OFTALMILINE OPTIKA. TUGIMEETOD NIKLI ERALDUMISE MÄÄRAMISEKS PRILLIRAAMIDELT JA PÄIKESEPRILLIDELT

Ophthalmic optics - Reference method for the testing of spectacle frames and sunglasses for nickel release

EESTI STANDARDIMIS- JA AKREDITEERIMISKESKUS
ESTONIAN CENTRE FOR STANDARDISATION AND ACCREDITATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 16128:2025 sisaldab Euroopa standardi EN 16128:2025 ingliskeelset teksti.	This Estonian standard EVS-EN 16128:2025 consists of the English text of the European standard EN 16128:2025.
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 and Accreditation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 22.10.2025.	Date of Availability of the European standard is 22.10.2025.
Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.	The standard is available from the Estonian Centre for Standardisation and Accreditation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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EUROPEAN STANDARD

NORME EUROPÉENNE

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Supersedes EN 16128:2015

English Version

Ophthalmic optics - Reference method for the testing of spectacle frames and sunglasses for nickel release

Optique ophtalmique - Méthode d'essai de référence relative à la libération du nickel par les montures de lunettes et les lunettes de soleil

Augenoptik - Referenzverfahren für die Bestimmung der Nickellässigkeit von Brillenfassungen und Sonnenbrillen

This European Standard was approved by CEN on 8 September 2025.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and United Kingdom.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (EN 16128:2025) has been prepared 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 April 2026, and conflicting national standards shall be withdrawn at the latest by April 2026.

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 16128:2015.

EN 16128:2025 includes the following significant technical changes with respect to EN 16128:2015:

— Clause 4 has been modified to give a better scientific explanation of why a sample that fails the coating test might pass the migration test. It also states that the coating test is not a screening test since a pass allows a product to be labelled as compliant with REACH. A revised flowchart (Figure 1) reinforces this. The warning about taking particular attention over handling samples to avoid additional damage has been reinforced;

— Clause 5 emphasizes that if a sample fails the coating test, then all parts of the sample have to be tested with the migration test, not just the part that failed;

— Clause 6 notes that the lenses are needed in the frame to protect the groove during the simulated wear and corrosion procedure. Although it applies to EN 12472, new Annex A provides illustrations of mounts that can be used to hold sample frames in the tumbling barrel;

— Clauses 7 and 8 refer to the new normative Annex B for advice on where to test sides. Both recommend that the test or dummy lenses are kept in the frame for the tests;

— More detailed advice on where to mask frames before the coating test has been provided in Clause 7. The new quality control samples are mentioned in the new Annex D. Photographic records of the samples are now required in the test report;

— Clause 8 now permits the use of a hermetically-sealed cabinet and laboratory oven to be used for the migration process as well as a climate chamber. The concentration of the control solution has been doubled and the volume halved, to avoid overloading the piece of test paper, which is suggested to be 10 % larger. Again, photographic records of the samples are now required in the test report;

— Annexes B, C and D have photographic figures to illustrate sample preparation since they give better clarity than drawings. The examples pictured provide no manufacturer markings and are in no way intended to promote a particular manufacturer or style;

— Annex E has been revised to recommend folding of the sealing film over the test or dummy lenses rather than wrapping around the rim.

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.

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

According to the CEN-CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Introduction

This document has been prepared under Mandate M/448 issued by the European Commission in the framework of Regulation (EC) No 1907/2006, REACH, in particular Commission Regulation (EC) No 552/2009 of 22 June 2009 amending regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and restriction of Chemicals (REACH) as regards Annex XVII RESTRICTIONS ON THE MANUFACTURE, PLACING ON THE MARKET AND USE OF CERTAIN DANGEROUS SUBSTANCES, PREPARATIONS AND ARTICLES.

The aim of the mandate was the development of a new method of analysis to detect the release of nickel from spectacle frames and sunglasses.

The availability of the new reference method for the determination of the release of nickel will provide the reliable framework to enforce the limit value for nickel release set forth by the European Regulation of 0,5 $\mu g \cdot cm^{-2} \cdot week^{-1}$ (expressed as 0,5 $\mu g/cm^2$/week in the Regulation). It will ensure a uniform application and control of the European legislation in all member states.

Harmonizing the test method for nickel release in all member states is vital with a view to protecting effectively the health of the end consumer, that is, the spectacle wearer. Nickel allergy is still the most frequent contact allergy in Europe and a significant health issue.

1 Scope

This document specifies the reference method for the testing of spectacle frames, ready-to-wear near-vision spectacles, sunglasses and spectacle frames used for eye and face protection for nickel release.

The reference method supports the demonstration of conformity with the limit value for nickel release of 0,5 $\mu g \cdot cm^{-2} \cdot week^{-1}$ set forth by European Regulation.

The reference method involves the procedural steps shown in Figure 1 and described in Clause 4.

This document applies to those parts of metal spectacle frames and those metal parts of combination spectacle frames that are intended to come into direct and prolonged contact with the skin of the wearer. This document also applies to those relevant metal parts of ready-to-wear near-vision spectacles, sunglasses and spectacle frames used for eye and face protection.

NOTE The reference method for articles apart from spectacle frames, ready-to-wear near-vision spectacles, sunglasses and spectacle frames used for eye and face protection is specified in EN 1811.

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.

EN 12472, *Method for the simulation of accelerated wear and corrosion for the detection of nickel release from coated items*

EN ISO 3696, *Water for analytical laboratory use — Specification and test methods (ISO 3696)*

EN ISO 7998:2005, *Ophthalmic optics — Spectacle frames — Lists of equivalent terms and vocabulary (ISO 7998:2005)*

EN ISO 12870:2025, *Ophthalmic optics — Spectacle frames — Requirements and test methods (ISO 12870:2024)*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN ISO 12870:2025, EN ISO 7998:2005 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp/

— IEC Electropedia: available at https://www.electropedia.org/

3.1
model
spectacle frame, ready-to-wear spectacles, sunglass or other item used for eye and face protection produced to the same design, using the same materials and surface treatment, and to which the scope of this document applies

3.2
test sample
spectacle frame, ready-to-wear spectacles, sunglass or other item used for eye and face protection submitted for testing