



SLOVENSKI STANDARD
SIST EN ISO 9917-1:2004
01-februar-2004

Dentistry - Water-based cements - Part 1: Powder/liquid acid-base cements (ISO 9917-1:2003)

Dentistry - Water-based cements - Part 1: Powder/liquid acid-base cements (ISO 9917-1:2003)

Zahnheilkunde - Wasserhärtende Zemente - Teil 1: Zemente, die beim Vermischen von Pulver und Flüssigkeit über eine Säure-Base-Reaktion abbinden (ISO 9917-1:2003)

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Art dentaire - Ciments a base d'eau - Partie 1: Ciments acido-basiques liquides/en poudre (ISO 9917-1:2003)

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English version

Dentistry - Water-based cements - Part 1: Powder/liquid acid-
base cements (ISO 9917-1:2003)

Art dentaire - Ciments à base d'eau - Partie 1: Ciments
acido-basiques liquides/en poudre (ISO 9917-1:2003)

Zahnheilkunde - Wasserhärtende Zemente - Teil 1:
Zemente, die beim Vermischen von Pulver und Flüssigkeit
über eine Säure-Base-Reaktion abbinden (ISO 9917-
1:2003)

This European Standard was approved by CEN on 3 October 2003.

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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 Management Centre has the same status as the official versions.

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

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Foreword

This document (EN ISO 9917-1:2003) 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of an identical text or by endorsement, at the latest by May 2004, and conflicting national standards shall be withdrawn at the latest by May 2004.

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

Endorsement notice

The text of ISO 9917-1:2003 has been approved by CEN as EN ISO 9917-1:2003 without any modifications.

NOTE Normative references to International Standards are listed in Annex ZA (normative).

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Annex ZA (normative)

Normative references to international publications with their relevant European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

NOTE Where an International Publication has been modified by common modifications, indicated by (mod.), the relevant EN/HD applies.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN</u>	<u>Year</u>
ISO 3696	1987	Water for analytical laboratory use – Specification and test methods	EN ISO 3696	1995
ISO 7491	2000	Dental materials - Determination of colour stability	EN ISO 7491	2000

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**Dentistry — Water-based cements —
Part 1:
Powder/liquid acid-base cements**

Art dentaire — Ciments à base d'eau —

Partie 1: Ciments acido-basiques liquides/en poudre

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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

ISO 9917-1 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 1, *Filling and restorative materials*.

This part of ISO 9917 cancels and replaces ISO 9917:1991, which has been technically revised.

ISO 9917 consists of the following parts, under the general title *Dental materials — Water-based cements*:

- *Part 1: Powder/liquid acid-base cements* [SIST EN ISO 9917-1:2004](https://standards.iteh.ai/catalog/standards/sist/48272732-feb5-4c91-9dea-250006714b96/sist-en-iso-9917-1-2004)
- *Part 2: Light-activated cements* [250006714b96/sist-en-iso-9917-1-2004](https://standards.iteh.ai/catalog/standards/sist/48272732-feb5-4c91-9dea-250006714b96/sist-en-iso-9917-1-2004)

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Dentistry — Water-based cements —

Part 1: Powder/liquid acid-base cements

1 Scope

This part of ISO 9917 specifies requirements and test methods for powder/liquid acid-base dental cements intended for permanent cementation, lining and restoration. It is applicable to both hand-mixed cements and encapsulated cements for mechanical mixing. It specifies limits for each of the properties according to whether the cement is intended for use as a luting agent, a base or liner, or a restorative material.

Specific qualitative and quantitative requirements for freedom from biological hazard are not included in this part of ISO 9917, but it is recommended that, in assessing possible biological or toxicological hazards, reference should be made to ISO 7405, *Dentistry — Preclinical evaluation of biocompatibility of medical devices used in dentistry — Test methods for dental materials*, and ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing*.

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2 Normative references

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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 3665, *Photography — Intra-oral dental radiographic film — Specification*

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

ISO 7491, *Dental materials — Determination of colour stability*

3 Terms and definitions

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

3.1

mixing time

that part of the working time required in order to obtain a satisfactory mix of the components

3.2

working time

period of time, measured from the start of mixing, during which it is possible to manipulate a dental material without an adverse effect on its properties

3.3 net setting time
period of time, measured from the end of mixing, until the material has set according to the criteria and conditions specified in Annex A

NOTE For the purposes of this part of ISO 9917, in view of the wide variation in mixing times of cements, the net setting time is determined from the end of mixing.

4 Classification

4.1 Chemical type

For the purposes of this part of ISO 9917, dental cements shall be classified on the basis of their chemical composition, as follows:

- a) zinc phosphate cement, see Clause B.1;
- b) zinc polycarboxylate cement, see Clause B.2;
- c) glass polyalkenoate cement, see Clause B.3.

Acid-base setting, water-based cements other than those listed above may fall within the scope of this part of ISO 9917. If the manufacturer wishes to claim conformity for a particular product, the manufacturer shall specify the type of material in accordance with 4.1 and 4.2 so that the correct performance limits are applied.

4.2 Application

For the purposes of this part of ISO 9917, materials shall be classified on the basis of their usage as follows:

- a) luting cements;
- b) bases or liners;
- c) restorative cements.

5 Material

5.1 General

The cement shall consist of a powder and liquid which, when mixed in accordance with the manufacturer's instructions, shall conform with the requirements in this clause and in Clauses 8 to 15.

5.2 Components

5.2.1 Liquid

For non-encapsulated cements, visually inspect the liquid. It shall be free from deposits or filaments on the inside of its container. There shall be no visible signs of gelation.

5.2.2 Powder

For non-encapsulated cements, visually inspect the powder. It shall be free from extraneous material. If the powder is coloured, the pigment shall be uniformly dispersed throughout the powder.

Encapsulated cements shall not be examined in this way.