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

*Optique ophtalmique — Lentilles de contact et produits d'entretien des  
lentilles de contact — Exigences fondamentales*

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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.

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

ISO 14534 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This third edition cancels and replaces the second edition (ISO 14534:2002), which has been technically revised.

## Introduction

Currently, contact lenses and contact lens care products are regulated in different ways in different countries. This International Standard was mandated by the Commission of the European Communities to CEN and was originally developed by a joint ISO/CEN working group to ensure a global input; its first edition was ISO 14534:1997. It is possible that other requirements are now needed in certain countries outside the European Union. It is hoped that the adoption of the third edition of this International Standard will be yet another step towards the harmonization of standards and mutual recognition.

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# Ophthalmic optics — Contact lenses and contact lens care products — Fundamental requirements

## 1 Scope

This International Standard specifies safety and performance requirements for contact lenses, contact lens care products, and other accessories for contact lenses.

This International Standard does not specify electrical safety and electromagnetic compatibility considerations that might arise from the use of electrical equipment in conjunction with contact lenses or contact lens care products.

## 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 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 11978, *Ophthalmic optics — Contact lenses and contact lens care products — Information supplied by the manufacturer*

ISO 11980, *Ophthalmic optics — Contact lenses and contact lens care products — Guidance for clinical investigations*

ISO 11986, *Ophthalmic optics — Contact lenses and contact lens care products — Determination of preservative uptake and release*

ISO 11987, *Ophthalmic optics — Contact lenses — Determination of shelf-life*

ISO 13212, *Ophthalmic optics — Contact lens care products — Guidelines for determination of shelf-life*

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

ISO 14729:2001 + Amd.1:2010, *Ophthalmic optics — Contact lens care products — Microbiological requirements and test methods for products and regimens for hygienic management of contact lenses*

ISO 14730, *Ophthalmic optics — Contact lens care products — Antimicrobial preservative efficacy testing and guidance on determining discard date*

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*