



**SLOVENSKI STANDARD**  
**SIST EN ISO 11980:2025**

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**Očesna optika - Kontaktne leče in izdelki za vzdrževanje kontaktnih leč - Zahteve in navodilo za klinične raziskave (ISO 11980:2025)**

Ophthalmic optics - Contact lenses and contact lens care products - Requirements and guidance for clinical investigations (ISO 11980:2025)

Augenoptik - Kontaktlinsen und Kontaktlinsenpflegemittel - Leitfaden für die klinische Prüfung (ISO 11980:2025)

Optique ophtalmique - Lentilles de contact et produits d'entretien pour lentilles de contact - Directives pour les investigations cliniques (ISO 11980:2025)

**Ta slovenski standard je istoveten z: EN ISO 11980:2025**

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**ICS:**

11.040.70      Oftalmološka oprema      Ophthalmic equipment

**SIST EN ISO 11980:2025**      **en,fr,de**

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EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

**EN ISO 11980**

July 2025

ICS 11.040.70

Supersedes EN ISO 11980:2012

English Version

## Ophthalmic optics - Contact lenses and contact lens care products - Requirements and guidance for clinical investigations (ISO 11980:2025)

Optique ophtalmique - Lentilles de contact et produits d'entretien pour lentilles de contact - Exigences et recommandations pour les investigations cliniques (ISO 11980:2025)

Augenoptik - Kontaktlinsen und Kontaktlinsenpflegemittel - Leitfaden für die klinische Prüfung (ISO 11980:2025)

This European Standard was approved by CEN on 24 June 2025.

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**CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels**

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## European foreword

This document (EN ISO 11980:2025) 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of an identical text or by endorsement, at the latest by January 2026, and conflicting national standards shall be withdrawn at the latest by January 2026.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

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**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  
2025-06**

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**ISO 11980:2025(en)**

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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](http://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](http://www.iso.org/members.html).

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**ISO 11980:2025(en)****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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