BRITISH STANDARD

BS EN ISO 11979-9:2006 +A1:2014

Ophthalmic implants — Intraocular lenses —

Part 9: Multifocal intraocular lenses

ICS 11.040.70

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National foreword

This British Standard is the UK implementation of EN ISO 11979-9:2006+A1:2014. It is identical to ISO 11979-9:2009, incorporating amendment 1:2014. It supersedes BS EN ISO 11979-9:2006, which is withdrawn.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to ISO text carry the number of the ISO amendment. For example, text altered by ISO amendment 1 is indicated by [A1] <A1>.

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.

The 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.

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

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11979-9:2006+A1

August 2014

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English Version

Ophthalmic implants - Intraocular lenses - Part 9: Multifocal intraocular lenses (ISO 11979-9:2006)

Implants ophtalmiques - Lentilles intraoculaires - Partie 9: Lentilles intraoculaires multifocales (ISO 11979-9:2006)

Ophthalmische Implantate - Intraokularlinsen - Teil 9: Multifokale Intraokularlinsen (ISO 11979-9:2006)

This European Standard was approved by CEN on 19 August 2006.

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Foreword

This document (EN ISO 11979-9:2006) 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of an identical text or by endorsement, at the latest by March 2007, and conflicting national standards shall be withdrawn at the latest by March 2007.

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Endorsement notice

The text of ISO 11979-9:2006 has been approved by CEN as EN ISO 11979-9:2006 without any modifications.

Foreword to amendment A1

This document (EN ISO 11979-9:2006/A1:2014) 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 Amendment to the European Standard EN ISO 11979-9:2006 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by February 2015, and conflicting national standards shall be withdrawn at the latest by February 2015.

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Endorsement notice

The text of ISO 11979-9:2006/Amd, 1:2014 has been approved by CEN as EN ISO 11979-9:2006/A1:2014 without any modification.

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INTERNATIONAL STANDARD

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Part 9: Multifocal intraocular lenses

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Foreword

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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 11979-9 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

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*

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