



SLOVENSKI STANDARD

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SIST EN 16128:2011

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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

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

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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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EUROPEAN STANDARD

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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 European Standard was approved by CEN on 19 September 2015.

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.

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COMITÉ EUROPÉEN DE NORMALISATION
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EN 16128:2015 (E)**European foreword**

This document (EN 16128:2015) 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of an identical text or by endorsement, at the latest by May 2016, and conflicting national standards shall be withdrawn at the latest by November 2018.

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 16128:2011 and CEN/TS 16677:2014.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports the harmonising effect of a restriction adopted under Regulation (EC) No 1907/2006 (REACH) of the European Parliament and the Council.

Compared to EN 16128:2011 and CEN/TS 16677:2014, the following changes have been made:

- a) Compared to EN 16128:2011, the reference test method has been substantially revised:

In the method according to EN 16128:2011 the parts to be tested for nickel release are placed in an artificial sweat test solution for one week. The concentration of dissolved nickel in the solution is determined by atomic absorption spectrometry, inductively-coupled plasma spectrometry or other appropriate analytical method.

The present standard provides, for parts with an organic coating, a coating test based on Electrochemical Impedance Spectroscopy (EIS). The coating test aims at demonstrating that the coating is of sufficient quality to prevent the release of nickel, thereby ensuring that the test sample's nickel release does not exceed the regulatory limit.

For parts without an organic coating, the present standard specifies a migration test. The migration test makes provision for quantitative testing for the amount of nickel released, to determine whether or not the model's nickel release 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.

See also the principle described in Clause 4.

- b) Compared to CEN/TS 16677:2014 the revisions and refinements made are relatively minor, as follows:

For the coating test, see Clause 7:

Amendment of the calculation and presentation of the test result including amendment of the threshold value (see 7.6);

The dummy or test lenses used in the simulation of wear and corrosion are to be kept in the frame.

For the migration test, see Clause 8:

Inclusion of the requirement to prepare and analyze a blank sample with every batch of test samples, along with the relevant specifications of sample preparation and procedure (see 8.4.4);

Specification that the incubation shall be made using a climate chamber; the previously permissible alternative to use an oven with a container for insertion of the test samples has been deleted (see 8.4.5);

Inclusion of more detailed specifications as to the permissible and non-permissible combination of the test papers from the various test areas for the analysis;

Inclusion of directions on how to proceed in the case that the design of a model does not allow the application of the test paper at (one of) the specified location(s);

Amendment of the procedure for the application and sealing of the test paper onto the test area using the sealing film; as an alternative to wrapping with the sealing film it is now also permissible to use a folding technique; see the revised Annex B;

Recommendation that the time between the retrieval of the test papers from the test samples and their extraction and analysis does not exceed 3 d (see 8.4.6).

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. (standards.iteh.ai)

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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 is the revision of the 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 of 0,5 µg/cm²/week set forth by European 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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1 Scope

This European Standard specifies the reference method for the testing of spectacle frames, ready-to-wear spectacles, sunglasses and other items 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 µg/cm²/week 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 spectacles, sunglasses and other items for eye and face protection.

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

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.

EN 12472, *Method for the simulation of 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 11380, *Optics and optical instruments — Ophthalmic optics — Formers (ISO 11380)*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

model

spectacle frame, ready-to-wear spectacles, sunglass or other item used for eye and face protection produced to a common 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

Note 1 to entry: Fronts or sides may be submitted separately 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).

EN 16128:2015 (E)**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

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 procedural steps:

- 1) Coating test, applicable only to test parts with an organic coating, based on Electrochemical Impedance Spectroscopy (EIS) and specified in Clause 7; the coating test aims at demonstrating that the coating of the test sample is of sufficient quality to prevent the release of nickel, thereby ensuring that the test sample's nickel release does not exceed the regulatory limit. The coating test is, however, not sensitive only to nickel ions, so a model can pass the migration test even though it failed the coating test.
- 2) Migration test for nickel ion release, specified in Clause 8; the migration test makes provision for quantitative testing for the amount of nickel released, to determine whether or not the model's nickel release 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.

For a model that failed the coating test, either new test samples or, subject to the requirements of the person ordering the test, the original test samples may be subjected to the migration test.

Metal frames that are uncoated, i.e. neither organic coating nor metal plating, 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 procedure.

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).

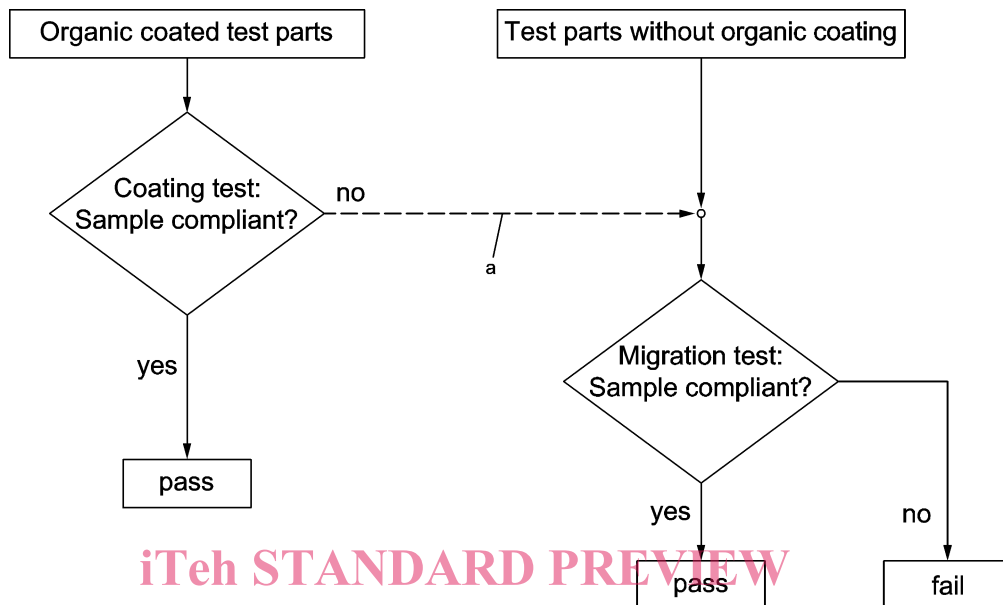
5 Selection of test samples

Two specimens of each model to be tested shall be selected at random for either the coating or the migration test.

The selected specimens shall be identified.

Test samples used for the coating test may 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. It is preferable that new test samples are used for the migration test.



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Key

- ^a The coating test is not sensitive only to nickel ions, so a model can pass the migration test even though it failed the coating test.

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Figure 1 — Diagrammatic overview of the reference test method

6 Simulation of wear and corrosion

6.1 Preparation of test samples

For spectacle frames, if not already fitted with dummy or demonstration lenses, the test samples shall be fitted with a pair of suitable organic lenses within the range of $-1,00$ D to $+1,00$ D and with an edge thickness of between 1,5 mm and 2,5 mm. These test lenses shall be edged either in accordance with the manufacturer's electronic instructions or with a digitally controlled edging machine that uses the tracing made of the individual test sample or, where appropriate, using a mechanical former in accordance with EN ISO 11380. The bevel angle of the edged lens shall be $120^{\circ} -2^{\circ} +3^{\circ}$ for spectacle frames featuring a rim with a groove.

For all test samples, sides and fronts shall be separated from each other. Removing end covers (side tips) from sides is optional. Unless they have a metal-bearing surface, nose pads shall be removed before the wear phase. Sides shall be dismantled from fronts, either by unscrewing the dowel (hinge) screw or by cutting the joint across the charniers.

WARNING — Care shall be taken not to damage the coating on areas that are subsequently tested, particularly the coating near any cut.

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

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6.2 Procedure

Perform the simulation of wear and corrosion according to EN 12472.

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 plastics 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 if the surface treatment of a model is able to limit the release of metal ions (hence including nickel), in order to identify good quality coatings. Test samples that are not identified as “pass” may be subjected to the migration test, see Clauses 4 and 5.

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

7.2 Apparatus and consumables

7.2.1 Masking agent, suitable for electroplating purposes and capable of electrically insulating the test part from the saline solution. Application of more than one coat is acceptable, and may be preferable.

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Test the masking agent to verify that it is suitable by using it to coat a metal strip without an organic coating and show that the adhesion is good and impedance results are high (greater than $5,0 \cdot 10^6 \Omega \cdot \text{cm}^2$).

NOTE 1 A metal strip with approximate dimensions of 2 mm thick, 6 mm wide, and 100 mm long is suitable.

It is useful if the masking agent is coloured or fluorescent, to make the masked areas more visible.

NOTE 2 Lacomit is the trade name of a suitable product.¹⁾

7.2.2 Deionized water, according to EN ISO 3696, grade 3 or to European Pharmacopoeia, for rinsing and preparation of the saline solution (7.4).

7.2.3 Sodium chloride of recognized pro analysis, p.a., grade or better, for preparation of the saline solution (7.4).

7.2.4 Degreasing solution, Sodium Dodecyl Sulfate (SDS) at a concentration of 0,5 % in deionized water, to clean the test samples after cutting, etc. and before testing. An appropriately diluted, neutral, commercially available detergent may also be used.

7.2.5 Apparatus for preparation of 1 % saline solution in deionized water.

1) Lacomit is an example of a suitable product available commercially. This information is given for the convenience of users of this document and does not constitute an endorsement by CEN of this product. Equivalent products may be used if they can be shown to lead to the same results.