

REFERENTSMEEETOD NIKLI ERALDUMISE  
MÄÄRAMISEKS 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

<p>See Eesti standard EVS-EN 1811:2023 sisaldab Euroopa standardi EN 1811:2023 ingliskeelset teksti.</p> <p>Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.</p> <p>Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 22.02.2023.</p> <p>Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.</p>	<p>This Estonian standard EVS-EN 1811:2023 consists of the English text of the European standard EN 1811:2023.</p> <p>This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.</p> <p>Date of Availability of the European standard is 22.02.2023.</p> <p>The standard is available from the Estonian Centre for Standardisation and Accreditation.</p>
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ICS 39.060

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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 tous les assemblages de tiges qui sont insérés dans les parties percées du corps humain et les articles 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 2 January 2023.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION  
COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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## European foreword

This document (EN 1811:2023) 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 August 2023, and conflicting national standards shall be withdrawn at the latest by August 2023.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 1811:2011+A1:2015.

EN 1811:2023 includes the following significant technical changes with respect to EN 1811:2011+A1:2015:

- unit for nickel release changed to  $\mu\text{g} \cdot \text{cm}^{-2} \cdot \text{week}^{-1}$  (expressed as  $\mu\text{g}/\text{cm}^2/\text{week}$  in the Regulation);
- Note 1 in Clause 1 shortened;
- Clause 3 Terms and definitions updated, terms surface finish and disassemble were added;
- Clause 5, permission of ready to use solutions in reagents added;
- notes for application of wax or lacquer added;
- information of number of test samples added,
- definition of sample area clarified;
- handling of small samples and filtering of release solution in the release procedure clarified;
- filtering of release solutions and blank solutions clarified;
- test report updated;
- Annex B, Requirements for Quality control material deleted;
- Annex B for preparation of samples revised;
- Table B.1, General procedure for post assemblies and inhomogeneous articles added;
- Figure B.9, Flowchart for sample preparation and testing procedure for complete watches added;
- Bibliography updated.

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

Any feedback and questions on this document should be directed to the users' national standards body. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

## Introduction

Nickel is the most frequent cause of contact allergy in Europe and adverse skin reaction to nickel has been known for many decades.

Skin absorption of a sufficient amount 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, is required to cause sensitization [9].

Once sensitized, further exposure to soluble nickel ions results in allergic contact dermatitis. It is known that sensitization to nickel requires higher exposure levels than does the elicitation in already sensitized 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 document which provides an *in vitro* chemical test that correlates as far as possible with the variable human biological reactions that occur when metallic or coated articles containing nickel are in direct and prolonged contact with the skin or inserted into pierced parts of the body. This document provides a test method to determine the release of nickel from an article immersed for one week in artificial sweat. Clinical patch-testing of a 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, Regulation (EC) No 1907/2006 of the European Parliament and of the Council (in the current version) [9] sets a nickel migration limit of  $0,5 \mu\text{g} \cdot \text{cm}^{-2} \cdot \text{week}^{-1}$  (expressed as  $\mu\text{g}/\text{cm}^2/\text{week}$  in the Regulation) for articles intended to come into direct and prolonged contact with the skin and a limit of less than  $0,2 \mu\text{g} \cdot \text{cm}^{-2} \cdot \text{week}^{-1}$  (expressed as  $\mu\text{g}/\text{cm}^2/\text{week}$  in the Regulation) for all post piercing assemblies inserted into pierced ears and other pierced parts of the human body.

## 1 Scope

This document 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 in 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 document.

NOTE Spectacle frames and sunglasses are subject to the requirements of EN 16128.

## 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 accelerated wear and corrosion for the detection of nickel release from coated items*

EN ISO 3696, *Water for analytical laboratory use — Specification and test methods (ISO 3696)*

## 3 Terms and definitions

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

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

### 3.1

#### **homogeneous**

of uniform composition throughout that cannot be separated into different materials

Note 1 to entry: A coated material is not homogeneous.

### 3.2

#### **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 and foreseeable conditions of use

### 3.3

#### **surface finish**

appearance and texture of a surface characterized by its smoothness or roughness

Note 1 to entry: In order of increasing smoothness, the surface finish can be typically described as cut finish, machined finish, brushed finish, matt finish, satin finish, mirror or polished finish.

### 3.4

#### **sample area**

*a*

surface(s) that is/are immersed in the test solution and not covered with a masking agent