

STN	Očná optika Referenčná skúšobná metóda na stanovenie uvolňovania niklu z okuliarových rámov a slnečných okuliarov	STN EN 16128 19 0530
------------	--	--

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

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. 01/26

Obsahuje: EN 16128:2025

Oznámením tejto normy sa ruší
STN EN 16128 (19 0530) z apríla 2016

141659



EUROPEAN STANDARD

EN 16128

NORME EUROPÉENNE

EUROPÄISCHE NORM

October 2025

ICS 11.040.70

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

EN 16128:2025 (E)**Contents**

Page

European foreword	4
Introduction	6
1 Scope	7
2 Normative references	7
3 Terms and definitions	7
4 Principle	8
5 Selection of test samples	9
6 Simulation of wear and corrosion	10
6.1 Preparation of test samples	10
6.2 Procedure	11
7 Coating test	11
7.1 General	11
7.2 Apparatus and consumables	12
7.3 Preparation of test samples for the coating test	13
7.3.1 Parts to be tested	13
7.3.2 Dismantling and/or cutting and/or masking	13
7.3.3 Determination of test area	15
7.3.4 Preparation of electrical contact area	15
7.4 Preparation of saline solution	15
7.5 Procedure	15
7.5.1 Preparation of the electro-chemical cell	15
7.5.2 Insertion and connection of the test part in the electro-chemical cell	16
7.5.3 Determination of open circuit potential and measurement of electrochemical impedance of test samples	16
7.5.4 Calibration and verification of the equipment	17
7.6 Calculation of results	17
7.6.1 General	17
7.6.2 Criteria for pass or fail of the test sample	17
7.7 Test report	17
8 Release of nickel and its quantitative analytical detection (migration test)	19
8.1 General	19
8.2 Apparatus and consumables	19
8.3 Preparation of test samples for the migration test	21
8.3.1 Parts to be tested – general	21
8.3.2 Small parts to be tested	21
8.3.3 Guidance on selection of test areas on the parts to be tested	21
8.3.4 Dismantling and degreasing	22
8.4 Procedure	22
8.4.1 Preparation of test paper including determination of its area	22
8.4.2 Preparation of artificial sweat solution	23
8.4.3 Applying artificial sweat solution to the test paper and attaching it to the test sample	24
8.4.4 Blank sample	25
8.4.5 Incubation of test sample with test paper attached (release of nickel into paper)	25

8.4.6	Retrieval of the test paper from the test samples.....	25
8.4.7	Analysis of the test papers for nickel	26
8.5	Calculation of migration test results	27
8.6	Interpretation of migration test results	28
8.6.1	General	28
8.6.2	Assessment of compliance.....	28
8.6.3	Retesting after a fail result with the migration test.....	29
8.7	Test report	29
Annex A (informative) Examples of mounting test samples in the EN 12472 tumbling barrel.....		
		31
Annex B (normative) Measuring device and identifying where to test sides		
		32
Annex C (informative) Cutting and masking of test samples (Coating test).....		
		38
Annex D (informative) Quality control material for the coating test.....		
		42
Annex E (normative) Selection of test areas and application of the test paper (Migration test) .		
		43
Bibliography		
		49

EN 16128:2025 (E)**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.

EN 16128:2025 (E)**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 $0,5 \mu\text{g}\cdot\text{cm}^{-2}\cdot\text{week}^{-1}$ (expressed as $0,5 \mu\text{g}/\text{cm}^2/\text{week}$ 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 $0,5 \mu\text{g}\cdot\text{cm}^{-2}\cdot\text{week}^{-1}$ 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)*

koniec náhľadu – text ďalej pokračuje v platenej verzii STN