

**SLOVENSKI STANDARD**  
**oSIST prEN ISO 9693:2019**  
**01-april-2019**

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**Zobozdravstvo - Preskušanje združljivosti za kovinsko-keramične in keramično-keramične sisteme (ISO/DIS 9693:2019)**

Dentistry - Compatibility testing for metal-ceramic and ceramic-ceramic systems (ISO/DIS 9693:2019)

Zahnheilkunde - Kompatibilitätsprüfungen für metall-keramische und keramisch-keramische Systeme (ISO/DIS 9693:2019)

Médecine bucco-dentaire - Essais de compatibilité pour systèmes métalliques-céramiques et céramiques-céramiques (ISO/DIS 9693:2019)

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11.060.10      Zobotehnični materiali      Dental materials

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# DRAFT INTERNATIONAL STANDARD

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## Dentistry — Compatibility testing for metal-ceramic and ceramic-ceramic systems

*Médecine bucco-dentaire — Essais de compatibilité pour systèmes métalliques-céramiques et céramiques-céramiques*

ICS: 11.060.10

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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](http://www.iso.org/directives)).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see [www.iso.org/patents](http://www.iso.org/patents)).

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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](http://www.iso.org/iso/foreword.html).

This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthodontic materials*.

This document is the combination of ISO 9693-1:2012 and ISO 9693-2:2016 in one document. This document cancels and replaces the first edition (ISO 9693-1:2012) and the first edition (ISO 9693-2:2016), which has been technically revised.

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

- This document focuses only on the compatibility of veneering ceramics fired on to metallic or ceramic substrate materials. Tests of dental veneering ceramics themselves, whether for either metal or ceramic substructures, are now contained in ceramics standard ISO 6872.
- Some clauses are relevant for all materials (e.g. measurement of thermal expansion coefficients).
- The de-bonding test (formerly denoted the Schwickerath bond characterization test) for veneering ceramic fired to a substrate is retained for metallic substrates and for ceramic substrates with an elastic modulus less than 250 GPa.
- A new requirement was added for metal-ceramic systems to undergo thermal shock testing according to either of two protocols.

## Introduction

Dental veneering ceramics and metal alloys or substructure ceramics are suitable materials for the fabrication of dental restorations. Compatibility between the veneering ceramic and the substructure material under mechanical and thermal loading is essential if they are to function in a prosthetic construction.

This document specifies requirements and test methods for assessing the risk of failure associated with masticatory forces and the oral environment.

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# Dentistry — Compatibility testing for metal-ceramic and ceramic-ceramic systems

## 1 Scope

This document specifies requirements and test methods to assess the thermomechanical compatibility between a veneering ceramic and a metallic or ceramic substructure material used for dental restorations.

This document applies only to the materials when used in combination. Compliance cannot be claimed for a single material.

For requirements for ceramic materials, see ISO 6872. For requirements for metallic materials see ISO 22674.

## 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 6872:2015, *Dentistry — Ceramic materials*

ISO 7405, *Dentistry — Evaluation of biocompatibility of medical devices used in dentistry*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 22674:2016, *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 6872, ISO 22674 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 <http://www.electropedia.org/>

### 3.1

#### **veneering ceramic**

full structure of fired ceramic layers applied to a substrate material

### 3.2

#### **conditioning**

process of treating the substructure to enhance the bonding of the veneering ceramic

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## 3.3

**liner**

substance, applied to the substructure and fired under appropriate time-temperature conditions, with the purpose to improve aesthetics and/or adherence of the veneering ceramic to the coated substructure-surface

## 4 Requirements

### 4.1 Biocompatibility

Specific qualitative and quantitative test methods for demonstrating freedom from unacceptable biological risks are not included in this document, but it is recommended that, for the assessment of such biological risks, reference be made to ISO 10993-1 and ISO 7405.

### 4.2 Physical properties

#### 4.2.1 General

The individual component materials shall fulfil the requirements of ISO 6872 for ceramics or ISO 22674 for metallic materials. The materials shall also comply with the requirements of 4.2.2 to 4.2.4 where applicable.

NOTE In particular, the elastic modulus of the substrate material must be determined in order to interpret the measurements in the de-bonding test.

#### 4.2.2 Thermal expansion

The coefficients of thermal expansion of the substructure ceramic and the veneering ceramic shall be determined according to ISO 6872.

The coefficients of thermal expansion of the metallic substructure material shall be determined according to ISO 22674.

The same measurement protocol shall be used for both the veneering and substructure materials (e.g. same lowest temperature).

Test in accordance with 6.1.

NOTE The measured values for coefficients of linear thermal expansion are compared with the manufacturer's values as a means of quality control, but the values cannot provide an assurance that the ceramic or metallic substructure and ceramic veneer are compatible.

#### 4.2.3 De-bonding/crack-initiation test

##### 4.2.3.1 Metallic substructure material

The debonding/crack-initiation strength of the metallic substructure material and at least one, nominated selected dental veneering ceramic shall be greater than 25 MPa.

Test in accordance with 6.4.

##### 4.2.3.2 Ceramic substructure material

For ceramic-ceramic combinations this test shall be used for zirconia-veneering ceramic only.

The de-bonding/crack-initiation strength of the ceramic substrate material and at least one nominated dental veneering ceramic present shall be greater than 20 MPa.