SLOVENSKI STANDARD
SIST EN ISO 14889:2014

01-februar-2014

Nadomešča:
SIST EN ISO 14889:2009

Očesna optika - Stekla očal - Temeljne zahteve za nebrušena gotova stekla (ISO 14889:2013)

Ophthalmic optics - Spectacle lenses - Fundamental requirements for uncut finished lenses (ISO 14889:2013)

Augenoptik - Brillengläser - Grundlegende Anforderungen an rohkantige fertige Brillengläser (ISO 14889:2013)

Optique ophtalmique - Verres de lunettes - Exigences fondamentales relatives aux verres finis non détourés (ISO 14889:2013)

Ta slovenski standard je istoveten z: **EN ISO 14889:2013**

ICS:

11.040.70	Oftalmološka oprema	Ophthalmic equipment

SIST EN ISO 14889:2014 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 14889

October 2013

ICS 11.040.70

Supersedes EN ISO 14889:2009

English Version

Ophthalmic optics - Spectacle lenses - Fundamental requirements for uncut finished lenses (ISO 14889:2013)

Optique ophtalmique - Verres de lunettes - Exigences fondamentales relatives aux verres finis non détourés (ISO 14889:2013)

Augenoptik - Brillengläser - Grundlegende Anforderungen an rohkantige fertige Brillengläser (ISO 14889:2013)

This European Standard was approved by CEN on 7 September 2013.

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

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

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Ref. No. EN ISO 14889:2013: E

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Foreword

This document (EN ISO 14889:2013) 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 April 2014, and conflicting national standards shall be withdrawn at the latest by April 2014.

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 14889:2009.

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.

For relationship with EU Directive, 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.

Endorsement notice

The text of ISO 14889:2013 has been approved by CEN as EN ISO 14889:2013 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 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

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs)	Qualifying remarks/Notes
4.3.1, 4.3.2, 4.4	7.1	Only in respect of toxicity and flammability. Testing acc. to subclauses 5.2 and 5.3.
4.4	9.2	Testing acc. to subclause 5.3.
4.3.2	9.3	Testing acc. to subclause 5.2.
6.1	13.1, 13.3	ER 13.3 a) is only partly addressed in subclause 6.1 e) of ISO 14889.

For devices intended by the manufacturer to be for dual use in accordance with Article 1(6) of Directive 93/42 EEC the following Table ZA.2 details the relevant essential requirements of Directive 89/686/EC on Personal Protective Equipment and their corresponding clauses of this European Standard. Table ZA.2 however, does not imply any citation in the OJEU under the PPE directive and thus does not provide presumption of conformity for the PPE directive.

Table ZA.2 — Relevant Essential Requirements from Directive 89/686/EEC on Personal Protective Equipment that are addressed by this European Standard (according to Article 1 (6) of amended Directive 93/42/EEC)

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 89/686/EEC	Qualifying remarks/Notes
—	—	**General** A manufacturer may claim that his lenses in addition of being corrective lenses be protective lenses that provide personal eye protection to the user. As a matter of fact, personal eye protection can relate to various kinds of risk, e.g. sunglare (indirect solar radiation[1)]), radiation other than indirect solar radiation, mechanical impact, etc. Some of those risks call for requirements that go beyond those for lenses the primary function of which is correction of vision. For the purposes of EN ISO 14889, the following applies.
—	—	**Corrective lenses with filter properties against sunglare (indirect solar radiation)** In accordance with the European Commission's "GUIDELINES ON THE APPLICATION OF COUNCIL DIRECTIVE 89/686/EEC OF 21 DECEMBER 1989 ON THE APPROXIMATION OF THE LAWS OF THE MEMBER STATES RELATING TO PERSONAL PROTECTIVE EQUIPMENT" such lenses are categorized as medical devices, thus falling under Directive 93/42/EEC. Compliance with the ERs of Directive 93/42/EEC, and of EN ISO 14889 as detailed by the above Table ZA.1 implies that the relevant requirements are met.
—	—	**Corrective lenses designed to provide protection other than protection against sunglare (indirect solar radiation)** Where corrective lenses are designed to provide protection other than protection against sunglare (indirect solar radiation), the relevant basic health and safety requirements of Directive 89/ 686/EEC apply. These are not addressed in EN ISO 14889. Refer to Directive 89/686/EEC and the relevant European Standard(s) on personal eye protection.

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

1) Indirect solar radiation implies general use for protection against solar radiation but not for direct observation of the sun.

INTERNATIONAL STANDARD

ISO 14889

Third edition
2013-10-01

Ophthalmic optics — Spectacle lenses — Fundamental requirements for uncut finished lenses

Optique ophtalmique — Verres de lunettes — Exigences fondamentales relatives aux verres finis non détourés

Reference number
ISO 14889:2013(E)