

Ophthalmic optics - Contact lenses and contact lens care products - Fundamental requirements (ISO 14534:2011)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-EN ISO 14534:2011 sisaldab Euroopa standardi EN ISO 14534:2011 ingliskeelset teksti.</p> <p>Standard on kinnitatud Eesti Standardikeskuse 30.04.2011 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.</p> <p>Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 01.04.2011.</p> <p>Standard on kättesaadav Eesti standardiorganisatsioonist.</p>	<p>This Estonian standard EVS-EN ISO 14534:2011 consists of the English text of the European standard EN ISO 14534:2011.</p> <p>This standard is ratified with the order of Estonian Centre for Standardisation dated 30.04.2011 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.</p> <p>Date of Availability of the European standard text 01.04.2011.</p> <p>The standard is available from Estonian standardisation organisation.</p>
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bioassay, marking, materials, microbiology, ophtalmic optics, optical equipment, optical instruments, optics, packages, packing, preservative agents, safety, safety requirements, specification (approval), specifications, storage, use, user information

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English Version

Ophthalmic optics - Contact lenses and contact lens care
products - Fundamental requirements (ISO 14534:2011)

Optique ophtalmique - Lentilles de contact et produits
d'entretien des lentilles de contact - Exigences
fondamentales (ISO 14534:2011)

Augenoptik - Kontaktlinsen und Kontaktlinsenpflegemittel -
Grundlegende Anforderungen (ISO 14534:2011)

This European Standard was approved by CEN on 31 March 2011.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

This document (EN ISO 14534:2011) has been prepared by Technical Committee ISO/TC 172 "Optics and photonics" in collaboration with Technical Committee CEN/TC 170 "Ophthalmic optics" the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by October 2011, and conflicting national standards shall be withdrawn at the latest by October 2011.

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

This document supersedes EN ISO 14534:2009.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 14534:2011 has been approved by CEN as EN ISO 14534:2011 without any modification.

Annex ZA (informative)

Relationship between this International Standard and the Essential Requirements of EC Directive 93/42/EEC

This International Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this International Standard and Directive 93/42/EEC

Clause(s)/sub-clause(s) of this International Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
All this standard.	1	
4	3, 4, 5, 6, 6a), 7.1, 7.2, 7.3, 7.5, 7.6, 8.1, 9.1, 10.1	
5	2, 6, 7.2, 9.2	
6	2, 3, 5, 6	
7	2, 3, 4, 5, 6, 7.1, 7.3, 8.2	
8	2, 3, 4, 6, 6a)	Clause 8 of this International Standard makes normative reference to a horizontal standard on clinical investigation, ISO 14155.
9	3, 5, 8.4, 8.5	
10	3, 7.2, 8.1, 8.3, 8.4, 8.5	
11	3, 5, 7.2, 7.6, 8.1, 8.3, 8.6, 8.7	
12	4, 5	
13	5, 8.7, 9.1, 13.1, 13.2, 13.3, 13.4, 13.5, 13.6	Labelling is partly addressed by normative reference to ISO 11978. Note that ISO 11978:2000: only partly addresses ER 13.6 a) (there is no reference to the authorized representative) and ER 13.3 f); and does not address ER 13.6 q) and that part of ER 13.6 h) that relates to single use.

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

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*

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.