BS EN ISO 14889:2013

BSI Standards Publication

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

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National foreword

This British Standard is the UK implementation of EN ISO 14889:2013. It supersedes BS EN ISO 14889:2009 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/172/3, Spectacles.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Compliance with a British Standard cannot confer immunity from legal obligations.

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EUROPEAN STANDARD

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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.

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

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 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 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 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 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.

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2. www.iso.org/directives

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received. www.iso.org/patents

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

The committee responsible for this document is ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This third edition cancels and replaces the second edition (ISO 14889:2003), subclauses 4.1, 4.4, 4.5.1 and 4.5.2 of which have been technically revised.

INTERNATIONAL STANDARD **ISO 14889:2013(E)**

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

1 Scope

This International Standard specifies fundamental requirements for uncut finished spectacle lenses. This International Standard is not applicable to protective spectacle lenses.

This International Standard takes precedence over the corresponding requirements of other standards, if differences exist.

2 Normative references

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. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 8980-1, *Ophthalmic optics — Uncut finished spectacle lenses — Part 1: Specifications for single-vision and multifocal lenses*

ISO 8980-2, *Ophthalmic optics — Uncut finished spectacle lenses — Part 2: Specifications for progressive power lenses*

ISO 8980-3:2013, *Ophthalmic optics — Uncut finished spectacle lenses — Part 3: Transmittance specifications and test methods*

ISO 8980-4, *Ophthalmic optics — Uncut finished spectacle lenses — Part 4: Specifications and test methods for anti-reflective coatings*

ISO 13666, *Ophthalmic optics — Spectacle lenses — Vocabulary*

ISO 21987, *Ophthalmic optics — Mounted spectacle lenses*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 13666 and the following apply.

3.1
manufacturer (of an uncut finished spectacle lens)
natural or legal person who places the uncut finished lens on the market

4 Fundamental requirements for spectacle lenses

4.1 Performance

In addition to the requirements specified in this International Standard, uncut finished lenses shall comply with the relevant parts of ISO 8980, and mounted lenses shall comply with ISO 21987.

4.2 Design

Spectacle lenses shall be designed so that the overall risk associated with their use according to the conditions intended by the manufacturer, relative to the risk when the spectacle lenses are not used, is