

**Põhimeetod nikli eraldumise määramiseks
needikomplektides, mis läbivad augustatud kehaosi ja
toodetes, mida kasutatakse nahaga vahetus pikaajalises
kontaktis**

Reference test method for release of nickel from 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>Käesolev Eesti standard EVS-EN 1811:2011 sisaldab Euroopa standardi EN 1811:2011 ingliskeelset teksti.</p> <p>Standard on kinnitatud Eesti Standardikeskuse 31.03.2011 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.</p> <p>Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 09.03.2011.</p> <p>Standard on kättesaadav Eesti standardiorganisatsioonist.</p>	<p>This Estonian standard EVS-EN 1811:2011 consists of the English text of the European standard EN 1811:2011.</p> <p>This standard is ratified with the order of Estonian Centre for Standardisation dated 31.03.2011 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.</p> <p>Date of Availability of the European standard text 09.03.2011.</p> <p>The standard is available from Estonian standardisation organisation.</p>
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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.

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.

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Foreword

This document (EN 1811:2011) has been prepared by Technical Committee CEN/TC 347 “Methods for analysis of allergens”, the secretariat of which is held by DS.

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 September 2011, and conflicting national standards shall be withdrawn at the latest by March 2013.

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, together with EN 16128:2011, supersedes EN 1811:1998 +A1:2008.

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.

List of the significant technical changes that have been made in this new version of EN 1811 in comparison with the former edition EN 1811:1998+A1:2008:

The scope of the former European Standard was divided: EN 1811:2011 is applicable for all products but spectacle frames and sunglasses; EN 16128:2011 is applicable for spectacle frames and sunglasses;

List of the significant technical changes of EN 1811:2011 as compared to the former European Standard:

- The scope was expanded to include all post assemblies which are inserted into pierced parts of the human body;
- The preparation of the test solution was tested and changed;
- The correction factor was eliminated and the concept of measurement uncertainty introduced;
- The Standard contains a new normative Annex C on the preparation of articles prior to nickel testing;

EN 16128:2011 is technically unchanged as compared to the former European Standard EN 1811:1998+A1:2008.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland 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.