SLOVENSKI STANDARD
SIST EN ISO 14534:2000

01-januar-2000

Oļesna optika - Kontaktne leļe in Izdelki za vzdrģevanje kontaktnih leļ - Temeljne zahteve (ISO 14534:1997)

Ophthalmic optics - Contact lenses and contact lens care products - Fundamental requirements (ISO 14534:1997)

Augenoptik - Kontaktlinsen und Kontaktlinsenpflegemittel - Grundlegende Anforderungen (ISO 14534:1997)

Optique ophtalmique - Lentilles de contact et produits d'entretien des lentilles de contact - Prescriptions fondamentales (ISO 14534:1997)

Ta slovenski standard je istoveten z: **EN ISO 14534:1997**

ICS:

11.040.70	Oftalmološka oprema	Ophthalmic equipment

SIST EN ISO 14534:2000 **en**

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 14534

December 1997

ICS 11.040.70

Descriptors: see ISO document

English version

Ophthalmic optics - Contact lenses and contact lens care products - Fundamental requirements (ISO 14534:1997)

Optique ophtalmique - Lentilles de contact et produits d'entretien des lentilles de contact - Prescriptions fondamentales (ISO 14534:1997)

Augenoptik - Kontaktlinsen und Kontaktlinsenpflegemittel - Grundlegende Anforderungen (ISO 14534:1997)

This European Standard was approved by CEN on 30 November 1997.

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 Central Secretariat 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 Central Secretariat 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, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

Foreword

The text of the International Standard ISO 14534:1997 has been prepared by Technical Committee ISO/TC 194 "Biological evaluation of medical devices" 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 June 1998, and conflicting national standards shall be withdrawn at the latest by June 1998.

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(s).

For relationship with EU Directives, see informative Annex ZB, which is an integral part of this standard.

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, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 14534:1997 was approved by CEN as a European Standard without any modification.

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 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.

Publication	Year	Title	EN	Year
ISO 10993-1	1992	Biological evaluation of medical devices - Part 1: Guidance on selection of tests	EN 30993-1	1994

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/CENELEC 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 annexes/paragraphs of Directive 93/42/EEC	Comments
All this standard	Annex IX: § I.1	
§ 4	Annex IX: § 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	Annex IX: § I.2; I.6; II.7.2; II.9.2	
§ 6	Annex IX: § I.2; I.3; I.5; I.6	
§ 7	Annex IX: § I.2; I.3; I.4; I.5; I.6; II.7.1; II.7.3; II.8.2	
§ 8	Annex IX: § I.2; I.4; I.6; II.14	
§ 9	Annex IX: § I.3; I.5; II.8.5	
§ 10	Annex IX: § I.3; II.7.2; II.8.3; II.8.4; II.8.5	
§ 11	Annex IX: § I.3; I.5; II.7.2; II.7.6; II.8.1; II.8.3; II.8.6	
§ 12	Annex IX: § I.4; I.5	
§ 13	Annex IX: § I.5; II.8.7; II.13.1; II.13.2; II.13.3; II.13.4; II.13.5; II.13.6	

INTERNATIONAL STANDARD

ISO 14534

First edition
1997-12-15

Ophthalmic optics — Contact lenses and contact lens care products — Fundamental requirements

Optique ophtalmique — Lentilles de contact et produits d'entretien des lentilles de contact — 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.

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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.