



SLOVENSKI STANDARD
oSIST prEN ISO 10873:2020
01-februar-2020

Zobozdravstvo - Lepila za zobne proteze (ISO/DIS 10873:2019)

Dentistry - Denture adhesives (ISO/DIS 10873:2019)

Zahnheilkunde - Prothesenhaftmittel (ISO/DIS 10873:2019)

Médecine bucco-dentaire - Adhésifs pour prothèses dentaires (ISO/DIS 10873:2019)

Ta slovenski standard je istoveten z: prEN ISO 10873

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Dentistry — Denture adhesives

Médecine bucco-dentaire — Adhésifs 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).

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).

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 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.

The committee responsible for this document is Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 7, *Oral care products*.

This second edition ~~replaces the first edition (ISO 10873:2010)~~, which has been technically revised.

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

- a powder/water ratio described in 7.5.4.1 and 7.6.4.1 has been revised.
- method of pH value measurement has been modified in part.
- surface roughness of the sample holder has been revised.

ISO/DIS 10873:2019(E)**Introduction**

Denture adhesives are used for the improvement in retention stability of removable denture to soft supporting tissues temporarily. This document is intended to determine the physical and chemical properties of denture adhesives.

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

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Dentistry — Denture adhesives

1 Scope

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

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 1942, *Dentistry — Vocabulary*

ISO 3696:1987, *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 7405, *Dentistry — Evaluation of biocompatibility of medical devices used in dentistry*

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

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 21148, *Cosmetics — Microbiology — General instructions for microbiological examination*

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at <https://www.iso.org/obp>

— IEC Electropedia: available at <http://www.electropedia.org/>

3.1

denture adhesives

denture adhesive 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 form

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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](#) or another validated method.

5.1.3 Microbiology

Testing for microbiological contamination shall be carried out according to appropriate methods such as those listed in Bibliography [1] to [12].

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 test shall be conducted at a temperature of $(23 \pm 3)^\circ\text{C}$.

7.2 pH value measurement

7.2.1 Apparatus and material

7.2.1.1 pH meter

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

7.2.1.1.2 pH meter, with a flat type pH compound electrode.

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7.2.1.2 Container

7.2.1.2.1 Glass container, of 500 ml capacity.

7.2.1.2.2 Container, of 35 X 10 mm.

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; 1987.

7.2.2.3 Sodium chloride, analytical grad