

PD CEN/TS 16677:2014



BSI Standards Publication

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

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National foreword

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A list of organizations represented on this committee can be obtained on request to its secretary.

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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 Technical Specification (CEN/TS) was approved by CEN on 15 March 2014 for provisional application.

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Contents	Page
Foreword.....	4
Introduction	5
1 Scope	6
2 Normative references	6
3 Terms and definitions	6
4 Principle.....	7
5 Sampling and preparation of test samples	8
5.1 Selection of test samples.....	8
5.2 Preparation and conditioning of test samples	8
6 Simulation of wear and corrosion.....	9
7 Coating test	9
7.1 General.....	9
7.2 Apparatus and consumables.....	9
7.3 Preparation of test samples for coating test	10
7.3.1 Parts to be tested.....	10
7.3.2 Dismantling and/or cutting and/or masking	11
7.3.3 Determination of test area	12
7.3.4 Preparation of electrical contact area	12
7.4 Preparation of saline solution	13
7.5 Procedure	13
7.5.1 Preparation of the electro-chemical cell	13
7.5.2 Insertion and connection of the test part in the electro-chemical cell.....	13
7.5.3 Determination of open circuit potential and measurement of electrochemical impedance of samples	14
7.5.4 Calibration of the potentiostat.....	14
7.6 Calculation of results	14
7.7 Test report	15
8 Release of nickel and its quantitative analytical detection (migration test).....	15
8.1 General.....	15
8.2 Apparatus and consumables.....	16
8.3 Preparation of test samples for migration test.....	17
8.3.1 Parts to be tested.....	17
8.3.2 Guidance on selection of test areas on the parts to be tested	18
8.3.3 Dismantling and degreasing.....	18
8.4 Procedure	18
8.4.1 Preparation of test paper including determination of its area	18
8.4.2 Preparation of artificial sweat solution.....	19
8.4.3 Applying artificial sweat to the test paper and attaching it to the test sample	21
8.4.4 Incubation of test sample with test paper attached (release of nickel into paper).....	21
8.4.5 Retrieval of the test paper from the test samples	22
8.4.6 Analysis of the paper for nickel present	22
8.5 Calculation of results	24
8.6 Interpretation of results	25
8.6.1 General.....	25
8.6.2 Assessment of non-compliance.....	25

8.7	Test report	25
Annex A	(informative) Cutting and masking of test samples (Coating test)	27
A.1	Fronts	27
A.2	Sides (temples)	28
Annex B	(normative) Selection of test areas and wrapping (Migration test)	29
B.1	Rims	29
B.2	Bridge and brace bar	30
B.3	Sides (temples)	31
B.4	Wrapping with sealing film	32
	Bibliography	33

Foreword

This document (CEN/TS 16677:2014) has been prepared by Technical Committee CEN/TC 170 "Ophthalmic optics", the secretariat of which is held by DIN.

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.

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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 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 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 document 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 3696:1995, *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 article
spectacle frame, ready-to-wear spectacles, sunglass or other item used for eye and face protection to which the scope of this document applies

3.2 test sample
spectacle frame, ready-to-wear spectacle, 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
that part of a test sample that is intended to come into direct and prolonged contact with the skin and shall 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 paper used for testing, at any stage of the procedure