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Dentistry — Polymer-based crown and veneering materials

Médecine bucco-dentaire — Produits à base de polymères pour couronnes et facettes

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthetic materials*.

This fourth edition cancels and replaces the third edition (ISO 10477:2018), which has been technically revised.

The main changes compared to the previous edition are as follows:

- missing exemption condition for opaque resin test specimens in line 6 of [Table 1](#) has been added;
- required number of specimen in [7.8](#) (Shade consistency and colour stability) has been corrected;
- several editorial changes to describe the procedures more precisely;
- addition of appropriate intervals for the storage times described in the procedures.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Specific qualitative and quantitative test methods for demonstrating freedom from unacceptable biological hazards are not included in this document, but it is recommended that, for the assessment of possible biological hazards, reference should be made to ISO 10993-1 and ISO 7405.

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Dentistry — Polymer-based crown and veneering materials

1 Scope

This document classifies polymer-based crown and veneering materials used in dentistry and specifies their requirements. It also specifies the test methods to be used to determine conformity to these requirements.

This document is applicable to polymer-based crown and veneering materials for laboratory-fabricated permanent veneers or crowns. It also applies to polymer-based dental crown and veneering materials for which the manufacturer claims adhesion to the substructure without macro-mechanical retention such as beads or wires.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 1942, *Dentistry — Vocabulary*

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

ISO 6344-1, *Coated abrasives — Grain size analysis — Part 1: Grain size distribution test*

ISO 6507-1, *Metallic materials — Vickers hardness test — Part 1: Test method*

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

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

ISO 22674, *Dentistry — Metallic materials for fixed and removable restorations and appliances*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

3.1

polymer-based crown and veneering material

composition of powders and liquids or pastes that may contain monomers, inorganic and/or polymeric fillers and that, when polymerized, is suitable for use as permanent dental veneers or crowns

Note 1 to entry: Polymerization is effected by mixing initiator(s) and activator(s) (“self-curing” materials) and/or by external energy activation [by heat (“heat-curing” materials), photoactivated materials, by visible light (“light-curing” materials) and/or by UV radiation].

Note 2 to entry: The polymer-based crown and veneering materials for laboratory-fabricated permanent veneers or crowns may or may not be attached to a substructure.

3.2

dentine resin

pigmented and slightly translucent *polymer-based crown and veneering material* (3.1) that simulates the natural appearance of dentine

3.3

enamel resin

translucent and slightly pigmented *polymer-based crown and veneering material* (3.1) that is packed in a layer over the dentine resin and that simulates the natural appearance of enamel

3.4

cervical resin

intensely pigmented and slightly translucent *polymer-based crown and veneering material* (3.1) with a colour that simulates the natural appearance of dentine of the cervical region of the tooth

3.5

opaque resin

intensely pigmented polymer-based crown and veneering material applied in thin layers with the purposes of completely masking the underlying material and bonding to it

Note 1 to entry: Therefore opaque resins are only required to fulfil the requirement 5.5.

4 Classification

The polymer-based crown and veneering materials described in this document shall be classified according to their activation system for polymerization.

- **Type 1:** polymer-based crown and veneering materials whose setting is effected by mixing initiator(s) and activator(s) (“self-curing” materials);
- **Type 2:** polymer-based crown and veneering materials whose setting is effected by the application of energy from an external source (“external-energy-activated” materials), such as heat and/or radiation (visible or UV range);
 - **Class 1:** polymer-based crown and veneering materials that do not contain a photo-polymerization initiator;
 - **Class 2:** polymer-based crown and veneering materials that contain a photo-polymerization initiator;
- **Type 3:** polymer-based crown and veneering materials whose setting is effected by mixing initiator(s) and activator(s) and also by the application of energy from an external source (“dual-cure” materials).

5 Requirements

5.1 General

The tests required for a crown and veneering material depend on the classification according to Type and Class.

See [Table 1](#) for the necessity of the specific tests described in [5.2](#) to [5.9](#).

Table 1 — Test protocol

Subclause	Property	Type 1	Type 2		Type 3
			Class 1	Class 2	
5.2	Depth of cure	—	—	+ ^a	—
5.3	Surface finish	+ ^a	+ ^a	+ ^a	+ ^a
5.4	Flexural strength	+ ^a	+ ^a	+ ^a	+ ^a
5.5	Bond strength	+	+	+	+
5.6 to 5.9	Water sorption, solubility, shade consistency, colour stability	+ ^a	+ ^a	+ ^a	+ ^a
+ carry out test; — do not test. ^a If the material is opaque resin, do not test.					

5.2 Depth of cure

5.2.1 General

Testing shall be carried out in accordance with [7.3](#).

5.2.2 Depth of cure, Type 2, Class 2 materials

For Type 2, Class 2 polymer-based crown and veneering materials, the hardness of the bottom surface shall be not less than 70 % of that of the top surface (see [Table 2](#)).

For Type 1, Type 2, Class 1 and Type 3 materials, no requirement is specified. This requirement is not applicable to opaque resins.

5.3 Surface finish

A test specimen polished in accordance with [7.4](#) shall have a glossy surface.

Testing shall be carried out in accordance with [7.4](#). This requirement is not applicable to opaque resins.

5.4 Flexural strength

The flexural strength shall be at least 50 MPa (see [Table 2](#)). This requirement is not applicable to opaque resins.

Testing shall be carried out in accordance with [7.5](#).

Table 2 — Physical and chemical requirements

Subclause	Property	Requirement
5.2	Depth of cure	Hardness of bottom surface ≥ 70 % of top surface
5.4	Flexural strength	≥ 50 MPa
5.5.1	Bond strength	≥ 5 MPa
5.5.2		≥ 80 % of the value claimed
5.6	Water sorption	≤ 40 $\mu\text{g}/\text{mm}^3$
5.7	Solubility	$\leq 7,5$ $\mu\text{g}/\text{mm}^3$

5.5 Bond strength

5.5.1 Special bonding system without macromechanical retention

If the manufacturer recommends a special bonding system without macromechanical retention, the strength of bond to the material used for the substructure shall be not less than 5 MPa (see [Tables 1](#) and [2](#)).

Testing shall be carried out in accordance with [7.6](#).

5.5.2 Values higher than 5 MPa

If the manufacturer claims a value higher than 5 MPa for the bond strength, then the bond strength shall be not less than 80 % of the value claimed.

Testing shall be carried out in accordance with [7.6](#).

5.6 Water sorption

The water sorption of the cured polymer-based crown and veneering material shall be not more than $40 \mu\text{g}/\text{mm}^3$ (see [Table 2](#)).

Testing shall be carried out in accordance with [7.7](#). This requirement is not applicable to opaque resins.

5.7 Solubility

The solubility in water of the cured polymer-based crown and veneering material shall be not more than $7,5 \mu\text{g}/\text{mm}^3$ (see [Table 2](#)).

Testing shall be carried out in accordance with [7.7](#). This requirement is not applicable to opaque resins.

5.8 Shade consistency

The colours of the cured polymer-based crown and veneering material from different batches (according to [6.1](#) and [6.2](#)) shall show no more than a slight difference with the colour indicated by the manufacturer.

Testing shall be carried out in accordance with [7.8](#) and ISO 7491. This requirement is not applicable to opaque resins.

5.9 Colour stability

The polymer-based crown and veneering material shall show no more than a slight change in colour.

Testing shall be carried out in accordance with [7.8](#) and ISO 7491. This requirement is not applicable to opaque resins.

5.10 Biocompatibility

See Introduction for guidance on biocompatibility.

6 Sampling

6.1 For all tests

The test sample shall consist of one or more packages of one selected shade, corresponding to the purpose of the test, from a single batch and contain sufficient (approximately 20 ml) material to carry out the specified tests, plus an allowance for any necessary repetition of tests.