SLOVENSKI STANDARD
SIST EN ISO 11980:2010

01-januar-2010

Nadomeģļ a:
SIST EN ISO 11980:2000

Oļ esna optika - Kontaktne leļ e in izdelki za vzdrģevanje kontaktnih leļ - Navodilo za kliniļ ne raziskave (ISO 11980:2009)

Ophthalmic optics - Contact lenses and contact lens care products - Guidance for clinical investigations (ISO 11980:2009)

Augenoptik - Kontaktlinsen und Kontaktlinsenpflegemittel - Leitfaden für die klinische Prüfung (ISO 11980:2009)

Optique ophtalmique - Lentilles de contact et produits d'entretien pour lentilles de contact - Directives pour les investigations cliniques (ISO 11980:2009)

Ta slovenski standard je istoveten z: **EN ISO 11980:2009**

ICS:

11.040.70	Oftalmološka oprema	Ophthalmic equipment

SIST EN ISO 11980:2010 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11980

October 2009

ICS 11.040.70

Supersedes EN ISO 11980:1997

English Version

Ophthalmic optics - Contact lenses and contact lens care products - Guidance for clinical investigations (ISO 11980:2009)

Optique ophtalmique - Lentilles de contact et produits d'entretien pour lentilles de contact - Directives pour les investigations cliniques (ISO 11980:2009)

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

This document (EN ISO 11980:2009) 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of an identical text or by endorsement, at the latest by April 2010, and conflicting national standards shall be withdrawn at the latest by April 2010.

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Endorsement notice

The text of ISO 11980:2009 has been approved by CEN as a EN ISO 11980:2009 without any modification.

INTERNATIONAL STANDARD

ISO 11980

Second edition
2009-10-15

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

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Case postale 56 • CH-1211 Geneva 20
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Fax + 41 22 749 09 47
E-mail copyright@iso.org
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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.

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.

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ISO 11980 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 11980:1997), of which it constitutes a technical revision. It also incorporates the Technical Corrigendum ISO 11980:1997/Cor.1:1998.

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].

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

1 Scope

This International Standard gives guidelines for the clinical investigation (CI) of the safety and performance of contact lenses and contact lens care products.

NOTE This International Standard attempts to harmonize the recognized regulatory requirements for the conduct of a CI to meet the marketing and labelling requirements for contact lenses and contact lens care products around the world. However, national requirements vary greatly. Wherever national practice or regulations dictate some legal requirement, this requirement takes precedence over this International Standard.

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 14155-1, *Clinical investigation of medical devices for human subjects — Part 1: General requirements*

ISO 14155-2, *Clinical investigation of medical devices for human subjects — Part 2: Clinical investigation plans*

ISO 14534, *Ophthalmic optics — Contact lenses and contact lens care products — Fundamental requirements*

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14155-1, ISO 14155-2, ISO 14534 and ISO 18369-1 apply.

4 Clinical investigational requirements

4.1 General

The general requirements for a CI and for a clinical investigation plan (CIP) given in ISO 14155-2 shall apply, with additional requirements given below.