SLOVENSKI STANDARD
SIST EN ISO 22112:2006

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Nadomeģ a:
SIST EN ISO 3336:2000
SIST EN ISO 4824:2000
SIST EN ISO 4824:2000/A1:2006

Zobozdravstvo - Umetni zobje za zobne proteze (ISO 22112:2005)

Dentistry - Artificial teeth for dental prostheses (ISO 22112:2005)

Zahnheilkunde - Künstliche Zähne für Dentalprothesen (ISO 22112:2005)

Art dentaire - Dents artificielles pour protheses dentaires (ISO 22112:2005)

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ICS:

11.060.10	Zobotehniļ ni materiali	Dental materials

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Dentistry - Artificial teeth for dental prostheses (ISO 22112:2005)

Art dentaire - Dents artificielles pour prothèses dentaires (ISO 22112:2005)

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This European Standard was approved by CEN on 6 February 2006.

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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 Central Secretariat has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

The text of ISO 22112:2005 has been prepared by Technical Committee ISO/TC 106 "Dentistry" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 22112:2006 by 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of an identical text or by endorsement, at the latest by September 2006, and conflicting national standards shall be withdrawn at the latest by September 2006.

This document replaces EN 3336:1996 and EN 4824:1996.

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

Endorsement notice

The text of ISO 22112:2005 has been approved by CEN as EN ISO 22112:2006 without any modifications.

INTERNATIONAL STANDARD

ISO 22112

First edition
2005-11-01

Dentistry — Artificial teeth for dental prostheses

Art dentaire — Dents artificielles pour prothèses dentaires

Reference number
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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 22112 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthodontic materials*.

This first edition cancels and replaces ISO 3336:1993, ISO 4824:1993 and ISO 4824:1993/Amd. 1:1997 which have been technically revised.

Dentistry — Artificial teeth for dental prostheses

1 Scope

This International Standard specifies the classification, requirements, and test methods for synthetic polymer and ceramic teeth that are manufactured for use in prostheses used in dentistry.

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 483 [1], *Plastics — Small enclosures for conditioning and testing using aqueous solutions to maintain the humidity at a constant value*

ISO 1567:1999, *Dentistry — Denture base polymers*

ISO 1942 [2], *Dentistry — Vocabulary*

ISO 3950:1984, *Dentistry — Designation system for teeth and areas of the oral cavity*

ISO 6873:1998, *Dental gypsum products*

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

3 Terms and definitions

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

3.1
diatoric teeth
teeth designed to be retained by anchorage slots and/or holes

3.2
pin teeth
teeth designed to be retained by headed pins

3.3
set
set of six anterior teeth or eight posterior teeth, as received from the manufacturer

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1) To be published. (Revision of ISO 483:1988)

2) To be published. [Revision of ISO 1942 (all parts):1989]

3.4
half-set
three teeth on one side of a set of anterior teeth or four teeth on one side of a set of posterior teeth

3.5
mould chart
chart representing the form, shape and dimensions of all individual teeth of a set

4 Classification

Artificial teeth are grouped in accordance with the following classification:

a) Type 1: anterior teeth;

b) Type 2: posterior teeth.

5 Requirements

5.1 General

5.1.1 Biocompatibility

Specific qualitative and quantitative requirements for freedom from biological hazard are not included in this International Standard, but it is recommended that, in assessing possible biological or toxicological hazards, reference be made to ISO 10993-1 and ISO 7405.

5.1.2 Dimensions of teeth

The dimensions of the teeth when examined in accordance with 7.2 shall not differ by more than 5 % for synthetic polymer teeth and 7 % for ceramic teeth from the values shown in the manufacturer's mould chart.

5.1.3 Colour and blending of shades

When tested in accordance with 7.3, sets of anterior and posterior teeth shall exhibit no perceptible colour difference compared with the manufacturer's shade guide (8.2.2) or nominated shade guide. Blended teeth shall show no line of demarcation between incisal and cervical portions on the facial aspects of the teeth.

NOTE This requirement is not intended to disallow especially designed demarcations placed to simulate borders of restorations or enamel imperfections found in natural teeth.

5.1.4 Surface finish

When inspected visually in accordance with 7.1, the teeth as received (excluding retention areas) shall have a smooth, lustrous, non-porous surface.

When ceramic teeth are tested in accordance with 7.4, the processing shall not have impaired the original finish of the teeth, and the teeth shall be capable of being ground and polished.

When synthetic polymer teeth are tested in accordance with 7.5, the teeth shall be capable of being polished to restore the original finish.

5.1.5 Freedom from porosity and other defects

Ceramic teeth shall not show more than a total of 16 pores of diameter greater than 30 µm on the four test surfaces when tested in accordance with 7.6. No more than six of those pores shall have diameters ranging from $\geqslant$ 40 µm and $\leqslant$ 150 µm. There shall be no pores of diameter greater than 150 µm.

Synthetic polymer teeth, when examined in accordance with 7.7, shall exhibit no porosity or defect, such as rough trimming, rough finish or visible impurities, on the coronal surfaces.

5.2 Ceramic teeth

5.2.1 Radioactivity

When tested in accordance with 7.8, ceramic teeth shall have an activity concentration of no more than 1,0 $Bq \cdot g^{-1}$ of uranium–238.

5.2.2 Anchorage

All ceramic diatoric teeth, examined in accordance with 7.9, shall provide a means of positive retention and have holes all of which shall be open and unsealed.

5.2.3 Resistance to thermal shock

Ceramic teeth shall, when tested in accordance with 7.10, show no signs of cracking.

5.3 Synthetic polymer teeth

5.3.1 Bonding to denture base polymers

All synthetic polymer teeth shall be capable of being bonded to heat-polymerized denture-base materials (Type 1), which conform to ISO 1567:1999. For five out of the six test specimens, the bond formed between the ridge lap portion of the teeth and the denture base polymer shall pass the test described in 7.11.

5.3.2 Resistance to blanching, distortion and crazing

When tested in accordance with 7.12, no teeth shall exhibit blanching or distortion. No teeth shall exhibit crazing with the exception of the ridge lap surfaces and the cervical portion of the teeth up to the cervical line.

5.3.3 Colour stability

When tested in accordance with 7.13, there shall be no perceptible colour change between the exposed and unexposed halves of the tooth and the unexposed tooth.

5.3.4 Dimensional stability

When tested in accordance with 7.14, the dimensional change of a tooth shall be within $\pm$ 2 % of its original mesio-distal dimension.

6 Sampling

The sample shall consist of six groups, each comprising sets of mandibular and maxillary anterior and posterior teeth (if available).

For comparisons with the manufacturer's shade guide, all available shades of anterior teeth and five shades of available posterior teeth shades shall be included.

Five mould sizes shall be included covering the range of mould sizes shown by the manufacturer’s mould chart. The teeth shall be representative of the physical dimensions of the brand and type.