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 STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 16128:2015 sisaldab Euroopa standardi EN 16128:2015 ingliskeelset teksti.	This Estonian standard EVS-EN 16128:2015 consists of the English text of the European standard EN 16128:2015.
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.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 04.11.2015.	Date of Availability of the European standard is 04.11.2015.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

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

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Supersedes CEN/TS 16677:2014, EN 16128:2011

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 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.

CEN members are the national standards bodies of 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 United Kingdom.

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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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.

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.

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).