



SLOVENSKI STANDARD SIST EN ISO 11980:2013

01-februar-2013

Nadomešča:
SIST EN ISO 11980:2010

Očesna optika - Kontaktne leče in izdelki za vzdrževanje kontaktnih leč - Navodilo za klinične raziskave (ISO 11980:2012)

Ophthalmic optics - Contact lenses and contact lens care products - Guidance for clinical investigations (ISO 11980:2012)

iTeh STANDARD PREVIEW
(standards.iteh.ai)

Optique ophtalmique - Lentilles de contact et produits d'entretien pour lentilles de contact - Directives pour les investigations cliniques (ISO 11980:2012)

<https://standards.iteh.ai/catalog/standards/sist/a99deaf8-b195-437f-b733-70983570d654/sist-en-iso-11980-2013>

Ta slovenski standard je istoveten z: EN ISO 11980:2012

ICS:

11.040.70 Oftalmološka oprema Ophthalmic equipment

SIST EN ISO 11980:2013 **en**

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN ISO 11980:2013](#)

<https://standards.iteh.ai/catalog/standards/sist/a99deaf8-b195-437f-b733-70983570d654/sist-en-iso-11980-2013>

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 11980

November 2012

ICS 11.040.70

Supersedes EN ISO 11980:2009

English Version

Ophthalmic optics - Contact lenses and contact lens care products - Guidance for clinical investigations (ISO 11980:2012)

Optique ophtalmique - Lentilles de contact et produits d'entretien pour lentilles de contact - Directives pour les investigations cliniques (ISO 11980:2012)

Augenoptik - Kontaktlinsen und Kontaktlinsenpflegemittel - Leitfaden für die klinische Prüfung (ISO 11980:2012)

This European Standard was approved by CEN on 14 November 2012.

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

CEN members are the national standards bodies of 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, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

[SIST EN ISO 11980:2013](https://standards.iteh.ai/catalog/standards/sist/a99deaf8-b195-437f-b733-70983570d654/sist-en-iso-11980-2013)

<https://standards.iteh.ai/catalog/standards/sist/a99deaf8-b195-437f-b733-70983570d654/sist-en-iso-11980-2013>



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

Management Centre: Avenue Marnix 17, B-1000 Brussels

Contents

Page

Foreword.....3

**iTeh STANDARD PREVIEW
(standards.iteh.ai)**

[SIST EN ISO 11980:2013](https://standards.iteh.ai/catalog/standards/sist/a99deaf8-b195-437f-b733-70983570d654/sist-en-iso-11980-2013)

<https://standards.iteh.ai/catalog/standards/sist/a99deaf8-b195-437f-b733-70983570d654/sist-en-iso-11980-2013>

Foreword

This document (EN ISO 11980:2012) 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 May 2013, and conflicting national standards shall be withdrawn at the latest by May 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 11980:2009.

According to the CEN/CENELEC Internal Regulations, the national standards organisations 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, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

iTeh STANDARD PREVIEW
(standards.iteh.ai) **Endorsement notice**

The text of ISO 11980:2012 has been approved by CEN as a EN ISO 11980:2012 without any modification.

[SIST EN ISO 11980:2013](https://standards.iteh.ai/catalog/standards/sist/a99deaf8-b195-437f-b733-70983570d654/sist-en-iso-11980-2013)

<https://standards.iteh.ai/catalog/standards/sist/a99deaf8-b195-437f-b733-70983570d654/sist-en-iso-11980-2013>

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN ISO 11980:2013](#)

<https://standards.iteh.ai/catalog/standards/sist/a99deaf8-b195-437f-b733-70983570d654/sist-en-iso-11980-2013>

INTERNATIONAL STANDARD

ISO
11980

Third edition
2012-11-15

Ophthalmic optics — Contact lenses and contact lens care products — Guidance for clinical investigations

*Optique ophtalmique — Lentilles de contact et produits d'entretien pour
lentilles de contact — Directives pour les investigations cliniques*

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN ISO 11980:2013](https://standards.iteh.ai/catalog/standards/sist/a99dea8-b195-437f-b733-70983570d654/sist-en-iso-11980-2013)

[https://standards.iteh.ai/catalog/standards/sist/a99dea8-b195-437f-b733-
70983570d654/sist-en-iso-11980-2013](https://standards.iteh.ai/catalog/standards/sist/a99dea8-b195-437f-b733-70983570d654/sist-en-iso-11980-2013)



Reference number
ISO 11980:2012(E)

© ISO 2012

iTeh STANDARD PREVIEW (standards.iteh.ai)

[SIST EN ISO 11980:2013](https://standards.iteh.ai/catalog/standards/sist/a99deaf8-b195-437f-b733-70983570d654/sist-en-iso-11980-2013)

<https://standards.iteh.ai/catalog/standards/sist/a99deaf8-b195-437f-b733-70983570d654/sist-en-iso-11980-2013>



COPYRIGHT PROTECTED DOCUMENT

© ISO 2012

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents	Page
Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Clinical investigational requirements	1
4.1 General	1
4.2 Additional requirements	1
4.3 Other considerations	4
Annex A (informative) Elements of a clinical investigation	5
Annex B (informative) Procedures for the evaluation of safety, physiological performance and effect on ocular tissues	18
Annex C (informative) The evaluation of visual, refractive and lens performance and subject acceptance	23
Bibliography	26

iTeh STANDARD PREVIEW (standards.iteh.ai)

[SIST EN ISO 11980:2013](https://standards.iteh.ai/catalog/standards/sist/a99deaf8-b195-437f-b733-70983570d654/sist-en-iso-11980-2013)

<https://standards.iteh.ai/catalog/standards/sist/a99deaf8-b195-437f-b733-70983570d654/sist-en-iso-11980-2013>

ISO 11980:2012(E)

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 11980 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 11980:2009), which has undergone minor revision in order to update the normative reference to ISO 14155 and to revise 4.2.1.1 b) 6) and the fifth row of Table A.1 (overnight wear).

This corrected version of ISO 11980:2012 incorporates the following correction:

- in Table A.12, the final equation corresponding to the total number of eyes has been inserted.

SIST EN ISO 11980:2013
<https://standards.iteh.ai/catalog/standards/sist/a99deaf8-b195-437f-b733-70983570d654/sist-en-iso-11980-2013>

Introduction

Currently, contact lenses and contact lens care products are regulated in different ways in different countries. This International Standard has been developed to encourage global harmonization. Widespread adoption of this International Standard should represent yet another step toward mutual recognition. This International Standard can also be used as a basis to fulfil design elements of ISO 9001^[1].

iTeh STANDARD PREVIEW (standards.iteh.ai)

[SIST EN ISO 11980:2013](https://standards.iteh.ai/catalog/standards/sist/a99deaf8-b195-437f-b733-70983570d654/sist-en-iso-11980-2013)

<https://standards.iteh.ai/catalog/standards/sist/a99deaf8-b195-437f-b733-70983570d654/sist-en-iso-11980-2013>

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN ISO 11980:2013](#)

<https://standards.iteh.ai/catalog/standards/sist/a99deaf8-b195-437f-b733-70983570d654/sist-en-iso-11980-2013>