INTERNATIONAL STANDARD

ISO 14534

Second edition
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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 3.

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 International Standard 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 optical instruments*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This second edition cancels and replaces the first edition (ISO 14534:1997), 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 published in 1997. Other requirements may now be needed in certain countries outside the European Union. It is hoped that the adoption of the current revision of this International Standard will be yet another step towards the harmonization of standards and mutual recognition.

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 and/or contact lens care products.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 8320-1:—[1], *Contact lenses and contact lens care products — Vocabulary — Part 1: Contact lenses*

ISO 8320-2, *Contact lenses and contact lens care products — Vocabulary — Part 2: Contact lens care products*

ISO 8321-1:—[2], *Ophthalmic optics — Specifications for material, optical and dimensional properties of contact lenses — Part 1: Rigid corneal and scleral contact lenses*

ISO 8321-2, *Ophthalmic optics — Specifications for material, optical and dimensional properties of contact lenses — Part 2: Single-vision hydrogel contact lenses*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing*

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

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

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1) To be published. (Revision in parts of ISO 8320:1986)

2) To be published. (Revision of ISO 8321-1:1991)

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

ISO 15223, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied*

3 Terms and definitions

For the purposes of this International Standard, the definitions given in ISO 8320-1 and ISO 8320-2 apply.

4 Safety and performance

4.1 The intended purpose of a contact lens, contact lens care product, or other accessory for contact lenses shall be documented.

4.2 The performance shall be demonstrated by an evaluation of existing information and history of human use, together with, if necessary, preclinical and clinical testing. In assessing safety and performance, each of the following shall be considered and the decisions shall be documented:

a) functional characteristics, intended purpose and conditions of use;

b) specific requirements for rigid contact lenses (see ISO 8321-1) and hydrogel contact lenses (ISO 8321-2);

c) microbiological properties, including bioburden, sterility, contact lens disinfection and preservation activities (see clause 10);

d) biocompatibility, including extractable substances, cytotoxicity, irritation, sensitization, oral toxicity, sterilization residues and degradation products (see ISO 10993-1);

e) clinical evaluation (see clause 8);

f) physical and chemical compatibility (including any preservative uptake and release) between contact lenses and contact lens care products and other accessories for contact lenses;

g) stability, including shelf-life and discard date (see clause 12);

h) other intended purposes, for example, cleaning efficacy or measuring function.

NOTE 1 For test methods, see the normative references and Bibliography.

4.3 In the absence of a relevant International Standard, the manufacturer shall demonstrate that the product is in accordance with claimed properties, by valid scientific evidence from laboratory and/or clinical studies.

NOTE 2 Manufacturers of contact lenses and contact lens care products are reminded of traceability requirements as mentioned in International Standards on quality management.

5 Risk analysis

5.1 A formal assessment of risk shall be carried out for each design of contact lens, contact lens care product or other accessory for contact lenses. Risk analysis shall be carried out using recognized methodology. The result of the risk analysis shall be documented for all aspects of safety, performance and labelling.

NOTE See for example ISO 14971-1 or EN 1441.

5.2 Each risk analysis shall be reviewed:

a) regularly;

b) whenever any changes are made to the product or its method of manufacture;

c) whenever any changes are made to the packaging or labelling; or

d) whenever relevant new information becomes known to the manufacturer.

6 Design

The design shall be documented, validated and verified to demonstrate that the required performance and safety are achieved when the product is used for its intended purpose.

7 Materials

Materials used for and during the manufacture of contact lenses, contact lens care products and other accessories for contact lenses shall be chosen with regard to the properties necessary to meet the requirements for safety, performance, manufacture, handling and compatibility with other materials with which they may come into contact.

The reasons for choosing the selected materials shall be documented.

8 Clinical evaluation

The safety and/or performance of a product for its intended purpose shall be clinically evaluated by one or more of the following methods:

a) compilation of relevant scientific literature currently available on the intended purpose and performance of the device and the evaluation techniques employed;

b) experience during previous use;

c) clinical investigation.

Any clinical investigation should comply with principles of good clinical practice such as laid down in ISO 14155, ISO 11980 and EN 540.

9 Manufacturing

Manufacturing processes shall be documented and controlled to ensure that the defined product quality is achieved. The product shall fulfil the quality requirements defined in the design documents or product specifications. These defined levels of chemical, physical or biological parameters shall be met, especially those concerning particulate and microbiological contaminants which could adversely affect practitioner or user safety and also the functional safety and reliability of the product.

NOTE For guidance on quality management, see the Bibliography.