

INTERNATIONAL  
STANDARD

**ISO**  
**4824**

Second edition  
1993-02-01

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**Dentistry — Ceramic denture teeth**

*Produits et matériel pour l'art dentaire — Dents en céramique*

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ISO 4824:1993

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Reference number  
ISO 4824:1993(E)

## 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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 4824 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Sub-Committee SC 2, *Prosthetic materials*.

This second edition cancels and replaces the first edition (ISO 4824:1981) of which it constitutes a technical revision, differing in the following respects.

- a) The title has been modified to include other ceramics in addition to porcelain.
- b) A statement concerning the addition of fluorescing agents has been added.

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International Organization for Standardization  
Case Postale 56 • CH-1211 Genève 20 • Switzerland

Printed in Switzerland

## Introduction

Specific qualitative and quantitative requirements of freedom from biological hazard are not included in this International Standard but it is recommended that, in assessing possible biological or toxicological hazards, reference should be made to ISO/TR 7405:1984, *Biological evaluation of dental materials*, or any more recent edition.

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# Dentistry — Ceramic denture teeth

## 1 Scope

This International Standard specifies the requirements and test methods for ceramic teeth suitable for use in the manufacture of removable prostheses.

## 2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 1567:1988, *Dentistry — Denture base polymers*.

ISO 1942-1:1989, *Dental vocabulary — Part 1: General and clinical terms*.

ISO 6873:1983, *Dental gypsum products*.

## 3 Definitions

For the purposes of this International Standard, the following definitions apply.

**3.1 anterior teeth (type I):** Teeth of forms approximating those of human anterior teeth. (See ISO 1942-1:1989, definition 1.043.)

**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 posterior teeth (type II):** Teeth approximating the form or function of human posterior teeth. (See ISO 1942-1:1989, definition 1.044.)

**3.5 set:** Set of six anterior pin teeth or eight posterior diatoric teeth, as received from the manufacturer.

**3.6 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.

## 4 Requirements

### 4.1 Material

Substances which will increase the radioactivity of the ceramic shall not be added.

### 4.2 Dimensions of teeth

The dimensions of the teeth when examined in accordance with 6.2 shall not differ by more than 7 % from the values shown in the manufacturer's mould chart.

### 4.3 Colour and blending of shades

Anterior teeth shall be a blend of two or more colours. Anterior teeth, and posterior teeth if blended, shall show no line of demarcation between incisal and cervical portions on the facial aspects of the teeth. This requirement is not intended to disallow especially designed demarcations placed to simulate filling borders or enamel imperfections found in natural teeth.

The shape, colour, visual appearance and blending of the teeth in all the sets of the sample (see clause 5) shall correspond to the manufacturer's shade guide when inspected visually against the same background in accordance with 6.1.

### 4.4 Biocompatibility

See the Introduction for guidance on biocompatibility.

## 4.5 Surface finish

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

When the teeth are tested in accordance with 6.3, the original finish of the teeth shall not have been impaired by the processing, and the teeth shall be capable of being ground and polished.

## 4.6 Anchorage of diatoric teeth

All diatoric teeth, examined in accordance with 6.4, shall provide a means of positive retention and have holes all of which shall be patent.

## 4.7 Resistance to thermal shock

The teeth shall, when tested in accordance with 6.5, show no signs of cracking.

## 4.8 Porosity

The teeth, when tested in accordance with 6.6, shall not show more than 16 pores of diameter greater than 30 µm. No more than six of those pores shall have diameters ranging from 40 µm and 150 µm. There shall be no pores of diameter greater than 150 µm.

## 5 Sampling

The sample shall consist of seven sets of teeth. Five shades and five mould sizes shall be included covering the range of shades and mould sizes shown by the manufacturer's shade guide and mould chart. The teeth shall be representative of the physical dimensions of the brand and type.

## 6 Inspection and test methods

### 6.1 Inspection

Visually examine without magnification all the teeth in each set for compliance with the requirements given in 4.3, 4.5 and 4.6.

### 6.2 Dimensions of teeth

#### 6.2.1 Apparatus

**6.2.1.1 Micrometer** accurate to  $\pm 0,01$  mm and fitted with parallel steel face pieces.

#### 6.2.2 Procedure

Measure the maximum mesio-distal dimension of each upper and lower set of teeth in the in-line plane

for conformity to the mould chart dimensions (4.2). Measure the maximum mesio-distal and cervico-incisal dimensions of the upper and lower left central incisors (21, 31), and the overall facio-lingual dimensions of the crowns of the upper and lower left first molars (26, 36), using a micrometer (6.2.1.1).

### 6.3 Surface finish

#### 6.3.1 Apparatus

**6.3.1.1 Wet, 300 grit silicon carbide lathe wheel**, of diameter  $63 \text{ mm} \pm 3 \text{ mm}$  and thickness  $4,7 \text{ mm} \pm 0,3 \text{ mm}$ , capable of being rotated at  $1\,700 \text{ r/min} \pm 300 \text{ r/min}$ .

#### 6.3.1.2 Equipment for polishing dental ceramic.

#### 6.3.2 Processing

##### 6.3.2.1 Preparation of specimens

Process a set (six or eight teeth) to a denture-base polymer complying with ISO 1567 (type I), using accepted denture compression packing techniques, and following the manufacturer's instructions. A gypsum product complying with ISO 6873 (type II or type III) and a suitable modelling wax shall be used.

##### 6.3.2.2 Procedure

After deflasking, using dental laboratory tools and techniques, remove any surplus denture base material from those surfaces of the teeth which are normally exposed. Polish the denture base material taking care to keep the polishing tools wet where appropriate.

After polishing, examine the teeth visually for evidence of any damage suffered in processing, excluding accidental damage by tools used in processing.

#### 6.3.3 Grinding

##### 6.3.3.1 Preparation of specimens

Using the lathe wheel (6.3.1.1), carefully grind the occlusal surfaces of posterior teeth or the incisal edges of anterior teeth from the sample of the processed teeth from 6.3.2, removing a layer of ceramic material approximately 1 mm thick. Rotate the wheel at  $1\,700 \text{ r/min} \pm 300 \text{ r/min}$ . Take care to avoid overheating the teeth during grinding.

##### 6.3.3.2 Procedure

Using dental laboratory techniques, polish the ground surfaces and note the quality as compared to the original finish.

## 6.4 Anchorage

### 6.4.1 Apparatus

**6.4.1.1 Stiff wire** of diameter less than that of the diatoric holes.

NOTE 1 A high tensile stainless steel wire is suitable.

### 6.4.2 Procedure

Visually examine each tooth of two sets (16 teeth) and ascertain whether the anchorage slots and/or holes are capable of providing positive retention for the denture base material. Probe with the stiff wire (6.4.1.1) to demonstrate the patency of the holes.

## 6.5 Resistance to thermal shock

### 6.5.1 Apparatus

**6.5.1.1 Electric oven**, controlled at  $100\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$ .

**6.5.1.2 Light source** of minimum illuminance of 1 000 lx.

**6.5.1.3 Magnifying glass** of  $\times 10$  magnification.

**6.5.1.4 Perforated container** of non-corrodible metal of suitable capacity to contain at least 16 teeth.

**6.5.1.5 Cleansing solution.**

NOTE 2 A 10 g/l solution of household detergent is suitable.

**6.5.1.6 Metal container** of ice water at  $1\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$ , sufficiently large to enable the perforated container to be completely immersed.

### 6.5.2 Preparation of specimens

Using the cleansing solution (6.5.1.5), thoroughly clean two sets of teeth of the same mould and shade, removing all traces of adherent wax.

### 6.5.3 Procedure

Place the teeth in the perforated container and transfer it to the oven at  $100\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$ . After 20 min, remove the container and immediately (within 3 s) immerse it in the ice water. After immersion for not less than 30 s, remove the container and return it to the oven at  $100\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$  for a further 15 min. Remove the container and allow it to cool to room temperature. Then examine each tooth by high intensity transillumination using  $\times 10$  magnification.

## 6.6 Porosity

### 6.6.1 Apparatus and materials

**6.6.1.1 Optical microscope**, capable of  $\times 100$  magnification, with photographic equipment.

**6.6.1.2 Mounting material** such as autopolymerizing polymethyl methacrylate (PMMA).

**6.6.1.3 Equipment** for the preparation of polished sections.

### 6.6.2 Preparation of specimens

Cut two teeth of a set in their long axis, using a diamond wheel under lubrication. Embed the four halves, exposing the cut surfaces, in the mounting material (6.6.1.2). Polish the exposed surfaces by progressively grinding with wet silicon carbide paper, commencing with 240 grit and finishing with 600 grit paper. Final polishing is to be performed using 0,3  $\mu\text{m}$  grade diamond paste or powder. Clear definition of the pores in each half tooth shall be obtained.

### 6.6.3 Procedure

Examine each of the four specimens in the following way. View the section under the microscope using incident reflected light and select the area with the highest porosity (but not in the region of the core, if present). Prepare a photomicrograph with a final enlargement of approximately  $\times 100$ ; a gauge mark should be included to facilitate determination of pore diameters. Inspect the photomicrograph and again select the region with the highest porosity. Count the pores in a circular area representing 1 mm diameter on the specimen, and record the following:

- the number of pores with diameters between 30  $\mu\text{m}$  and 40  $\mu\text{m}$ ;
- the number of pores with diameters between 40  $\mu\text{m}$  and 150  $\mu\text{m}$ ;
- whether or not any pore has a diameter greater than 150  $\mu\text{m}$ .

Alternative methods such as scanning electron microscopy or image analysis may be used in place of optical microscopy.

### 6.6.4 Assessment of results

If one or two of the specimens fails to comply with any of the requirements of 4.8, repeat the test. If any of the four specimens from the second sample do not comply with all the requirements of 4.8, the teeth shall be deemed not to comply with 4.8.

## 7 Packaging, marking, labelling and information to be supplied by manufacturer

### 7.1 Packaging

The teeth shall be supplied in mounted sets in containers that protect the contents against damage during normal transport, storage and handling.

### 7.2 Marking, labelling

#### 7.2.1 Marking on mounts

The following information shall be clearly marked on each mount:

- a) manufacturer's name or brand name;
- b) mould designation;
- c) shade designation;
- d) the country of origin.

#### 7.2.2 Marking on containers

The manufacturer's name or brand name shall appear, in clear and indelible markings, on each container or on a label securely attached to each container.

#### 7.2.3 Information to be supplied by manufacturer

**7.2.3.1** The manufacturer shall supply on request a mould chart which shall:

- a) depict, lifesize, the shapes of the teeth including the labial profile of the central incisors;
- b) state the dimensions of the teeth in millimetres. In the case of anterior teeth (type I), the overall width of a set shall be stated together with the mesio-distal width and the inciso-cervical length (i.e. length excluding neck, if present) of the left central incisor. In the case of posterior teeth (type II), the overall width of half-sets of upper and lower teeth shall be stated.

**7.2.3.2** The manufacturer shall supply on request a shade guide.

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