

---

---

## Dentistry — Denture adhesives

*Médecine bucco-dentaire — Adhésifs pour prothèses dentaires*

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

[ISO 10873:2010](https://standards.iteh.ai/catalog/standards/sist/7927fe4b-05d7-441d-a0f0-c8e402809669/iso-10873-2010)

<https://standards.iteh.ai/catalog/standards/sist/7927fe4b-05d7-441d-a0f0-c8e402809669/iso-10873-2010>



**PDF disclaimer**

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

ISO 10873:2010

<https://standards.iteh.ai/catalog/standards/sist/7927fe4b-05d7-441d-a0f0-c8e402809669/iso-10873-2010>



**COPYRIGHT PROTECTED DOCUMENT**

© ISO 2010

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office  
Case postale 56 • CH-1211 Geneva 20  
Tel. + 41 22 749 01 11  
Fax + 41 22 749 09 47  
E-mail [copyright@iso.org](mailto:copyright@iso.org)  
Web [www.iso.org](http://www.iso.org)

Published in Switzerland

## Contents

Page

Foreword .....	iv
<b>1</b> <b>Scope</b> .....	<b>1</b>
<b>2</b> <b>Normative references</b> .....	<b>1</b>
<b>3</b> <b>Terms and definitions</b> .....	<b>1</b>
<b>4</b> <b>Classification</b> .....	<b>2</b>
<b>5</b> <b>Requirements</b> .....	<b>2</b>
<b>5.1</b> <b>General</b> .....	<b>2</b>
<b>5.2</b> <b>Specific requirements for Type 1 adhesives</b> .....	<b>2</b>
<b>5.3</b> <b>Specific requirements for Type 2 adhesives</b> .....	<b>2</b>
<b>6</b> <b>Sampling</b> .....	<b>3</b>
<b>7</b> <b>Test methods</b> .....	<b>3</b>
<b>7.1</b> <b>Test conditions</b> .....	<b>3</b>
<b>7.2</b> <b>pH value measurement</b> .....	<b>3</b>
<b>7.3</b> <b>Determination of stability — Aging procedure</b> .....	<b>4</b>
<b>7.4</b> <b>Test of washability (for Type 1 adhesives)</b> .....	<b>4</b>
<b>7.5</b> <b>Adhesion strength test I (for Type 1 adhesives)</b> .....	<b>4</b>
<b>7.6</b> <b>Adhesion strength test II (for Type 1 adhesives)</b> .....	<b>7</b>
<b>7.7</b> <b>Adhesion strength test (for Type 2 adhesives)</b> .....	<b>8</b>
<b>7.8</b> <b>Peeling test (for Type 2 adhesives)</b> .....	<b>10</b>
<b>7.9</b> <b>Consistency test (for Type 2 adhesives)</b> .....	<b>11</b>
<b>7.10</b> <b>Assessment</b> .....	<b>12</b>
<b>8</b> <b>Accompanying information</b> .....	<b>13</b>
<b>8.1</b> <b>Information to be included in the manufacturer's instructions</b> .....	<b>13</b>
<b>8.2</b> <b>Labelling on the package</b> .....	<b>14</b>
<b>Bibliography</b> .....	<b>15</b>

## 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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. 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.

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.

ISO 10873 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 7, *Oral care products*.

## iTeh STANDARD PREVIEW (standards.iteh.ai)

ISO 10873:2010

<https://standards.iteh.ai/catalog/standards/sist/7927fe4b-05d7-441d-a0f0-c8e402809669/iso-10873-2010>

# Dentistry — Denture adhesives

## 1 Scope

This International Standard classifies denture adhesives used by wearers of removable dentures; it also specifies requirements, test methods and instructions to be supplied for the use of such products.

This International Standard is applicable to denture adhesives for use by the public and excludes the dental lining materials prescribed or applied by dental professionals.

This International Standard does not specify qualitative or quantitative requirements for freedom from biological hazards. For assessing possible biological hazards, see ISO 7405 and ISO 10993-1.

## 2 Normative references

The following referenced documents are indispensable for the application 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 10873:2010

ISO 3696, *Water for analytical laboratory use — Specification and test methods*

ISO 7823-2, *Plastics — Poly(methyl methacrylate) sheets — Types, dimensions and characteristics — Part 2 Extruded sheets*

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 and the following apply.

### 3.1

#### **denture adhesives**

dental product placed on the intaglio surface (fitting surface) of a removable denture to temporarily improve its retention to soft supporting tissues

### 3.2

#### **glue type**

denture adhesive in powder, cream, sheet or tape form with water-soluble polymer as adhesive constituent

### 3.3

#### **liner type**

denture adhesive in non-aqueous paste form

## 4 Classification

For the purposes of this International Standard, denture adhesives are categorized as one of the following types:

- a) **Type 1:** glue type:
  - Class 1: powder form;
  - Class 2: cream form;
  - Class 3: sheet or tape form.
- b) **Type 2:** liner type.

## 5 Requirements

### 5.1 General

#### 5.1.1 Biocompatibility

Particular attention should be given to assessing the effects on biocompatibility from the release of metallic ions from the denture adhesive.

#### 5.1.2 pH value

Denture adhesives shall have a pH value within the range of 4 to 10 when tested in accordance with 7.2.

#### 5.1.3 Microbiology

Testing for microbiological contamination shall be carried out according to appropriate methods such as those listed in References [11] to [14] or those specified in ISO 16212, ISO 18416, ISO 21148, ISO 21149, ISO 21150, ISO 22717, ISO 22718 and ISO 29621.

#### 5.1.4 Stability

The denture adhesive shall show no signs of deterioration which may affect compliance with this International Standard after being subjected to one of the aging procedures specified in 7.3.

### 5.2 Specific requirements for Type 1 adhesives

#### 5.2.1 Washability

There shall be no residual lump when tested in accordance with 7.4.

#### 5.2.2 Strength of the adhesion to the prosthesis

Adhesion strength shall not be less than 5 kPa when tested in accordance with 7.5 and 7.6.

### 5.3 Specific requirements for Type 2 adhesives

#### 5.3.1 Adhesion strength

Adhesion strength shall not be less than 5 kPa when tested in accordance with 7.7.

### 5.3.2 Peeling property

There shall be no residual lump when tested in accordance with 7.8.

### 5.3.3 Consistency

Consistency shall not be less than 15 mm when tested in accordance with 7.9.

## 6 Sampling

The sample shall be taken from one lot and shall be sufficient to complete all tests specified in Clause 7.

## 7 Test methods

### 7.1 Test conditions

All tests shall be conducted at a temperature of  $(23 \pm 3)$  °C.

### 7.2 pH value measurement

#### 7.2.1 Apparatus and material

7.2.1.1 **pH meter**, with a glass and comparison electrode assembly with an accuracy of  $\pm 0,02$ .

7.2.1.2 **Glass container**, of 500 ml capacity.

7.2.1.3 **Circular filter paper**, used to separate fine precipitates for chemical analysis.

#### 7.2.2 Reagents

7.2.2.1 **Propylene glycol**, analytical grade.

7.2.2.2 **Water**, grade 3 in accordance with ISO 3696.

#### 7.2.3 Procedure

##### 7.2.3.1 Type 1 adhesives

###### 7.2.3.1.1 Class 1 and Class 2

Take  $(1,0 \pm 0,1)$  g of a Class 1 or Class 2 denture adhesive, add 5 g of propylene glycol (7.2.2.1) to disperse it, and while stirring, add 300 ml of water (7.2.2.2) and mix them sufficiently. Insert the electrode of the pH meter (7.2.1.1) into the dispersion and take the pH meter reading 3 min after the insertion.

###### 7.2.3.1.2 Class 3

Take  $(1,0 \pm 0,1)$  g of a Class 3 denture adhesive, add 300 ml of water and mix them sufficiently. Insert the electrode of the pH meter and take the pH meter reading 3 min after the insertion.

##### 7.2.3.2 Type 2

Take  $(1,0 \pm 0,1)$  g of denture adhesive, spread evenly over a radius of approximately 40 mm on a piece of filter paper (7.2.1.3). Place the filter paper in a glass container (7.2.1.2) and add 300 ml of water to it. After immersing in water for 1 h, insert the electrode of the pH meter into water and take the pH meter reading 3 min after the insertion.

### 7.3 Determination of stability — Aging procedure

Store the denture adhesives in their original containers at  $(40 \pm 2)^\circ\text{C}$  at  $(75 \pm 5)\%$  relative humidity for 3 months or at such conditions of time and temperature as will simulate storage at room temperature for 30 months<sup>[15]</sup>.

### 7.4 Test of washability (for Type 1 adhesives)

#### 7.4.1 Apparatus and materials

7.4.1.1 **Water bath**, capable of being maintained at a temperature of  $(37 \pm 2)^\circ\text{C}$ .

7.4.1.2 **Poly(methyl methacrylate) plate (PMMA)**, approximately 50 mm × 50 mm, in accordance with ISO 7823-2.

#### 7.4.2 Reagent

7.4.2.1 **Water**, in accordance with 7.2.2.2.

#### 7.4.3 Procedure

Apply the denture adhesive on the PMMA plate (7.4.1.2) evenly following the manufacturer's instructions for use and immerse the plate in water for 1 h in the water bath (7.4.1.1) maintained at  $(37 \pm 2)^\circ\text{C}$ .

Wash the PMMA plate following the manufacturer's instructions for use and inspect the PMMA plate surface with the naked eye, without magnification. Repeat the tests to obtain five test results.

### 7.5 Adhesion strength test I (for Type 1 adhesives)

#### 7.5.1 General

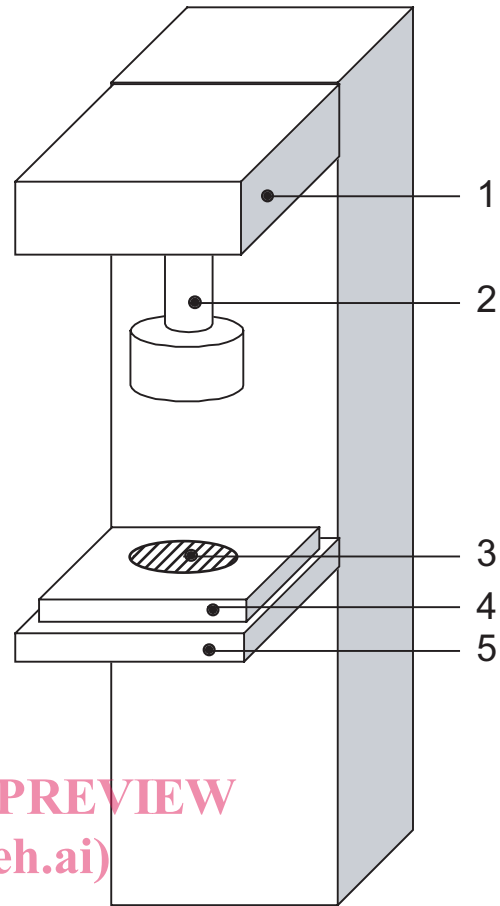
<https://standards.iteh.ai/catalog/standards/sist/7927fe4b-05d7-441d-a0f0-c8e402809669/iso-10873-2010>

Conduct the following adhesion strength test within 3 min after removal from the water bath.

#### 7.5.2 Apparatus

7.5.2.1 **Adhesion test instrument**, having a sample stand, of capacity up to 10 N (for both frame and load cell), with a cross-head speed up to 5 mm/min. See Figure 1.



**Key**

- 1 load detecting part
- 2 pressure sensitive shaft
- 3 denture adhesive
- 4 sample holder
- 5 sample stand

NOTE This is an example of a test instrument.

iTeh STANDARD PREVIEW  
(standards.iteh.ai)

ISO 10873:2010

<https://standards.iteh.ai/catalog/standards/sist/7927fe4b-05d7-441d-a0f0-c8e402809669/iso-10873-2010>  
**Figure 1 — Adhesion test instrument**

**7.5.2.2 Sample holder I**, having a hole with a diameter of  $(22 \pm 1)$  mm and a depth of  $(0,5 \pm 0,1)$  mm, made of poly(methyl methacrylate) complying with ISO 7823-2. See Figure 2 a).

**7.5.2.3 Sample holder II**, having a raised circular part with a diameter of  $(22 \pm 1)$  mm and a height of  $(5,0 \pm 0,1)$  mm made of poly(methyl methacrylate) complying with ISO 7823-2. See Figure 2 b).

**7.5.2.4 Pressure sensitive shaft**, having a circular base with a diameter of  $(20,0 \pm 0,5)$  mm, made of poly(methyl methacrylate) complying with ISO 7823-2. See Figure 3.

**7.5.2.5 Water bath**, in accordance with 7.4.1.1.

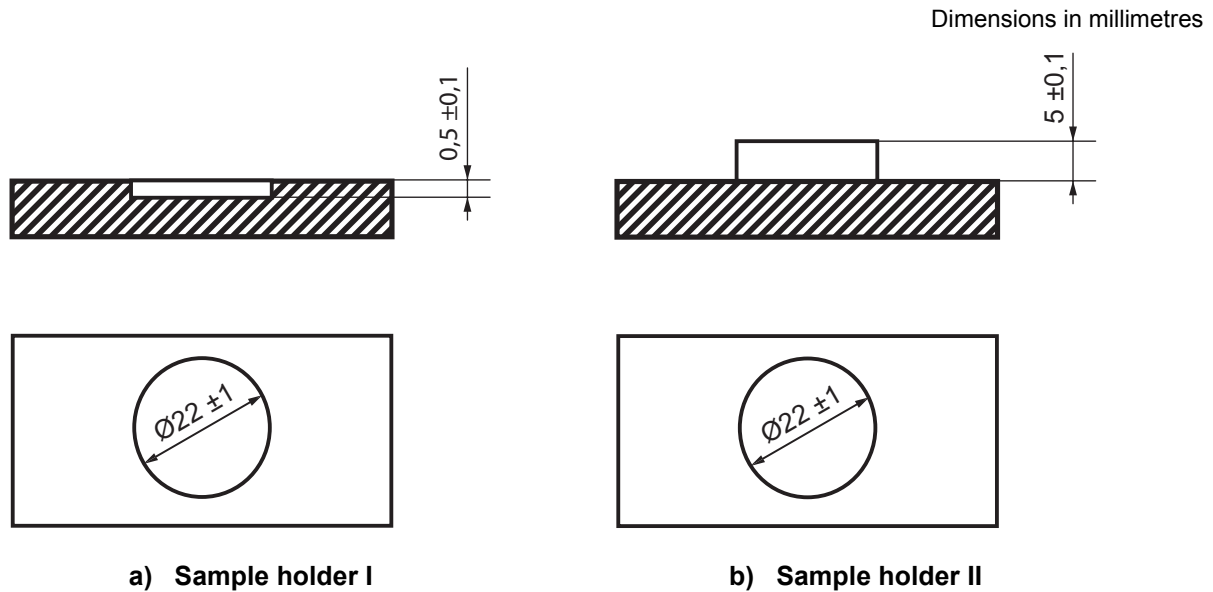


Figure 2 — Sample holders

7.5.3 Reagent

7.5.3.1 Water, in accordance with 7.2.2.2.

7.5.4 Procedure

7.5.4.1 Class 1 denture adhesive

iTeH STANDARD PREVIEW  
(standards.iteh.ai)  
<https://standards.iteh.ai/catalog/standards/sist/7927fe4b-05d7-441d-a0f0-c8e402809669/iso-10873-2010>

Add water (7.2.2.2) to 1 g to 3 g of a Class 1 denture adhesive powder in a powder/water mass ratio of 4 and mix them homogeneously. Leave the mixture in a sealed container for 5 min before using it as a sample.

Slightly overfill the hole of holder I (7.5.2.2) with the mixture, flatten the surface, and then immerse the sample/sample holder I assembly in water for 1 min in the water bath (7.4.1.1) maintained at  $(37 \pm 2) ^\circ\text{C}$ . Take out the sample/sample holder I assembly from the water bath and shake it once to remove water from the surface. Set the sample/sample holder I assembly on the sample stand of the adhesion test instrument (7.5.2.1) so that the load is applied to the centre of the sample.

Apply a load up to  $(9,8 \pm 0,2) \text{ N}$  at cross-head speed of 5 mm/min by the pressure sensitive shaft (7.5.2.4) to the sample, maintain the load in the position for 30 s and pull it toward the opposite direction at cross-head speed of 5 mm/min. Record the maximum force measured by the pressure sensitive shaft and calculate the force per unit area as the adhesion strength. See Figure 3 a). Repeat the test four times to obtain five results.

7.5.4.2 Class 2 denture adhesive

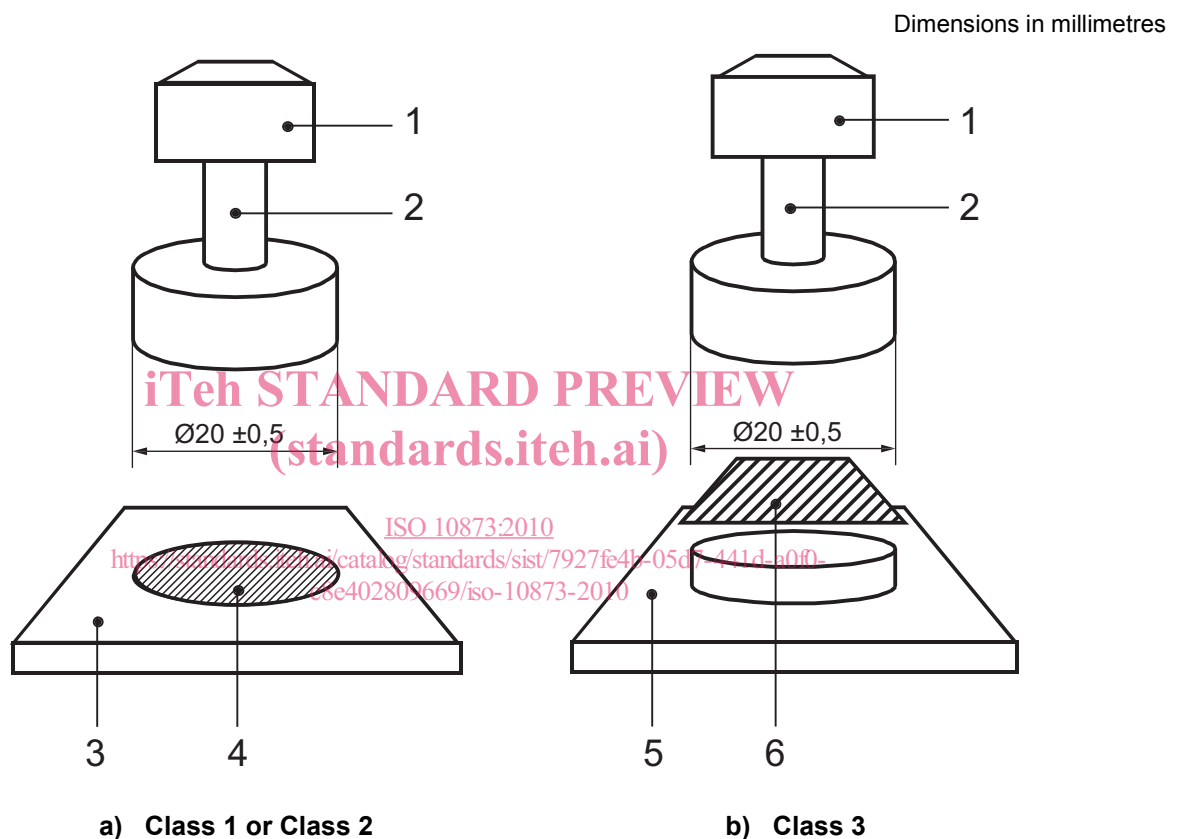
Slightly overfill the hole of the sample holder I with a Class 2 denture adhesive, flatten the surface, and then immerse the sample/sample holder I assembly in water for 1 min in the water bath maintained at  $(37 \pm 2) ^\circ\text{C}$ . Take out the sample/sample holder I assembly and shake it once to remove water from the surface. Set the sample/sample holder I assembly on the sample stand of the adhesion test instrument (7.5.2.1) so that the load is applied to the centre of the sample.

Apply a load up to  $(9,8 \pm 0,2) \text{ N}$  at cross-head speed of 5 mm/min by the pressure sensitive shaft to the sample, maintain the load in the position for 30 s and pull it toward the opposite direction at cross-head speed of 5 mm/min. Record the maximum force measured by the pressure sensitive shaft and calculate the force per unit area as the adhesion strength. See Figure 3 a). Repeat the test four times to obtain five results.

### 7.5.4.3 Class 3 denture adhesive

Take a Class 3 denture adhesive so that the minimum dimensions of its total area will be  $21 \text{ mm} \times 21 \text{ mm}$  and after immersing this in water for 5 s in the water bath maintained at  $(37 \pm 2) \text{ }^\circ\text{C}$ , take out and shake it once to remove water from the surface. Place the sample immediately on the sample holder II (7.5.2.3) so that the sample evenly covers the raised circular part and set the sample/sample holder II assembly on the sample stand of the adhesion test instrument so that the load is applied to the centre of the sample.

Apply a load up to  $(9,8 \pm 0,2) \text{ N}$  at cross-head speed of  $5 \text{ mm/min}$  by the pressure sensitive shaft (7.5.2.4) to the sample, maintain the load in the position for 30 s and pull it toward the opposite direction at cross-head speed of  $5 \text{ mm/min}$ . Record the maximum force measured by the pressure sensitive shaft and calculate the force per unit area as the adhesion strength. See Figure 3 b). Repeat the test four times to obtain five results.



#### Key

- 1 load detector
- 2 pressure sensitive shaft
- 3 sample holder I
- 4 Class 1 or Class 2 sample
- 5 sample holder II
- 6 Class 3 sample

Figure 3 — Layout for adhesion test instrument

## 7.6 Adhesion strength test II (for Type 1 adhesives)

### 7.6.1 General

Conduct the following adhesion strength test within 3 min after removal from the water bath.