

<b>STN</b>	<b>Očné implantáty. Vnútročné šošovky. Časť 9: Multifokálne vnútročné šošovky (ISO 11979-9: 2006). Zmena A1</b>	<b>STN EN ISO 11979-9/A1</b>  19 5300
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Ophthalmic implants - Intraocular lenses - Part 9: Multifocal intraocular lenses (ISO 11979-9:2006)

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 11979-9:2006/A1:2014, ISO 11979-9:2006/Amd 1:2014

**120201**

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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.

EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

**EN ISO 11979-9:2006/A1**

August 2014

ICS 11.040.70

English Version

**Ophthalmic implants - Intraocular lenses - Part 9: Multifocal  
intraocular lenses (ISO 11979-9:2006/Amd 1:2014)**

Implants ophtalmiques - Lentilles intraoculaires - Partie 9:  
Lentilles intraoculaires multifocales (ISO 11979-9:2006/Amd  
1:2014)

Ophthalmische Implantate - Intraokularlinsen - Teil 9:  
Multifokale Intraokularlinsen (ISO 11979-9:2006/Amd  
1:2014)

This amendment A1 modifies the European Standard EN ISO 11979-9:2006; it was approved by CEN on 18 July 2014.

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EUROPEAN COMMITTEE FOR STANDARDIZATION  
COMITÉ EUROPÉEN DE NORMALISATION  
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**CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels**

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## **Foreword**

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of an identical text or by endorsement, at the latest by February 2015, and conflicting national standards shall be withdrawn at the latest by February 2015.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

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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.

First edition  
2006-09-01

**AMENDMENT 1**  
2014-08-15

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# **Ophthalmic implants — Intraocular lenses —**

## **Part 9: Multifocal intraocular lenses**

### **AMENDMENT 1**

*Implants ophtalmiques — Lentilles intraoculaires —*

*Partie 9: Lentilles intraoculaires multifocales*

*AMENDEMENT 1*



Reference number  
ISO 11979-9:2006/Amd.1:2014(E)

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Published in Switzerland

## 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 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:

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

**koniec náhľadu – text ďalej pokračuje v platenej verzii STN**