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Ophthalmic optics - Contact lenses - Part 2: Tolerances
(ISO 18369-2:2017)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 18369-2:2017 sisaldab Euroopa standardi EN ISO 18369-2:2017 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 18369-2:2017 consists of the English text of the European standard EN ISO 18369-2:2017.
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Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 20.09.2017.	Date of Availability of the European standard is 20.09.2017.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

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ICS 01.040.11, 11.040.70

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EUROPEAN STANDARD

EN ISO 18369-2

NORME EUROPÉENNE

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English Version

Ophthalmic optics - Contact lenses - Part 2: Tolerances (ISO 18369-2:2017)

Optique ophtalmique - Lentilles de contact - Partie 2:
Tolérances (ISO 18369-2:2017)

Augenoptik - Kontaktlinsen - Teil 2:
Grenzabweichungen (ISO 18369-2:2017)

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

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

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European foreword

This document (EN ISO 18369-2:2017) 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of an identical text or by endorsement, at the latest by March 2018, and conflicting national standards shall be withdrawn at the latest by March 2018.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 18369-2:2012.

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 18369-2:2017 has been approved by CEN as EN ISO 18369-2:2017 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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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 18369-2:2012), which has been technically revised.

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

Ophthalmic optics — Contact lenses —

Part 2: Tolerances

1 Scope

This document specifies the tolerance limits of the principal optical and physical parameters of rigid corneal, rigid scleral and soft contact lenses at the time of manufacture.

These tolerances might not apply to other purposes, for example, shelf-life studies.

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

ISO 18369-3:2017, *Ophthalmic optics — Contact lenses — Part 3: Measurement methods*

ISO 18369-4:2017, *Ophthalmic optics — Contact lenses — Part 4: Physicochemical properties of contact lens materials*

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 General

4.1 Tolerance limits for contact lenses

When tested as described in ISO 18369-3, the dimensional and optical properties for contact lenses shall be as specified within the appropriate tolerance limits given in [Table 1](#), [Table 2](#) and [Table 3](#).

When tested as described in ISO 18369-4, the material properties for contact lenses shall be as specified, within the appropriate tolerance limits given in [Table 4](#).