Form 36

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Interested committees:

Title: Draft BS EN ISO 10477 Dentistry - Polymer-based crown and veneering materials.

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Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

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Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx

1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex **(e.g. 3.1)**	Paragraph/ Figure/Table/Note	**Type of comment**	**Commend (justification for change) by the MB**	**Proposed change by the MB**	**Secretariat observations on each comment submitted**
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	

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DRAFT International Standard

ISO/DIS 10477

Dentistry — Polymer-based crown and veneering materials

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

ICS: 11.060.10

ISO/TC **106**/SC **2**

Secretariat: **ANSI**

Voting begins on:
2025-03-10

Voting terminates on:
2025-06-02

This document is circulated as received from the committee secretariat.

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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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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*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This fifth edition cancels and replaces the fourth edition (ISO 10477:2020), which has been technically revised.

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

— addition of printed materials in Clause 4 as Type 2 Class 3;

— addition of milled materials in Clause 4 as Type 4.

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.

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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

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 6344-2, *Coated abrasives — Determination and designation of grain size distribution — Part 2: Macrogrit sizes P12 to P220*

ISO 6344-3, *Coated abrasives — Determination and designation of grain size distribution — Part 3: Microgrit sizes P240 to P5000*

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

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

ISO 7500-1, *Metallic materials — Calibration and verification of static uniaxial testing machines — Part 1: Tension/compression testing machines — Calibration and verification of the force-measuring system*

ISO 8601-1, *Date and time — Representations for information interchange — Part 1: Basic rules*

ISO 18739, *Dentistry — Vocabulary of process chain for CAD/CAM systems*

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

ISO/ASTM 52900:2021, *Additive manufacturing — General principles — Fundamentals and vocabulary*

ISO 5139, *Dentistry — Polymer-based composite machinable blanks*

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 http://www.iso.org/obp

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

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3.1
polymer-based crown and veneering material
composition of powders, liquids, pastes (after full polymerization) or polymerized discs or blocks (already polymerized by the manufacturer) that may contain monomers, inorganic and/or polymeric fillers 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 simulates the natural appearance of enamel

3.4
cervical resin
intensely pigmented and slightly translucent *polymer-based crown and veneering material* (3.1) 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* (3.1) applied in thin layers with the purposes of completely masking the underlying material and bonding to it

Note 1 to entry: Opaque resins are only required to fulfil the requirement of 5.5.

3.6
milling
synonym subtractive manufacturing: process of machining, grinding, or reducing a larger bulk object to create a smaller detailed three-dimensional object using CAD/CAM methods

Note 1 to entry: The term milling is used in this document as it is a common term in dental technology and clinical dentistry for the processing of these materials

3.7
printing
synonym additive manufacturing: process in which a liquid photopolymer in a *vat* (3.8) is selectively cured by light-activated polymerization. The liquid photopolymer may contain fillers.

Note 1 to entry: The term printing is used in this document as it is a common term in dental technology and clinical dentistry for the processing of these materials

3.8
vat
small tub, part of the polymerization device that contains the liquid photopolymer.

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);

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