

Ophthalmic optics - Contact lenses - Part 4:
Physicochemical properties of contact lens materials
(ISO 18369-4:2017, Corrected version 2017-10-01)

EESTI STANDARDI EESSÕNA

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English Version

Ophthalmic optics - Contact lenses - Part 4:
Physicochemical properties of contact lens materials (ISO
18369-4:2017, Corrected version 2017-10-01)

Optique ophtalmique - Lentilles de contact - Partie 4:
Propriétés physicochimiques des matériaux des
lentilles de contact (ISO 18369-4:2017, Version
corrigée 2017-10-01)

Augenoptik - Kontaktlinsen - Teil 4: Physikalisch-
chemische Eigenschaften von
Kontaktlinsenmaterialien (ISO 18369-4:2017,
korrigierte Fassung 2017-10-01)

This European Standard was approved by CEN on 1 July 2017.

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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (EN ISO 18369-4:2017) 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of an identical text or by endorsement, at the latest by March 2018, and conflicting national standards shall be withdrawn at the latest by March 2018.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 18369-4:2017.

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 18369-4:2017, Corrected version 2017-10-01 has been approved by CEN as EN ISO 18369-4:2017 without any modification.

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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).

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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 second edition cancels and replaces the first edition (ISO 18369-4:2006), which has been technically revised.

A list of all parts in the ISO 18369 series can be found on the ISO website.

This corrected version of ISO 18369-4:2017 incorporates the following corrections.

- “lens” has been replaced by “contact lens” throughout the text.
- “saline” has been replaced by “saline solution” throughout the text.
- In 4.1, “repeatability and reproducibility” has been added before (R&R) to improve clarity.
- In 4.3.2.1, “single vision” has been replaced by “single-vision”.
- In 4.3.5, “lens ruptures” has been replaced by “sample ruptures”.
- In 4.5.2, “D line” has been replaced by “D-line”.
- In 4.5.4.2.2, “4.5.4.1” has been replaced by “4.5.4.1.3”, and “4.5.4.2” has been replaced by “4.5.4.2.1”.
- In A.7.1, “Figure A.1” has been replaced by “Figure A.2” in two instances.
- In A.7.2, “sample” has been replaced by “test sample” in three instances.
- In A.9.7, “(p_A)” has been replaced by “ p_A ”.
- In Figure A.2, Key 2, “anterior chamber” has been replaced by “anterior environmental chamber”.
- In Figure A.2, Key 3, “posterior chamber” has been replaced by “posterior environmental chamber”.

- In Annex C, “lens” has been replaced by “hydrogel contact lens”.
- In D.2, “critical angle” has been replaced by “critical angle of incidence”.
- “may” has been replaced by “can” in
 - 4.2.1;
 - 4.2.2;
 - 4.3.1, second sentence, first “may”;
 - 4.4.1, third paragraph, last sentence;
 - 4.4.3.5.1, second sentence;
 - 4.4.3.5.2, NOTE;
 - A.9.5, fifth sentence.
- Additional minor editorial changes have been made to improve clarity.

Ophthalmic optics — Contact lenses —

Part 4:

Physicochemical properties of contact lens materials

1 Scope

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

ISO 18369-1:2017, *Ophthalmic optics — Contact lenses — Part 1: Vocabulary, classification system and recommendations for labelling specifications*

ISO 18369-3:2017, *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.

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>

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 non-hydrogel materials that have been used to produce commercially available contact lenses.