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# INTERNATIONAL STANDARD



# 3336

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INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION

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## Dentistry — Synthetic resin teeth

*Art dentaire — Dents en résine synthétique*

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## FOREWORD

ISO (the International Organization for Standardization) is a worldwide federation of national standards institutes (ISO member bodies). The work of developing International Standards is carried out through ISO technical committees. Every member body interested in a subject for which a technical committee has been set up 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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council.

International Standard ISO 3336 was developed by Technical Committee ISO/TC 106, *Dentistry*, and was circulated to the member bodies in October 1976.

It has been approved by the member bodies of the following countries:

Australia	India	Sweden
Brazil	Israel	Switzerland
Canada	Mexico	Turkey
Czechoslovakia	Netherlands	United Kingdom
France	New Zealand	U.S.A.
Germany	South Africa, Rep. of	

No member body expressed disapproval of the document.

# Dentistry – Synthetic resin teeth

## 1 SCOPE AND FIELD OF APPLICATION

This International Standard specifies requirements and corresponding test methods for synthetic resin teeth manufactured for use in prosthetic dentistry.

## 2 REFERENCE

ISO/R 1567, *Denture base polymer*.

## 3 CLASSIFICATION

For the purpose of this International Standard, synthetic resin teeth are classified into the following types :

Type I : Teeth approximating the various forms of human anterior teeth

Type II : Teeth approximating the various forms of human posterior teeth

## 4 REQUIREMENTS

### 4.1 Material

The teeth shall be manufactured from synthetic resins, such as poly(methyl methacrylate) and its co-polymers, which have suitable properties for use as artificial teeth.

### 4.2 Size and shape

The manufacturer shall provide a mould chart depicting the shapes of teeth and giving dimensions, in metric units, as follows :

Type I : The overall width of a complete set (six teeth), as well as the mesio-distal width and the cervico-incisal length of the central left incisor.

Type II : The overall width of an upper half-set (four teeth) with the teeth mounted in line.

The mould chart shall indicate clearly the basis for these measurements.

### 4.3 Colour and blend

Teeth of Type I shall be blended and shall show no line of demarcation between incisal (occlusal) and gingival portions on the labial (buccal) aspects of the teeth. If blending is used with Type II teeth, the same conditions shall apply.

The colour, visual appearance, and blending shall correspond, within the limits of professional acceptance, to the manufacturer's guide when inspected in accordance with 5.2 against the same background. The background shall be of a colour suitable for the purpose.

### 4.4 Freedom from irritants

The teeth as supplied by the manufacturer, and after processing according to his instructions, shall neither cause prolonged damage to contacting oral tissues nor have any adverse systemic effect.

NOTE When specific toxicity tests are available, it is envisaged that these will be included in this International Standard.

### 4.5 Freedom from imperfections

The teeth shall be free from defects which would impair their serviceability. No porosity shall be visible when the teeth are examined in accordance with 5.4.2.

### 4.6 Surface finish

#### 4.6.1 Retention of finish

The original finish of the teeth shall be maintained during processing and reprocessing to a degree that the light buffing detailed in 5.4.3 or similar treatment as prescribed by the manufacturer will restore them to their original condition.

#### 4.6.2 Repolish

The teeth shall be capable of being ground and repolished equal to the original surface lustre, using normal dental polishing methods or by following any special instructions supplied by the manufacturer.

### 4.7 Bonding

The ridge lap portion of the teeth shall form a bond with denture-base polymer when tested in accordance with 5.4.4.

### 4.8 Mechanical properties

The teeth shall be tested to determine such mechanical properties as are considered appropriate, using those methods and limits acceptable to the interested parties.

#### 4.9 Colour stability to light

When tested in accordance with 5.4.5, the test specimen shall not show more than a slight change in colour (perceptible with difficulty).

#### 4.10 Resistance to blushing, distortion and crazing

The teeth shall be resistant to blushing, distortion and crazing when tested in accordance with 5.4.6.

#### 4.11 Dimensional stability

A tooth shall show no dimensional change in excess of  $\pm 2\%$  of its original width when tested in accordance with 5.4.7.

### 5 SAMPLING, INSPECTION, MEASURING AND TESTING PROCEDURES

#### 5.1 Sampling

Five complete sets of upper and lower teeth (each set of a different mould and shade) of whichever Type is to be tested, procured at retail and delivered on the original mountings and in the original condition, shall constitute the sample for testing.

#### 5.2 Inspection

Inspect each set of teeth visually for Type (clause 3), shape in conformity to the mould chart (4.2), colour and blend (4.3), freedom from imperfections (porosity or rough trimming and surface finish) (4.5), and packing (clause 6).

Carry out the inspections for change in colour or finish (4.3, 5.4.3 and 5.4.5) in diffuse daylight. The light in the visible range shall be of the same type as a standard light source of type D 55 (see ICI\* Publication No. 15, 1971) and shall have a colour temperature between 4 750 and 6 500 K, an irradiance of not less than 1 000 lx and an aperture angle of not less than  $35^\circ$ .

#### 5.3 Dimensions

Measure the width of each set of teeth for conformity to the mould chart dimensions within  $\pm 2$  mm. Measure the mesio-distal width and cervico-incisal length of the left central incisor tooth for conformity within  $\pm 0,50$  mm.

#### 5.4 Test methods

##### 5.4.1 Test conditions

Unless otherwise specified, use a temperature of  $23 \pm 2^\circ\text{C}$  and a relative humidity of 45 to 55 % for testing.

##### 5.4.2 Porosity

Examine four teeth for porosity with 10 X magnification on any exposed surface after preparation in the following manner.

Section the teeth by wet grinding to provide a flat surface  $1,5 \pm 0,5$  mm from the incisal edge or cusp tip. Grind another parallel surface to provide a specimen thickness of  $2,5 \pm 0,5$  mm.

Examine both surfaces for porosity with 10 X magnification.

##### 5.4.3 Surface finish

###### 5.4.3.1 APPARATUS

Normal dental laboratory equipment for denture flasking, processing, finishing and polishing (see 5.4.3.2 for details of muslin wheel used in polishing).

###### 5.4.3.2 PROCEDURE

Process three teeth to a denture-base polymer which complies with ISO/R 1567, using the customary denture compression packing technique and following the manufacturer's directions. Use a dental gypsum for investment. Position the teeth so they are contacted by the gypsum.

After removal from the flask, polish the teeth for not longer than 1 min with a soft 18 to 36 ply muslin wheel at a circumferential speed of  $650 \pm 350$  m/min (a wheel with a diameter of 70 mm rotating at  $1\ 500\ \text{min}^{-1}$  will have a circumferential speed of 329 m/min and a 100 mm wheel rotating at  $3\ 500\ \text{min}^{-1}$  will have a circumferential speed of 1 010 m/min). Keep at least 10 mm between the outer diameter of the wheel and the stitching or other reinforcement.

After polishing, the surface of the processed teeth shall be equal in finish to that of the teeth as received.

Roughen the occlusal surface of one of the processed teeth by grinding carefully, so that excessive heat is not developed, with a silicon carbide wheel of less than  $65\ \mu\text{m}$  grit, approximately 20 mm diameter and 5 mm width. Polish the ground surface with the muslin wheel and chalk.

This polished surface shall be equal to that of the teeth as received. Make all comparisons by visual inspection in accordance with 5.2.

##### 5.4.4 Bonding

###### 5.4.4.1 APPARATUS

a) **Metal form** of the design illustrated in figure 1 a) which incorporates a trough 5 mm wide by 1,5 mm deep for use in mounting the teeth.

\* International Commission on Illumination.

b) **Normal dental laboratory apparatus** for denture flasking and processing.

c) **Tensile testing apparatus** with the specially designed grips illustrated in figure 1 c).

#### 5.4.4.2 PROCEDURE

Grind a set of six upper anteriors on the ridge lap to represent a gum-fitting situation. Mount these teeth on a metal form as illustrated in figure 1 a), so that about one-half of the lingual surface of the incised portion of the tooth and about one-half of the tooth projects beyond the mount. Flask the mounted teeth in dental gypsum (see figure 1 b)). Remove the metal mount and flush the wax from the teeth and flush with clean boiling water containing a detergent, followed by plain boiling water. Process acrylic resin denture-base material complying with the requirements of ISO/R 1567, Type 1, to the teeth according to the manufacturer's directions.

Test the plastics-mounted teeth in a machine designed to permit a direct pull on the incisal part of the lingual surface in a labial direction at a consistent height above the acrylic bar (see figure 1 c)). Use equipment which does not permit lateral deflection or change of position.

Test each tooth to failure. The bond shall be considered satisfactory if the break does not follow the tooth surface and denture-base resin remains firmly attached to the tooth.

#### 5.4.5 Colour stability to light

##### 5.4.5.1 APPARATUS

a) **Light source**, consisting of a combined tungsten filament/mercury discharge lamp with an internal reflector. The lamp shall have been in use for not less than 50 h and not more than 400 h, and shall have the following characteristics :

110 – 130 or 220 – 240 V a.c., 275 – 300 W;

UV radiation at 500 mm from the lamp in the following ranges :

UV – A (380 to 315 nm) =  $19 \pm 3$  W/m<sup>2</sup>

UV – B (315 to 280 nm) =  $6,5 \pm 3$  W/m<sup>2</sup>

UV – C (< 280 nm) < 0,1 W/m<sup>2</sup>

Relative spectral energy distribution at a distance of 500 mm at the following wavelengths :

313 nm :  $4,5 \pm 1,5$  W/m<sup>2</sup>

302,5 nm :  $1,5 \pm 0,6$  W/m<sup>2</sup>

297 nm :  $0,75 \pm 0,4$  W/m<sup>2</sup>

289 nm :  $0,15 \pm 0,1$  W/m<sup>2</sup>

280 nm : < 0,1 W/m<sup>2</sup>

b) **Turntable**, rotating at  $33 \text{ min}^{-1}$ , and carrying a disc of 180 to 200 mm diameter.

c) **Base and stand arrangement**, allowing the turntable and disc to be centred under the lamp at a certain distance (see figure 2).

#### 5.4.5.2 PROCEDURE

Expose tooth specimens to radiation in the following way.

Position the specimen on the disc at 75 mm from the centre of the turntable. Centre the disc under the lamp with a distance of 350 to 400 mm between the plane of the top surface of the specimen and the bottom of the lamp.

After starting the turntable, expose the specimen to the radiation of the lamp for 24 h, maintaining the temperature of the specimen during this time at  $37 \pm 5$  °C, for example by means of air circulation.

After the exposure, compare the specimen with an unexposed duplicate by visual inspection according to 5.2.

#### 5.4.6 Resistance to blushing, distortion and crazing

##### 5.4.6.1 APPARATUS

**Temperature-controlled water-bath.**

##### 5.4.6.2 CONDITIONING OF TEST SPECIMEN

Carry out this test on one or more teeth in the as-received condition and one or more teeth after they have been subjected to the following conditioning cycle.

Submerge the teeth in test tubes filled with water placed in the water-bath so that the test tubes do not contact the vessel. Heat the water-bath from room temperature to 100 °C in from 5 to 20 min, and hold at this temperature (100 °C) for 3 h.

In order to control the loss of water from the surfaces of teeth, allow specimens to cool in water to  $23 \pm 2$  °C then remove and allow to dry for 1 h prior to testing.

##### 5.4.6.3 PROCEDURE

Immerse the teeth in methyl methacrylate monomer for 5 s and remove. Repeat the immersion after 1 min and then allow the teeth to dry on a towel for 2 h at room temperature.

If any blushing, blanching or change in colour, any distortion or crazing can be seen by visual examination or low-power magnification (10 X) when viewed under the standard lighting conditions specified in 5.2, the teeth shall be deemed to have failed to pass this test.

#### 5.4.7 Dimensional stability

##### 5.4.7.1 APPARATUS

a) **Suitable grinding equipment.**

b) **Micrometer** fitted with parallel steel face pieces, giving readings to an accuracy of 0,01 mm.

#### 5.4.7.2 PROCEDURE

Prepare the tooth for test by grinding two parallel flats on the sides at the point of maximum width. Mount the tooth on an approximately 13 mm cube of wax with the labial surface uppermost and the cingulum embedded in the wax. Measure the maximum width of the tooth with the micrometer.

After taking this reading, invest the tooth and wax block in dental gypsum and process it to a denture-base polymer as specified in 5.4.3. Measure the maximum width of the tooth again.

#### 6 PACKING

The teeth shall be supplied suitably mounted in sets with the following information clearly marked on the mounts :

- a) manufacturer's name or mark;
- b) mould designation;
- c) shade designation.

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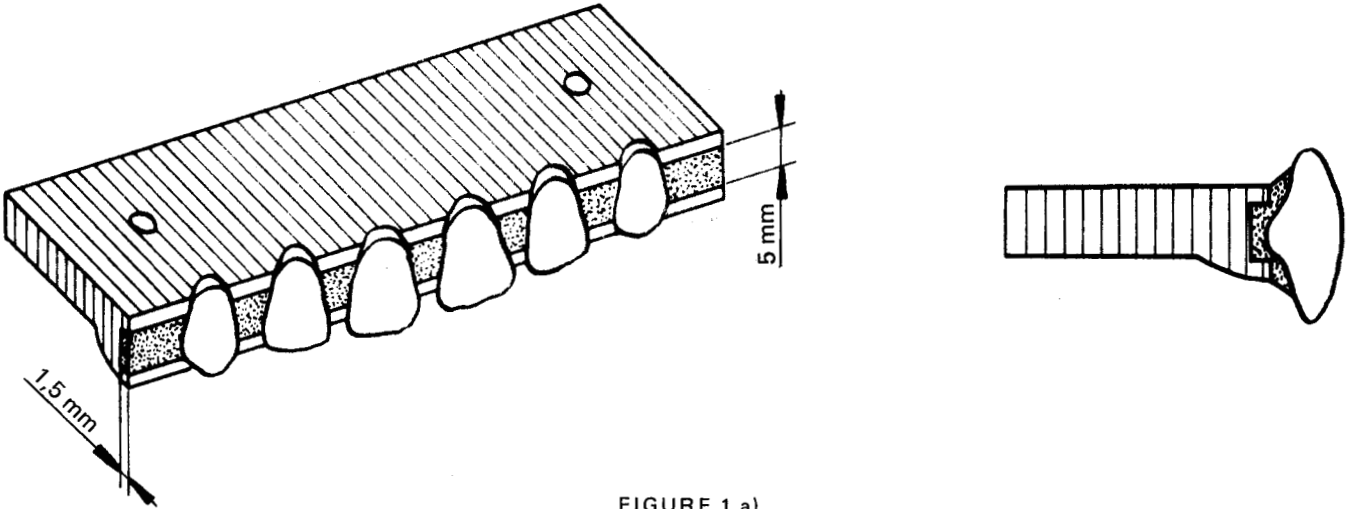


FIGURE 1 a)

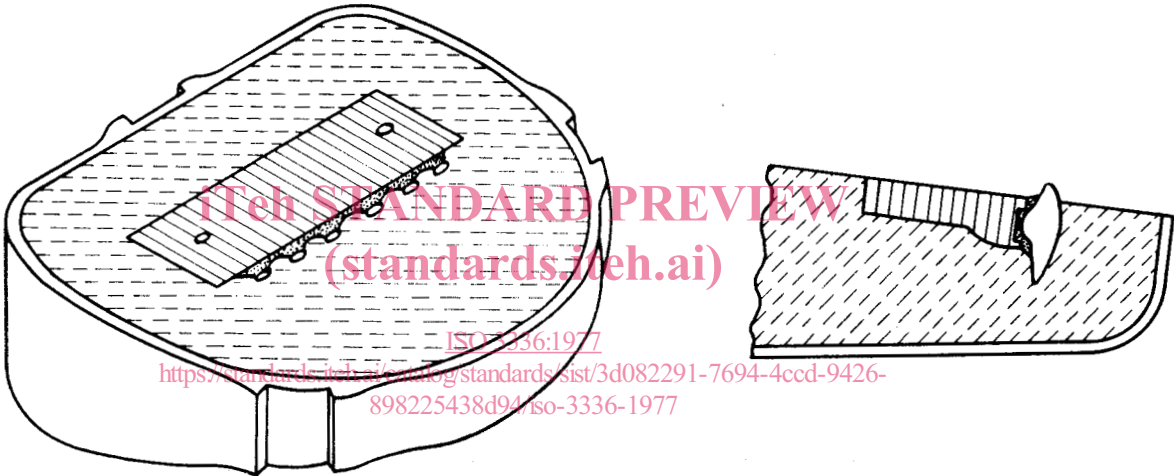


FIGURE 1 b)

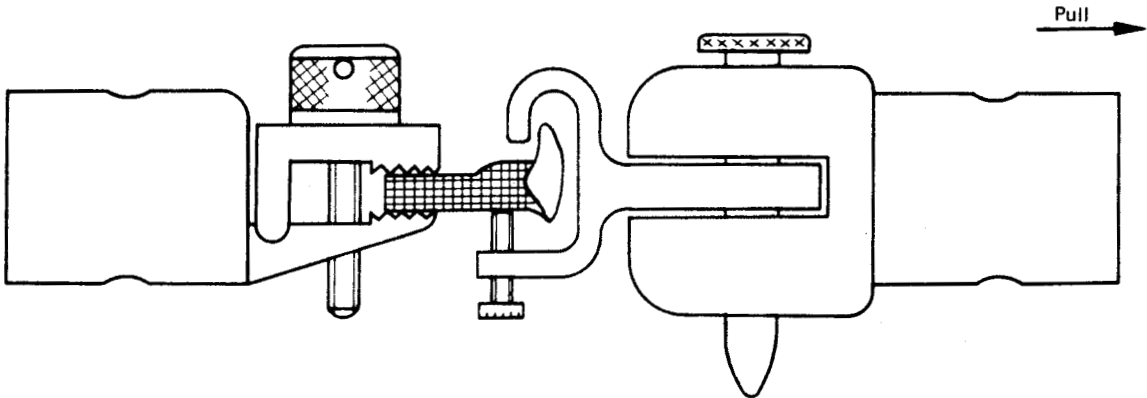


FIGURE 1 c)

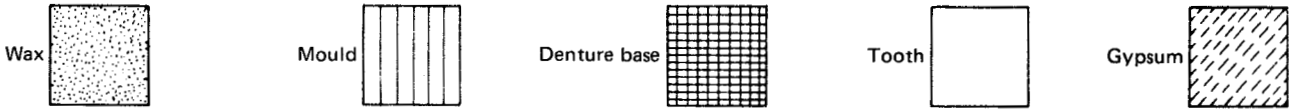
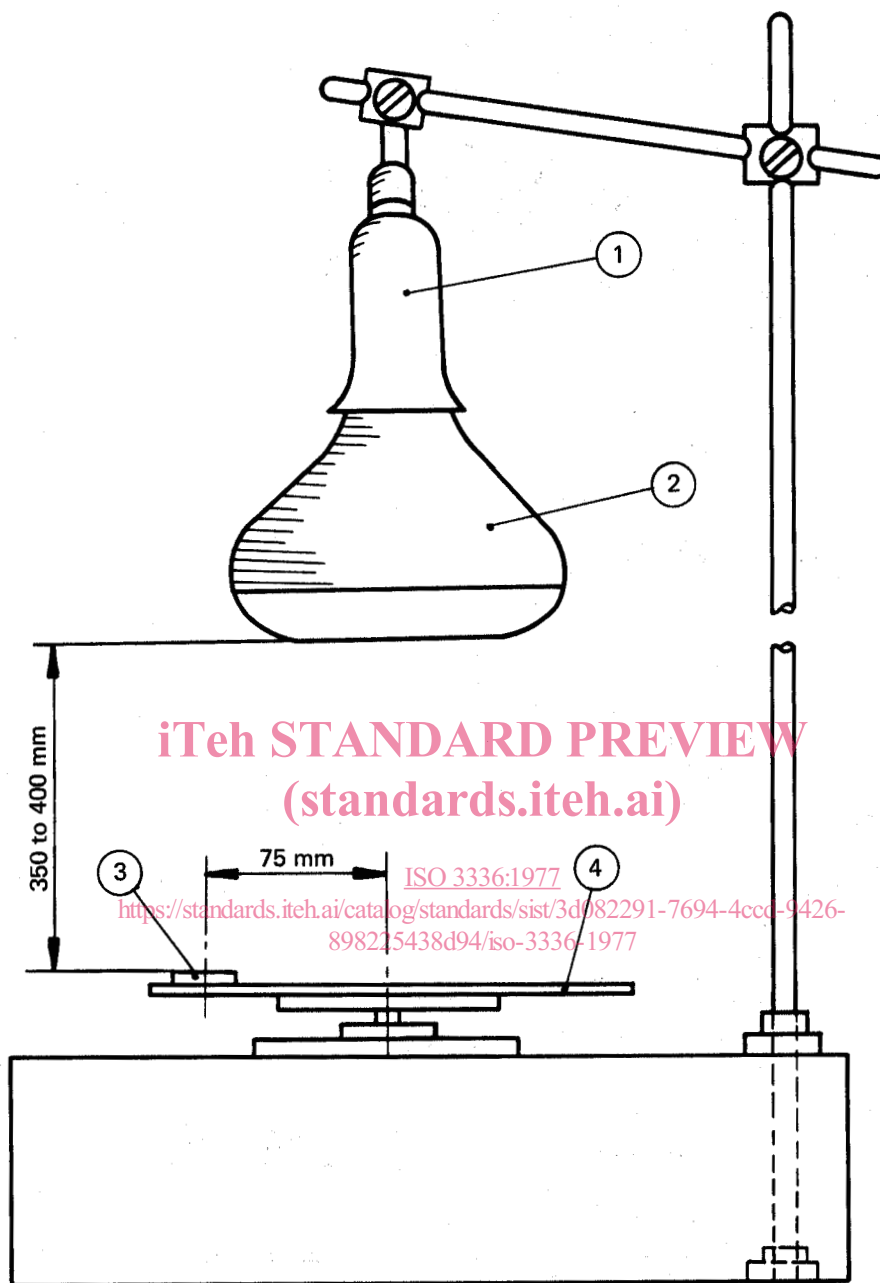


FIGURE 1 – Apparatus and mould for bonding test



- 1 Combined tungsten filament/mercury discharge lamp
- 2 Internal reflector
- 3 Specimen
- 4 Turntable

FIGURE 2 – Apparatus for the testing of colour stability to light