



BSI Standards Publication

**Reference test method for
release of nickel from all
post assemblies which are
inserted into pierced parts of
the human body and articles
intended to come into direct
and prolonged contact with
the skin**

National foreword

This British Standard is the UK implementation of EN 1811:2011+A1:2015, incorporating corrigendum May 2012. It supersedes BS EN 1811:2011, which is withdrawn.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to CEN text carry the number of the CEN amendment. For example, text altered by CEN amendment A1 is indicated by A1 A1.

The UK participation in its preparation was entrusted to Technical Committee STI/53, Specifications and test methods for jewellery and horology.

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

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

© The British Standards Institution 2015.
Published by BSI Standards Limited 2015

ISBN 978 0 580 88663 8

ICS 39.060

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 August 2011.

Amendments/corrigenda issued since publication

Date	Text affected
31 July 2012	Implementation of CEN corrigendum May 2012: Clauses 5.8 and 5.9 replaced
31 August 2015	Implementation of CEN amendment A1:2015

English Version

Reference test method for release of nickel from all post assemblies which are inserted into pierced parts of the human body and articles intended to come into direct and prolonged contact with the skin

Méthode d'essai de référence relative à la libération du nickel par les assemblages de tiges qui sont introduites dans les parties percées du corps humain et les produits destinés à entrer en contact direct et prolongé avec la peau

Referenzprüfverfahren zur Bestimmung der Nickellässigkeit von sämtlichen Stäben, die in durchstochene Körperteile eingeführt werden und Erzeugnissen, die unmittelbar und länger mit der Haut in Berührung kommen

This European Standard was approved by CEN on 5 February 2011 and includes Corrigendum 1 issued by CEN on 30 May 2012 and Amendment 1 approved by CEN on 20 June 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



Contents

Page

European foreword	4
Introduction	5
1 Scope	6
2 Normative references	6
3 Terms and definitions	6
4 Principle of the procedure	7
5 Reagents	7
6 Apparatus	8
7 Samples	9
7.1 Sample area	9
7.1.1 Definition of sample area	9
7.1.2 Determination of sample area	9
7.1.3 Masking of areas other than sample area	9
7.2 Sample degreasing before testing	9
7.3 Quality control samples	9
8 Procedure	10
8.1 Preparation of test solution	10
8.2 Release procedure	10
8.3 Determination of nickel	11
8.3.1 General	11
8.3.2 Calibration solutions	11
8.3.3 Detection limit and quantification limit	11
8.3.4 Number of test samples	11
8.3.5 Number of replicate measurements	11
8.4 Blank tests	11
9 Calculations	11
9.1 Nickel release	11
9.2 Interpretation of results	12
9.2.1 General	12
9.2.2 Conformity assessment (A ₁)	12
9.2.3 Uncertainty budget	13
10 Test report	13
Annex A (informative) (A ₁) Expanded measurement uncertainty of the test procedure and compliance assessment	14
Annex B (normative) Requirements for quality control material	16
Annex C (normative) Requirements for preparation of all post assemblies which are inserted into pierced parts of the human body and articles intended to come into direct and prolonged contact with the skin prior to nickel testing	18
C.1 General	18
C.2 Requirements and principle	18
C.3 Determination of the nickel release test method	18
C.4 Determination of surfaces coming into direct and prolonged contact with the skin or pierced parts of the body	18

C.4.1	Procedures for homogeneous and inhomogeneous articles	18
C.4.1.1	General	18
C.4.1.2	Homogeneous articles and all post assemblies	19
C.4.1.3	Procedure for inhomogeneous articles	19
C.4.1.3.1	General.....	19
C.4.1.3.2	Situation 1.....	19
C.4.1.3.2.1	General	19
C.4.1.3.2.2	Procedure 1	19
C.4.1.3.2.3	Result.....	19
C.4.1.3.3	Situation 2.....	19
C.4.1.3.3.1	General	19
C.4.1.3.3.2	Procedure 2.....	19
C.4.1.3.3.3	Result.....	20
C.4.1.3.4	Situation 3.....	20
C.4.1.3.4.1	General	20
C.4.1.3.4.2	Procedure 3.....	20
C.4.2	Jewellery products	20
C.4.2.1	General	20
C.4.2.2	Post assemblies and associated parts	20
C.4.2.2.1	Parts coming into direct and prolonged contact with the skin and/or pierced parts of the body.....	20
C.4.2.2.2	Decorative attachments of post assemblies.....	21
C.4.2.3	Necklaces, bracelets, chains and anklets.....	22
C.4.2.4	Bangles.....	23
C.4.2.5	Rings.....	23
C.4.2.6	Watches	24
C.4.2.6.1	General.....	24
C.4.2.6.2	Parts to be tested.....	24
C.4.2.6.3	Parts to be removed from watch before testing	25
C.4.3	Other articles such as textiles, footwear, garments, leather goods and mobile phones	25
C.5	Methods of determining the surface areas	26
C.5.1	Surface area measurements	26
C.5.2	Minimum surface area.....	26
C.5.3	Simplification of surface area determination using common shapes of consumer products	26
C.6	Testing apparatus prior to nickel release testing	26
Annex D (informative)	Articles made from composite materials	28
Bibliography.....		29

European foreword



This document (EN 1811:2011+A1:2015) has been prepared by Technical Committee CEN/TC 347 "Methods for analysis of allergens", the secretariat of which is held by  SNV .



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 January 2016, and conflicting national standards shall be withdrawn at the latest by January 2016.

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 includes Corrigendum 1 issued by CEN on 30 May 2012 and Amendment 1 approved by CEN on 20 June 2015.

This document supersedes  EN 1811:2011 .

The start and finish of text introduced or altered by amendment is indicated in the text by tags  .

The modifications of the related CEN Corrigendum have been implemented at the appropriate places in the text and are indicated by the tags  .

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association.

This document supports essential requirements of Commission Regulation (EC) No 1907/2006 (REACH) of the European Parliament and the Council.

 *deleted text* 

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

Adverse skin reaction to nickel has been known for many decades. Nickel is the most frequent cause of contact allergy in Europe, and 10 % to 20 % of the patch tested female population and 1 % to 3 % of the patch tested male population are allergic to nickel. Skin absorption of nickel ions, which are released from some nickel-containing materials which are inserted into pierced ears or other pierced parts of the human body or which are in direct and prolonged contact with the skin, causes sensitisation. Further exposure to soluble nickel salts results in allergic contact dermatitis. It is known that sensitisation to nickel requires higher exposure levels than does the elicitation in already sensitised individuals. There is a large variation in the degree of sensitivity to nickel between individuals. This widespread health problem has forced the introduction of a number of measures designed to reduce its prevalence. These measures include the requirements of this standard which provides an *in-vitro* chemical test that correlates as far as possible with the variable human biological reactions that occur when metallic articles containing nickel are in direct and prolonged contact with the skin and pierced parts of the body. The standard provides a measure of the amount of nickel release from an article immersed for one week in artificial sweat. The standard also describes the preparation of a quality control material intended to assist a laboratory in achieving an acceptable precision.

Clinical patch-testing of a small selection of nickel-containing alloys and coatings on nickel-sensitized persons indicates that high and low results achieved with the present analytical method correspond closely with patch-test reactivity. Moreover, a nickel migration limit of $0,5 \mu\text{g}/\text{cm}^2/\text{week}$ for articles intended to come into direct and prolonged contact with the skin and a nickel migration limit of less than $0,2 \mu\text{g}/\text{cm}^2/\text{week}$ for all post piercing assemblies inserted into pierced ears and other pierced parts of the human body has been set in Commission Regulation (EC) No 1907/2006 of the European Parliament and the Council (in the current version).

1 Scope

This European Standard specifies a method for simulating the release of nickel from all post assemblies which are inserted into pierced ears and other pierced parts of the human body and articles intended to come into direct and prolonged contact with the skin in order to determine whether such articles are in compliance with No. 27 Annex XVII of Regulation (EC) No 1907/2006 of the European Parliament and of the Council (REACH).

Spectacle frames and sunglasses are excluded from the scope of this European Standard.

NOTE Spectacle frames and sunglasses are subject to the requirements of EN 16128:2011 which provides an unchanged re-publication of the technical requirements that had previously been specified in EN 1811:1998, but restricted in scope to apply only to spectacle frames and sunglasses.

2 Normative references

The following referenced documents are indispensable for the application of this document. 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)*

3 Terms and definitions

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

3.1

barrette

component used to secure the watchstrap to the case

3.2

homogeneous

consisting of a single material having a common surface finish

3.3

post assembly

ear stud or body piercing article

3.4

release solution

solution resulting from the release procedure according to 8.2

3.5

representative

best estimate for the effective release rate of all surfaces which are in direct and prolonged contact with the skin or pierced parts of the body under normal conditions of use

NOTE This property is defined with respect to the release rate.