



SLOVENSKI STANDARD

SIST EN ISO 14534:2002

01-november-2002

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SIST EN ISO 14534:2000

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Ophthalmic optics - Contact lenses and contact lens care products - Fundamental requirements (ISO 14534:2002)

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Augenoptik - Kontaktlinsen und Kontaktlinsenpflegemittel - Grundlegende Anforderungen (ISO 14534:2002)

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Optique ophtalmique - Lentilles de contact et produits d'entretien des lentilles de contact - Exigences fondamentales (ISO 14534:2002)

Ta slovenski standard je istoveten z: EN ISO 14534:2002

ICS:

11.040.70 Oftalmološka oprema Ophthalmic equipment

SIST EN ISO 14534:2002

en

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 14534

June 2002

ICS 11.040.70

Supersedes EN ISO 14534:1997

English version

Ophthalmic optics - Contact lenses and contact lens care products - Fundamental requirements (ISO 14534:2002)

Optique ophtalmique - Lentilles de contact et produits d'entretien des lentilles de contact - Exigences fondamentales (ISO 14534:2002)

Augenoptik - Kontaktlinsen und Kontaktlinsenpflegemittel - Grundlegende Anforderungen (ISO 14534:2002)

This European Standard was approved by CEN on 30 May 2002.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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

Management Centre: rue de Stassart, 36 B-1050 Brussels

EN ISO 14534:2002 (E)

CORRECTED 2002-07-31

Foreword

This document (ISO 14534:2002) has been prepared by Technical Committee ISO/TC 172 "Optics and optical instruments" 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 December 2002, and conflicting national standards shall be withdrawn at the latest by December 2002.

This document supersedes EN ISO 14534:1997.

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 ZB, 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, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 14534:2002 has been approved by CEN as a European Standard without any modifications.

NOTE Normative references to International Standards are listed in annex ZA (normative).

Annex ZA (normative)

Normative references to international publications with their relevant European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

NOTE Where an International Publication has been modified by common modifications, indicated by (mod.), the relevant EN/HD applies.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN</u>	<u>Year</u>
ISO 8320-2	2001	Contact lenses and contact lens care products - Vocabulary - Part 2: Contact lens care products	EN ISO 8320-2	2001
ISO 8321-1	1991	Optics and optical instruments - Contact lenses - Part 1: Specification for rigid corneal and scleral contact lenses	EN ISO 8321-1	1996
ISO 8321-2	2000	Optics and optical instruments - Contact lenses - Part 2: Specifications for single-vision hydrogel lenses	EN ISO 8321-2	2000
ISO 10993-1	1997	Biological evaluation of medical devices - Part 1: Evaluation and testing	EN ISO 10993-1	1997
ISO 11978	2000	Ophthalmic optics - Contact lenses and contact lens care products - Information to be supplied by the manufacturer	EN ISO 11978	2000
ISO 11987	1997	Ophthalmic optics - Contact lenses - Methods for the determination of shelf-life	EN ISO 11987	1997
ISO 13212	1999	Ophthalmic optics - Contact lens care products - Guidelines for the determination of shelf-life	EN ISO 13212	1999

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ISO 14729	2001	Ophthalmic optics - Contact lens care products - Microbiological requirements and test methods for products and regimens for hygienic management of contact lenses	EN ISO 14729	2001
ISO 14730	2000	Ophthalmic optics - Contact lens care products - Antimicrobial preservative efficacy testing and guidance on discard dating of multi-dose preserved contact lens care products	EN ISO 14730	2000

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Annex ZB (informative)

Clauses of this European Standard addressing essential requirements or other provisions of EU Directives.

This European standard 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 93/42/EEC.

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

The following clauses of this standard, as detailed in table ZB.1, are likely to support requirements of Directive: 93/42/EEC.

Compliance with the clauses of this standard provides one means of conforming with the specific essential requirements of the Directive concerned and associated EFTA regulations.

Table ZB.1: Correspondence between this European Standard and EU Directives

Clauses/ Sub-clauses of this European Standard	Corresponding fundamental requirements of Directive 93/42/EEC	Comments
All this standard	I.1	
4	I.3; I.4; I.5; I.6; II.7.1; II.7.2; II.7.3; II.7.5; II.7.6; II.9.1; II.10.1	
5	I.2; I.6; II.7.2; II.9.2	
6	I.2; I.3; I.5; I.6	
7	I.2; I.3; I.4; I.5; I.6; II.7.1; II.7.3; II.8.2	
8	I.2; I.4; I.6; II.14	
9	I.3; I.5; II.8.5	
10	I.3; II.7.2; II.8.3; II.8.4; II.8.5	
11	I.3; I.5; II.7.2; II.7.6; II.8.1; II.8.3; II.8.6	
12	I.4; I.5	
13	I.5; II.8.7; II.13.1; II.13.2; II.13.3; II.13.4; II.13.5; II.13.6	

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INTERNATIONAL STANDARD

ISO
14534

Second edition
2002-06-15

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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