INTERNATIONAL STANDARD

ISO 11979-9

First edition 2006-09-01 AMENDMENT 1

2014-08-15

Ophthalmic implants — Intraocular lenses —

Part 9: Multifocal intraocular lenses

AMENDMENT 1

iTeh STANDARD PREVIEW Implants ophtalmiques — Lentilles intraoculaires — (StPartie 9: Lentilles intraoculaires multifocales

AMENDEMENT 1 ISO 11979-9:2006/Amd 1:2014

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The committee responsible for this document is ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, Opthalmic optics and instruments.

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Ophthalmic implants — Intraocular lenses —

Part 9: Multifocal intraocular lenses

AMENDMENT 1

Page 1, Clause 1

In the first sentence delete "rotationally symmetric".

Page 1, Clause 2

Delete the following references:

ISO 14155-1, Clinical investigation of medical devices for human subjects — Part 1: General requirements

ISO 14155-2, Clinical investigation of medical devices for human subjects — Part 2: Clinical investigation plans

Add the following reference **STANDARD PREVIEW**

ISO 14155, Clinical investigation of medical devices for human subjects — Good clinical practice

Page 1, Clause 3

ISO 11979-9:2006/Amd 1:2014 Replace "ISO 14155h1pand ISO 144155;2"at with a ISO 144155"/9c2d4-e680-41d7-9e24b01321a12ada/iso-11979-9-2006-amd-1-2014

Page 2, Clause 4

Delete 4.1 and 4.2, and replace with:

"The requirements of ISO 11979-3 apply."

Page 2, Clause 5

Delete 5.1, 5.2, 5.3 and 5.4, and replace with:

"The requirements of ISO 11979-2 apply."

Page 3, Clause 6

In 6.1 first line, replace "ISO 14155-1" with "ISO 14155".

In 6.1 second line, replace "ISO 14155-1, ISO 14155-2" with "ISO 14155".

Page 4, Clause 7

Delete the entire contents of the clause and replace with:

"The requirements of ISO 11979-4 together with ISO 11979-4:2008/Amd.1:2012 apply."

Page 6, Annex A

Delete the entire contents of this Annex and instead refer to ISO 11979-2.

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