

Ophthalmic optics - Contact lenses - Part 4: Physicochemical properties of contact lens materials

Ophthalmic optics - Contact lenses - Part 4:
Physicochemical properties of contact lens materials

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-EN ISO 18369-4:2006 sisaldab Euroopa standardi EN ISO 18369-4:2006 ingliskeelset teksti.</p> <p>Käesolev dokument on jõustatud 20.09.2006 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.</p> <p>Standard on kättesaadav Eesti standardiorganisatsioonist.</p>	<p>This Estonian standard EVS-EN ISO 18369-4:2006 consists of the English text of the European standard EN ISO 18369-4:2006.</p> <p>This document is endorsed on 20.09.2006 with the notification being published in the official publication of the Estonian national standardisation organisation.</p> <p>The standard is available from Estonian standardisation organisation.</p>
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<p>Käsitlusala:</p> <p>This part of ISO 18369 specifies the methods of testing the physicochemical properties of contact lens materials. These are extraction, rigid lens flexure and breakage, oxygen permeability, refractive index and water content.</p>	<p>Scope:</p> <p>This part of ISO 18369 specifies the methods of testing the physicochemical properties of contact lens materials. These are extraction, rigid lens flexure and breakage, oxygen permeability, refractive index and water content.</p>
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Võtmesõnad: contact lenses, determination of content, gravimetric analysis, ophthalmic equipment, optical equipment, optics, refractometric analysis, tests, water

English Version

**Ophthalmic optics - Contact lenses - Part 4: Physicochemical
properties of contact lens materials (ISO 18369-4:2006)**

Optique ophtalmique - Lentilles de contact - Partie 4:
Propriétés physicochimiques des matériaux des lentilles de
contact (ISO 18369-4:2006)

Augenoptik - Kontaktlinsen - Teil 4: Physikalisch-
chemische Eigenschaften von Kontaktlinsenmaterialien
(ISO 18369-4:2006)

This European Standard was approved by CEN on 24 May 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.

CEN members are the national standards bodies of 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.



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

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Foreword

This document (EN ISO 18369-4:2006) 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 February 2007, and conflicting national standards shall be withdrawn at the latest by February 2007.

This document supersedes EN ISO 10339:1999, EN ISO 10340:1996, EN ISO 11984:1999, EN ISO 9913-1:1998, EN ISO 9913-2:2000, EN ISO 9914:1996.

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 18369-4:2006 has been approved by CEN as EN ISO 18369-4:2006 without any modifications.

NOTE A-Deviations are given in Annex ZA (informative).

ANNEX ZA (informative)
A-deviations

A-deviation: National deviation due to regulations, the alteration of which is for the time being outside the competence of the CEN/CENELEC member.

This European Standard does not fall under any Directive of the EC. In the relevant CEN/CENELEC countries these A-deviations are valid instead of the provisions of the European Standard until they have been removed.

The legislative situation in Germany requires the unit "dioptré" be designated by the symbol "dpt" instead of "D".

This is to avoid conflict with the rules of ISO 1000 being the basic International Standard on symbols and units and with the respective basic resolution of the CGPM (International Conference on Weights and Measures).

Identification of the regulation:

Gesetz über die Einheiten im Messwesen vom 02.07.1969 in der Fassung der Bekanntmachung vom 22.04.1985; and

Ausführungsverordnung zum Gesetz über Einheiten im Messwesen (Einheitenverordnung - EinhV) vom 13.12.1985, § 1 und Anlage 1, Nr. 9.

Ophthalmic optics — Contact lenses —

Part 4:

**Physicochemical properties of contact
lens materials**

Optique ophtalmique — Lentilles de contact —

*Partie 4: Propriétés physicochimiques des matériaux des lentilles de
contact*



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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 18369-4 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This first edition cancels and replaces ISO 9913-1:1996, ISO 9913-2:2000, ISO 9914:1995, ISO 10339:1997, ISO 10340:1995 and ISO 11984:1999, which have been technically revised.

ISO 18369 consists of the following parts, under the general title *Ophthalmic optics — Contact lenses*:

- *Part 1: Vocabulary, classification system and recommendations for labelling specifications*
- *Part 2: Tolerances*
- *Part 3: Measurement methods*
- *Part 4: Physicochemical properties of contact lens materials*

Introduction

The ISO 18369 series applies to contact lenses, which are devices worn over the front surface of the eye in contact with the precorneal tear film. This part of ISO 18369 covers rigid (hard) corneal and scleral contact lenses, as well as soft contact lenses. Rigid lenses maintain their own shape unsupported and are made of transparent optical-grade plastics, such as polymethylmethacrylate (PMMA), cellulose acetate butyrate (CAB), polyacrylate/siloxane copolymers, rigid polysiloxanes (silicone resins), butylstyrenes, fluoropolymers, and fluorosiloxanes, etc. Soft contact lenses are easily deformable and require support for proper shape. A very large subset of soft contact lenses consists of transparent hydrogels containing water in concentrations greater than 10 %. Soft contact lenses can also be made of non-hydrogel materials, e.g. flexible polysiloxanes (silicone elastomers).

The ISO 18369 series is applicable to determining allowable tolerances of parameters and properties important for proper functioning of contact lenses as optical devices. The ISO 18369 includes tolerances for single vision contact lenses, bifocal lenses, lenses that alter the flux density and/or spectral composition of transmitted visible light (tinted or pigmented contact lenses, such as those with enhancing, handling, and/or opaque tints), and lenses that significantly attenuate ultraviolet radiation (UV-absorbing lenses). The ISO 18369 series of standards covers contact lenses designed with spherical, toric, and aspheric surfaces, and recommended methods for the specification of contact lenses.

Ophthalmic optics — Contact lenses —

Part 4:

Physicochemical properties of contact lens materials

1 Scope

This part of ISO 18369 specifies the methods of testing the physicochemical properties of contact lens materials. These are extraction, rigid lens flexure and breakage, oxygen permeability, refractive index and water content.

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 3696:1987, *Water for analytical laboratory use — Specification and test methods*

ISO 18369-1:2006, *Ophthalmic optics — Contact lenses — Part 1: Vocabulary, classification system and recommendations for labelling specifications*

ISO 18369-3:2006, *Ophthalmic optics — Contact lenses — Part 3: Measurement methods*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 18369-1 apply.

4 Physicochemical properties of contact lenses

4.1 Repeatability, test methods and units of measure

The physicochemical properties or conditions listed in Table 1 are measurable characteristics of hydrogel and nonhydrogel materials that have been successfully manufactured into contact lenses. In addition, Table 1 includes repeatability, test methods, and units of measure for these characteristics. If alternative methods are used, they should be so stipulated.