

# SVENSK STANDARD

## SS-EN ISO 10873:2010



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**Tandvård – Fixativ för proteser (ISO 10873:2010)**

**Dentistry – Denture adhesives (ISO 10873:2010)**

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EUROPEAN STANDARD

**EN ISO 10873**

NORME EUROPÉENNE

EUROPÄISCHE NORM

September 2010

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ICS 97.170

English Version

## Dentistry - Denture adhesives (ISO 10873:2010)

Médecine bucco-dentaire - Adhésifs pour prothèses  
dentaires (ISO 10873:2010)

Zahnheilkunde - Prothesenhaftmittel (ISO 10873:2010)

This European Standard was approved by CEN on 11 September 2010.

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## **Foreword**

This document (EN ISO 10873:2010) has been prepared by Technical Committee ISO/TC 106 "Dentistry" in collaboration with Technical Committee CEN/TC 55 "Dentistry" the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2011, and conflicting national standards shall be withdrawn at the latest by March 2011.

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### **Endorsement notice**

The text of ISO 10873:2010 has been approved by CEN as a EN ISO 10873:2010 without any modification.



# 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 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.