

**Oftalmiline optika. Prilliläätsed. Põhinõuded
mõõtulõikamata viimistletud prilliläätsedele**

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

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 14889:2013 sisaldab Euroopa standardi EN ISO 14889:2013 inglisekeelset teksti.	This Estonian standard EVS-EN ISO 14889:2013 consists of the English text of the European standard EN ISO 14889:2013.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 02.10.2013.	Date of Availability of the European standard is 02.10.2013.
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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 détournés (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.

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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of an identical text or by endorsement, at the latest by April 2014, and conflicting national standards shall be withdrawn at the latest by April 2014.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
—	—	<p>General</p> <p>A manufacturer may claim that his lenses in addition of being corrective lenses be protective lenses that provide personal eye protection to the user.</p> <p>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.</p> <p>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.</p>
—	—	<p>Corrective lenses with filter properties against sunglare (indirect solar radiation)</p> <p>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.</p>
—	—	<p>Corrective lenses designed to provide protection other than protection against sunglare (indirect solar radiation)</p> <p>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.</p>

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

Contents

Page

Foreword	iv
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Fundamental requirements for spectacle lenses	1
4.1 Performance.....	1
4.2 Design.....	1
4.3 Materials.....	2
4.4 Mechanical strength.....	2
4.5 Transmittance.....	2
5 Test methods	3
5.1 General.....	3
5.2 Inflammability.....	3
5.3 Test for mechanical strength.....	3
6 Identification	5
6.1 Identification of the spectacle lens to be stated on the package of each individual spectacle lens or in an accompanying document.....	5
6.2 Information to be made available.....	6

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