International Standard

ISO 11980

# Ophthalmic optics — Contact lenses and contact lens care products — Requirements and guidance for clinical investigations

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

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# Contents

Page

**Foreword** ... **iv**

**Introduction** ... **vi**

**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 ... 2

4.2.1 Study design ... 2

4.2.2 Contact lens and contact lens care product variables ... 4

4.3 Other considerations ... 5

**Annex A** (informative) **Elements of a clinical investigation (CI)** ... **6**

**Annex B** (informative) **Grading scales for the evaluation of safety, physiological performance and effect on ocular tissues** ... **19**

**Annex C** (informative) **The evaluation of visual, refractive and lens performance and subjective performance** ... **25**

**Bibliography** ... **29**

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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.

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 document 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).

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For an explanation of 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 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*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 170, *Ophthalmic optics*,in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This fourth edition cancels and replaces the third edition (ISO 11980:2012), which has been technically revised.

The main changes are as follows:

— the title was changed to reflect the requirements;

— the Scope was clarified;

— the inclusion and exclusion criteria (4.2.1.1) were clarified;

— the appropriate controls in 4.2.1.2, 4.2.1.3 and A.2.2 were clarified;

— the clinical assessment variables (4.2.2.2 and 4.2.2.3) were updated and clarified;

— the guidance for minimum completed participants were updated and the material and design details (Table A.1) were clarified;

— the contact lens group information for contact lens care product testing (A.2.2.2) was updated;

— the statistical considerations (A.2.3) were clarified;

— the details of serious adverse events (A.2.4.2) were clarified;

— examples of significant adverse events (A.2.4.3) were added;

— to clarify suggested reporting of results, Tables A.2 to A.15 were updated;

— a bulbar conjunctival staining grading scale (B.7) was added;

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— to clarify quadrants of interest, Figure B.2 was updated;

— grading scales for anterior chamber cells and flare (B.9) were added;

— the visual performance testing (C.2) was clarified;

— the refractive performance (C.3) was clarified;

— the front surface deposits grading scale (C.6.2) was revised;

— the Bibliography was updated.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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# Introduction

Currently, contact lenses and contact lens care products are regulated in different ways in different countries. This document has been developed to encourage global alignment. Widespread adoption of this document can represent yet another step toward universal recognition. This document can also be used as a basis to fulfil design elements of ISO 9001 and or ISO 13485 as well as related national laws.

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# Ophthalmic optics — Contact lenses and contact lens care products — Requirements and guidance for clinical investigations

## 1 Scope

This document gives requirements and guidelines for the clinical investigation (CI) to establish the safety and performance of contact lenses and contact lens care products.

NOTE 1 This document attempts to align the recognised 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 document.

NOTE 2 For indications beyond correction of refractive error, additional considerations for safety and performance are to be included in the clinical investigation plan (CIP).

## 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 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

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, ISO 14534 and ISO 18369-1 apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

## 4 Clinical investigational requirements

### 4.1 General

The general requirements for a CI and for a CIP given in ISO 14155 shall apply, with additional requirements given below.

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