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AMENDMENT 1
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**Ophthalmic implants — Intraocular
lenses —**

**Part 10:
Phakic intraocular lenses**

AMENDMENT 1

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*Implants ophtalmiques — Lentilles intraoculaires —
Partie 10: Lentilles intraoculaires phaques*

AMENDEMENT 1
ISO 11979-10:2006/Amd 1:2014

<https://standards.iteh.ai/catalog/standards/sist/048364da-ecfd-463f-b7f8-4e278c64432e/iso-11979-10-2006-amd-1-2014>



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Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
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The committee responsible for this document is ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

[ISO 11979-10:2006/Amd 1:2014](https://standards.iteh.ai/catalog/standards/sist/048364da-ecfd-463f-b7f8-4e278c64432e/iso-11979-10-2006-amd-1-2014)

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Ophthalmic implants — Intraocular lenses —

Part 10: Phakic intraocular lenses

AMENDMENT 1

Page 1, Clause 1

In the first sentence, set full stop after “phakic eye” and delete what follows thereafter.

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:

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

Page 1, Clause 3

Replace “ISO 14155-1 and ISO 14155-2” with “ISO 14155”.

Page 1, Clause 4

Delete 4.1, 4.2, 4.3 and 4.4, and replace with:

“The requirements of ISO 11979-2 apply.”

Page 2, Clause 5

Delete the contents and replace with:

“The requirements of ISO 11979-3 apply.”

Page 2, Clause 6

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

In 6.1 second line, replace “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.”

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