ILNAS

Institut luxembourgeois de la normalisation
de l'accréditation, de la sécurité et qualité
des produits et services

ILNAS-EN 16128:2015

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

11/2015

National Foreword

This European Standard EN 16128:2015 was adopted as Luxembourgish Standard ILNAS-EN 16128:2015.

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ILNAS-EN 16128:2015

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 16128

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

English Version

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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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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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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of an identical text or by endorsement, at the latest by May 2016, and conflicting national standards shall be withdrawn at the latest by November 2018.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.