SLOVENSKI STANDARD
oSIST prEN ISO 9333:2021

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Zobozdravstvo - Materiali za spajkanje (ISO/DIS 9333:2021)

Dentistry - Brazing materials (ISO/DIS 9333:2021)

Zahnheilkunde - Hartlote (ISO/DIS 9333:2021)

Médecine bucco-dentaire - Produits pour brasage (ISO/DIS 9333:2021)

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Dentistry — Brazing materials

Médecine bucco-dentaire — Produits pour brasage

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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*.

This third edition cancels and replaces the second edition (ISO 9333:2006), which has been technically revised.

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

— exclusion of brazing materials with silver as main component from the scope;

— clarification of definitions (Clause 3) and harmonisation with ISO/DIS 22674:2021;

— harmonization of corrosion requirements (4.4) with ISO/DIS 22674:2021 and ISO 10271;

— analysis of corrosion elements is required in 7.4.2;

— harmonization of melting range requirements (7.5) with ISO/DIS 22674:2021;

— requirement for test report was added as Clause 8;

— IFU requirement for working temperature was added in Clause 9;

— labelling requirement for marking of working temperature was added in Clause 10 as optional.

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.

Dentistry — Brazing materials

1 Scope

This document specifies requirements and test methods for dental brazing materials suitable for use in metallic restorations.

Excluded are brazing materials with silver as main component.

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

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

ISO 15223-1:2021, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 22674:2016, *Dentistry — Metallic materials for fixed and removable restorations and appliances*

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 terminological 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.or

3.1
base metal
any metallic element with the exception of noble metals and silver

[SOURCE: ISO 22674:2016, 3.1, modified — text in parentheses was deleted in the definition.]

3.2
brazing material
alloy suitable for use as a filler material in operations in which dental alloy parts are joined by brazing to form dental appliances and restorations

Note 1 to entry: The process and principle of brazing are identical to soldering. Brazing is done at higher temperatures than soldering.

3.3
flux
chemical cleaning agent, flowing agent, or purifying agent supporting the flow of the molten brazing material for wetting of the substrate

3.4
noble metal
gold, metals of the platinum group and rhenium

[SOURCE: ISO 22674:2016, 3.2, modified — "rhenium" was added in the definition.]

3.5
working temperature
temperature based on the liquidus temperature plus x (whereby x is given by the manufacturer of the brazing material)

4 Requirements

4.1 Chemical composition

4.1.1 Metallic materials to be joined

The metallic materials to be joined shall conform to ISO 22674:2016, 5.1 and 5.2.

4.1.2 Reported composition

For all elements that are present in excess of 1,0 % (mass fraction), the percentage by mass of each of the constituent elements shall be declared by the manufacturer and shall be reported to a precision of 0,1 % (mass fraction).

Any element that is present in a concentration in excess of 0,1 % (mass fraction), but not in excess of 1 % (mass fraction), shall be identified either by name or symbol.

4.1.3 Permitted deviation from the reported composition

4.1.3.1 Noble-metal based brazing material

For noble-metal based brazing material, the percentage of each of the constituents shall not deviate by more than 0,5 % (mass fraction) from the values stated in the instructions for use.

4.1.3.2 Base-metal based brazing material

For base-metal based brazing material, all elements, present with more than 20 % (mass fraction) shall not deviate from the value stated in the instructions for use by more than 2 % (mass fraction). Those elements present in excess of 1 % (mass fraction), but not in excess of 20 % (mass fraction) shall not deviate from the value stated in the instruction for use by more than 1 % (mass fraction).

4.1.4 Hazardous elements

4.1.4.1 Recognised hazardous elements

For the purposes of this document the elements nickel, cadmium, beryllium and lead are designated to be hazardous elements.

4.1.4.2 Permitted limits for hazardous elements

The brazing material shall contain no more than 0,02 % (mass fraction) of cadmium or beryllium or lead. If the brazing material contains more than 0,1 % (mass fraction) of nickel, the percentage shall not exceed the amount indicated on the package or label or insert.