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STN	**Očná optika Okuliarové šošovky Základné požiadavky na hotové šošovky s neobrúsenými okrajmi (ISO 14889: 2025)**	**STN EN ISO 14889 19 5023**

Ophthalmic optics - Spectacle lenses - Fundamental requirements for uncut finished lenses (ISO 14889:2025)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 08/25

Obsahuje: EN ISO 14889:2025, ISO 14889:2025

Oznámením tejto normy sa ruší
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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 14889

June 2025

ICS 11.040.70

Supersedes EN ISO 14889:2013, EN ISO 14889:2013/A1:2017

English Version

Ophthalmic optics - Spectacle lenses - Fundamental requirements for uncut finished lenses (ISO 14889:2025)

Optique ophtalmique - Verres de lunettes - Exigences fondamentales relatives aux verres finis non détourés (ISO 14889:2025)

Augenoptik - Brillengläser - Grundlegende Anforderungen an rohkantige fertige Brillengläser (ISO 14889:2025)

This European Standard was approved by CEN on 28 April 2025.

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European foreword

This document (EN ISO 14889:2025) 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of an identical text or by endorsement, at the latest by December 2025, and conflicting national standards shall be withdrawn at the latest by December 2025.

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 supersedes EN ISO 14889:2013 and EN ISO 14889:2013/A1:2017.

This document has been prepared under a standardization request addressed to CEN by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

For the relationship with EU Legislation, see informative Annex ZA, which is an integral part of this document.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

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Endorsement notice

The text of ISO 14889:2025 has been approved by CEN as EN ISO 14889:2025 without any modification.

Annex ZA
(informative)

Relationship between this European standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered

This European standard has been prepared under M/575 to provide one voluntary means of conforming to the General Safety and Performance Requirements of Regulation (EU) 2017/745 of 5 April 2017 concerning medical devices [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up.

Once this standard is cited in the Official Journal of the European Union under that Regulation, 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 General Safety and Performance Requirements of that Regulation, and associated EFTA Regulations.

Where a definition in this standard differs from a definition of the same term set out in Regulation (EU) 2017/745, the differences shall be indicated in this Annex Z. For the purpose of using this standard in support of the requirements set out in Regulation (EU) 2017/745, the definitions set out in this Regulation prevail.

Where the European standard is an adoption of an International Standard, the scope of this standard can differ from the scope of the European Regulation that it supports. As the scope of the applicable regulatory requirements differ from nation to nation and region to region, the standard can only support European regulatory requirements to the extent of the scope of the European regulation for medical devices (EU) 2017/745).

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 Regulation (EU) 2017/745. This means that risks have to be ‘reduced as far as possible’, ‘reduced to the lowest possible level’, ‘reduced as far as possible and appropriate’, ‘removed or reduced as far as possible’, ‘eliminated or reduced as far as possible’, ’removed or minimized as far as possible’, or ‘minimized’, according to the wording of the corresponding General Safety and Performance Requirement.

NOTE 2 The manufacturer’s policy for determining **acceptable risk** must be in compliance with General Safety and Performance Requirements 1, 2, 3, 4, 5, 8, 9, 10, 11, 14, 16, 17, 18, 19, 20, 21 and 22 of the Regulation.

NOTE 3 When a General Safety and Performance 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 Regulation (EU) 2017/745 [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s)/Subclause(s) of this EN	Remarks/Notes
10.1 (a)	4.3.2, 5.2	4.3.2 and 5.2 of the standard only meet the requirements of Annex I, GSPR 10.1 (a) of the Regulation in respect of flammability.
10.1 (b)	4.3.1	4.3.1 of the standard only meets the requirements of Annex I, GSPR 10.1 (b) of the Regulation in respect of physiological compatibility.
10.1 (f)	4.4, 5.3	4.4 and 5.3 of the standard only meet the requirements of Annex I, GSPR 10.1 (f) of the Regulation in respect of mechanical strength.
14.2 (a)	4.4, 5.3	4.4 and 5.3 of the standard only meet the requirements of Annex I, GSPR 14.2 (a) of the Regulation in respect of mechanical strength.
14.3	4.3.2, 5.2	4.3.2 and 5.2 of the standard only meet the requirements of Annex I, GSPR 14.3 of the Regulation in respect of flammability.
23.1 (a)	6	Clause 6 of the standard only meets the requirements of Annex I, GSPR 23.1 (a) of the Regulation in respect of permanent or non-permanent marking and product identification.
23.1 (b)	6	Clause 6 of the standard only meets the requirements of Annex I, GSPR 23.1 (b) of the Regulation in respect of permanent or non-permanent marking and product identification.
23.2 (c)	6.1.1	6.1.1 of the standard only meets the requirements of Annex I,

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General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s)/Subclause(s) of this EN	Remarks/Notes
		GSPR 23.2 (c) of the Regulation in respect of manufacturer's name.

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 product(s) falling within the scope of this standard.

Table ZA.2 — Normative references from Clause 2 of this document and their corresponding European publications

Reference in Clause 2	International Standard edition	Title	Corresponding European Standard Edition
ISO 8980-1	ISO 8980-1:2017	Ophthalmic optics — Uncut finished spectacle lenses — Part 1: Specifications for single-vision and multifocal lenses	EN ISO 8980-1:2017
ISO 8980-2	ISO 8980-2:2017	Ophthalmic optics — Uncut finished spectacle lenses — Part 2: Specifications for power-variation lenses	EN ISO 8980-2:2017
ISO 8980-3	ISO 8980-3:2022	Ophthalmic optics — Uncut finished spectacle lenses — Part 3: Transmittance specifications and test methods	EN ISO 8980-3:2022
ISO 8980-4	ISO 8980-4:2006	Ophthalmic optics — Uncut finished spectacle lenses — Part 4: Specifications and test methods for anti-reflective coatings	EN ISO 8980-4:2006
ISO 13666	ISO 13666:2019	Ophthalmic optics – Spectacle lenses - Vocabulary	EN ISO 13666:2019

Table ZA.3 — Prevailing terms of regulation (EU) 2017/745 for the use of this European standard under that regulation

Term used in this EN	Regulation (EU) 2017/745	Clause(s)/Subclause(s) of this EN	Remarks/Notes
Manufacturer	Article 2 (30)	3.1	This definition is consistent with EU regulation 2017/745. Nevertheless, this definition differs from the definition set in Article 2 (30) of MDR 2017/745. This definition was condensed to match ophthalmic industry practice.

For devices intended by the manufacturer to be for dual use in accordance with Chapter I, Article I, item 3 of Regulation (EU) 2017/745 the following Table ZA.4 details the relevant essential requirements of Regulation (EU) 2016/425 on Personal Protective Equipment and their corresponding clauses of this European Standard. Table ZA.4 however, does not imply any citation in the OJEU under the PPE Regulation and thus does not provide presumption of conformity for the PPE Regulation.

Table ZA.4 — Relevant Essential Health and Safety Requirements from Regulation (EU) 2016/425 Personal Protective Equipment that are addressed by this European Standard (Chapter I, Article I, item 3) of Regulation (EU) 2017/745

Essential Health and Safety from Regulation (EU) 2016/425	Clause(s)/Subclause(s) of this EN	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[a]), 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.

Essential Health and Safety from Regulation (EU) 2016/425	Clause(s)/Subclause(s) of this EN	Remarks/Notes
—	—	**Corrective lenses with filter properties against sunglare (indirect solar radiation[a])** In accordance with the European Commission's "Guide to Application of Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on Personal Protective Equipment and repealing Council Directive 89/686/EEC" such lenses are categorized as medical devices, thus falling under Regulation (EU) 2017/745. Compliance with the GSPRs of Regulation (EU) 2017/745, 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[a])** Where corrective lenses are designed to provide protection other than protection against sunglare (indirect solar radiation), the relevant basic health and safety requirements of Regulation (EU) 2016/425 apply. These are not addressed in EN ISO 14889. Refer to Regulation (EU) 2016/425 and the relevant European Standard(s) on personal eye protection.

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

International Standard

ISO 14889

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

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

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Foreword

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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 document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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This document was prepared by Technical Committee ISO/TC 172, *Optics and photonics,* Subcommittee SC 7, *Ophthalmic optics and instruments*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 170, *Ophthalmic optics,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This fourth edition cancels and replaces the third edition (ISO 14889:2013), which has been technically revised. It also incorporates the Amendment ISO 14889:2013/Amd.1:2017.

The main changes are as follows:

— dated reference and titles have been brought up-to-date;

— editorial update of the whole document;

— Figure 1 has been updated;

— Terminology has been changed from "inflammability" to "resistance to ignition".

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International Standard **ISO 14889:2025(en)**

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

1 Scope

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

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

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 power-variation lenses*

ISO 8980-3:2022, *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*