



SLOVENSKI STANDARD SIST EN ISO 10873:2021

01-september-2021

Nadomešča:
SIST EN ISO 10873:2010

Zobozdravstvo - Lepila za zobne proteze (ISO 10873:2021)

Dentistry - Denture adhesives (ISO 10873:2021)

Zahnheilkunde - Prothesenhaftmittel (ISO 10873:2021)

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

iTeh STANDARD PREVIEW
(standards.iteh.ai)

Ta slovenski standard je istoveten z: **EN ISO 10873:2021**

<https://standards.iteh.ai/catalog/standards/sist/e74732e4-70a6-4049-bad4-ad6a02e2bd5b/sist-en-iso-10873-2021>

ICS:

11.060.01	Zobozdravstvo na splošno	Dentistry in general
71.100.70	Kozmetika. Toaletni pripomočki	Cosmetics. Toiletries

SIST EN ISO 10873:2021

en

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

SIST EN ISO 10873:2021

<https://standards.iteh.ai/catalog/standards/sist/e74732e4-70a6-4049-bad4-ad6a02e2bd5b/sist-en-iso-10873-2021>

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 10873

July 2021

ICS 97.170

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.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

SIST EN ISO 10873:2021

<https://standards.iteh.ai/catalog/standards/sist/e74732e4-70a6-4049-bad4-ad6a02e2bd5b/sist-en-iso-10873-2021>



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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

Contents	Page
European foreword.....	3

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 10873:2021
<https://standards.iteh.ai/catalog/standards/sist/e74732e4-70a6-4049-bad4-ad6a02e2bd5b/sist-en-iso-10873-2021>

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.

Any feedback and questions on this document should be directed to the users' national standards body/national committee. A complete listing of these bodies can be found on the CEN websites.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

[https://standards.iteh.ai/catalog/standards/sist/e74732e4-70a6-4049-bad4-](https://standards.iteh.ai/catalog/standards/sist/e74732e4-70a6-4049-bad4-ad6a02e2bd5b/sist-en-iso-10873-2021)

[ad6a02e2bd5b/sist-en-iso-10873-2021](https://standards.iteh.ai/catalog/standards/sist/e74732e4-70a6-4049-bad4-ad6a02e2bd5b/sist-en-iso-10873-2021)

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

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 10873:2021

<https://standards.iteh.ai/catalog/standards/sist/e74732e4-70a6-4049-bad4-ad6a02e2bd5b/sist-en-iso-10873-2021>

INTERNATIONAL STANDARD

**ISO
10873**

Second edition
2021-07

Dentistry — Denture adhesives

Médecine bucco-dentaire — Adhésifs pour prothèses dentaires

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN ISO 10873:2021](https://standards.iteh.ai/catalog/standards/sist/e74732e4-70a6-4049-bad4-ad6a02e2bd5b/sist-en-iso-10873-2021)

<https://standards.iteh.ai/catalog/standards/sist/e74732e4-70a6-4049-bad4-ad6a02e2bd5b/sist-en-iso-10873-2021>



Reference number
ISO 10873:2021(E)

© ISO 2021

iTeh STANDARD PREVIEW (standards.iteh.ai)

SIST EN ISO 10873:2021

<https://standards.iteh.ai/catalog/standards/sist/e74732e4-70a6-4049-bad4-ad6a02e2bd5b/sist-en-iso-10873-2021>



COPYRIGHT PROTECTED DOCUMENT

© ISO 2021

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Classification	2
4.1 General	2
4.2 Types and classes	2
5 Requirements	2
5.1 General	2
5.1.1 Biocompatibility	2
5.1.2 pH value	2
5.1.3 Microbiology	2
5.1.4 Stability	2
5.2 Specific requirements for Type 1 adhesives	2
5.2.1 Washability	2
5.2.2 Strength of the adhesion to the prosthesis	2
5.3 Specific requirements for Type 2 adhesives	3
5.3.1 Adhesion strength	3
5.3.2 Peeling property	3
5.3.3 Consistency	3
6 Sampling	3
7 Measurements and test methods	3
7.1 Test conditions	3
7.2 pH value measurement	3
7.2.1 Apparatus and material	3
7.2.2 Reagents	3
7.2.3 Procedure	4
7.3 Determination of stability — Aging procedure	4
7.4 Test of washability (for Type 1 adhesives)	4
7.4.1 Apparatus and materials	4
7.4.2 Reagent	5
7.4.3 Procedure	5
7.5 Adhesion strength test I (for Type 1 adhesives)	5
7.5.1 General	5
7.5.2 Apparatus	5
7.5.3 Procedure	7
7.6 Adhesion strength test II (for Type 1 adhesives)	9
7.6.1 General	9
7.6.2 Apparatus	9
7.6.3 Procedure	9
7.7 Adhesion strength test (for Type 2 adhesives)	10
7.7.1 Apparatus	10
7.7.2 Procedure	12
7.8 Peeling test (for Type 2 adhesives)	12
7.8.1 Apparatus and materials	12
7.8.2 Reagent	13
7.8.3 Procedure	13
7.9 Consistency test (for Type 2 adhesives)	13
7.9.1 Apparatus	13
7.9.2 Procedure	15
7.10 Assessment	15

ISO 10873:2021(E)

8	Packaging	16
9	Accompanying information	16
9.1	Information to be included in the instructions for use	16
9.2	Labelling on the package	17
	Bibliography	18

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 10873:2021

<https://standards.iteh.ai/catalog/standards/sist/e74732e4-70a6-4049-bad4-ad6a02e2bd5b/sist-en-iso-10873-2021>

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 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 www.iso.org/iso/foreword.html.

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 [7.5.3.1](#) and [7.6.3.1](#) 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 www.iso.org/members.html.

ISO 10873:2021(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.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 10873:2021

<https://standards.iteh.ai/catalog/standards/sist/e74732e4-70a6-4049-bad4-ad6a02e2bd5b/sist-en-iso-10873-2021>