International Standard

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

The main changes are as follows:

— materials for additive manufacturing have been added to Clause 4 as type 2 class 3;

— materials for subtractive manufacturing have been added to Clause 4 as type 4;

— editorial updates have been made.

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, for the assessment of possible biological hazards, reference should be made to ISO 10993-1 [1] and ISO 7405 [2].

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

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

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*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942, ISO 18739 as well as the following apply.

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

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

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

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3.1
polymer-based crown and veneering material
dental material supplied as a composite of powders and liquids or pastes that can contain monomers, either inorganic fillers or polymeric fillers, or both, or pre-polymerized blocks or discs that can contain polymers and inorganic fillers, and that, when polymerized or processed, is suitable for use as permanent dental veneers or crowns

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

Note 2 to entry: The polymer-based crown and veneering materials for laboratory-fabricated permanent veneers or crowns can be used without substructure or can be attached to a substructure.

3.2
dentine resin
pigmented and slightly translucent *polymer-based crown and veneering material* (3.1) used to simulate the natural appearance of the dentine in a resin-based restoration or dental prosthesis

3.3
enamel resin
translucent, lightly pigmented *polymer-based crown and veneering material* (3.1) used to simulate the natural appearance of enamel, including the incisal portion of a resin-based restoration or dental prosthesis

3.4
cervical resin
intensely pigmented slightly translucent *polymer-based crown and veneering material* (3.1) having colours simulating those of cervical parts of natural teeth

3.5
opaque resin
polymer-based crown and veneering material (3.1) which, when applied to a substructure in accordance with the manufacturer's instructions, bonds to the surface and forms a layer that masks the underlying colour

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

3.6
subtractive manufacturing
milling
process of machining, grinding or reducing a larger bulk object to create a smaller detailed three-dimensional object using computer-aided design software and computer-aided manufacturing methods

Note 1 to entry: The term *milling* (3.6) 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
additive manufacturing
AM
printing
process of joining materials to make parts from 3D model data, usually layer upon layer, as opposed to *subtractive manufacturing* (3.6) and formative manufacturing methodologies

Note 1 to entry: The term *printing* (3.7) is used in this document as it is a common term in dental technology and clinical dentistry for the processing of these materials.

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3.8
vat photopolymerization
VPP
additive manufacturing (3.7) process in which liquid photopolymer in a *vat* (3.9) is selectively cured by photo-activated polymerization

Note 1 to entry: The liquid photopolymer can consist of monomers and photo-polymerization initiators and contain fillers.

Note 2 to entry: The term *printing* (3.7) can be used instead of the term *vat photopolymerization* (3.8) in dental technology and clinical dentistry for the processing of these materials.

3.9
vat
small tub, part of the polymerization device that contains the liquid photopolymer

3.10
computer-aided milling machine
computer-aided machining device designed for *subtractive manufacturing* (3.6) of dental restorations and dental prostheses using rotary instruments for cutting and grinding

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), e.g. heat or radiation (visible or UV range) or both;

  — 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 photopolymerization initiator and are not intended for additive manufacturing (printing);

  — Class 3: polymer-based crown and veneering materials that are intended for additive manufacturing, e.g. vat photopolymerization (printing);

— Type 3: polymer-based crown and veneering materials whose setting is affected by mixing initiator(s) and activator(s) and also by the application of energy from an external source (“dual-cure” materials);

— Type 4: polymer-based crown and veneering materials that are intended for subtractive manufacturing (e.g. milling).

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.

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