

STN	Očné implantáty. Vnútročné šošovky. Časť 10: Vnútročné šošovky Phakic (ISO 11979-10: 2006). Zmena A1	STN EN ISO 11979-10/A1 19 5300
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Ophthalmic implants - Intraocular lenses - Part 10: Phakic intraocular lenses (ISO 11979-10:2006)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 01/15

Obsahuje: EN ISO 11979-10:2006/A1:2014, ISO 11979-10:2006/Amd 1:2014

120202

Úrad pre normalizáciu, metrológiu a skúšobníctvo SR, odbor SÚTN, 2015
Podľa zákona č. 264/1999 Z. z. v znení neskorších predpisov sa môžu slovenské technické normy
rozmnožovať a rozširovať iba so súhlasom Úradu pre normalizáciu, metrológiu a skúšobníctvo SR.

ICS 11.040.70

English Version

Ophthalmic implants - Intraocular lenses - Part 10: Phakic intraocular lenses (ISO 11979-10:2006/Amd 1:2014)

Implants ophtalmiques - Lentilles intraoculaires - Partie 10:
Lentilles intraoculaires phaques (ISO 11979-10:2006/Amd
1:2014)

Ophthalmische Implantate - Intraokularlinsen - Teil 10:
Phake Intraokularlinsen (ISO 11979-10:2006/Amd 1:2014)

This amendment A1 modifies the European Standard EN ISO 11979-10:2006; it was approved by CEN on 18 July 2014.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

This document (EN ISO 11979-10:2006/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 11979-10:2006 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of an identical text or by endorsement, at the latest by February 2015, and conflicting national standards shall be withdrawn at the latest by February 2015.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 11979-10:2006/A1:2014 has been approved by CEN as EN ISO 11979-10:2006/A1:2014 without any modification.

First edition
2006-08-15

AMENDMENT 1
2014-08-01

Ophthalmic implants — Intraocular lenses —

Part 10: Phakic intraocular lenses

AMENDMENT 1

Implants ophtalmiques — Lentilles intraoculaires —

Partie 10: Lentilles intraoculaires phaques

AMENDEMENT 1



Reference number
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Foreword

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

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*

koniec náhľadu – text ďalej pokračuje v platenej verzii STN