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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

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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.

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*

ISO 18369-1, *Ophthalmic optics — Contact lenses — Part 1: Vocabulary, classification system and recommendations for labelling specifications*

ISO 18369-2, *Ophthalmic optics — Contact lenses — Part 2: Tolerances*

ISO 22442 (all parts), *Medical devices utilizing animal tissues and their derivatives*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 18369-1 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 and hydrogel contact lenses as specified in ISO 18369-2;

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

d) biocompatibility, including extractable substances, cytotoxicity, irritation, sensitization, sterilization residues, and degradation products — the relevant requirements of ISO 10993-1 shall apply;

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 as specified in ISO 11986;

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

h) other intended purposes, e.g. cleaning efficacy or measuring function.

NOTE For test methods, see the references in Clause 2 and the 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 or clinical studies.

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

5 Risk assessment

5.1 A formal risk assessment shall be carried out for each design of contact lens, contact lens care product or other accessory for contact lenses. Risk assessment shall be carried out using recognized methodology. The result of the risk assessment shall be documented for all aspects of safety, performance and labelling. ISO 14971 shall apply.

5.2 Each risk assessment 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;

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

7.1 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.

7.2 For materials of animal origin, ISO 22442 (all parts) shall apply.

7.3 The reasons for choosing the selected materials shall be documented.

8 Clinical evaluation

The safety and 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 shall comply with principles of good clinical practice such as laid down in ISO 14155 and ISO 11980.

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 references in the Bibliography.

10 Microbiological requirements

10.1 Contact lenses

10.1.1 Lenses delivered sterile

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

Lenses labelled sterile shall be sterilized by a validated method. The sterility assurance level and the sterilization method shall be documented.

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

NOTE This subclause covers lenses delivered sterile, hence the new term “sterile barrier system” in accordance with ISO 11607-1[54] is used rather than the previous term “primary package”.

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.

NOTE ISO 11737-1[35] provides guidance on test methods including validation for determining bioburden on medical devices.

10.1.3 Trial lenses

Manufacturers of reusable trial lenses shall provide instructions for their safe maintenance between each use.

NOTE ISO/TS 19979[6] provides guidance for hygienic management of multi-patient use contact lenses.

10.2 Contact lens care products

10.2.1 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/g, unless otherwise justified, and which is free from the following pathogens: *Staphylococcus aureus*, *Pseudomonas aeruginosa*, and *Escherichia coli*.

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

NOTE ISO 13408-1[37] provides guidance on aseptic fill.

10.2.3 Contact lens care solutions intended for use on more than one occasion shall be preserved in accordance with ISO 14730 throughout their labelled shelf-lives and up to the discard date.

10.2.4 Contact lens care products intended for contact lens disinfection shall have an antimicrobial activity in accordance with ISO 14729 throughout their labelled shelf-lives.

NOTE EN 1040[47] and EN 1275[48] are not applicable to contact lens disinfecting products.

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 10.2.2).

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 product sterility under normal conditions of storage, transport and handling of the product until the sterile barrier system 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 and 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 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

12.1 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 all specifications under defined storage conditions in accordance with ISO 11987 for contact lenses and in accordance with ISO 13212 for contact lens care products.

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

a) be preserved in accordance with ISO 14730; 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.

12.3 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 12.2 b).

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

NOTE ISO 14730 provides requirements, guidance and test methods for preservative efficacy testing of contact lens care products and for discard dating.

13 Labelling and information supplied by the manufacturer

13.1 General

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

13.2 Additional information requirements for contact lenses

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

13.2.2 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.

13.2.3 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.

13.3 Additional information requirements for contact lens care products

13.3.1 Products that are terminally sterilized to a SAL of 10^{-6} or less shall be labelled sterile using the symbol STERILE as specified in ISO 15223-1 (see also EN 980[7]). Products that are prepared aseptically shall be labelled sterile using the symbol STERILE A as specified in ISO 15223-1 (see also EN 980[7]).

13.3.2 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.

13.3.3 Contact lens-disinfecting products conforming to the stand-alone primary requirements (see ISO 14729:2001 + Amd.1:2010, 5.1) may be labelled as contact lens disinfecting solutions or products. The labelling and instructions for use shall clearly state all steps required to ensure care of each contact lens for wearer safety. The omission of any step, such as rubbing the lens, shall not be emphasized or highlighted in the labelling and instructions for use.

13.3.4 Products for contact lens disinfection that do not meet the requirements of ISO 14729:2001 + Amd.1:2010, 5.1 (primary criteria), but do meet the requirements of ISO 14729:2001 + Amd.1:2010, 5.2 (secondary criteria) and of ISO 14729:2001 + Amd.1:2010, 5.3 (regimen criteria) shall be labelled as components of a system. Labelling shall clearly specify all steps required to assure care of each contact lens for wearer safety. No single component within the system shall be labelled as a contact lens disinfecting solution or contact lens disinfectant.

13.3.5 The manufacturer of the contact lens container shall provide recommendations on selection, use and discard of the contact lens container.

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