Dentistry - Pre-capsulated dental amalgam (ISO 20749:2023)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 20749:2023 sisaldab Euroopa standardi EN ISO 20749:2023 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 20749:2023 consists of the English text of the European standard EN ISO 20749:2023.
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 12.07.2023.	Date of Availability of the European standard is 12.07.2023.
Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.	The standard is available from the Estonian Centre for Standardisation and Accreditation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.060.10

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 20749

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English Version

Dentistry - Pre-capsulated dental amalgam (ISO 20749:2023)

Médecine bucco-dentaire - Amalgame dentaire en capsules prédosées (ISO 20749:2023)

Zahnheilkunde - Dentalamalgam in Kapseln (ISO 20749:2023)

This European Standard was approved by CEN on 13 March 2023.

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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
EUROPÄISCHES KOMITEE FÜR NORMUNG

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

Ref. No. EN ISO 20749:2023 E

European foreword

This document (EN ISO 20749:2023) 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 January 2024, and conflicting national standards shall be withdrawn at the latest by January 2024.

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 20749:2018.

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 20749:2023 has been approved by CEN as EN ISO 20749:2023 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 document 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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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 1, *Filling and restorative 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 second edition cancels and replaces the first edition (ISO 20749:2017), which has been technically revised.

The main changes 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 fracture stress 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 has been reduced to 2,5 mm;

— a 20 min cooling time before weighing has been added for the determination of the yield of dental amalgam from a capsule;

— 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 subclause, "Principle", has been added in which a brief summary explains the method adopted;

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

— a new Clause 7, "Report", has been added which 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

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 is made to ISO 10993-1 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.

This document is restricted to dental amalgam products marketed in pre-capsulated form, alone. Other products intended for use 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 described in ISO 24234.

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

ISO 21920-2, *Geometrical product specifications (GPS) — Surface texture: Profile — Part 2: Terms, definitions and surface texture parameters*

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

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

ISO 23325:2020, *Dentistry — Corrosion resistance of dental amalgam*

Globally Harmonized System of Classification and Labelling of Chemicals (GHS). United Nations, New York and Geneva, 9th Revised Edition, 2021, eISBN 978-92-1-005213-9

Recommendations on the Transport of Dangerous Goods, Model Regulations. United Nations, New York and Geneva, 22st Edition (Vol.1), 2022, eISBN 978-92-1-005219-1