BS EN ISO 22112:2017

BSI Standards Publication

Dentistry - Artificial teeth for dental prostheses (ISO 22112:2017)

bsi.

National foreword

This British Standard is the UK implementation of EN ISO 22112:2017. It is identical to ISO 22112:2017. It supersedes BS EN ISO 22112:2006, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/106/2, Prosthodontic materials.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Published by BSI Standards Limited 2017

ISBN 978 0 580 92377 7

ICS 11.060.10

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 September 2017.

Amendments/corrigenda issued since publication

Date	Text affected

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 22112

August 2017

ICS 11.060.10

Supersedes EN ISO 22112:2006

English Version

Dentistry - Artificial teeth for dental prostheses (ISO 22112:2017)

Médecine bucco-dentaire - Dents artificielles pour prothèses dentaires (ISO 22112:2017)

Zahnheilkunde - Künstliche Zähne für Dentalprothesen (ISO 22112:2017)

This European Standard was approved by CEN on 6 May 2017.

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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN ISO 22112:2017: E

European foreword

This document (EN ISO 22112:2017) 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 February 2018, and conflicting national standards shall be withdrawn at the latest by February 2018.

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 22112:2006.

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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Contents

Page

Foreword ..... **v**

1 Scope **1**

2 Normative references **1**

3 Terms and definitions **1**

4 Classification **2**

5 Requirements **2**
5.1 General 2
5.1.1 Biocompatibility 2
5.1.2 Dimensions of teeth 2
5.1.3 Colour and blending of shades 2
5.1.4 Surface finish 2
5.1.5 Porosity and other defects 3
5.2 Ceramic teeth 3
5.2.1 Radioactivity 3
5.2.2 Anchorage 3
5.2.3 Resistance to thermal shock 3
5.3 Polymer teeth 3
5.3.1 Bonding to denture base polymer 3
5.3.2 Resistance to blanching, distortion and crazing 3
5.3.3 Colour stability 3
5.3.4 Dimensional stability 3

6 Sampling **4**

7 Measurement and test methods **4**
7.1 Visual inspection 4
7.2 Dimensions of teeth 4
7.2.1 Reagents and/or materials 4
7.2.2 Apparatus 4
7.2.3 Procedure 4
7.3 Comparison with shade guide 5
7.3.1 Reagents and/or materials 5
7.3.2 Apparatus 5
7.4 Surface finish of ceramic teeth 5
7.4.1 Reagents and/or materials 5
7.4.2 Apparatus 6
7.4.3 Processing 6
7.4.4 Grinding 6
7.5 Surface finish of polymer teeth 6
7.5.1 Reagents and/or materials 6
7.5.2 Apparatus 7
7.5.3 Processing 7
7.6 Porosity of ceramic teeth and other defects 7
7.6.1 Reagents and/or materials 7
7.6.2 Apparatus 7
7.6.3 Preparation of specimens 8
7.6.4 Procedure 8
7.7 Porosity of polymer teeth and other defects 8
7.7.1 Reagents and/or materials 8
7.7.2 Apparatus 8
7.7.3 Procedure 8
7.8 Radioactivity of ceramic teeth 9
7.8.1 Reagents and/or materials 9
7.8.2 Apparatus 9

7.8.3 Sample preparation 10
7.8.4 Counting procedure 10
7.8.5 Assessment of results 10
7.9 Anchorage of ceramic teeth to denture base polymers 10
7.9.1 Reagents and/or materials 10
7.9.2 Apparatus 10
7.9.3 Procedure 10
7.10 Resistance of ceramic teeth to thermal shock 10
7.10.1 Reagents and/or materials 10
7.10.2 Apparatus 10
7.10.3 Preparation of specimens 11
7.10.4 Procedure 11
7.11 Bonding of polymer teeth to denture-base polymers 11
7.11.1 Reagents and/or materials 11
7.11.2 Apparatus 11
7.11.3 Procedure 12
7.12 Resistance to blanching, distortion and crazing of polymer teeth 13
7.12.1 Sampling 13
7.12.2 Reagents and/or materials 14
7.12.3 Apparatus 14
7.12.4 Conditioning of test specimens 14
7.12.5 Procedure for exposure to monomer 14
7.12.6 Visual inspection 15
7.13 Colour stability of polymer teeth 15
7.13.1 General 15
7.13.2 Reagents and/or materials 15
7.13.3 Procedure 15
7.14 Dimensional stability of polymer teeth 15
7.14.1 Reagents and/or materials 15
7.14.2 Apparatus 15
7.14.3 Procedure 15

8 Marking, labelling, and information to be supplied by the manufacturer 16
8.1 Marking and labelling 16
8.2 Information to be supplied by manufacturer 16
8.2.1 Mould chart 16
8.2.2 Shade guide 16
8.3 Manufacturer's instructions for use 16

9 Packaging 16

Bibliography 17

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 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 the following URL: www.iso.org/iso/foreword.html.

This document was prepared by ISO/TC 106 *Dentistry*, Subcommittee SC 2 *Prosthodontic materials*.

This second edition cancels and replaces the first edition (ISO 22112:2005), which has been technically revised.

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

— clarification of colour and blending requirement for multi-layered teeth (5.1.3);

— clarification of test procedure for surface finishing (7.5);

— for testing of radioactivity of ceramic teeth: gamma spectroscopy system is added (7.8).

This page deliberately left blank

INTERNATIONAL STANDARD **ISO 22112:2017(E)**

Dentistry - Artificial teeth for dental prostheses (ISO 22112:2017)

1 Scope

This document specifies the classification, requirements, and test methods for artificial teeth such as ceramic teeth and polymer teeth that are industrially manufactured for use in dental prostheses.

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 483, *Plastics — Small enclosures for conditioning and testing using aqueous solutions to maintain the humidity at a constant value*

ISO 1942, *Dentistry — Vocabulary*

ISO 3950, *Dentistry — Designation system for teeth and areas of the oral cavity*

ISO 6344-1, *Coated abrasives — Grain size analysis — Part 1: Grain size distribution test*

ISO 6873:2013, *Dentistry — Gypsum products*

ISO 7491:2000, *Dental materials — Determination of colour stability*

ISO 20795-1, *Dentistry — Base polymers — Part 1: Denture base polymers*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 and ISO 20795-1 and the following apply.

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

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

— ISO Online browsing platform: available at http://www.iso.org/obp

3.1
artificial teeth
manufactured product designed to simulate and replace natural teeth

3.2
diatoric teeth
teeth designed to be retained by anchorage slots and/or holes

3.3
pin teeth
teeth designed to be retained by headed pins

3.4
set
set of six anterior teeth or eight posterior teeth, as received from the manufacturer