Tandvård – Zinkoxid/eugenolcement och eugenolfria zinkoxidcement (ISO 3107:2004)


Denna standard ersätter SS-EN 23107, utgåva 1.


This standard supersedes the Swedish Standard SS-EN 23107, edition 1.

This European Standard was approved by CEN on 23 September 2004.

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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.
Foreword

This document (EN ISO 3107:2004) has been prepared by Technical Committee ISO/TC 106 "Dentistry" in collaboration with Technical Committee CEN/TC 55 "Dentistry", the secretariat of which is held by DIN.

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of an identical text or by endorsement, at the latest by April 2005, and conflicting national standards shall be withdrawn at the latest by April 2005.

This document supersedes EN 23107:1991.

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

Endorsement notice

The text of ISO 3107:2004 has been approved by CEN as EN ISO 3107:2004 without any modifications.
Introduction

Specific qualitative and quantitative requirements for freedom from biological hazard are not included in this International Standard, but it is recommended that, in assessing possible biological or toxicological hazards, reference be made to ISO 10993-1 and ISO 7405.
Dentistry — Zinc oxide/eugenol and zinc oxide/non-eugenol cements

1 Scope

This International Standard specifies the requirements and performance test methods for non-water-based zinc oxide/eugenol cements suitable for use in restorative dentistry for temporary cementation, for permanent cementation, for cavity liners and bases and as temporary restorations.

This International Standard is also applicable to non-eugenol cements containing zinc oxide and aromatic oils suitable for temporary cementation.

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.

ISO 2590, General method for the determination of arsenic — Silver diethyldithiocarbamate photometric method

ISO 3696:1987, Water for analytical laboratory use — Specification and test methods

ISO 8601, Data elements and interchange formats — Information interchange — Representation of dates and times

3 Classification

For the purposes of this document, the following classification for cements is used, based on their intended use:

a) Type I: for temporary cementation;
   1) Class 1: setting cement;
   2) Class 2: non-setting cement.

b) Type II: for permanent cementation;

c) Type III: for bases and temporary restorations;

d) Type IV: for cavity liners.
4 Requirements

4.1 Performance requirements

When tested in accordance with the appropriate test methods specified in Clause 6, cements shall comply with the performance requirements specified in Table 1.

<table>
<thead>
<tr>
<th>Type and Class</th>
<th>Setting time at 37 °C min.</th>
<th>max.</th>
<th>Compressive strength at 24 h MPa min.</th>
<th>max.</th>
<th>Disintegration after 24 h % (mass fraction) max.</th>
<th>Film thickness µm max.</th>
<th>Acid-soluble arsenic content mg/kg max.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type I, Class 1</td>
<td>4</td>
<td>10</td>
<td>35</td>
<td></td>
<td>N/A*</td>
<td>25</td>
<td>2</td>
</tr>
<tr>
<td>Type I, Class 2 Penetration at 1 h</td>
<td>N/A*</td>
<td></td>
<td>N/A*</td>
<td></td>
<td>N/A*</td>
<td>25</td>
<td>2</td>
</tr>
<tr>
<td>Type II</td>
<td>4</td>
<td>10</td>
<td>35</td>
<td></td>
<td>1,5</td>
<td>25</td>
<td>2</td>
</tr>
<tr>
<td>Type III</td>
<td>3</td>
<td>10</td>
<td>25</td>
<td></td>
<td>1,5</td>
<td>N/A*</td>
<td>2</td>
</tr>
<tr>
<td>Type IV</td>
<td>4</td>
<td>10</td>
<td>5</td>
<td></td>
<td>1,5</td>
<td>N/A*</td>
<td>2</td>
</tr>
</tbody>
</table>

N/A* not applicable.

4.2 Biocompatibility

Guidance on biocompatibility is given in ISO 10993-1 and ISO 7405 (see Bibliography).

5 Sampling

The test sample shall consist of packages prepared for retail sale from the same batch containing enough material to carry out the specified tasks plus an allowance for repeats.

6 Test methods

6.1 Preparation of test specimens

Prepare the test material in accordance with the manufacturer's instructions (7.2)

Prepare all specimens at (23 ± 1) °C and a relative humidity of (50 ± 5) %. Before the start of mixing, condition the test samples and apparatus in these conditions for at least 1 h.

Prepare the cement according to the manufacturer's instructions. Mix sufficient cement to ensure that the preparation of each specimen is completed from one mix. Prepare a fresh mix for each specimen.

6.2 Determination of setting time

6.2.1 Apparatus

6.2.1.1 Cabinet, capable of being maintained at a temperature of (37 ± 1) °C and a relative humidity not less than 95 %.

6.2.1.2 Indenter needle.