



BSI Standards Publication

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

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## National foreword

This Published Document is the UK implementation of ISO/TR 22979:2017. It supersedes PD ISO/TR 22979:2006 which is withdrawn.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 secretary.

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© The British Standards Institution 2017  
Published by BSI Standards Limited 2017

ISBN 978 0 580 85343 2

ICS 11.040.70

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This Published Document was published under the authority of the Standards Policy and Strategy Committee on 30 September 2017.

### Amendments/corrigenda issued since publication

<u>Date</u>	<u>Text affected</u>
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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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## 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](http://www.iso.org/directives)).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see [www.iso.org/patents](http://www.iso.org/patents)).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

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.

# 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).<sup>[1-9]</sup> It addresses factors to be considered in the risk management process of modifications to anterior and posterior chamber IOLs in accordance with ISO 11971.<sup>[11]</sup> 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 none 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.