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NEEDIKOMPLEKTIDES, MIS LÄBIVAD AUGUSTATUD  
KEHAOSI JA TOODETES, MIDA KASUTATAKSE NAHAGA  
VAHETUS PIKAAJALISES KONTAKTIS**

**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**

**EESTI STANDARDI EESSÕNA****NATIONAL FOREWORD**

See Eesti standard EVS-EN 1811:2011+A1:2015 sisaldab Euroopa standardi EN 1811:2011+A1:2015 ingliskeelset teksti.	This Estonian standard EVS-EN 1811:2011+A1:2015 consists of the English text of the European standard EN 1811:2011+A1:2015.
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 29.07.2015.	Date of Availability of the European standard is 29.07.2015.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

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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.

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## 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.

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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.