

# ILNAS

Institut luxembourgeois de la normalisation  
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## ILNAS-EN ISO 11979-8:2017

### **Ophthalmic implants - Intraocular lenses - Part 8: Fundamental requirements (ISO 11979-8:2017)**

Implants ophtalmiques - Lentilles  
intraoculaires - Partie 8: Exigences  
fondamentales (ISO 11979-8:2017)

Ophthalmische Implantate -  
Intraokularlinsen - Teil 8: Grundlegende  
Anforderungen (ISO 11979-8:2017)

05/2017



## National Foreword

This European Standard EN ISO 11979-8:2017 was adopted as Luxembourgish Standard ILNAS-EN ISO 11979-8:2017.

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ILNAS-EN ISO 11979-8:2017

EUROPEAN STANDARD **EN ISO 11979-8**

NORME EUROPÉENNE

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English Version

**Ophthalmic implants - Intraocular lenses - Part 8:  
Fundamental requirements (ISO 11979-8:2017)**

Implants ophtalmiques - Lentilles intraoculaires -  
Partie 8: Exigences fondamentales (ISO 11979-8:2017)

Ophthalmische Implantate - Intraokularlinsen - Teil 8:  
Grundlegende Anforderungen (ISO 11979-8:2017)

This European Standard was approved by CEN on 8 March 2017.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION  
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EUROPÄISCHES KOMITEE FÜR NORMUNG

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

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## European foreword

This document (EN ISO 11979-8:2017) 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 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 November 2017, and conflicting national standards shall be withdrawn at the latest by November 2017.

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.

This document supersedes EN ISO 11979-8:2015.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

The following referenced documents are indispensable for the application of this document. For undated references, the latest edition of the referenced document (including any amendments) applies. For dated references, only the edition cited applies. However, for any use of this standard ‘within the meaning of Annex ZA’, the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When an IEC or ISO standard is referred to in the ISO standard text, this shall be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated version of the ISO or IEC standard, as listed below.

NOTE The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

**Table 1 — Correlation between normative references and dated EN and ISO standards**

| Normative references<br>as listed in Clause 2 of the<br>ISO standard | Equivalent dated standard     |                               |
|--|-------------------------------|-------------------------------|
|  | EN                            | ISO                           |
| ISO 11979-1  | EN ISO 11979-1:2012           | ISO 11979-1:2012              |
| ISO 11979-2  | EN ISO 11979-2:2014           | ISO 11979-2:2014              |
| ISO 11979-3  | EN ISO 11979-3:2012           | ISO 11979-3:2012              |
| ISO 11979-4  | EN ISO 11979-4:2008 + A1:2012 | ISO 11979-4:2008 + Amd.1:2012 |
| ISO 11979-5  | EN ISO 11979-5:2006           | ISO 11979-5:2006              |
| ISO 11979-6  | EN ISO 11979-6:2014           | ISO 11979-6:2014              |
| ISO 11979-7  | EN ISO 11979-7:2014           | ISO 11979-7:2014              |
| ISO 11979-9  | EN ISO 11979-9:2006 + A1:2014 | ISO 11979-9:2006 + Amd.1:2014 |

| Normative references<br>as listed in Clause 2 of the<br>ISO standard | Equivalent dated standard         |                                   |
|--|-----------------------------------|-----------------------------------|
|  | EN                                | ISO                               |
| ISO 11979-10   | EN ISO 11979-10:2006 +<br>A1:2014 | ISO 11979-10:2006 +<br>Amd.1:2014 |
| ISO 14155  | EN ISO 14155:2011 + AC:2011       | ISO 14155:2011 + Cor.1:2011       |
| ISO 14630  | EN ISO 14630:2012                 | ISO 14630:2012                    |
| ISO 14971  | EN ISO 14971:2012                 | ISO 14971:2007                    |

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#### Endorsement notice

The text of ISO 11979-8:2017 has been approved by CEN as EN ISO 11979-8:2017 without any modification.