SLOVENSKI STANDARD
SIST EN ISO 14889:2014/A1:2018

01-februar-2018

Očesna optika - Stekla očal - Temeljne zahteve za nebrušena gotova stekla - Dopolnilo A1 (ISO 14889:2013/Amd 1:2017)

Ophthalmic optics - Spectacle lenses - Fundamental requirements for uncut finished lenses - Amendment 1 (ISO 14889:2013/Amd 1:2017)

Augenoptik - Brillengläser - Grundlegende Anforderungen an rohkantige fertige Brillengläser - Änderung 1 (ISO 14889:2013/Amd 1:2017)

Optique ophtalmique - Verres de lunettes - Exigences fondamentales relatives aux verres finis non détourés - Amendement 1 (ISO 14889:2013/Amd 1:2017)

Ta slovenski standard je istoveten z: **EN ISO 14889:2013/A1:2017**

ICS:

11.040.70	Oftalmološka oprema	Ophthalmic equipment

SIST EN ISO 14889:2014/A1:2018 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 14889:2013/A1

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English Version

Ophthalmic optics - Spectacle lenses - Fundamental requirements for uncut finished lenses - Amendment 1 (ISO 14889:2013/Amd 1:2017)

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This amendment A1 modifies the European Standard EN ISO 14889:2013; it was approved by CEN on 5 December 2017.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant 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 amendment 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, Serbia, 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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Ref. No. EN ISO 14889:2013/A1:2017 E

Contents

Page

European foreword

This document (EN ISO 14889:2013/A1:2017) 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 Amendment to the European Standard EN ISO 14889:2013 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 2018, and conflicting national standards shall be withdrawn at the latest by June 2018.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

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.

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies.

When an IEC or ISO standard is referred to in the ISO standard text, this shall be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated version of the ISO or IEC standard, as listed below.

NOTE The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

Table — Correlation between normative references and dated EN and ISO standards

Normative references as listed in Clause 2 of the ISO standard	Equivalent dated standard	
	EN	ISO or IEC
ISO 8980-1	EN ISO 8980-1:2017	ISO 8980-1:2017
ISO 8980-2	EN ISO 8980-2:2017	ISO 8980-2:2017
ISO 8980-3	EN ISO 8980-3:2013	ISO 8980-3:2013
ISO 8980-4	EN ISO 8980-4:2006	ISO 8980-4:2006
ISO 13666	EN ISO 13666:2012	ISO 13666:2012

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, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 14889:2013/Amd 1:2017 has been approved by CEN as EN ISO 14889:2013/A1:2017 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC [OJ L 169] aimed to be covered

This European Standard has been prepared under a Commission's standardization request [M/023 concerning the development of European Standards related to medical devices] to provide one voluntary means of conforming to essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [OJ L 169].

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative 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.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC as amended by 2007/47/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with Essential Requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

NOTE 3 This Annex ZA is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 — Correspondence between this European Standard and Annex I of Directive 93/42/EEC [OJ L 169]

Essential Requirements of directive 93/42/EEC	Clause(s)/subclause(s) of this EN	Remarks/Notes
7.1	4.3.1, 4.3.2, 5.2	4.3.2 and 5.2 of the standard only meet the requirements of Annex I, ER 7.1 first dash of the Directive in respect of flammability. 4.3.1 of the standard only meets the requirements of Annex I, ER 7.1 second dash of the Directive in respect of physiological compatibility. Annex I, ER 7.1 third dash of the Directive is not covered.

Essential Requirements of directive 93/42/EEC	Clause(s)/subclause(s) of this EN	Remarks/Notes
9.2	4.4, 5.3	4.4 and 5.3 of the standard only meet the requirements of Annex I, ER 9.2 first dash of the Directive in respect of mechanical strength. Annex I, ER 9.2 second and third dash of the Directive are not covered.
9.3	4.3.2	4.3.2 of the standard only meets the requirements of Annex I, ER 9.3 of the Directive in respect of flammability.
13.1	6	Clause 6 of the standard only meets the requirements of Annex I, ER 13.1 of the Directive in respect of permanent or non-permanent marking and product identification.
13.3 a)	6.1.1	6.1.1 of the standard only meets the requirements of Annex I, ER 13.3 a) of the Directive in respect of manufacturer's name. The requirement for the manufacturer's address or the name and address of the Authorized Representative (if required) are not covered.

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the products falling within the scope of this standard.

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.

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