EESTI STANDARD

17:5000

Oftalmiline optika. Prilliläätsed. Põhinõuded mõõtulõikamata viimistletud prilliläätsedele

Ophthalmic optics - Spectacle lenses - Fundamental ci finisi Portugina Companya Portugina Companya requirements for uncut finished lenses

EESTI STANDARDIKESKUS

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 14889:2009 sisaldab Euroopa standardi EN ISO 14889:2009 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 14889:2009 consists of the English text of the European standard EN ISO 14889:2009.
Standard on kinnitatud Eesti Standardikeskuse 31.07.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 31.07.2009 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 25.03.2009.	Date of Availability of the European standard text 25.03.2009.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

ICS 11.040.70

Võtmesõnad: aid to vision, binoculars, definition, definitions, materials, ophtalmic optics, optical glass, optics, properties, rimless, specification (approval), specifications, spectacle lenses, spectacles (eyeglasses), strength of materials, testing, uncut finished

* Orelie

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EUROPEAN STANDARD NORME EUROPÉENNE **EUROPÄISCHE NORM**

EN ISO 14889

March 2009

ICS 11.040.70

Supersedes EN ISO 14889:2003

English Version

Ophthalmic optics - Spectacle lenses - Fundamental requirements for uncut finished lenses (ISO 14889:2003)

Optique ophtalmique - Verres de lunettes - Exigences fondamentales relatives aux verres finis non détourés (ISO 14889:2003)

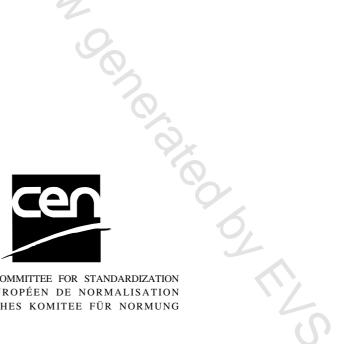
Augenoptik - Brillengläser - Grundlegende Anforderungen an rohkantige fertige Brillengläser (ISO 14889:2003)

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.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN ISO 14889:2009: E

Foreword

The text of ISO 14889:2003 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 14889:2009 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 14889:2003.

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 14889:2003 has been approved by CEN as a EN ISO 14889:2009 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.

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4, 5	I.1, I.3	
4.2, 4.3.1	I.2, I.6, I.6 a)	New ER I.6 a) is implicitly covered by subclause 4.3.1 of EN ISO 14889. Manufacturers will have to take new ER I.6.a) into consideration when preparing their declaration of conformity.
4.3.1, 4.3.2, 4.4, 5.2, 5.3	II.7.1	
4.4, 5.3	II.9.2	
4.3.2, 5.2	II.9.3	2
6	II.13.1, II.13.3	The relevant Essential Requirement of II.13.3 a) is only partly addressed in subclause 6.1 e) of EN ISO 14889.

Table ZA.1 – Correspondence between this European Standard and Directive 93/42/EEC

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 addi- tion of being corrective lenses be protective lenses that provide personal eye protection to the user.
	0.	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.
	5	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.
	- 0.	Corrective lenses with filter properties against sunglare (indirect solar radiation)
	C L C L	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.

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 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 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, 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

3 Terms and definitions

For the purposes of this International Standard, the terms and definitions given in ISO 13666 as well as the following.

3.1

manufacturer (of an uncut finished spectacle lens)

natural or legal person who places the uncut finished lens on the market