

**Ophthalmic optics - Contact lenses - Part 2: Tolerances  
(ISO 18369-2:2012)**

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English Version

**Ophthalmic optics - Contact lenses - Part 2: Tolerances (ISO  
18369-2:2012)**

Optique ophtalmique - Lentilles de contact - Partie 2:  
Tolérances (ISO 18369-2:2012)

Augenoptik - Kontaktlinsen - Teil 2: Grenzabweichungen  
(ISO 18369-2:2012)

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

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## Foreword

This document (EN ISO 18369-2:2012) 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of an identical text or by endorsement, at the latest by June 2013, and conflicting national standards shall be withdrawn at the latest by June 2013.

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

This document supersedes EN ISO 18369-2:2006.

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### Endorsement notice

The text of ISO 18369-2:2012 has been approved by CEN as a EN ISO 18369-2:2012 without any modification.

## Introduction

ISO 18369 is applicable to contact lenses, which are devices worn over the front surface of the eye in contact with the preocular 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).

ISO 18369 is applicable to determining allowable tolerances of parameters and properties important for the proper functioning of contact lenses as optical devices. 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). ISO 18369 covers contact lenses designed with spherical, toric and aspheric surfaces, and recommended methods for the specification of contact lenses.

# Ophthalmic optics — Contact lenses —

## Part 2: Tolerances

### 1 Scope

This part of ISO 18369 specifies the tolerance limits of the principal optical and physical parameters of rigid, soft and rigid scleral contact lenses.

### 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 18369-1, *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*

ISO 18369-4:2006, *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.

### 4 Tolerances for rigid contact lenses

When tested as described in ISO 18369-3, the dimensional and optical properties of corneal and scleral rigid contact lenses shall be as specified, within the appropriate tolerance limits given in Tables 1 and 2. Each dimension and optical property specified shall be determined using a test method with measurement reproducibility better than one-half the tolerance limit specified for the property. For fenestration, truncation and displacement, measured values shall not differ from the specified values by more than 10 %.

### 5 Tolerances for soft contact lenses

When tested as described in ISO 18369-3, the dimensional and optical properties for soft contact lenses shall be as specified, within the appropriate tolerance limits given in Table 3. Each dimension and optical property specified shall be determined using a test method with measurement reproducibility better than one-half the tolerance limit specified for the property. For truncation and displacement, measured values shall not differ from the specified values by more than 10 %.

### 6 Conditioning of contact lenses prior to testing

Contact lenses shall be equilibrated as specified in the relevant test method cited in ISO 18369-3 or as specified by the manufacturer. Lenses made of hydrogel materials shall be equilibrated in the standard saline described in ISO 18369-3 or an equivalent solution for the particular method of measurement.