



SLOVENSKI STANDARD

SIST EN ISO 9917-1:2008

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Dentistry - Water-based cements - Part 1: Powder/liquid acid-base cements (ISO 9917-1:2007)

Zahnheilkunde - Wasserhärtende Zemente - Teil 1: Zemente, die beim Vermischen von Pulver und Flüssigkeit über eine Säure-Base-Reaktion abbinden (ISO 9917-1:2007)

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Art dentaire - Ciments à base d'eau - Partie 1: Ciments acido-basiques liquides/en poudre (ISO 9917-1:2007)

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English Version

Dentistry - Water-based cements - Part 1: Powder/liquid acid-
base cements (ISO 9917-1:2007)

Art dentaire - Ciments à base d'eau - Partie 1: Ciments
acido-basiques liquides/en poudre (ISO 9917-1:2007)

Zahnheilkunde - Wasserhärtende Zemente - Teil 1:
Zemente, die beim Vermischen von Pulver und Flüssigkeit
über eine Säure-Base-Reaktion abbinden (ISO 9917-
1:2007)

This European Standard was approved by CEN on 8 October 2007.

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 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 Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, 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 United Kingdom.

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

Management Centre: rue de Stassart, 36 B-1050 Brussels

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Foreword

This document (EN ISO 9917-1:2007) 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 2008, and conflicting national standards shall be withdrawn at the latest by April 2008.

This document supersedes EN ISO 9917-1:2003.

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, 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.

Endorsement notice

The text of ISO 9917-1:2007 has been approved by CEN as a EN ISO 9917-1:2007 without any modification.

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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 second edition cancels and replaces the first edition (ISO 9917-1:2003), of which it constitutes a minor revision.

The main purpose for modification of this part of ISO 9917 was to include a new test method for acid erosion, a new test and requirement for radio-opacity and to distinguish between the requirements for manufacturer's instructions for hand-mixed cements and those for capsulated cements.

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 and ISO 10993-1.

A bibliography has been added to this document.

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

- *Part 1: Powder/liquid acid-base cements*
- *Part 2: Light-activated cements*

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. This part of ISO 9917 is applicable to both hand-mixed and capsulated cements for mechanical mixing. This part of ISO 9917 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 as a restorative material. This part of ISO 9917 is not intended to address resin-modified water-based cements.

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 3665:1996, *Photography — Intra-oral dental radiographic film — Specification*

ISO 3696:1987, *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 such a product, the type of material for which equivalence of properties is claimed shall be specified 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, the application of water-based cements shall be classified as follows:

- a) luting;
- b) bases or lining;
- c) restoration.

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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 to requirements in this clause and Clause 8.

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.

5.3 Unset cement

The cement shall be mixed in accordance with Clause 6, and then visually inspected. It shall be homogeneous and of a smooth consistency.