SLOVENSKI STANDARD
SIST EN ISO 14534:2009

01-maj-2009

Nadomeģļ a:
SIST EN ISO 14534:2002

Oļ esna optika - Kontaktne leļ e in izdelki za vzdrģevanje kontaktnih leļ - Temeljne zahteve (ISO 14534:2002)

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

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

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 14534:2009**

ICS:

11.040.70	Oftalmološka oprema	Ophthalmic equipment

SIST EN ISO 14534:2009 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 14534

March 2009

ICS 11.040.70

Supersedes EN ISO 14534:2002

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 7 March 2009.

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 CEN 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 CEN Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, 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 United Kingdom.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

The text of ISO 14534:2002 has been prepared by Technical Committee ISO/TC 172 “Optics and optical instruments” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 14534:2009 by 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 September 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.

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 14534:2002.

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 93/42/EEC, as amended by Directive 2007/47/EC.

For relationship with EU Directive 93/42/EEC as amended by Directive 2007/47/EC, 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, 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 14534:2002 has been approved by CEN as a EN ISO 14534:2009 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC

This European 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 Communities 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 European Standard and Directive 93/42/EEC

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
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; I.6 a)	Clause 8 of this standard makes reference to two horizontal standards on clinical investigation, ISO 14155 and EN 540. Note that EN 540 has been withdrawn since and a revised edition of ISO 14155 has become available and published in two parts. The correct European Standards to use instead of these two are EN ISO 14155-1 and EN ISO 14155-2.
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	ER 13.3 a) is only partly addressed in EN ISO 14534 (with regard to the identification of authorized representative).

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

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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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.