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## Dentistry — Artificial teeth for dental prostheses

*Médecine bucco-dentaire — Dents artificielles pour prothèses  
dentaires*

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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)).

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

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

This second edition cancels and replaces the first edition (ISO 22112:2005), which has been technically revised.

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

- clarification of colour and blending requirement for multi-layered teeth ([5.1.3](#));
- clarification of test procedure for surface finishing ([7.5](#));
- for testing of radioactivity of ceramic teeth: gamma spectroscopy system is added ([7.8](#)).

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# Dentistry — Artificial teeth for dental prostheses

## 1 Scope

This document specifies the classification, requirements, and test methods for artificial teeth such as ceramic teeth and polymer teeth that are industrially manufactured for use in dental prostheses.

## 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 483, *Plastics — Small enclosures for conditioning and testing using aqueous solutions to maintain the humidity at a constant value*

ISO 1942, *Dentistry — Vocabulary*

ISO 3950, *Dentistry — Designation system for teeth and areas of the oral cavity*

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

ISO 6873:2013, *Dentistry — Gypsum products*

ISO 7491:2000, *Dental materials — Determination of colour stability*

ISO 20795-1, *Dentistry — Base polymers — Part 1: Denture base polymers*  
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## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 and ISO 20795-1 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 <http://www.iso.org/obp>

### 3.1

#### **artificial teeth**

manufactured product designed to simulate and replace natural teeth

### 3.2

#### **diatoric teeth**

teeth designed to be retained by anchorage slots and/or holes

### 3.3

#### **pin teeth**

teeth designed to be retained by headed pins

### 3.4

#### **set**

set of six anterior teeth or eight posterior teeth, as received from the manufacturer

**3.5  
half-set**

three teeth on one side of a set of anterior teeth or four teeth on one side of a set of posterior teeth

**3.6  
mould chart**

chart representing the form, shape and dimensions of all individual teeth of a set

## **4 Classification**

For the purposes of this document, artificial teeth are classified into the following types:

- Type 1: anterior teeth;
- Type 2: posterior teeth.

## **5 Requirements**

### **5.1 General**

#### **5.1.1 Biocompatibility**

Specific qualitative and quantitative requirements for freedom from biological hazard are not included in this document, but it is recommended that, in assessing possible biological or toxicological hazards, reference be made to ISO 10993-1 and ISO 7405.

#### **5.1.2 Dimensions of teeth**

The designation of the teeth shall be as given in ISO 3950.

The dimensions of the teeth when examined in accordance with 7.2 shall not differ by more than 5 % for polymer teeth and 7 % for ceramic teeth from the values shown in the manufacturer's mould chart.

#### **5.1.3 Colour and blending of shades**

When tested in accordance with 7.3, sets of anterior and posterior teeth shall exhibit no perceptible colour difference compared with the manufacturer's shade guide (8.2.2) or nominated shade guide. Multi-layered teeth shall show no line of demarcation between incisal and cervical portions on the facial aspects of the teeth.

NOTE This requirement is not intended to disallow especially designed demarcations placed to simulate borders of restorations or enamel imperfections found in natural teeth.

#### **5.1.4 Surface finish**

When inspected visually in accordance with 7.1, the teeth as received (excluding retention areas) shall have a smooth, lustrous, non-porous surface.

When ceramic teeth are tested in accordance with 7.4, the processing shall not have impaired the original finish of the teeth, and the teeth shall be capable of being ground and polished.

When polymer teeth are tested in accordance with 7.5, the teeth shall be capable of being polished to restore the original finish.



### 5.1.5 Porosity and other defects

Ceramic teeth shall not show more than a total of 16 pores of diameter greater than 30 µm on the four test surfaces when tested in accordance with 7.6. No more than six of those pores shall have diameters ranging from  $\geq 40$  µm and  $\leq 150$  µm. There shall be no pores of diameter greater than 150 µm.

Examine the ceramic teeth in accordance with 7.6.

Polymer teeth shall exhibit no porosity or defect, such as rough trimming, rough finish or visible impurities, on the coronal surfaces.

Examine the polymer teeth in accordance with 7.7.

## 5.2 Ceramic teeth

### 5.2.1 Radioactivity

When tested in accordance with 7.8, ceramic teeth shall have an activity concentration of no more than 1,0 Bq·g<sup>-1</sup> of uranium-238.

### 5.2.2 Anchorage

All ceramic diatoric teeth, examined in accordance with 7.9, shall provide a means of positive retention and have holes all of which shall be open and unsealed.

### 5.2.3 Resistance to thermal shock

Ceramic teeth shall, when tested in accordance with 7.10, show no signs of cracking.

## 5.3 Polymer teeth

### 5.3.1 Bonding to denture base polymer

All polymer teeth shall be capable of being bonded to heat-polymerizable denture-base materials which conform to ISO 20795-1. For five out of the six test specimens, the bond formed between the ridge lap portion of the teeth and the denture base polymer shall pass the test specified in 7.11.

NOTE Additional information for another bonding test between polymer teeth and denture base polymer is given in ISO/TS 19736.

### 5.3.2 Resistance to blanching, distortion and crazing

When tested in accordance with 7.12, no teeth shall exhibit blanching or distortion. No teeth shall exhibit crazing with the exception of the ridge lap surfaces and the cervical portion of the teeth up to the cervical line.

### 5.3.3 Colour stability

When tested in accordance with 7.13, there shall be no perceptible colour change between the exposed and unexposed halves of the tooth and the unexposed tooth.

### 5.3.4 Dimensional stability

When tested in accordance with 7.14, the dimensional change of a tooth shall be within  $\pm 2$  % of its original mesio-distal dimension.

## 6 Sampling

The sample shall consist of six groups, each comprising sets of mandibular and maxillary anterior and posterior teeth (if available).

For comparisons with the manufacturer's shade guide, all available shades of anterior teeth and five shades of available posterior teeth shades shall be included.

Five mould sizes shall be included covering the range of mould sizes shown by the manufacturer's mould chart. The teeth shall be representative of the physical dimensions of the brand and type.

## 7 Measurement and test methods

### 7.1 Visual inspection

Visually examine without magnification all the teeth in each set for compliance with the requirements given in [5.1.3](#) and [5.1.4](#).

### 7.2 Dimensions of teeth

#### 7.2.1 Reagents and/or materials

##### 7.2.1.1 Teeth sample (see [Clause 6](#)).

#### 7.2.2 Apparatus

##### 7.2.2.1 Micrometer, accurate to $\pm 0,01$ mm and fitted with parallel anvils.

##### 7.2.2.2 Mould chart.

#### 7.2.3 Procedure

[Figure 1](#) defines the symbols for the dimensions (given in parentheses as  $l_1$  to  $l_8$ ).

Use a micrometer ([7.2.2.1](#)) for the following measurements.

Measure the maximum mesio-distal dimension of each upper ( $l_1$ ,  $l_5$ ) and lower ( $l_3$ ,  $l_7$ ) set of teeth ([7.2.1.1](#)) in the in-line plane.

NOTE The numerical tooth designations (given in parentheses) are in accordance with ISO 3950.

Measure the maximum mesio-distal ( $l_2$ ,  $l_4$ ) and cervico-incisal ( $h_1$ ,  $h_2$ ) dimensions of the upper and lower left central incisors (21, 31), and the overall facio-lingual ( $l_6$ ,  $l_8$ ) dimensions of the crowns of the upper and lower left first molars (26, 36).

Check the measured values for conformity to the mould chart dimensions (see [5.1.2](#)).

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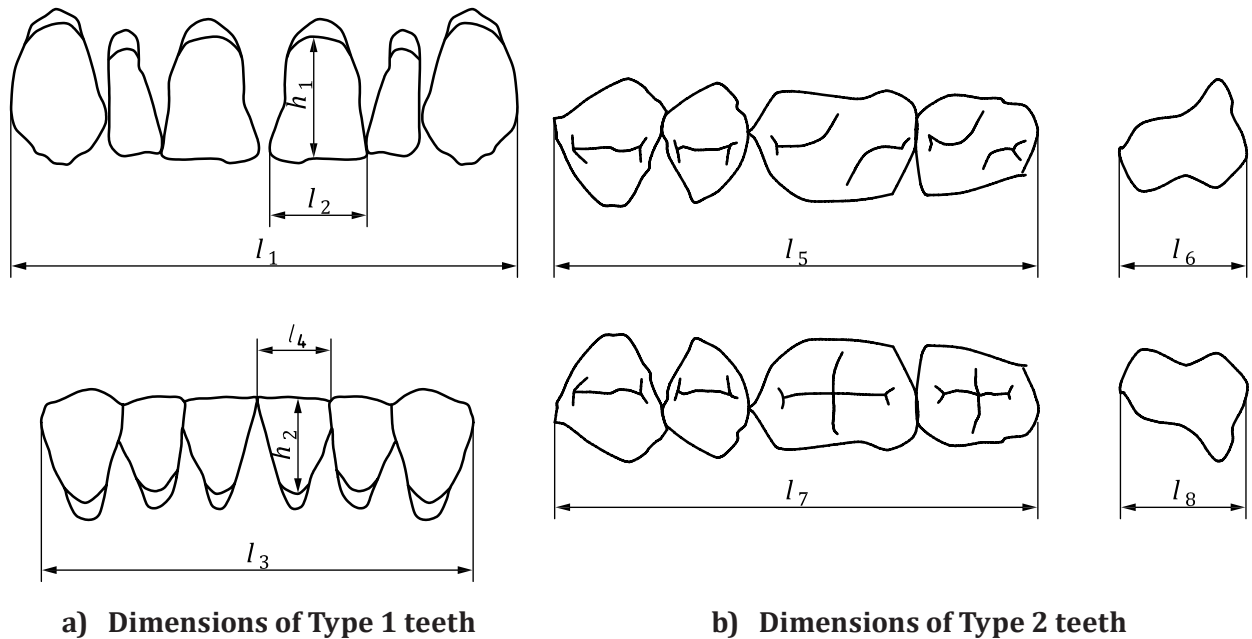


Figure 1 — Dimensions of teeth

### 7.3 Comparison with shade guide

#### 7.3.1 Reagents and/or materials

##### 7.3.1.1 Teeth sample (see Clause 6)

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#### 7.3.2 Apparatus

##### 7.3.2.1 Shade guide.

Select a maxillary central incisor of all available anterior shades and/or a maxillary premolar tooth (see Clause 6) from each of the five different posterior tooth shades for evaluation. Evaluate in accordance with ISO 7491:2000, 3.2.3. Compare the labial surfaces of each tooth to be tested to the shade guide by holding the tooth alongside and in the same plane as the corresponding shade guide tooth, with the test tooth first on one side of the shade guide tooth and then on the other.

If there is no perceptible colour difference, the tooth complies with 5.1.3.

### 7.4 Surface finish of ceramic teeth

#### 7.4.1 Reagents and/or materials

##### 7.4.1.1 Denture base polymer, heat-polymerizable, complying with ISO 20795-1.

##### 7.4.1.2 Dental gypsum, for investment, complying with ISO 6873:2013, Type 2 or Type 3.

##### 7.4.1.3 Dental modelling wax.

##### 7.4.1.4 Lathe wheel, 300 grit silicon carbide, of diameter $(63 \pm 3)$ mm and thickness $(4,7 \pm 0,3)$ mm, capable of being rotated at $(1\ 700 \pm 300)$ r/min.