



SLOVENSKI STANDARD
oSIST prEN ISO 5139:2022
01-april-2022

Zobozdravstvo - Polimerni kompozitni polizdelki, ki jih je mogoče obdelovati
(ISO/DIS 5139:2022)

Dentistry - Polymer-based composite machinable blanks (ISO/DIS 5139:2022)

Zahnheilkunde - Maschinell bearbeitbare Rohlinge aus Kompositen auf Polymerbasis
(ISO/DIS 5139:2022)

Médecine bucco-dentaire - Ébauches usinables en composite à base de polymères
(ISO/DIS 5139:2022)

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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 of 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 www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 9, *Dental CAD/CAM system*.

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.

Requirements for the materials properties of polymer-based composite machinable blanks are not included in this document, but these requirements will be included in a revision of ISO 10477, Dentistry–Polymer-based crown and veneering materials.

The test method to determine the bonding properties between blank and holding jig and the test method to determine shear bond strength to milled blank surface are not included in this document, but it is recommended to adopt the test procedure given in [Annex C](#) and D when measuring these properties. They will be included in a revision of this document when information becomes available to Technical Committee ISO/TC 106/SC 9.

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Dentistry — Polymer-based composite machinable blanks

1 Scope

This document specifies the characteristics of polymer-based composite machinable blanks with respect to the milling process, and provides the test methods that address the clinical issues specific to those materials. In addition, it specifies the items to be described on the packaging and materials, as well as descriptions to be included in the instructions for use.

The polymer-based composite machinable blanks that this document covered are blanks that are used for fabricating dental restorative appliances (e.g. single crowns or inlays) by milling processes. They do not include large-sized blanks (e.g. discs) that allow for fabrication of two or more units of crowns or bridges from one blank.

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 4049, *Dentistry — Polymer-based restorative materials*

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

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/FDIS 18675:2021, *Dentistry — Machinable ceramic 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 <https://www.iso.org/obp>

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

3.1

polymer-based composite machinable blanks

piece of solid *polymer-based composite* (3.2) that is subjected to subtractive methods to remove material from the piece leaving the final desired part

3.2

polymer-based composite

polymer-based dental material including either organic filler or inorganic filler, or both fillers that have been treated by a coupling agent to ensure chemical bonding with the polymeric matrix

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3.3 holding jig mandrel

jig attaching a composite resin block to be mounted for milling machine

4 Characteristics

4.1 Requirement

Measure five product blanks in accordance with the method described in 6.2. The dimensions of all blanks shall not be smaller than 0,25 mm nor larger than 1,00 mm than the size specified in 8 d).

4.2 Recommendations

4.2.1 Machining damage

The machining damage of blanks should be evaluated in accordance with the methods described in 6.3.

4.2.2 Machinability

The machinability of blanks can be evaluated using the test method for merlon fracture test given in ISO/FDIS 18675, 8.

4.2.3 Bonding properties between blank and holding jig

The bonding properties between blank and holding jig should be evaluated. An example of the test method for bonding properties is described in Annex C.

5 Sampling

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

6 Test methods

6.1 General

Test specimens shall be prepared and tested at (23 ± 2) °C. The relative humidity shall be not less than 30 %.

6.2 Size of blanks

6.2.1 Apparatus

Micrometre, with an accuracy of 0,01 mm.

6.2.2 Procedure

Measure five blanks using a micrometre at the points where the size is specified by the manufacturer in the instructions for use 8 e).

6.3 Machining damage

6.3.1 General

Perform machining damage test according to the method described in ISO/FDIS 18675:2021, 7. Specifically, measure the three-point flexural strength for the control specimen fabricated by cutting and grinding and for the machined specimen fabricated using a milling machine, and compare the results between these specimens.

6.3.2 Apparatus

6.3.2.1 Oven, set at (37 ± 1) °C.

6.3.2.2 Universal mechanical testing machine, capable of a crosshead speed of $(1 \pm 0,5)$ mm/min and an ability to measure applied loads between 10 N and [1 000 N or 2 500 N] ;e.g. see ISO 7500-1

6.3.2.3 Fixture for three-point bending, consisting of support rollers $((1,5 \pm 0,2)$ mm to $(2 \pm 0,2)$ mm, in diameter) positioned with their centres $(12,0 \pm 0,1)$ mm apart. The load shall be applied at the midpoint between the supports by means of a third roller $((1,5 \pm 0,2)$ mm to $(2 \pm 0,2)$ mm, in diameter). Rollers shall be made from hardened steel or other hard material having a hardness greater than 40 HRC (Rockwell C-scale) and have a smooth surface with a roughness less than $0,5 \mu\text{m Ra}$. It is recommended to measure the actual spacing between the centres of the support rollers (l) to ensure it is $(12,0 \pm 0,5)$ mm.

6.3.2.4 Micrometre, with an accuracy of $0,01$ mm.

6.3.2.5 CAD/CAM milling machine

6.3.3 Water

Water shall conform to ISO 3696:1987, Grade 2.
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6.3.4 Preparation of test specimens

6.3.4.1 Test specimen dimensions

Width: $w = (4 \pm 0,2)$ mm (dimension of the side at right angles to the direction of the applied load)

Thickness: $b = (1,2 \pm 0,2)$ mm (dimension of the side parallel to the direction of the applied load)

Lengths shall be at least 2 mm longer than the test span $(12,0 \pm 0,1)$ mm.

When the edge chamfer is necessary, it shall be prepared in accordance with the method described in ISO 6872:2015, 7.3.1.2.1.

NOTE The dimensions of test specimen specified in this document are not verified for the measurement of flexural strength absolute values for composite resin materials. There are some published scientific papers that flexural strength test of composite machinable blanks were performed at this size.

6.3.4.2 Test parameters

Test span: $l = (12,0 \pm 0,5)$ mm (centre-to-centre distance between support rollers).