



**SLOVENSKI STANDARD**  
**kSIST-TS FprCEN/TS 16677:2014**  
**01-januar-2014**

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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 - Referenzprüfverfahren zur 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

**Ta slovenski standard je istoveten z: FprCEN/TS 16677**

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**ICS:**

11.040.70	Oftalmološka oprema	Ophthalmic equipment
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TECHNICAL SPECIFICATION  
SPÉCIFICATION TECHNIQUE  
TECHNISCHE SPEZIFIKATION

**FINAL DRAFT**  
**FprCEN/TS 16677**

February 2014

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ICS 11.040.70

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 draft Technical Specification is submitted to CEN members for formal vote. It has been drawn up by the Technical Committee CEN/TC 170.

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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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## **Foreword**

This document (FprCEN/TS 16677:2014) 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 Formal Vote.

## 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 (revision of EN 16128:2011, previously EN 1811:1998). The elaboration and adoption of the present document is a first step towards, ultimately, revision of EN 16128:2011.

The availability of the new reference method for the determination of the release of nickel from spectacle frames and sunglasses will provide the reliable framework to enforce the limit value for nickel release of  $0,5 \mu\text{g}/\text{cm}^2/\text{week}$  set forth by European Regulation. It will ensure a uniform application and control of the European legislation in all member states.

Harmonising the test method for nickel release in all member states, thereby ensuring that spectacle frames and sunglasses placed in the market are safe, is vital with a view to protecting effectively the health and safety 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.

# FprCEN/TS 16677:2014 (E)

## 1 Scope

This document specifies the reference method for the testing of spectacle frames and sunglasses for nickel release.

The reference method supports the demonstration of conformity with the limit value for nickel release of  $0,5 \mu\text{g}/\text{cm}^2/\text{week}$  set forth by European Regulation and makes provision for a uniform application and control of the European legislation in all member states.

The reference method involves the following procedural steps (see also Clause 4):

- Simulation of wear and corrosion;
- EIS coating test (optional);
- Laboratory test: Release of nickel and its quantitative analytical detection.

This document applies to those parts of metal spectacle frames and those metal parts of combination spectacle frames that come into direct and prolonged contact with the skin of the wearer. This document also applies to those relevant metal parts of articles for eye and face protection, including sunglasses.

The EIS coating test method can be applied only to metal parts which have been coated with an organic, electrically insulating, layer.

This document does not apply to products other than spectacle frames and articles for eye and face protection, which includes sunglasses.

**NOTE** The reference method for products other than spectacle frames and of articles for eye and face protection, including sunglasses is specified in EN 1811:2011.

## 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 3696:1995, *Water for analytical laboratory use — Specification and test methods (ISO 3696:1987)*

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

#### part

<of a test sample> that part of a sample spectacle frame or article used for eye and face protection, including a sunglass frame, that shall be tested

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

### 3.2

#### component

spectacle or sunglass front, bridge or side, or component of an eye and face protector, that can be separated from the test sample without cutting



**3.3****test paper**

piece of paper used for testing, at any stage of the procedure

**3.4****test sample**

spectacle frame or article used for eye and face protection, including a sunglass frame, submitted for testing

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

**3.5****extraction sample**

solution obtained after extracting the test paper and making up to the required volume

**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 with low or no nickel content.

**3.7****appropriate equipment**

equipment enabling to perform the procedure while avoiding contamination by nickel or other metal ions, either from the material of the equipment or deposits on it

Note 1 to entry: For the laboratory test note that "normal" glassware could induce Nickel contamination; therefore if using glass, use borosilicate glass, or use plastics suitable for the purpose.

**4 Principle**

Following the simulation of 2-years' wear according to EN 12472, the product (spectacle frame or sunglasses) can be submitted to a coating test ("pre-test") or directly to a laboratory test.

The coating test (see Clause 7) is based on electro-impedance spectroscopy (EIS). The EIS coating test is optional and indicative and essentially aims at demonstrating that the protective coating of the product is of sufficient quality to prevent the release of nickel. The EIS coating test is of such nature that it can be applied on-site by e.g. the manufacturers, importers and authorities as a part of quality control. If the result of the EIS coating test is "pass", it may be assumed that the product is not releasing nickel at a rate greater than  $0,5 \mu\text{g}/\text{cm}^2/\text{week}$ . If the EIS coating test result is "fail" or gives rise to doubt, and also for all cases where the optional EIS coating test is not performed, the "laboratory test" for nickel ion release makes provision for quantitative testing for the amount of nickel released, in the order of magnitude necessary to give a definitive answer whether or not the frame's nickel release exceeds the limit value of  $0,5 \mu\text{g}/\text{cm}^2/\text{week}$ .

The laboratory test (see Clause 8) is the reference method as regards the demonstration of conformity with the requirements of European legislation. It will typically be carried out by a test laboratory and comprises two steps: Release of nickel by artificial sweat into a test paper and the subsequent quantitative analytical detection of the nickel released into the paper, either by solid sampling or by extraction followed by nickel determination. The necessary detection limit is in the range of 5 ppt (for solid sampling) and in the range of 5 ppb (for extraction followed by nickel determination).

See Figure 1.

Requirements for sampling and guidance as to which parts of the frames shall be subject to testing are given in 5.1, and in 7.3.1 (for the EIS coating test) and 8.3.1 (for the laboratory test).

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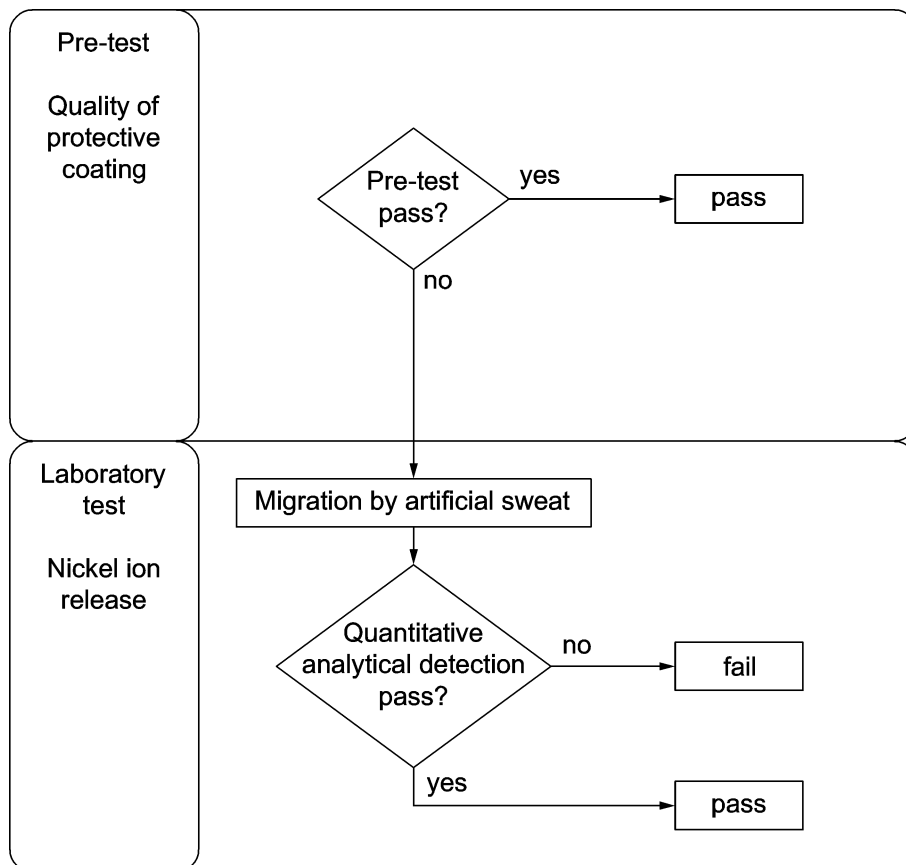


Figure 1 — Flowchart

## 5 Sampling and preparation of test samples

### 5.1 Selection of test samples

For the EIS coating test, two specimens of each spectacle frame and/or sunglass model to be tested shall be selected at random.

For the laboratory test, two specimens of each spectacle frame and/or sunglass model to be tested shall be selected at random.

The selected specimens shall be identified as test sample 1 and test sample 2.

Subject to the agreement by the person ordering the test, samples used for the EIS coating test ("pre-test") can be tested in a subsequent laboratory test, but not vice versa.

If a sample is likely to be subjected to the laboratory test after the coating test, it should be washed in deionised water immediately after the coating test and allowed to dry to avoid any corrosion by the sodium chloride. The simulated wear and corrosion test in Clause 6 should not be repeated. It is preferable that new samples are used for the laboratory test.

Prior to performing the EIS coating test (see Clause 7) and/or the laboratory test (see Clause 8), as applicable, all test samples shall be prepared and conditioned as specified in 5.2, then be subjected to the simulation of 2-years' wear as specified in EN 12472 (see Clause 6).

## 5.2 Preparation and conditioning of test samples

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.

Spectacle sides and fronts shall be separated from each other, and end covers (side tips) removed from sides where appropriate. Unless they have a metal-bearing surface, remove nose pads before the wear phase. Dismantling of sides from fronts may be done either by unscrewing the joint screw or by cutting the joint across the charniers.

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

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

## 6 Simulation of 2-years' wear

Prior to submission to the selected test, the test samples shall be subject to the method for simulation of 2-years' wear according to EN 12472.

Fix fronts and sides separately onto the retaining system and slide into the rotating barrel.

When the accelerated wear process is completed, remove the test samples. Gently swirl the sample(s) for 2 min in degreasing solution at room temperature. Rinse thoroughly with de-ionised water and gently dry in an air stream. After degreasing, handle the samples with appropriate tools or clean protective gloves.

Remove lenses from fronts by unscrewing the closing block joint.

NOTE Pushing dummy lenses out is very likely to damage the coating.

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

Then subject the test samples' components to the selected test: EIS coating test, see Clause 7, and/or laboratory test, see Clause 8.

## 7 EIS method (coating test)

### 7.1 General

The purpose of the EIS test is to verify if the surface treatment of a metal spectacle frame or sunglass is able to limit the release of metal ions (hence including nickel), in order to identify good coatings that definitely pass from those whose results are borderline or fail. Test samples which are not identified as good shall be subjected to the laboratory test. If the coating test gives a pass result, there is no need to do a laboratory test.

The parts of spectacle frames needing consideration are only those likely to come into direct and prolonged contact with the skin of the wearer, that is, the sides (temples), bridge and rims. See 7.3.1.

This method can only be applied to test samples with organic coatings but not with conductive coatings such as metal plating, rolled gold and/or for test samples made from uncoated metal.