



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*

**Fourth edition
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Foreword

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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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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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