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



EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 22674:2022 sisaldab Euroopa standardi EN ISO 22674:2022 ingliskeelset teksti.

This Estonian standard EVS-EN ISO 22674:2022 consists of the English text of the European standard EN ISO 22674:2022.

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 21.09.2022.

Date of Availability of the European standard is 21.09.2022.

Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.

The standard is available from the Estonian Centre for Standardisation and Accreditation.

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ICS 11.060.10

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EUROPEAN STANDARD

NORME EUROPÉENNE

EN ISO 22674

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

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

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of an identical text or by endorsement, at the latest by March 2023, and conflicting national standards shall be withdrawn at the latest by March 2023.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.

This document supersedes EN ISO 22674:2016.

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 website.

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, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 22674:2022 has been approved by CEN as EN ISO 22674:2022 without any modification.

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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).

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 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 10.4.

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 bu.

Representation Seneral and Artiflet. are not included in this document, but it is recommended to adopt the test procedure given in Annex A when measuring these properties.

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

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