



SLOVENSKI STANDARD
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Očesna optika - Referenčna preskusna metoda za ugotavljanje sproščanja niklja iz okvirjev očal in sončnih očal

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

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

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

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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 draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 170.

If this draft becomes a European Standard, 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.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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

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prEN 16128:2024 (E)

European foreword

This document (prEN 16128:2024) has been prepared by Technical Committee CEN/TC 170 “Ophthalmic optics”, the secretariat of which is held by DIN.

This document is currently submitted to the CEN Enquiry.

This document will supersede EN 16128:2015.

EN 16128:2024 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;
- 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 informative 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.

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.

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prEN 16128:2024 (E)**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 12870:2018, *Ophthalmic optics—Spectacle frames — Requirements and test methods*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN ISO 12870:2018, 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

3.3

test part

part of a test sample that is intended to come into direct and prolonged contact with the skin and is due to be tested

Note 1 to entry: These parts are defined in 7.3.1 (for the coating test) and in 8.3.1 (for the migration test).

3.4

test paper

piece of laboratory cellulose paper used for testing, at any stage of the procedure after being cut to size for testing

3.5

extraction solution

solution obtained after extraction of nickel ions from the test paper

3.6

appropriate tool

tool enabling the procedure to be performed without causing contamination by nickel or other metal ions, either from the material of the tool or deposits on it

Note 1 to entry: Such tools could be made from plastics, titanium, or stainless steels.

3.7

appropriate equipment

equipment enabling the procedure to be performed without causing contamination by nickel or other metal ions, either from the material of the equipment or deposits on it

3.8

electrically non-conductive coating

covering, on a substrate, that does not conduct an electrical current and has protective and/or decorative properties

Note 1 to entry: These non-conductive coatings are generally based on organic polymers.

4 Principle

Following the simulation of wear and corrosion according to the method specified in EN 12472 (see Clause 6), the reference method comprises the following two tests, either of which can be used to claim compliance:

- 1) Coating test, applicable only to test parts with an electrically non-conductive coating, based on Electrochemical Impedance Spectroscopy (EIS) and specified in Clause 7. Its aim is to demonstrate the ability of the electrically non-conductive coating to limit any release of metal ions from the test sample substrate as indicated by the impedance threshold, thereby ensuring that the nickel release from the test sample does not exceed the regulatory limit. The coating test is a test of the ability of the electrically non-conductive coating to prevent the release of metal ions from the substrate of the test sample.
- 2) Migration test for nickel ion release, specified in Clause 8 is a quantitative test to determine whether or not the nickel release from the model exceeds the regulatory limit. The migration test comprises two steps: Release of nickel by artificial sweat solution into a test paper and the subsequent quantitative analytical detection of the nickel released into the paper.

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If a part of the sample fails the coating test, that part of the same test sample can be retested with the coating test (7.5.3).

If a sample fails the coating test and the laboratory's client wishes to proceed further with testing, either new test samples or, subject to the requirements of the laboratory's client, the original test samples shall be subjected to the migration test in order to verify whether nickel ions are subsequently released and to obtain a quantitative value. For example, a thin coating on a substrate (such as a titanium alloy) that does not release nickel might fail the coating test but pass the migration test.

Metal frames that are uncoated (i.e., neither organic coated nor metal plated) and made of homogeneous alloys or metals do not require the simulation of wear and corrosion specified in Clause 6 and shall be tested directly in accordance with Clause 8. Unless the manufacturer certifies that a component is homogeneous and uncoated, the component shall be assumed to be coated.

Figure 1 illustrates the relationship between the two tests; the coating test is not a screening test since a pass allows a product to be labelled as compliant with REACH. In addition to frames without an electrically non-conductive coating, the coating test cannot be applied to the following for technical reasons: very small components (e.g., screw heads, trims on sides, side tips or fronts – see 8.3.2) and frames fitted with magnets (e.g., to hold clip-ons).

Requirements for sampling and guidance as to which parts of the test samples shall be subject to testing (the test parts) are given in Clause 5 and in 7.3.1 (for the coating test) and 8.3.1 (for the migration test).

WARNING: Test laboratories shall pay particular attention to the careful handling of test samples and test parts during all stages of this standard, using appropriate tools when needed. Poor handling, particularly when dismantling or cutting a test sample, may cause additional damage that causes a failure.

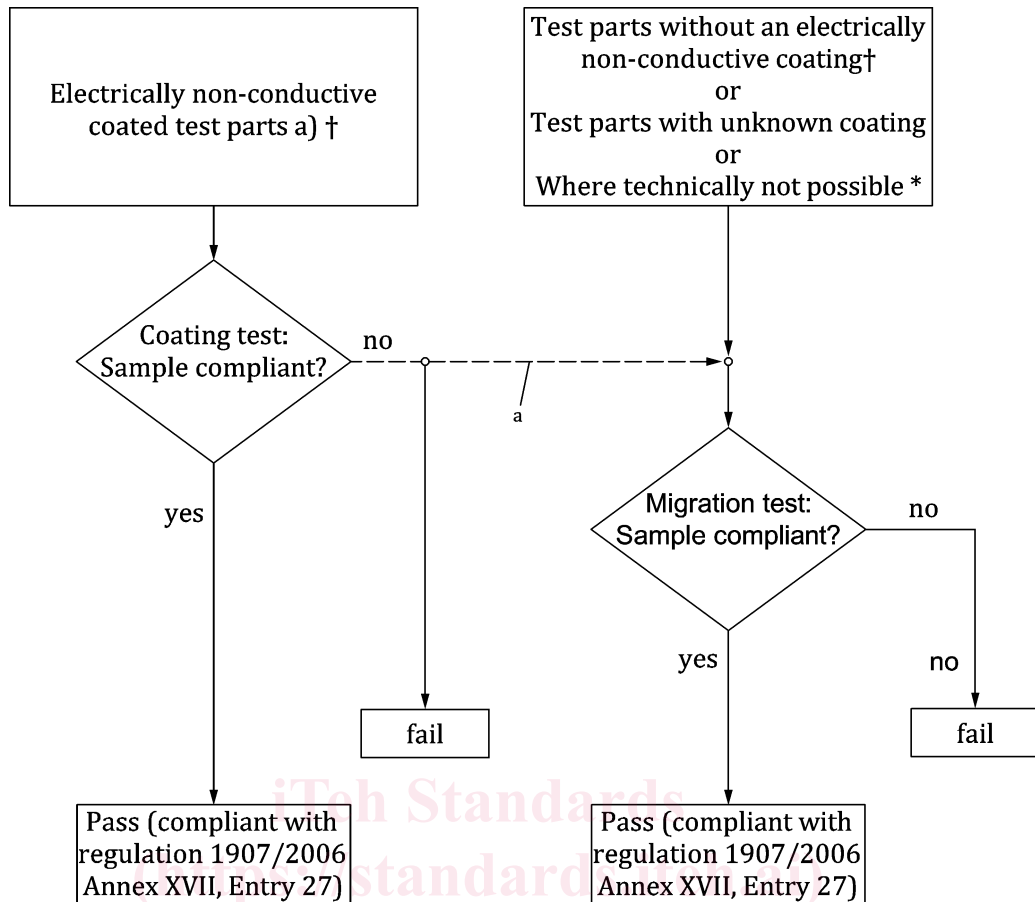
5 Selection of test samples

The laboratory's client should select, at random, two representative specimens of each model to be tested for either the coating or the migration test.

The selected specimens shall be identified.

Test samples used for the coating test can be tested in a subsequent migration test, but not vice versa.

If a test sample is likely to be subjected to the migration test after the coating test, it shall be washed thoroughly in deionized water immediately after the coating test and allowed to dry to avoid corrosion from sodium chloride.

**Key**

- a The coating test is a test of the ability of the electrically non-conductive coating to prevent the release of metal ions from the substrate of the test sample. If a sample fails the coating test and the laboratory's client wishes to proceed further with testing, the samples or new samples shall be subjected to the migration test in order to verify whether nickel ions are subsequently released and to obtain a quantitative value. See clause 4.
- † On the request of the laboratory's client, test samples can be tested directly using the migration test, but the extra information about the coating that is obtained by using the coating test will be unknown.
- * The coating test cannot be used to test very small components, e.g., screw heads, trims on sides, side tips or fronts. It also cannot be used with frames fitted with magnets, e.g., to hold clip-ons.
If a sample fails, conductivity of parts not in contact with the skin (for example, trims) must be verified using an electric circuit tester and shall be masked if uncoated.

Figure 1 — Diagrammatic overview of the reference test method

6 Simulation of wear and corrosion

6.1 Preparation of test samples

Samples should be fitted with test lenses, which should preferably be supplied or specified by the laboratory's client, i.e., the manufacturer or importer or authorized representative.

NOTE 1 The lenses protect the edges of the groove, so that testing without lenses can cause a false failure.

If the client agrees, then the dummy or demonstration lenses can be used.

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NOTE 2 The greater thickness of organic prescription spectacle lenses can give superior protection to the edge of the groove than a dummy or demonstration lens.

If test lenses are not supplied or specified, then the testing laboratory shall contact the frame manufacturer for a recommendation for the test lens's material, power, thickness, curvature and, as appropriate, bevel angle or edge profile.

In the absence of supply or specifications from the manufacturer or an inability to contact the manufacturer, test lenses are recommended to be of suitable material for the type of frame and have a vertex power of $(0,00 \pm 0,25)$ D, a centre thickness of $(2,00 \pm 0,2)$ mm and a curvature appropriate for the frame.

For all test samples, sides and fronts shall be separated from each other. Sides shall be dismantled from fronts, either by unscrewing the dowel (hinge) screw or by cutting the joint across the charniers (leaves of the hinge).

Unless they have a metal-bearing surface, nose pads shall be removed. Removing end covers (side tips) from sides is optional.

To avoid subsequent difficulties with masking the pad box for the coating test, it is recommended that, except for frames fitted with pads having a metal-bearing surface, the pads be removed by cutting off the pad arms complete with the pad box and pads – see 7.3.2.

Ensure that all the separate test parts remain identified throughout all steps of the overall procedure.

6.2 Procedure

Perform the simulation of wear and corrosion according to EN 12472. Ensure that the paste is not used after its shelf life has expired.

NOTE Fronts can conveniently be clamped by means of the dummy or test lenses, and sides on the part that is covered by the end cover (temple tip). See Annex A. EN 12472 specifies that the back surface of the front and inside of the sides face towards the axis of the assembly.

When the simulation is completed, remove the test samples. Gently swirl them for 2 min in degreasing solution (see 7.2.4) at room temperature. Rinse thoroughly with deionized water. Gently dry in a clean air stream or allow to dry on absorbent paper.

After degreasing, handle the test samples with appropriate tools or clean laboratory gloves.

Disassemble three-piece rimless fronts. Disassemble fronts of combination frames and remove any plastic parts.

Then subject the test parts to the selected test: coating test, see Clause 7, and/or migration test, see Clause 8.

7 Coating test**7.1 General**

The purpose of the coating test is to verify whether the surface treatment of a model is able to limit sufficiently the release of metal ions (including nickel), as indicated by the impedance threshold limit. Test samples that are not identified as “pass” can be retested if 7.5.3 applies or be subjected to the migration test, see Clauses 4 and 5.

The parts of test samples needing consideration are only those intended to come into direct and prolonged contact with the skin of the wearer, see 7.3.1.