Irish Standard
I.S. EN ISO 11979-8:2006

Ophthalmic implants - Intraocular lenses - Part 8: Fundamental requirements (ISO 11979-8:2006)

I.S. EN ISO 11979-8:2006

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English Version

Ophthalmic implants - Intraocular lenses - Part 8: Fundamental requirements (ISO 11979-8:2006)

Implants ophtalmiques - Lentilles intraoculaires - Partie 8: Exigences fondamentales (ISO 11979-8:2006)

Ophthalmische Implantate - Intraokularlinsen - Teil 8: Grundlegende Anforderungen (ISO 11979-8:2006)

This European Standard was approved by CEN on 26 June 2006.

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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

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Foreword

This document (EN ISO 11979-8:2006) has been prepared by Technical Committee ISO/TC 172 "Optics and optical instruments" 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of an identical text or by endorsement, at the latest by January 2007, and conflicting national standards shall be withdrawn at the latest by January 2007.

This document supersedes EN 13503-8:2000.

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.

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

Endorsement notice

The text of ISO 11979-8:2006 has been approved by CEN as EN ISO 11979-8:2006 without any modifications.

ANNEX ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC (Medical Device Directive)

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide one means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC (Medical Device Directive).

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, 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.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC (Medical Device Directive)

Clause(s)/Sub-clause(s) of this European Standard	Essential Requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
4 & 5	I.1 I.3 II.9.2 II.12.7.1	For optical properties ref. to EN ISO 11979-2, for mechanical properties ref. to EN ISO 11979-3, for multifocal IOLs ref. to EN ISO 11979-9 and for phakic IOLs ref. to EN ISO 11979-10.
6	I.1 II.7.1 II.7.3 II.7.5 II.7.6 II.9.2	For biocompatibility and interaction with YAG-laser ref. to EN ISO 11979-5.
7	I.1 I.4 I.6 II.7.6 II.9.2 II.14	For clinical investigation reference to EN ISO 14155-1, -2 and EN ISO 11979-7, and to EN ISO 11979-9 &-10, as applicable.

Table ZA.1 (*continued*)

Clause(s)/Sub-clause(s) of this European Standard	Essential Requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
9	I.1 I.2 II.7.2 II.7.5 II.8.1 II.8.4	Sterility requirement. Reference to EN ISO 14630. Protection against the contaminant that is ethylen oxide. Protection against leakage.
10	I.3 I.5 II.8.3 II.8.6 II.9.2	For shelf-life and transport reference to EN ISO 11979-6.
11 & 12	II.8.7 II.13.1 II.13.2 II.13.3 II.13.5 II.13.6	For labelling and information reference to EN ISO 11979-4, and to EN ISO 11979-9 &-10, as applicable.

WARNING: Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.