Irish Standard
I.S. EN ISO 14534:2015

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

I.S. EN ISO 14534:2015

Incorporating amendments/corrigenda/National Annexes issued since publication:

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 14534

January 2015

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Supersedes EN ISO 14534:2011

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 7 January 2015.

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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-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

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

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Foreword

The text of ISO 14534:2011 has been prepared by Technical Committee ISO/TC 172 “Optics and photonics” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 14534:2015 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of an identical text or by endorsement, at the latest by July 2015, and conflicting national standards shall be withdrawn at the latest by July 2015.

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 14534:2011.

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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

EN ISO 14534:2015 (E)

Table – Correlations between undated normative references and dated EN and ISO standards

Normative references as listed in Clause 2	Equivalent dated standard	
	EN	ISO
ISO 10993-1	EN ISO 10993-1:2009 + AC:2010	ISO 10993-1:2009 + Cor.1:2010
ISO 11978	EN ISO 11978:2014	ISO 11978:2014
ISO 11980	EN ISO 11980:2012	ISO 11980:2012
ISO 11986	EN ISO 11986:2010	ISO 11986:2010
ISO 11987	EN ISO 11987:2012	ISO 11987:2012
ISO 13212	EN ISO 13212:2014	ISO 13212:2014
ISO 14155	EN ISO 14155:2011 + AC:2011	ISO 14155:2011 + Cor.1:2011
ISO 14729:2001 + Amd.1:2010	EN ISO 14729:2001 + A1:2010	ISO 14729:2001 + Amd.1:2010
ISO 14730	EN ISO 14730:2014	ISO 14730:2014
ISO 14971	EN ISO 14971:2007	ISO 14971:2007
ISO 15223-1	EN ISO 15223-1:2012	ISO 15223-1:2012
ISO 18369-1	EN ISO 18369-1:2006	ISO 18369-1:2006
ISO 18369-2	EN ISO 18369-2:2012	ISO 18369-2:2012
ISO 22442 (all parts)	EN ISO 22442-1:2007, EN ISO 22442-2:2007, EN ISO 22442-3:2007, —	ISO 22442-1:2007, ISO 22442-2:2007, ISO 22442-3:2007, ISO/TR 22442-4:2010,

Endorsement notice

The text of ISO 14534:2011 has been approved by CEN as EN ISO 14534:2015 without any modification.

Annex ZA
(informative)

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

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 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 European Standard and Directive 93/42/EEC on Medical Devices

Clause(s)/sub-clause(s) of this European Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4, 5, 10, 11	7.2	
4, 7	7.3	
4	7.5	
4, 11	7.6	
4, 10, 11	8.1	
7	8.2	
10, 11	8.3	
9, 10	8.4	
9, 10	8.5	
11	8.6	
11.4	8.7	
4.2, 13.1	9.1	Sub-clause13.1 makes normative reference to EN ISO 11978. The relevant requirement for contact lenses is provided in EN ISO 11978:2014, Table 1, item 16 h). The relevant requirements for contact lens care products are provided in EN ISO 11978:2014, Table 2, items 10, 16, 19, 20, and 27.
5	9.2	
4	10.1	

Clause(s)/sub-clause(s) of this European Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
13.1, 13.2, 13.3	13.1	Sub-clause13.1 makes normative reference to EN ISO 11978. The labelling requirements for contact lenses are provided in EN ISO 11978:2014, Table 1. The labelling requirements for contact lens care products are provided in EN ISO 11978:2014, Table 2.
13.1, 13.3.1	13.2	Sub-clause13.1 makes normative reference to EN ISO 11978. The relevant requirement is provided in EN ISO 11978:2014, sub-clause 4.1.
13.1, 13.2, 13.3	13.3	Sub-clause13.1 makes normative reference to EN ISO 11978. The labelling requirements for contact lenses are provided in EN ISO 11978:2014, Table 1. The labelling requirements for contact lens care products are provided in EN ISO 11978:2014, Table 2.
13.1, 13.2, 13.3	13.4	Sub-clause13.1 makes normative reference to EN ISO 11978. The labelling requirements on intended purpose for contact lenses are provided in EN ISO 11978:2014, Table 1. The labelling requirements on intended purpose for contact lens care products are provided in EN ISO 11978:2014, Table 2.
13.1, 13.2, 13.3	13.5	Sub-clause13.1 makes normative reference to EN ISO 11978. The relevant labelling requirements for contact lenses are provided in EN ISO 11978:2014, Table 1, items 2 and 4. The relevant labelling requirements for contact lens care products are provided in EN ISO 11978:2014, Table 2, items 2, 4 and 16.
13.1, 13.2, 13.3	13.6	Sub-clause13.1 makes normative reference to EN ISO 11978. The labelling requirements for contact lenses are provided in EN ISO 11978:2014, Table 1. The labelling requirements for contact lens care products are provided in EN ISO 11978:2014, Table 2.

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

I.S. EN ISO 14534:2015

INTERNATIONAL STANDARD

ISO 14534

Third edition
2011-04-01

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

Reference number
ISO 14534:2011(E)

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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 2.

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 document 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 photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This third edition cancels and replaces the second edition (ISO 14534:2002), 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 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.

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*