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**Dentistry — Polymer-based filling,  
restorative and luting materials**

*Art dentaire — Produits d'obturation, de restauration et de scellement à  
base de polymères*

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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 3.

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 International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 4049 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 1, *Filling and restorative materials*.

This third edition cancels and replaces the second edition (ISO 4049:1988), which has been technically revised to include those polymer-based restorative materials (inlay/onlay materials) that are processed outside the mouth, in either the dental operator or laboratory. These have been added as Class 2, group 2 materials in a redesigned Classification (see clause 4). Materials that cure by both chemical means and external energy application (dual cure materials) have also been added to the Classification as Class 3 materials.

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## Introduction

This International Standard now includes requirements for materials intended for the restoration of occlusal surfaces (type 1 materials). It does not cover materials intended to prevent caries (see ISO 6874) or those used for veneering metal sub-frames (see ISO 10477). The broad group of polymeric restorative materials that is covered by this standard is subject to rapid developments and during the drafting of this standard several new types of material have been marketed. These include “condensable” and “flowable” composites and “ormocers”. The manufacturers of such materials have the option of claiming compliance with this standard but it should be noted that the materials were not included in any collaborative testing during the preparation of this standard.

Also, this International Standard now includes requirements for polymer-based luting materials that are intended for cementing of restorations and appliances such as inlays, onlays, crowns and bridges. This has resulted in new tests and requirements for the working time and film thickness of luting materials.

In comparison with ISO 4049:1988, alterations have been made to the requirements for flexural properties (see 5.2.9) and water sorption (see 5.2.10). These requirements have been changed following collaborative testing and review of published data.

Changes have been made to the test methods for water sorption and solubility (see 7.12) and radio-opacity (see 7.14.) in order to clarify simplify and improve the accuracy of these tests.

Specific qualitative and quantitative requirements for freedom from biological hazard are not included in this International Standard, but it is recommended that when assessing possible biological or toxicological hazards reference should be made to ISO 10993-1 and ISO 7405.

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# Dentistry — Polymer-based filling, restorative and luting materials

## 1 Scope

This International Standard specifies requirements for dental polymer-based filling and restorative materials and polymer-based luting materials supplied in a form suitable for mechanical mixing, hand-mixing, or intra-oral and extra-oral external energy activation, and intended for use primarily for the direct or indirect restoration of cavities in the teeth.

The luting materials covered by this International Standard are intended for use in the cementing or fixation of restorations and appliances such as inlays, onlays, veneers, crowns and bridges.

This International Standard does not cover requirements for polymeric materials intended for veneering indirectly restoration metal sub-frames (see ISO 10477) and materials intended to prevent caries (see ISO 6874).

## 2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

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

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

ISO 7491:1999, *Dental materials — Determination of colour stability of dental materials.*

ISO 8601:1988, *Data elements and interchange formats — Information interchange — Representation of dates and times.*

## 3 Terms and definitions

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

### 3.1

#### **opaquer luting material**

intensely pigmented polymer-based luting material intended to mask underlying tooth structure

### 3.2

#### **opaque**

shade of a polymer-based restorative material intended to be less translucent than a non-opaque shade

## 4 Classification

For the purposes of this International Standard, dental polymer-based restorative materials are categorized as one of the following types.

- a) **Type 1:** polymer-based filling and restorative materials claimed by the manufacturer as suitable for restorations involving occlusal surfaces;
- b) **Type 2:** all other polymer-based filling and restorative materials.

NOTE 1 It is not necessary to classify polymer-based luting materials into types.

The three classes of dental polymer-based filling, restorative and luting materials are as follows.

- **Class 1:** materials whose setting is effected by mixing an initiator and activator (“self-curing” materials).
- **Class 2:** materials whose setting is effected by the application of energy from an external source, such as blue light or heat (“external-energy-activated” materials). They are subdivided as follows:
  - 1) **Group 1:** materials whose use requires the energy to be applied intra-orally;
  - 2) **Group 2:** materials whose use requires the energy to be applied extra-orally. When fabricated, these materials will be luted into place.

Certain materials may be claimed by manufacturers to be both Group 1 and Group 2. In this event the material should fulfil the requirements for both groups.

NOTE 2 Class 2 luting materials will fall into Group 1 only.

- **Class 3:** materials that are cured by the application of external energy and also have a self-curing mechanism present [“dual cure” materials; see 8.3 e)].

## 5 Requirements

### 5.1 Biocompatibility

See the Introduction for guidance on biocompatibility. See ISO 7405 and ISO 10993-1 for further information.

### 5.2 Physical and chemical properties

#### 5.2.1 General

If a filling and restorative material is supplied by the manufacturer in various shades, each shade, including opaque shades, shall be capable of satisfying all the requirements for sensitivity to ambient light (5.2.7), depth of cure (5.2.8), shade (5.3) and colour stability (5.4) appropriate to the material type and class. If the material is supplied such that it can be “tinted” or “blended” to the user’s specification, the material shall comply with the requirements both when used alone and when used with the maximum recommended proportion of tint or blender [see 8.3 d)].

Similarly, if the manufacturer supplies a luting material in various shades, each shade, including opaquer luting materials, shall be capable of satisfying all the requirements for depth of cure (5.2.8). Colour stability (5.4) of luting materials shall not be tested unless the manufacturer claims such a property.



In respect of the other requirements of 5.2 and those of 5.5, only one representative shade of luting, filling and restorative materials shall be tested. This representative shade shall be either that classified by the manufacturer as “universal” or, in the event that no shade is so classified, that shade corresponding to “A3” in the Vita®<sup>1)</sup> classification of shade.

### 5.2.2 Film thickness of luting materials

The film thickness of luting materials when determined in accordance with 7.5 shall be no more than 10 µm above any value claimed by the manufacturer and in any event shall be no greater than 50 µm.

### 5.2.3 Working time, Class 1 and Class 3 filling and restorative materials

The working time for Class 1 and Class 3 filling and restorative materials, determined in accordance with 7.6, shall be not less than 90 s.

### 5.2.4 Working time, Class 1 and Class 3 luting materials

When tested in accordance with 7.7, the material shall be capable of forming a thin layer; during its formation there shall be no detectable change in its homogeneity.

### 5.2.5 Setting time, Class 1 materials

The setting time for Class 1 filling and restorative materials, determined in accordance with 7.8, shall be not more than 5 min. The setting time for Class 1 luting materials, determined in accordance with 7.8, shall be not more than 10 min.

### 5.2.6 Setting time, Class 3 materials

The setting time for Class 3 materials, determined in accordance with 7.8, shall be not more than 10 min.

### 5.2.7 Sensitivity to ambient light, Class 2 materials

When tested in accordance with 7.9, the material shall remain physically homogeneous.

### 5.2.8 Depth of cure, Class 2 materials

When determined in accordance with 7.10, the depth of cure of Class 2 filling and restorative materials shall be not less than 1 mm if they are labelled by the manufacturer as opaque, or not less than 1,5 mm for other filling and restorative materials.

The depth of cure of luting materials when determined in accordance with 7.10 shall not be less than 0,5 mm if they are labelled by the manufacturer as opaquer materials, or not less than 1,5 mm for other materials.

In any event, the values for all materials, with the exception of opaquer luting materials, shall be no more than 0,5 mm below the value stated by the manufacturer.

### 5.2.9 Flexural strength, type 1 and type 2 materials

The flexural strength of type 1 and type 2 materials, determined in accordance with 7.11, shall be equal to or greater than the limits specified in Table 1.

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1) Vita® is the trade name of a product supplied by Vita Zahnfabrik, H. Rauter GmbH & Co. KG, Postfach 1338, D-79704 Bad Säckingen, Germany. This information is given for the convenience of the users of this International Standard and does not constitute an endorsement of this product by ISO.

**Table 1 — Minimum flexural strength**

<b>Type 1</b>	Class 1	80 MPa
	Class 2, group 1	80 MPa
	Class 2, group 2	100 MPa
	Class 3	80 MPa
<b>Type 2</b>	Class 1	50 MPa
	Class 2, group 1	50 MPa
	Class 3	50 MPa

### 5.2.10 Water sorption and solubility

When determined in accordance with 7.12:

- a) the water sorption of all materials shall be less than or equal to 40 µg/mm<sup>3</sup>.
- b) the solubility of all materials shall be less than or equal to 7,5 µg/mm<sup>3</sup>.

### 5.3 Shade, filling and restorative materials

When the material is assessed in accordance with 7.13 and ISO 7491, the shade of the set material shall match closely that of the manufacturer's shade guide. If a shade guide is not supplied by the manufacturer, then the manufacturer shall nominate a commercially available shade guide that shall be used in assessing compliance with this requirement [see 8.3 l)]. In addition, the set material shall be evenly pigmented when viewed without magnification.

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### 5.4 Colour stability after irradiation and water sorption

When the material is tested in accordance with 7.13 and ISO 7491, no more than a slight change in colour shall be observed for filling and restorative materials. In respect of luting materials, colour stability shall be tested only in the event of a manufacturer's claim for colour stability. In the event of such a claim, no more than a slight change in colour shall be observed after the material has been tested in accordance with 7.13 and ISO 7491.

### 5.5 Radio-opacity

If the manufacturer claims that the material is radio-opaque [see 8.2.3 h)], the radio-opacity, determined in accordance with 7.14, shall be equal to or greater than that of the same thickness of aluminium and no less than 0,5 mm of any value claimed by the manufacturer. In the event of a dispute regarding the compliance of a material with this requirement, Method A (7.14.2, 7.14.3, 7.14.4) shall be used.

**Table 2 — Physical and chemical property requirements 5.2.3, 5.2.5, 5.2.6, 5.2.8, 5.2.10 for filling and restorative materials (see Table 1 for minimum flexural strength)**

Material Class	Requirement (subclause)				
	Working time (5.2.3) s min.	Setting time (5.2.5, 5.2.6) min max.	Depth of cure <sup>a</sup> (5.2.8) mm min.	Water sorption (5.2.10) $\mu\text{g}/\text{mm}^3$ max.	Solubility (5.2.10) $\mu\text{g}/\text{mm}^3$ max.
Class 1	90	5 (5.2.5)	—	40	7,5
Class 2	—	—	1 (opaque shade) 1,5 (others)	40	7,5
Class 3	90	10 (5.2.6)	—	40	7,5

<sup>a</sup> The values for all materials shall be no more than 0,5 mm below the value stated by the manufacturer.

**Table 3 — Physical and chemical property requirements 5.2.2, 5.2.4, 5.2.5, 5.2.6, 5.2.8 5.2.10 for luting materials**

Material Class	Requirement (subclause)					
	Film thickness <sup>a</sup> (5.2.2) $\mu\text{m}$ max.	Working time (5.2.4) s min.	Setting time (5.2.5, 5.2.6) min max.	Depth of cure <sup>b</sup> (5.2.8) mm min.	Water sorption (5.2.10) $\mu\text{g}/\text{mm}^3$ max.	Solubility (5.2.10) $\mu\text{g}/\text{mm}^3$ max.
Class 1	50	60	10 (5.2.5)	—	40	7,5
Class 2	50	—	—	0,5 (opaquer) 1,5 (others)	40	7,5
Class 3	50	60	10 (5.2.6)	—	40	7,5

<sup>a</sup> The determined value shall be no more than 10  $\mu\text{m}$  above any value claimed by the manufacturer.

<sup>b</sup> The values for all materials, with exception of opaquer luting materials, shall be no more than 0,5 mm below the value stated by the manufacturer.

## 6 Sampling

The test sample shall consist of packages prepared for retail sale from the same batch and containing enough material to carry out the specified tests, plus an allowance for repeat tests, if necessary.

NOTE 50 g should be sufficient.

## 7 Test methods

### 7.1 General reagent — Water

For the tests use water prepared in accordance with ISO 3696 Grade 2.

## 7.2 Test conditions

Unless specified otherwise by the manufacturer, prepare and test all specimens at  $(23 \pm 1)$  °C. Control the relative humidity to ensure that it remains greater than 30 % at all times. If the material was refrigerated for storage, allow it to attain  $(23 \pm 1)$  °C.

For Class 3 materials, the tests for working time (see 7.6) and setting time (see 7.8) shall be performed in the absence of activating radiation. Ambient light, both natural and artificial, is capable of activating these materials. For good control the test should be performed in a dark room with any artificial light filtered by a yellow filter<sup>2)</sup>.

## 7.3 Inspection

Inspect visually to check that requirements specified in clause 8 have been met.

## 7.4 Preparation of test specimens

For the preparation of Class 2 and Class 3 materials, reference should be made to the manufacturer's instructions [see 8.3 e)] that state the external energy source or sources recommended for the materials to be tested. Care shall be taken to ensure that the source is in a satisfactory operating condition.

Mix or otherwise prepare the material in accordance with the manufacturer's instructions and the test conditions specified in 7.2.

Where fully cured specimens are required for testing (7.11 to 7.14), it is important to ensure that the specimens are homogeneous after removal from the mould. There should be no voids, clefts or air-blows present when viewed without magnification.

Some polymer-based materials, particularly certain luting materials, have a chemical affinity for base metals. This property creates difficulty when removing specimens from metal moulds. Reference shall be made to the information supplied by the manufacturer (see 8.3) regarding this property and, if it is claimed, moulds for the preparation of specimens of such materials may be made from non-metallic material such as high density polyethylene.

## 7.5 Measurement of film thickness of luting materials

### 7.5.1 Apparatus

**7.5.1.1 Two glass plates**, optically flat, square or circular, each having a contact surface area of  $(200 \pm 25)$  mm<sup>2</sup>. Each plate shall be of a uniform thickness of not less than 5 mm.

**NOTE** If it is desired to re-use the plates after testing, the glass surface may be coated with a release agent that has no effect on the film thickness of the material under test.

**7.5.1.2 Loading device** of the type illustrated in Figure 1, or an equivalent means, whereby a force of  $(150 \pm 2)$  N may be applied vertically to the specimen via the upper glass plate. In Figure 1, the anvil that is attached to the bottom of the rod shall be horizontal and parallel to the base. The load shall be applied smoothly and in such a manner that no rotation occurs.

**NOTE** A holder may be used to assist in the positioning of the plates. Such a device consists of a baseplate with three vertical pins to align circular plates or four pins to align square plates (see Figure 2).

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2) Polyester filter 101, Lee Filters, Andover, Hants, UK, is an example of a suitable product available commercially. This information is given for the convenience of the users of this International Standard and does not constitute an endorsement of this product by ISO.