SLOVENSKI STANDARD
SIST EN ISO 11980:2000

01-januar-2000

Oļ esna optika - Kontaktne leļ e in izdelki za vzdrģevanje kontaktnih leļ - Navodilo za kliniļ ne raziskave (ISO 11980:1997)

Ophthalmic optics - Contact lenses and contact lens care products - Guidance for clinical investigations (ISO 11980:1997)

Augenoptik - Kontaktlinsen und Kontaktlinsenpflegemittel - Leitfaden für die klinische Prüfung (ISO 11980:1997)

Optique ophtalmique - Lentilles de contact et produits d'entretien pour lentilles de contact - Lignes directrices pour les investigations cliniques (ISO 11980:1997)

Ta slovenski standard je istoveten z: **EN ISO 11980:1997**

ICS:

11.040.70	Oftalmološka oprema	Ophthalmic equipment

SIST EN ISO 11980:2000 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11980

December 1997

ICS 11.040.70

Descriptors: see ISO document

English version

Ophthalmic optics - Contact lenses and contact lens care products - Guidance for clinical investigations (ISO 11980:1997)

Optique ophtalmique - Lentilles de contact et produits d'entretien pour lentilles de contact - Lignes directrices pour les investigations cliniques (ISO 11980:1997)

Augenoptik - Kontaktlinsen und Kontaktlinsenpflegemittel - Leitfaden für die klinische Prüfung (ISO 11980:1997)

This European Standard was approved by CEN on 30 November 1997.

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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

CORRECTED 1998-01-15

Foreword

The text of the International Standard ISO 11980:1997 has been prepared by Technical Committee ISO/TC 172 "Optics and optical instruments" 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 1998, and conflicting national standards shall be withdrawn at the latest by June 1998.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 11980:1997 was approved by CEN as a European Standard without any modification.

NOTE: Normative references to International Standards are listed in annex ZA (normative). A-deviations are given in Annex ZB (informative).

Annex ZA (normative)
Normative references to international publications with their relevant European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

Publication	Year	Title	EN	Year
ISO 14534	1997	Ophthalmic optics - Contact lenses and contact lens care products - Fundamental requirements	EN ISO 14534	1997

ANNEX ZB (informative)

A-deviations

A-deviation: National deviation due to regulations, the alteration of which is for the time being outside the competence of the CEN/CENELEC member.

This European Standard does not fall under any Directive of the EC. In the relevant CEN/CENELEC countries these A-deviations are valid instead of the provisions of the European Standard until they have been removed.

The legislative situation in Germany requires the unit "dioptre" be designated by the symbol "dpt" instead of "D".

This is to avoid conflict with the rules of ISO 1000 being the basic International Standard on symbols and units and with the respective basic resolution of the CGPM (International Conference on Weights and Mesures).

Identification of the regulation:

Gesetz über die Einheiten im Meßwesen vom 02.07.1969 in der Fassung der Bakanntmachung vom 22.04.1985; and

Ausführungsverordnung zum Gesetz über Einheiten im Meßwesen (Einheitenverordnung - EinhV) vom 13.12.1985, § 1 und Anlage 1, Nr. 9

INTERNATIONAL STANDARD

ISO 11980

First edition
1997-12-15

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 — Lignes directrices pour les investigations cliniques

Reference number
ISO 11980:1997(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.

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.

International Standard ISO 11980 was prepared by Technical Committee ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

Annexes A to D of this International Standard are for information only.

International Organization for Standardization
Case postale 56 • CH-1211 Genève 20 • Switzerland
Internet central@iso.ch
X.400 c=ch; a=400net; p=iso; o=isocs; s=central

Printed in Switzerland

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 a global harmonization. It is hoped that the adoption of this International Standard will be yet another step toward Mutual Recognition. This International Standard could also be used as a basis to fulfil design elements of ISO 9001.

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

1 Scope

This International Standard provides guidance for the clinical investigation of the safety and performance of contact lenses and contact lens care products.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard, are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 14155:1996 *Clinical investigation of medical devices*

ISO 14534:1997, *Ophthalmic optics - Contact lenses and contact lens care products - Fundamental requirements*

NOTE This International Standard attempts to harmonize the recognized regulatory requirements for the generation of clinical data to meet the marketing 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.

Some examples of additional requirements /guidance documents are found in annex D.

3 Definitions

For the purposes of this International Standard, the definitions given in ISO 14155 and ISO 14534 apply.

NOTE Additional definitions can be found in ISO 8320-1 and ISO 8320-2 (see annex D).

4 General clinical investigational requirements

General requirements and guidance for a clinical investigation are given in ISO 14155.

The clinical investigator shall inform the sponsor, the monitor and national regulatory authorities, if applicable, about any severe adverse event and about all adverse device effects in a timely manner (ISO 14155).