INTERNATIONAL STANDARD

ISO 14534

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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*

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.

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 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.

NOTE ISO 11737-1 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 A guidance document for manufacturers developing methods and procedures to be followed by the eye care practitioner for the hygienic management of multipatient use contact lenses is currently under preparation. It is anticipated that this will be published as an ISO Technical Specification under reference ISO/TS 19979.

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 per gram, 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 1 ISO 13408-1 provides guidance for aseptic fill.

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 or EN 980. Products that are prepared aseptically shall be labelled sterile using the symbol STERILE A as specified in ISO 15223 or EN 980/A2.

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

10.2.4 Contact lens care products intended for the contact lens disinfection shall have an antimicrobial activity according to ISO 14729 throughout their labelled shelf-lives.

NOTE 2 EN 1040 and EN 1275 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 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 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 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

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 according to ISO 11987 for contact lenses and according to ISO 13212 for contact lens care products.

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

a) be preserved according to 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 The labelling of contact lenses and contact lens care products shall comply with ISO 11978.

NOTE The use of graphical symbols is recommended (see, for example, ISO 15223, EN 980, EN 980/A2).

13.2 For lenses delivered non-sterile, the information to be provided by the manufacturer shall include the 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.

13.3 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.

13.4 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.

13.5 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.

13.6 Contact lens disinfecting products conforming to the stand alone primary requirements (see 5.1 of ISO 14729:2001) may be labelled as contact lens disinfecting solutions/products. Labelling shall clearly specify all steps required to assure care of each contact lens for wearer safety.

13.7 Products for contact lens disinfection that do not meet the requirements of 5.1 of ISO 14729:2001 (primary criteria) but do meet the requirements of 5.2 of ISO 14729:2001 (secondary criteria) and of 5.3 of ISO 14729:2001 (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.

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