... 2
4.2.1 General ... 2
4.2.2 Level A modifications ... 2
4.2.3 Level B modifications ... 2
4.2.4 Level C modifications ... 2
4.2.5 Clinical investigation with multiple IOL models ... 3

5 Considerations for the assignment of modification level ... **3**
5.1 General ... 3
5.2 Risk assessment ... 3
5.3 Special considerations ... 3
5.3.1 Phakic lenses ... 3
5.3.2 Anterior chamber lenses ... 3
5.3.3 Posterior chamber lenses intended for implantation in the sulcus ... 4

6 Modifications of optical design features ... **4**
6.1 Optical design changes ... 4
6.2 Multifocal lenses (MIOL) ... 4
6.3 Toric lenses (TIOL) ... 4
6.4 Accommodating lenses (AIOL) ... 4

7 Modifications to the mechanical design ... **5**
7.1 General ... 5
7.2 Mechanical analysis ... 5

8 Modifications to material ... **5**
8.1 Interchanging IOL materials ... 5
8.2 New materials ... 5

Annex A (informative) **Examples of modifications to a parent IOL model** ... **6**

Annex B (informative) **Mechanical data analysis** ... **11**

Bibliography ... **22**

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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.

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 documents 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*, SC 7 *Ophthalmic optics and instruments*.

This second edition cancels and replaces the first edition (ISO/TR 22979:2006), which has been technically revised.

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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 document provides guidance on the application of all parts of the ISO 11979 series of International Standards for intraocular lenses (IOLs).[1–9] It addresses factors to be considered in the risk management process of modifications to anterior and posterior chamber IOLs in accordance with ISO 14971.[11] It also suggests methods of data analysis and interpretation that can be used to determine the need for a clinical investigation and its design.

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*

3 Terms and definitions

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

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

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://www.iso.org/obp

NOTE The terms listed are related to Annex B.

3.1
open-loop IOL
IOL model which contains two loops, each loop having one end attached to the body of the IOL and the other end free

3.2
closed-loop IOL
IOL model, which contains two loops, each loop having both ends attached to the body of the optic

3.3
hybrid open-loop/closed-loop IOL
IOL model which contains two loops, with one loop having one end attached to the body of the IOL and the other end free, and the other loop having both ends attached to the body of the IOL

4 Modifications to parent models

4.1 General

IOLs, that are modifications of a parent IOL, have different requirements for clinical investigations depending on the risk associated with the modifications and depending on their location in the eye.

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