

Ophthalmic implants — Intraocular lenses —

Part 7: Clinical investigations

ICS 11.040.70

National foreword

This British Standard is the UK implementation of EN ISO 11979-7:2006+A1:2012. It is identical to ISO 11979-7:2006, incorporating amendment 1:2012. It supersedes BS EN ISO 11979-7:2006 which is withdrawn.

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

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with a British Standard cannot confer immunity from legal obligations.

Amendments/corrigenda issued since publication

Date	Comments
29 February 2012	Implementation of ISO amendment 1:2012, with CEN endorsement A1:2012: Annex B text replaced

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 May 2006

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ISBN 978 0 580 71469 6

English Version

Ophthalmic implants - Intraocular lenses - Part 7: Clinical investigations (ISO 11979-7:2006)

Implants ophtalmiques - Lentilles intraoculaires - Partie 7:
Investigations cliniques (ISO 11979-7:2006)

Ophthalmische Implantate - Intraokularlinsen - Teil 7:
Klinische Prüfungen (ISO 11979-7:2006)

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Foreword

This document (EN ISO 11979-7:2006) has been prepared by Technical Committee ISO/TC 172 "Optics and optical instruments" 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of an identical text or by endorsement, at the latest by November 2006, and conflicting national standards shall be withdrawn at the latest by November 2006.

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Endorsement notice

The text of ISO 11979-7:2006 has been approved by CEN as EN ISO 11979-7:2006 without any modifications.

Foreword to amendment A1

This document (EN ISO 11979-7:2006/A1:2012) 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 2012, and conflicting national standards shall be withdrawn at the latest by July 2012.

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Endorsement notice

The text of ISO 11979-7:2006/Amd 1:2012 has been approved by CEN as a EN ISO 11979-7:2006/A1:2012 without any modification.

INTERNATIONAL STANDARD

ISO
11979-7

Second edition
2006-05-01

Ophthalmic implants — Intraocular lenses —

Part 7: Clinical investigations



Reference number
ISO 11979-7:2006(E)

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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ISO 11979-7 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This second edition cancels and replaces the first edition (ISO 11979-7:2001), which has been technically revised.

ISO 11979 consists of the following parts, under the general title *Ophthalmic implants — Intraocular lenses*:

- *Part 1: Vocabulary*
- *Part 2: Optical properties and test methods*
- *Part 3: Mechanical properties and test methods*
- *Part 4: Labelling and information*
- *Part 5: Biocompatibility*
- *Part 6: Shelf-life and transport stability*
- *Part 7: Clinical investigations*
- *Part 8: Fundamental requirements*
- *Part 9: Multifocal intraocular lenses*
- *Part 10: Phakic intraocular lenses*