SLOVENSKI STANDARD
oSIST prEN ISO 20749:2022

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Zobozdravstvo - Pripravljeni zobni amalgam (ISO/DIS 20749:2022)

Dentistry - Pre-capsulated dental amalgam (ISO/DIS 20749:2022)

Zahnheilkunde – Dentalamalgam in Kapseln (ISO/DIS 20749:2022)

Médecine bucco-dentaire - Amalgame dentaire en capsules prédosées (ISO/DIS 20749:2022)

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ICS:

11.060.10 Zobotehnični materiali Dental materials

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Dentistry — Pre-capsulated dental amalgam

Médecine bucco-dentaire — Amalgame dentaire encapsulée

ICS: 11.060.10

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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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 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 the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 1, *Filling and Restorative Materials*.

The Scope of this document is restricted to dental amalgam products marketed in pre-capsulated form, alone. Other products intended for use in the in the production of dental amalgam restorations (dental amalgam alloy as a free-flowing powder supplied in bulk masses, dental amalgam alloy powder supplied as compressed tablets and dental mercury sachets) are within the scope of ISO 24234, 2021.

This second edition cancels and replaces the first edition (ISO 20749, 2017), which has been technically revised.

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

— a requirement for corrosion resistance has been added;

— the roughness measure used to specify the finish required on working surfaces of test-piece moulds has been changed from R_k to R_a;

— an instruction to abrade lightly the ends of the cylindrical test-pieces, if required, for removing flash has been deleted;

— the requirement for early compression strength has been altered. Measurement of the value is made at 2 h and not at 1 h;

— the thickness of the sheet specified for the mould to test for the consistency of dental amalgam from capsule to capsule is reduced to 2,5 mm;

— when determining the yield of dental amalgam from a capsule, a 20 min cooling time before weighing has been added;

— additional items of information have been added to each of the test reports;

— the edition number of the manufacturer's instructions and information, and the date of its introduction have been added as a requirement to the manufacturer's instructions;

— for each test method used to determine conformity to a requirement, a new sub-clause, "Principle", has been added in which a brief summary is present to explain the method adopted;

— for each test method used to determine conformity to a requirement, a new sub-clause, "Report", has been added;

— a new Clause, "7 Report", has been added. It provides details of the evaluation that are to accompany a statement of conformity to this document overall.

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

This is the second edition of ISO 20749, *Dentistry — Pre-capsulated dental amalgam*.

Specific qualitative and quantitative test methods for demonstrating freedom from unacceptable biological hazard are not included in this document and it is recommended that, for the assessment of possible biological hazards, reference should be made to ISO 10993 and ISO 7405.

Dentistry — Pre-capsulated dental amalgam

1 Scope

This document specifies the requirements and test methods for dental amalgam products supplied to the user in capsules, pre-dosed with dental amalgam alloy powder and dental mercury in quantities suitable for the creation of a single dental restoration.

This document specifies the requirements and test methods for the capsule and the requirements for packaging and marking.

This document is not applicable to other metallic materials in which an alloy powder reacts with an alloy that is liquid at ambient temperature to produce a solid metallic material intended for dental restoration.

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 286-2, *Geometrical product specifications (GPS) — ISO code system for tolerances on linear sizes — Part 2: Tables of standard tolerance classes and limit deviations for holes and shafts*

ISO 1942, *Dentistry — Vocabulary*

ISO 3310-1, *Test sieves — Technical requirements and testing — Part 1: Test sieves of metal wire cloth*

ISO 3864-2, *Graphical symbols — Safety colours and safety signs — Part 2: Design principles for product safety labels*

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

ISO 4287, *Geometrical Product Specifications (GPS) — Surface texture: Profile method — Terms, definitions and surface texture parameters*

ISO 7488, *Dentistry — Mixing machines for dental amalgam*

ISO 15223-1:2016, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 23325, *Dentistry — Corrosion resistance of dental amalgam*

Globally Harmonized System of Classification and Labelling of Chemicals (GHS). United Nations, New York and Geneva, 8th Edition, 2019, eISBN 978-92-1-004083-9

UN Recommendations on the Transport of Dangerous Goods, Model Regulations. United Nations, New York and Geneva, 21st Edition, 2019, eISBN 978-92-1-004112-6

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.org/

3.1
dental amalgam alloy
alloy in fine particles, composed mainly of silver, tin and copper, which when mixed with *dental mercury* (3.2) produces a dental amalgam for dental restoration

[SOURCE: ISO 24234:2021, 3.1]

3.2
dental mercury
mercury supplied for use in the preparation of dental amalgam

[SOURCE: ISO 24234:2021, 3.2]

3.3
pre-capsulated product
product supplied in a sealed capsule that contains measured amounts of *dental amalgam alloy* (3.1) powder and *dental mercury* (3.2) with masses that are appropriate for the production of a mass of dental amalgam that is considered to be suitable for a single small or medium size restoration in a single tooth

Note 1 to entry: The dental amalgam alloy powder and dental mercury are separated by a barrier that is broken immediately prior to mixing, allowing their contact. The capsule remains sealed until mixing has been completed.

[SOURCE: ISO 24234:2021, 3.3]

3.4
self-activating capsule
pre-capsulated product capsule in which contact between the *dental amalgam alloy* (3.1) powder and the *dental mercury* (3.2) occurs automatically during mixing

[SOURCE: ISO 20749:2017, 3.4]

3.5
mechanically-activated capsule
pre-capsulated product capsule in which force is applied to the ends of the capsule to rupture the barrier between the *dental amalgam alloy* (3.1) powder and the *dental mercury* (3.2) for activation, before placing the capsule in the mechanical mixing machine

[SOURCE: ISO 20749:2017, 3.5]

3.6
activation
action that renders the capsulated *dental amalgam alloy* (3.1) powder and *dental mercury* (3.2) mixable

[SOURCE: ISO 20749:2017, 3.6]

3.7
dental amalgam pellet
coherent mass of dental amalgam that is produced by mixing and drops from the opened and upended capsule

Note 1 to entry: A light tap of the rim of the open capsule on a hard surface may be required to dislodge the pellet and is permitted

[SOURCE: ISO 20749:2017, 3.7]

3.8
mixing machine for dental amalgam
DEPRECATED TERM: amalgamator
electrically-powered mixing machine that operates using an oscillating action for mixing *dental amalgam alloy* (3.1) powder and *dental mercury* (3.2) (in a capsule) to produce a dental amalgam

[SOURCE: ISO 24234: 2021, 3.6]

4 Requirements

4.1 Package and capsule contamination

The interior of the packaging container and the outer surface of the capsules shall be free of both dental mercury and dental amalgam alloy powder contamination when tested in accordance with 6.1.

4.2 Chemical composition and purity of the dental amalgam alloy

The manufacturer shall declare every element that is present in a concentration greater than, or equal to a mass fraction of 0,1 %. All alloying elements present in concentrations greater than a mass fraction of 0,5 % shall be given by name with mass fraction values rounded to the nearest whole percentage point. Alloying elements that are present in concentrations between a mass fraction of 0,1 and 0,5 % shall be named without a percentage value.

Test in accordance with 6.2.

The chemical composition shall comply with Table 1.

The total mass fraction for other elements present in concentrations greater than a mass fraction of 0,01 % but below a mass fraction of 0,1 % that are not declared as alloying elements, shall not exceed a mass fraction of 0,1 %.

Table 1 — Requirements for chemical composition of the dental amalgam alloy

Element	Mass fraction %
Silver	≥ 40
Tin	≤ 32
Copper	≤ 30
Indium	≤ 5
Palladium	≤ 1
Platinum	≤ 1
Zinc	≤ 2
Mercury	≤ 3

4.3 Large particles in the dental amalgam alloy powder

When conformity to this requirement is determined in accordance with 6.3, the proportion of the dental amalgam alloy powder that occurs as particles that have a size greater than 150 µm shall not exceed a mass fraction of 0,1 %.