

Ophthalmic optics - Contact lenses and contact lens care products - Determination of physical compatibility of contact lens care products with contact lenses (ISO 11981:2017)

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 11981:2017 sisaldab Euroopa standardi EN ISO 11981:2017 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 11981:2017 consists of the English text of the European standard EN ISO 11981:2017.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
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English Version

Ophthalmic optics - Contact lenses and contact lens care products - Determination of physical compatibility of contact lens care products with contact lenses (ISO 11981:2017)

Optique ophtalmique - Lentilles de contact et produits d'entretien des lentilles de contact - Détermination de la compatibilité physique des produits d'entretien des lentilles de contact avec les lentilles de contact (ISO 11981:2017)

Augenoptik - Kontaktlinsen und Kontaktlinsenpflegemittel - Bestimmung der physikalischen Verträglichkeit von Kontaktlinsenpflegemitteln mit Kontaktlinsen (ISO 11981:2017)

This European Standard was approved by CEN on 4 November 2017.

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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 CEN-CENELEC Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION  
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EUROPÄISCHES KOMITEE FÜR NORMUNG

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## European foreword

This document (EN ISO 11981:2017) 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of an identical text or by endorsement, at the latest by June 2018, and conflicting national standards shall be withdrawn at the latest by June 2018.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 11981:2009.

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 11981:2017 has been approved by CEN as EN ISO 11981:2017 without any modification.

# Contents

Page

<b>Foreword</b> .....	<b>iv</b>
<b>1 Scope</b> .....	<b>1</b>
<b>2 Normative references</b> .....	<b>1</b>
<b>3 Terms and definitions</b> .....	<b>1</b>
<b>4 Principle</b> .....	<b>2</b>
4.1 Detection of changes in contact lens characteristics.....	2
4.2 Method to distinguish reversible from irreversible changes in contact lens characteristics.....	3
<b>5 Selection of test lenses</b> .....	<b>4</b>
<b>6 Procedure</b> .....	<b>4</b>
6.1 Test method to detect changes in contact lens characteristics .....	4
6.2 Test method to distinguish reversible from irreversible changes in contact lens characteristics.....	5
6.3 Interpretation of results .....	5
<b>7 Test report</b> .....	<b>5</b>
<b>Bibliography</b> .....	<b>7</b>

## 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](http://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](http://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 11981:2009), which has been revised for clarity and to update all normative references.

# Ophthalmic optics — Contact lenses and contact lens care products — Determination of physical compatibility of contact lens care products with contact lenses

## 1 Scope

This document describes the general procedure and performance criteria for assessing the physical compatibility of contact lens care products with contact lenses and for determining whether the observed changes are reversible.

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

ISO 18369-2, *Ophthalmic optics — Contact lenses — Part 2: Tolerances*

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 and the following 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 <https://www.iso.org/obp>

### 3.1 cycle

sequence of events, following instructions for use or recommendations by the manufacturer of the contact lens care product, to occur between the time the contact lens is removed from the eye and before it is placed back into the eye

### 3.2 standard saline solution

specific phosphate buffered saline at a pH of  $7,4 \pm 0,1$  and a nominal osmolarity of  $310 \pm 5$  mOsm

Note 1 to entry: The provisions for formulation and preparation of standard saline solution are given in ISO 18369-3:2017, 4.9.

### 3.3 control solution

standard saline solution or appropriate justified alternative solution used to cycle contact lenses

Note 1 to entry: Control solutions are not required to comply with this document, but can be used to gain further information about the test.