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**Očesni vsadki (implantati) - Intraokularne leče - 9. del: Večgoriščna stekla (ISO/DIS 11979-9:2005)**

Ophthalmic implants - Intraocular lenses - Part 9: Multifocal lenses (ISO/DIS 11979-9:2005)



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## Ophthalmic implants - Intraocular lenses - Part 9: Multifocal lenses (ISO/DIS 11979-9:2005)

Implants ophtalmiques - Lentilles intraoculaires - Partie 9: Lentilles multifocales (ISO/DIS 11979-9:2005)

This draft European Standard is submitted to CEN members for parallel enquiry. It has been drawn up by the Technical Committee CEN/TC 170.

If this draft becomes a European Standard, 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.

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

**Management Centre: rue de Stassart, 36 B-1050 Brussels**



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## Foreword

This document (prEN ISO 11979-9:2005) 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 document is currently submitted to the parallel Enquiry.

### Endorsement notice

The text of ISO 11979-9:2005 has been approved by CEN as prEN ISO 11979-9:2005 without any modifications.

**DRAFT INTERNATIONAL STANDARD** ISO/DIS 11979-9

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# Ophthalmic implants — Intraocular lenses —

## Part 9: Multifocal lenses

*Implants ophtalmiques — Lentilles intraoculaires —*

*Partie 9: Lentilles multifocales*

ICS 11.040.70



**ISO/CEN PARALLEL ENQUIRY**

The CEN Secretary-General has advised the ISO Secretary-General that this ISO/DIS covers a subject of interest to European standardization. **In accordance with the ISO-lead mode of collaboration as defined in the Vienna Agreement, consultation on this ISO/DIS has the same effect for CEN members as would a CEN enquiry on a draft European Standard.** Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month FDIS vote in ISO and formal vote in CEN.

**In accordance with the provisions of Council Resolution 15/1993 this document is circulated in the English language only.**

**Conformément aux dispositions de la Résolution du Conseil 15/1993, ce document est distribué en version anglaise seulement.**

**To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.**

**Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.**

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 11979-9 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.



ISO 11979 consists of the following parts, under the general title *Ophthalmic implants — Intraocular lenses*:



— *Part 1: Vocabulary*

— *Part 2: Optical properties and test methods*

— *Part 3: Mechanical properties and test methods*

— *Part 4: Labelling and information*

— *Part 5: Biocompatibility*

— *Part 6: Shelf-life and transport stability*

— *Part 7: Clinical investigations*

— *Part 8: Fundamental requirements*

— *Part 9: Multifocal lenses*

— *Part 10: Phakic intraocular Lenses*

This standard contains three Annexes. Annex A is normative. Annexes B and C are informative.

# Ophthalmic implants — Intraocular lenses — Part 9: Multifocal lenses

## 1 Scope

This standard applies to any intraocular lens whose optic provides two or more rotationally symmetric powers and whose primary indication is the correction of aphakia with the added benefit of useful vision at more than one distance (e.g., distance and near).

NOTE The term “near vision” as used in this standard includes useful vision at a distance of claimed benefit; e.g., near and/ or intermediate distances.

## 2 Normative references



The following referenced documents are indispensable for the application 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 11979-1, *Ophthalmic implants – Intraocular lenses – Part 1: Vocabulary*

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

ISO 14155-1, *Clinical investigation of medical devices – Part 1: General requirements*

ISO 14155-2, *Clinical investigation of medical devices – Part 2: Clinical investigation plans*

ISO 14971-1, *Medical devices – Risk management – Part 1: Application of risk analysis*

## 3 Terms and definitions

For the purposes of this document the definitions given in ISO 11979-1, ISO 14155-1 and ISO 14155-2 apply.

## 4 Physical requirements

### 4.1 General

This section applies to the physical properties of multifocal intraocular lenses (MIOLs) in the assembled or final form, as intended for implantation in the human eye.