INTERNATIONAL STANDARD

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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 — Prescriptions fondamentales

Reference number
ISO 14534:1997(E)

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.

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.

International Standard ISO 14534 was prepared by ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

Annex A of this International Standard is for information only.

For the purposes of this International Standard, the CEN annex regarding fulfilment of European Council Directives has been removed.

International Organization for Standardization
Case postale 56 • CH-1211 Genève 20 • Switzerland
Internet central@iso.ch
X.400 c=ch; a=400net; p=iso; o=isocs; s=central

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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 has been developed by a joint ISO/CEN working group to ensure a global input. Different requirements may currently be needed in specific countries outside the European Union. It is hoped that the adoption of this International Standard will be yet another step toward 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 standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 11978: –[1], *Optics and optical instruments - Contact lenses and contact lens care products - Information to be supplied by the manufacturer for contact lens wearers.*

ISO 10993-1:1997, *Biological evaluation of medical devices - Part 1: Evaluation and testing.*

3 Definitions

For the purposes of this International Standard, the following definitions apply:

3.1 contact lens

Any lens designed to be worn on the front surface of the eye.

NOTE The term contact lens includes plano lenses, afocal lenses and trial lenses.

[1] To be published.

3.2 trial lens

Lens used by the practitioner for the sole purpose of selecting the contact lens parameters.

3.3 contact lens care product

Contact lens accessory intended for use in maintaining the safety and performance of a contact lens after opening and removal of the contact lens from its original shipping package.

NOTE This definition includes all devices recommended for use in the management of contact lens hygiene, for hydrating contact lenses, or for alleviating discomfort of contact lens wear by physical means.

3.4 other accessories for contact lenses

Item used for handling contact lenses or as part of a contact lens regimen excluding contact lens care products, e.g. lens container (lens case) or suction cup used to aid the insertion of a contact lens onto or removal from the surface of the eye.

NOTE This definition does not include the primary packaging (e.g. vials, blister packs or mailers) intended by the manufacturer to be used only for shipment of the contact lenses.

3.5 intended purpose

Use for which a device is intended according to the information supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials.

3.6 performance

Suitability of a device to achieve its intended purpose.

3.7 hygienic management

Procedure by which contact lenses are maintained in a condition for safe re-use.

3.8 tamper-evident package

Package having an indicator or barrier to entry which, if damaged, breached or missing, can reasonably be expected to provide visible evidence to practitioners or users that the package may have been opened.

3.9 discard date

Specified period of time from first use when a product's continued use should cease.

4 Safety and performance

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

The performance shall be demonstrated by an evaluation of existing information and human use history and, 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 and hydrogel contact lenses;

NOTE 1 See for example ISO 8321-1 for rigid contact lenses and ISO 8321-2 for hydrogel contact lenses.

c) microbiological properties, including bioburden, sterility, 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, measuring function).

NOTE 2 For test methods see annex A.

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

NOTE 3 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

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 or prEN 1441.

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.

NOTE 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, especially concerning particulate and microbiological contaminants which could adversely affect practitioner or user safety and also the functional safety and reliability of the product, shall be met.

NOTE For guidance on quality management see A.1.

10 Microbiological requirements

NOTE See A.6 for additional information on International Standards concerning microbiology and test methods.

10.1 Contact lenses

10.1.1 Lenses delivered sterile

Hydrogel lenses shall be supplied sterile. The sterility assurance level (S.A.L.) shall be 10^{-6} or less.

Lenses delivered sterile shall be packaged in such a way that they remain sterile under normal storage, transport and handling conditions until the primary package is opened or damaged.

10.1.2 Lenses delivered non-sterile

Lenses delivered non-sterile shall be manufactured and packaged by a process demonstrated to yield, during its shelf-life, a product with an average bioburden of less than 100 cfu (colony-forming units) per lens.

10.1.3 Trial lenses

Manufacturers of re-usable trial lenses shall provide instructions for their safe maintenance between each use.

10.2 Contact lens care products

Contact lens care products in solid dosage form shall be manufactured and packaged by a process demonstrated to yield, during its shelf-life, a product with an average bioburden of less than 100 cfu per gram, unless otherwise justified, and which is free from the following pathogens: *Staphylococcus aureus*, *Pseudomonas aeruginosa* and *Escherichia coli*.

Liquid contact lens care products shall be supplied sterile. They shall be either supplied terminally sterilized (S.A.L. of 10^{-6} or less) or prepared aseptically according to a validated and documented process (S.A.L. of 10^{-3} or less).

NOTE 1 Products that are either terminally sterilized to a S.A.L. of 10^{-6} or less or aseptically prepared to a S.A.L. of 10^{-3} or less may be labelled sterile using the symbol STERILE as specified in prEN 980.

Contact lens care solutions intended for use on more than one occasion shall be adequately preserved (see clause 12).

Contact lens care products intended for the disinfection of contact lenses shall have an adequate antimicrobial activity.

NOTE 2 ISO 14729 provides requirements and test methods for antimicrobial activity testing.

NOTE 3 Additional requirements may apply for the safe maintenance of trial lenses between each use (see 10.1.3).

10.3 Other accessories for contact lenses

Products labelled sterile shall be sterilized by a validated method. The sterility assurance level and the sterilization method shall be documented. (See 10.2.)

11 Packaging

11.1 The packaging of contact lenses, contact lens care products, and other accessories for contact lenses shall be so designed that it protects the products against foreseeable damage and does not adversely affect their function, safety or performance under normal conditions of storage, transport and handling (see clause 5).

11.2 The packaging for products which are labelled sterile shall maintain their sterility under normal conditions of storage, transport and handling of the product until the primary package is opened or damaged or until the expiry date has been reached.

11.3 The packaging for products which are not labelled sterile shall maintain the cleanliness of the product under normal conditions of transport and storage prior to use or within the stated shelf-life.

11.4 The packaging for all products which are labelled sterile and all contact lens care products in solid dosage form shall be tamper-evident.

The packaging and/or label of the product shall distinguish between identical or similar products which are sold in both sterile and non-sterile conditions.

12 Shelf-life and discard date

Shelf-life of contact lenses and contact lens care products shall be established on the basis of testing that demonstrates that each product in the unopened package remains within specification under defined storage conditions.

NOTE 1 Suitable test methods are described in ISO 11987 for contact lenses and ISO 13212 for contact lens care products.

Liquid contact lens care products packaged in multiple-dose containers shall:

a) be adequately preserved, or
b) be packaged in a container designed and labelled to minimize the risk of injury resulting from in-use contamination. Consideration should be given to the volume and size of the container, the maximum period of use after opening the container, and the addition of any special warnings or precautions in the labelling that would contribute to minimizing the risk of an injury due to contamination.

NOTE 2 ISO 14730 provides requirements and test methods for preservation efficacy testing of contact lens care products.

Liquid contact lens care products that are not adequately preserved shall be packaged in single-use containers or in multiple-dose containers that meet the requirements of 12 b) above.

Discard-dating of contact lenses and contact lens care products shall be based on documented evidence.

13 Labelling and information supplied by the manufacturer

The labelling of contact lenses and contact lens care products shall comply with ISO 11978.

NOTE 1 The use of graphical symbols is recommended (e.g. prEN 980).

For lenses delivered non-sterile, the information to be provided by the manufacturer shall include appropriate instructions such as contraindications, warnings and precautions or any other information necessary for the safe use of contact lenses or contact lens care products.

NOTE 2 The CEN annex regarding fulfilment of the essential requirements of the 93/42/EEC Council Directive is found only in EN ISO 14534:1997.

If the manufacturer states that the contact lens is to be replaced at defined intervals, this time period shall be stated in the information supplied by the manufacturer.

If a manufacturer supplies trial lens sets, the method for the maintenance of the trial lenses shall be stated. If there are restrictions in the time or number of occasions the lenses are to be used, this shall be stated.

For preserved products intended for use on more than one occasion, the labelling and instructions for use shall include a statement advising the user of the maximum period of use after opening before the product is to be discarded, assuming compliance with the manufacturer's instructions.

Disinfection products conforming to the "stand-alone" requirements may be labelled as disinfecting solutions/products.

Products for the disinfection of contact lenses which fail to perform adequately in the "stand-alone test" but meet the acceptance criteria of the "regimen test" shall be labelled as components of a system. Labelling shall clearly specify all steps required to assure proper care (hygienic management) of each lens for wearer safety. No single component within the system shall be labelled as a disinfecting solution or disinfectant.

NOTE 3 The terms "stand-alone" and "regimen test" are described in ISO 14729.

Annex A
(informative)

Bibliography

A.1 Quality management

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A.2 Terminology, labelling, information

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ISO 8320-2: –[2], *Optics and optical instruments - Vocabulary on contact lenses and contact lens care products - Part 2: Contact lens care products*

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A.3 Biological evaluation

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ISO 10993-5:1992, *Biological evaluation of medical devices - Part 5: Tests for cytotoxicity: in vitro methods*

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ISO 10993-12:1996, *Biological evaluation of medical devices - Part 12: Sample preparation and reference materials*

ISO 11986: –[2], *Optics and optical instruments - Contact lenses and contact lens care products - Test methods for preservative uptake and release*

A.4 Physical properties

ISO 8321-1:1991, *Optics and optical instruments - Contact lenses - Part 1: Specification for rigid corneal and scleral contact lenses*

ISO 8321-2: –[2], *Optics and optical instruments - Contact lenses - Part 2: Specification for hydrogel contact lenses*

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ISO/TR 10993-9:1994, *Biological evaluation of medical devices - Part 9: Degradation of materials related to biological testing*

ISO 11986: –[2], *Optics and optical instruments - Contact lenses and contact lens care products - Test methods for preservative uptake and release*

A.6 Microbiological properties

ISO 14729: –[2], *Optics and optical instruments - Contact lenses and contact lens care products - Antimicrobial activity of products for disinfection of contact lenses*

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