
Irish Standard
I.S. EN ISO 11979-8:2017

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

**I.S. EN ISO 11979-8:2017**

*Incorporating amendments/corrigenda/National Annexes issued since publication:*

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## National Foreword

I.S. EN ISO 11979-8:2017 is the adopted Irish version of the European Document EN ISO 11979-8:2017, Ophthalmic implants - Intraocular lenses - Part 8: Fundamental requirements (ISO 11979-8:2017)

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*In line with international standards practice the decimal point is shown as a comma (,) throughout this document.*

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

# EN ISO 11979-8

May 2017

ICS 11.040.70

Supersedes EN ISO 11979-8:2015

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.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

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



Ref. No. EN ISO 11979-8:2017 E

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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 as listed in Clause 2 of the 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 as listed in Clause 2 of the ISO standard | Equivalent dated standard | |
|---|---|---|
| | EN | ISO |
| ISO 11979-10 | EN ISO 11979-10:2006 + A1:2014 | ISO 11979-10:2006 + 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 |

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

## Endorsement notice

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

# Annex ZA
(informative)

# Relationship between this European Standard and the Essential Requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered

This European Standard has been prepared under a Commission's standardization request [M/023 concerning the development of European Standards related to medical devices] to provide one voluntary means of conforming to essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [OJ L 169].

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding essential requirements of that Directive and associated EFTA regulations.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC as amended by 2007/47/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with Essential Requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

NOTE 3 This Annex ZA is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

**Table ZA.1 — Correspondence between this European Standard and Annex I of Directive 93/42/EEC [OJ L 169]**

| Essential Requirements of Directive 93/42/EEC | Clause(s)/sub-clause(s) of this EN | Remarks/Notes |
|---|---|---|
| 7.2 | 9.1, 9.2 | ER 7.2 is only met in respect of ethylene oxide and bacterial endotoxins and only in respect of manufacturing. |
| 7.5 | 9.1, 9.2 | ER 7.5 is only met in respect of ethylene oxide and bacterial endotoxins and only in respect of manufacturing. |
| 8.1 | 9.1, 9.2 | ER 8.1 is met in respect of ethylene oxide and bacterial endotoxins only. |
| 8.4 | 9.1 | ER 8.4 is met in respect of ethylene oxide sterilization only. Manufacturing is not covered. |

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the products falling within the scope of this standard.

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INTERNATIONAL STANDARD

**ISO 11979-8**

Third edition
2017-04

# Ophthalmic implants — Intraocular lenses —

## Part 8: Fundamental requirements

*Implants ophtalmiques — Lentilles intraoculaires —*

*Partie 8: Exigences fondamentales*

Reference number
ISO 11979-8:2017(E)



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# Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This third edition cancels and replaces the second edition (ISO 11979-8:2006), which has been technically revised. It also incorporates the Amendment ISO 11979-8:2006/Amd 1:2011.

A list of all the parts in the ISO 11979 series can be found on the ISO website.

# Ophthalmic implants — Intraocular lenses —

# Part 8: Fundamental requirements

## 1 Scope

This document specifies fundamental requirements for all types of intraocular lenses intended for surgical implantation into the anterior segment of the human eye, excluding corneal implants and transplants.

## 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 11979-2, *Ophthalmic implants — Intraocular lenses — Part 2: Optical properties and test methods*

ISO 11979-3, *Ophthalmic implants — Intraocular lenses — Part 3: Mechanical properties and test methods*

ISO 11979-4, *Ophthalmic implants — Intraocular lenses — Part 4: Labelling and information*

ISO 11979-5, *Ophthalmic implants — Intraocular lenses — Part 5: Biocompatibility*

ISO 11979-6, *Ophthalmic implants — Intraocular lenses — Part 6: Shelf-life and transport stability testing*

ISO 11979-7, *Ophthalmic implants — Intraocular lenses — Part 7: Clinical investigations*

ISO 11979-9[1)], *Ophthalmic implants — Intraocular lenses — Part 9: Multifocal intraocular lenses*

ISO 11979-10, *Ophthalmic implants — Intraocular lenses — Part 10: Phakic intraocular lenses*

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

ISO 14630, *Non-active surgical implants — General requirements*

ISO 14971, *Medical devices — Application of risk management to medical devices*

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 11979-1 apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://www.iso.org/obp

1) ISO 11979-7 is under revision. The revised standard will incorporate multifocal intraocular lenses. When the revised standard is published, ISO 11979-9 will be withdrawn.

## 4 Safety and performance

The safety and performance of an intraocular lens shall be demonstrated by pre-clinical and clinical evaluation, including suitable risk analysis in accordance with ISO 14971.

In cases where a test method referenced in this document is not suitable for a certain design or a certain application, an alternative test method devised by the manufacturer shall be validated, justified and documented.

## 5 Optical and mechanical properties

The manufacturer shall ensure that the intraocular lens conforms to applicable requirements in ISO 11979-2, ISO 11979-3, ISO 11979-9 and ISO 11979-10. The manufacturer shall record and justify any deviations from those standards.

## 6 Biocompatibility

The manufacturer shall have documented evidence that demonstrates the intraocular lens to be biocompatible by assessment in accordance with ISO 11979-5.

Manufacturers can take into consideration previous experience and data when determining the extent of further biocompatibility testing.

## 7 Clinical evaluation

The first step in the clinical evaluation is a review of the available literature (published and unpublished) in order to determine if that information is sufficient to demonstrate the safety and performance of the device (see ISO 14155). One option is to demonstrate that the new intraocular lens model is a minor modification of a model, the safety and performance of which has previously been demonstrated.

NOTE ISO/TR 22979 provides a framework for assessment whether or not a modification is minor.

If the clinical evaluation identifies the need for a clinical investigation, the requirements of ISO 14155 shall apply. In addition, the following standards apply depending on the type of the intraocular lens:

a) ISO 11979-7 for monofocal intraocular lenses for the correction of aphakia;

b) ISO 11979-9 for multifocal intraocular lenses for the correction of aphakia;

c) ISO 11979-10 for phakic monofocal intraocular lenses.

## 8 Manufacturing

Intraocular lenses shall be manufactured in such a way that the specified design attributes are achieved.

## 9 Sterilization

### 9.1 General

Intraocular lenses shall be supplied sterile. Sterilization shall adhere to the general provisions laid out in ISO 14630.

For sterilization by ethylene oxide (EO), the following applies:

a) for the assay of EO residues, an exhaustive solvent or head space extraction method shall be chosen;

b) the residue of EO in intraocular lenses shall not exceed 0,5 µg EO per lens per day, or 1,25 µg per lens;