Dentistry - Denture adhesives (ISO 10873:2021)



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See Eesti standard EVS-EN ISO 10873:2021 sisaldab Euroopa standardi EN ISO 10873:2021 ingliskeelset teksti.

This Estonian standard EVS-EN ISO 10873:2021 consists of the English text of the European standard EN ISO 10873:2021.

Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.

This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.

Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 14.07.2021.

Date of Availability of the European standard is 14.07.2021.

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### ICS 97.170

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# **EUROPEAN STANDARD**

# **EN ISO 10873**

# NORME EUROPÉENNE

**EUROPÄISCHE NORM** 

July 2021

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Supersedes EN ISO 10873:2010

### **English Version**

# Dentistry - Denture adhesives (ISO 10873:2021)

Médecine bucco-dentaire - Adhésifs pour prothèses dentaires (ISO 10873:2021)

Zahnheilkunde - Prothesenhaftmittel (ISO 10873:2021)

This European Standard was approved by CEN on 6 May 2021.

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CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

## **European foreword**

This document (EN ISO 10873:2021) 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of an identical text or by endorsement, at the latest by January 2022, and conflicting national standards shall be withdrawn at the latest by January 2022.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 10873:2010.

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### **Endorsement notice**

The text of ISO 10873:2021 has been approved by CEN as EN ISO 10873:2021 without any modification.

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### Foreword

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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 <a href="www.iso.org/directives">www.iso.org/directives</a>).

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For an explanation of the voluntary nature of standards, 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 <a href="https://www.iso.org/iso/foreword.html">www.iso.org/iso/foreword.html</a>.

This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 7, *Oral care products*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 10873:2010), which has been technically revised. The main changes compared to the previous edition are as follows:

- the powder/water ratio described in <u>7.5.3.1</u> and <u>7.6.3.1</u> has been revised;
- the method for pH value measurement has been modified in part;
- the surface roughness of the sample holder has been revised.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at <a href="https://www.iso.org/members.html">www.iso.org/members.html</a>.

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### 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.

anti. It is recommended that, in assessing possible biological hazards, reference be made to ISO 7405 and ISO 10993-1.

# **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 8601-1, Date and time — Representations for information interchange — Part 1: Basic rules

### 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 <a href="https://www.iso.org/obp">https://www.iso.org/obp</a>
- IEC Electropedia: available at <a href="http://www.electropedia.org/">http://www.electropedia.org/</a>

### 3.1

### denture adhesive

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

Note 1 to entry: The intaglio surface is also known as the fitting surface.

[SOURCE: ISO 1942:2020, 3.3.1.23, modified — Note 1 to entry has been added.]

### 3.2

### glue type

denture adhesive (3.1) in powder, cream, sheet or tape form with a water-soluble polymer as the adhesive constituent

#### 3.3

### liner type

denture adhesive (3.1) in non-aqueous form