



SLOVENSKI STANDARD
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Dentistry - Polymer-based crown and bridge materials (ISO 10477:2004)

Zahnheilkunde - Kronen- und Brückenkunststoffe (ISO 10477:2004)

Art dentaire - Produits a base de polymeres pour couronnes et ponts (ISO 10477:2004)

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Ta slovenski standard je istoveten z: EN ISO 10477:2004

ICS:

11.060.10 Z[à[c @ ã } ã ã æ ã ã ã ã Dental materials

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NORME EUROPÉENNE

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Dentistry - Polymer-based crown and bridge materials (ISO 10477:2004)

Art dentaire - Produits à base de polymères pour couronnes et ponts (ISO 10477:2004)

Zahnheilkunde - Kronen- und Brückenkunststoffe (ISO 10477:2004)

This European Standard was approved by CEN on 10 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.

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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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

EN ISO 10477:2004 (E)**Foreword**

This document (EN ISO 10477:2004) 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of an identical text or by endorsement, at the latest by April 2005, and conflicting national standards shall be withdrawn at the latest by April 2005.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 ISO 10477:1996.

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 10477:2004 has been approved by CEN as EN ISO 10477:2004 without any modifications.

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INTERNATIONAL
STANDARD

ISO
10477

Second edition
2004-10-01

**Dentistry — Polymer-based crown and
bridge materials**

Art dentaire — Produits à base de polymères pour couronnes et ponts

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Reference number
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ISO 10477:2004(E)**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 10477 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthetic materials*.

This second edition cancels and replaces the first edition (ISO 10477:1992), which has been technically revised. It also incorporates the amendment ISO 10477:1992/Amd.1:1998.

The following changes were made:

- a) addition of a bonding test, <https://standards.iteh.ai/catalog/standards/sist/eb2df457-caac-45ba-97a1-9eaacd8b50cd/sist-en-iso-10477-2005>
- b) addition of a table for the test protocol and two tables of results.

Introduction

Specific qualitative and quantitative requirements for freedom from biological hazards are not included in this International Standard. Assessment of possible biological hazards is covered in ISO 10993-1 and ISO 7405.

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Dentistry — Polymer-based crown and bridge materials

1 Scope

This International Standard classifies polymer-based dental crown and bridge materials and specifies their requirements. It also specifies the test methods to be used to determine compliance with these requirements.

This International Standard is applicable to polymer-based dental crown and bridge materials for laboratory-fabricated permanent facings or anterior crowns that may or may not be attached to a metal substructure. It also applies to polymer-based dental crown and bridge materials for which the manufacturer claims adhesion to the metal substructure without macromechanical retention such as beads or wires.

This International Standard is not applicable to polymer-based materials that are used to make crowns, veneers or repairs in the operatory, nor does it cover the application of those materials to stress-bearing areas of posterior teeth.

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.

- SIST EN ISO 10477:2005
<http://www.iso.org/standards/catalog/standards/sist/eb2df457-caac-45ba-97a1-9eaacd8b50cd/sist-en-iso-10477-2005>
- ISO 1562, *Dentistry — Casting gold alloys*
- ISO 3696:1987, *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 8891, *Dental casting alloys with noble metal content of at least 25 % but less than 75 %*

3 Terms and definitions

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

3.1

polymer-based crown and bridge material

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

NOTE 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].

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3.2 dentine resin
pigmented and slightly translucent polymer-based crown and bridge material that simulates the natural appearance of dentine

3.3 enamel resin
translucent and slightly pigmented polymer-based crown and bridge material 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 bridge material 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 bridge material for masking the underlying metal substructure

4 Classification

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

- **Type 1** polymer-based crown and bridge materials whose setting is effected by mixing initiator(s) and activator(s) (“self-curing” materials);
- **Type 2** polymer-based crown and bridge materials whose setting is effected by the application of energy from an external source (“external-energy-activated” materials), such as heat and/or light or UV radiation;
 - **Class 1** polymer-based crown and bridge materials that do not contain a light or UV-sensitive initiator;
 - **Class 2** polymer-based crown and bridge materials that contain a light or UV-sensitive initiator;
- **Type 3** polymer-based crown and bridge 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 Biocompatibility**

See the Introduction for guidance on biocompatibility.

5.2 Sensitivity to ambient light, Type 2, Class 2 polymer-based crown and bridge materials

The polymer-based crown and bridge materials Type 2, Class 2 shall remain physically homogeneous when exposed to ambient light (see Table 1).

Testing shall be carried out in accordance with 7.3.

NOTE For Type 1, Type 2, Class 1 and Type 3 materials, no requirement is specified.