

SLOVENSKI STANDARD SIST EN ISO 22674:2022

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Nadomešča:

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Zobozdravstvo - Kovinski materiali za stalne in zamenljive zobne obnove in orodja (ISO 22674:2022)

Dentistry - Metallic materials for fixed and removable restorations and appliances (ISO 22674:2022)

Zahnheilkunde - Metallische Werkstoffe für festsitzenden und herausnehmbaren Zahnersatz und Applikationen (ISO 22674:2022)

Médecine bucco-dentaire - Matériaux métalliques pour les restaurations fixes et amovibles et les appareillages (ISO 22674:2022)

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11.060.10 Zobotehnični materiali Dental materials

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EUROPEAN STANDARD NORME EUROPÉENNE EUROPÄISCHE NORM **EN ISO 22674**

September 2022

ICS 11.060.10

Supersedes EN ISO 22674:2016

English Version

Dentistry - Metallic materials for fixed and removable restorations and appliances (ISO 22674:2022)

Médecine bucco-dentaire - Matériaux métalliques pour les restaurations fixes et amovibles et les appareillages (ISO 22674:2022)

Zahnheilkunde - Metallische Werkstoffe für festsitzenden und herausnehmbaren Zahnersatz und Applikationen (ISO 22674:2022)

This European Standard was approved by CEN on 26 August 2022.

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EN ISO 22674:2022 (E)

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European foreword

This document (EN ISO 22674:2022) 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of an identical text or by endorsement, at the latest by March 2023, and conflicting national standards shall be withdrawn at the latest by March 2023.

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.

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ISO 22674

Third edition 2022-08

Dentistry — Metallic materials for fixed and removable restorations and appliances

Médecine bucco-dentaire — Matériaux métalliques pour les restaurations fixes et amovibles et les appareils

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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).

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

This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthodontic materials*], 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 third edition cancels and replaces the second edition (ISO 22674:2016), which has been technically revised.

The main changes are as follows:

- addition of products produced using additive and subtractive manufacturing;
- revision of definitions and addition of new definitions for modern manufacturing techniques;
- addition of an overview of symbols in <u>Clause 4</u> as <u>Table 1</u>;
- harmonization of symbols in formulae and Figures;
- static determination of elastic modulus was added in 8.4.1.3 (as an additional option);
- a requirement for a test report was added as <u>Clause 9</u>;
- a requirement for labelling the alloy composition on the package was added in <u>10.4</u>.

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.

Introduction

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

Requirements for the performance of metals and alloys used for the metallic component of a metal-ceramic restoration contained in this document supersede such requirements formerly contained in ISO 9693. The requirements for the performance of ceramic material and the metal-ceramic bond in metal-ceramic restorative systems are specified in ISO 9693.

Requirements for the proof stress and minimum elongation after fracture for Type 0 metallic materials are not included in this document, but it is recommended to adopt the test procedure given in $\underbrace{Annex\ A}$ when measuring these properties.

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Dentistry — Metallic materials for fixed and removable restorations and appliances

1 Scope

This document specifies requirements and test methods for metallic materials that are suitable for the fabrication of dental restorations and appliances. Included are metallic materials recommended for use either with or without a ceramic veneer, or recommended for both uses. Furthermore, this document specifies requirements for packaging and marking of the products and for the instructions for use of these materials, including products delivered for sale to a third party.

This document does not apply to alloys for dental amalgam (see ISO 24234), dental brazing materials (see ISO 9333), or metallic materials for orthodontic appliances (e.g. wires, brackets, bands and screws).

This document is not applicable to magnetic attachment, which are specified in ISO 13017.

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 Malaras Iteh. 21

ISO 3696, Water for analytical laboratory use — Specification and test methods

ISO 5832-2, Implants for surgery — Metallic materials — Part 2: Unalloyed titanium

ISO 5832-3, Implants for surgery — Metallic materials — Part 3: Wrought titanium 6-aluminium 4-vanadium alloy

ISO 6344-3, Coated abrasives — Determination and designation of grain size distribution — Part 3: Microgrit sizes P240 to P5000

ISO 6892-1, Metallic materials — Tensile testing — Part 1: Method of test at room temperature

ISO 7500-1, Metallic materials — Calibration and verification of static uniaxial testing machines — Part 1: Tension/compression testing machines — Calibration and verification of the force-measuring system

ISO 9513, Metallic materials — Calibration of extensometer systems used in uniaxial testing

ISO 9693, Dentistry — Compatibility testing for metal-ceramic and ceramic-ceramic systems

ISO 10271:2020, Dentistry — Corrosion test methods for metallic materials

ISO 15223-1:2021, Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements

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 terminology databases for use in standardization at the following addresses:

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

IEC Electropedia: available at https://www.electropedia.org/

3.1

additive manufacturing

process of joining materials to make parts from 3D model data, usually layer upon layer, as opposed to subtractive manufacturing (3.19) and formative manufacturing methodologies

[SOURCE: ISO/ASTM 52900:2021, 3.1.2, modified — Notes 1 and 2 to entry have been deleted.]

3.2

appliance

prefabricated metallic device such as attachments and bars

3.3

as-cast state

metallurgical condition of the *metallic material* (3.15) in its solid state when removed from the casting machine

Note 1 to entry: This condition is dependent upon the manufacturer's recommended cooling procedure (e.g. bench cooling).

3.4

base metal

metallic element, with the exception of *noble metals* (3.16) and silver

3.5

base-metal alloy

alloy having a base metal (3.4) as the principal element

3.6

bench-cooling

process whereby a casting is retained in its investment with exposed metal uppermost and placed on a flat, insulating surface at ambient temperature in freely circulating air until its temperature falls to ambient

3.7

casting alloy

metallic material (3.15) designed for casting into an investment mould

3.8

ceramic veneer

thin ceramic surface layer present on a *metallic material* (3.15) restoration to provide an aesthetic effect

3.9

elastic modulus

Young's modulus

ratio of elastic stress to elastic strain

3.10

hardening

heat-treatment of a *metallic material* (3.15) producing a condition which provides a higher 0,2 % proof stress than the *as-cast state* (3.3)

Note 1 to entry: If recommended by the manufacturer, explicit instructions are required in the instructions for use.

3.11

hazardous element

element that is known for its potential to produce an adverse biological effect

Note 1 to entry: The presence of such an element (as an alloying addition or as an impurity) in a dental alloy does not imply that the alloy, in itself, is hazardous.

3.12

heat treatment

thermal treatment of a *metallic material* (3.15) such as a material stress relieving process, including softening (3.18), hardening (3.10), ceramic firing

3.13

metal-ceramic restoration

dental restoration with a *ceramic veneer* (3.8) bonded to a *metallic material* (3.15) substructure by firing

Note 1 to entry: This can apply also to the metallic material used for such a restoration. In this context, metalceramic alloy is a synonym.

Note 2 to entry: If recommended, such a metallic material may be used without a ceramic veneer.

3.14

metallic base

metal with highest concentration by mass fraction in the alloy

metallic material

material with properties that are associated with an alloy, noble metal (3.16) or base metal (3.4)

Note 1 to entry: This may be a pure element, commercially pure metal or an alloy.

3.16

noble metal

metal containing gold, metal of the platinum group and/or rhenium

3.17

one-surface inlay

inlay restoration that is exposed to the oral environment on one and no more of the surfaces that are used to define the tooth for the purposes of charting

3.18

softening

heat-treatment of a *metallic material* (3.15) producing a condition which provides a lower 0,2 % proof stress than the as-cast state (3.3)

Note 1 to entry: If recommended by the manufacturer, explicit instructions are required in the instructions for use.

3.19

subtractive manufacturing

manufacturing process where a solid material such as milling blank is reduced by milling, grinding, eroding or similar techniques to the final shape

4 Symbols and classification

4.1 Symbols

<u>Table 1</u> gives an overview about the symbols used in this document.