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BS EN ISO 22674:2016



BSI Standards Publication

Dentistry — Metallic materials for fixed and removable restorations and appliances (ISO 22674:2016)

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This British Standard is the UK implementation of EN ISO 22674:2016. It supersedes BS EN ISO 22674:2006 which is withdrawn.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.

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Dentistry - Metallic materials for fixed and removable restorations and appliances (ISO 22674:2016)

Médecine bucco-dentaire - Matériaux métalliques pour les restaurations fixes et amovibles et les appareillages (ISO 22674:2016)

Zahnheilkunde - Metallische Werkstoffe für festsitzenden und herausnehmbaren Zahnersatz und Applikationen (ISO 22674:2016)

This European Standard was approved by CEN on 24 October 2015.

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.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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European foreword

This document (EN ISO 22674:2016) 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of an identical text or by endorsement, at the latest by August 2016, and conflicting national standards shall be withdrawn at the latest by August 2016.

This document supersedes EN ISO 22674:2006.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

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, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 22674:2016 has been approved by CEN as EN ISO 22674:2016 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 on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: [Foreword - Supplementary information](#)

The committee responsible for this document is ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthetic materials*.

This second edition cancels and replaces the first edition (ISO 22674:2006), which has been technically revised with the following changes:

- Corrosion resistance measurement was referred to the recent standard ISO 10271:2011.
- A second tarnish test was included, referring to provisions in ISO 10271:2011.
- Clarification of the term "free of" was added to the requirements of composition and labelling;
- Lead was added as a hazardous element.
- Measurement of elasticity was revised. Beside the method of calculation of elastic modulus using an extensometer, other alternative methods were added, namely, the flexure method in three- and four-point bending and the acoustic resonance method.
- Informative [Annex A](#) was added, dealing with tensile testing of non-cast Type 0 metallic materials intended for use in a thickness between 0,1 and 0,5 mm.
- Normative [Annex B](#) was added, giving information on calculation of uncertainty for elastic measurement.
- Informative [Annex C](#) was added, giving information for measurement of Poisson ratio.

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Introduction

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 hazards, reference has to 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 International Standard 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 continue to be specified in ISO 9693-1.

Requirements for the proof stress and minimum elongation after fracture for Type 0 metallic materials are not included in this International Standard, but it is recommended to adopt the test procedure given in [Annex A](#) when measuring these properties. Requirements will be included in a revision of this International Standard when information becomes available to Technical Committee ISO/TC 106/SC 2.

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Dentistry — Metallic materials for fixed and removable restorations and appliances

1 Scope

This International Standard classifies metallic materials that are suitable for the fabrication of dental restorations and appliances, including metallic materials recommended for use either with or without a ceramic veneer, or recommended for both uses, and specifies their requirements. Furthermore, it specifies requirements with respect to packaging and marking the products and to the instructions to be supplied for the use of these materials, including products delivered for sale to a third party.

This International Standard does not apply to alloys for dental amalgam (ISO 24234), dental brazing materials (ISO 9333), or metallic materials for orthodontic appliances (ISO 15841) (e.g. wires, brackets, bands and screws).

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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 5832-3¹⁾, *Implants for surgery — Metallic materials — Part 3: Wrought titanium 6-aluminium 4-vanadium alloy*

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

ISO 6892-1²⁾, *Metallic materials — Tensile testing — Part 1: Method of test at room temperature*

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

ISO 9693-1, *Dentistry — Compatibility testing — Part 1: Metal-ceramic systems*

ISO 10271:2011, *Dentistry — Corrosion test methods for metallic materials*

ISO 15223-1:2012, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

3 Terms and definitions

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

3.1

base metal

any metallic element with the exception of noble metals (i. e. gold and metals of the platinum group) and silver

1) To be published.

2) To be published.