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Dentistry - Polymer-based crown and veneering materials (ISO 10477:2018)

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ICS 11.060.10

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10477

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English Version

Dentistry - Polymer-based crown and veneering materials (ISO 10477:2018)

Médecine bucco-dentaire - Produits à base de polymères pour couronnes et facettes (ISO 10477:2018)

Zahnheilkunde - Kronen- und Verblendkunststoffe (ISO 10477:2018)

This European Standard was approved by CEN on 13 May 2018.

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European foreword

This document (EN ISO 10477:2018) 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of an identical text or by endorsement, at the latest by January 2019, and conflicting national standards shall be withdrawn at the latest by January 2019.

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Endorsement notice

The text of ISO 10477:2018 has been approved by CEN as EN ISO 10477:2018 without any modification.

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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, *Prosthodontic materials.*

This third edition cancels and replaces the second edition (ISO 10477:2004), which has been technically revised.

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

— the limitation to anterior crowns has been deleted;

— the limitation to metal substructure has been deleted;

— the test for ambient light testing has been deleted.

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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

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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:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at https://www.iso.org/obp

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.

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