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| STN | Stomatológia Kapslový dentálny amalgám (ISO 20749: 2023) | STN EN ISO 20749 85 6391 |
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Dentistry - Pre-capsulated dental amalgam (ISO 20749:2023)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 10/23

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

EN ISO 20749:2023 (E)

| Contents | Page |
|-------------------------------|-------------|
| European foreword..... | 3 |

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of an identical text or by endorsement, at the latest by January 2024, and conflicting national standards shall be withdrawn at the latest by January 2024.

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INTERNATIONAL STANDARD

ISO 20749

Second edition
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Dentistry — Pre-capsulated dental amalgam

*Médecine bucco-dentaire — Amalgame dentaire en capsules
prédosées*



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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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Contents

| | Page |
|--|------------|
| Foreword | v |
| Introduction | vii |
| 1 Scope | 1 |
| 2 Normative references | 1 |
| 3 Terms and definitions | 2 |
| 4 Requirements | 3 |
| 4.1 Package and capsule contamination..... | 3 |
| 4.2 Chemical composition and purity of the dental amalgam alloy..... | 3 |
| 4.3 Large particles in the dental amalgam alloy powder..... | 3 |
| 4.4 Loss of mass from the capsule during mixing..... | 3 |
| 4.5 Yield of dental amalgam from the capsule..... | 3 |
| 4.6 Consistency of the dental amalgam from capsule to capsule..... | 4 |
| 4.7 Properties of the dental amalgam..... | 4 |
| 4.7.1 General..... | 4 |
| 4.7.2 Creep..... | 4 |
| 4.7.3 Dimensional changes during hardening..... | 4 |
| 4.7.4 Compressive fracture stress at 2 h..... | 4 |
| 4.7.5 Compressive fracture stress at 24 h..... | 4 |
| 4.8 Appearance of mixed dental amalgam before setting..... | 5 |
| 4.9 Corrosion resistance of the dental amalgam..... | 5 |
| 4.10 Length tolerance for the capsule..... | 5 |
| 5 Sampling | 5 |
| 6 Test methods | 5 |
| 6.1 Package and capsule contamination..... | 5 |
| 6.1.1 Principle..... | 5 |
| 6.1.2 Test sample..... | 5 |
| 6.1.3 Apparatus..... | 5 |
| 6.1.4 Procedure..... | 5 |
| 6.1.5 Treatment of the results..... | 6 |
| 6.1.6 Report..... | 6 |
| 6.2 Chemical composition and purity of the dental amalgam alloy..... | 6 |
| 6.2.1 Principle..... | 6 |
| 6.2.2 Test sample..... | 6 |
| 6.2.3 Apparatus..... | 6 |
| 6.2.4 Procedure..... | 7 |
| 6.2.5 Treatment of the results..... | 7 |
| 6.2.6 Report..... | 7 |
| 6.3 Large particles in the dental amalgam alloy powder..... | 8 |
| 6.3.1 Principle..... | 8 |
| 6.3.2 Test sample..... | 8 |
| 6.3.3 Apparatus..... | 8 |
| 6.3.4 Procedure..... | 8 |
| 6.3.5 Treatment of the results..... | 8 |
| 6.3.6 Report..... | 8 |
| 6.4 Loss of mass from the capsule during mixing..... | 9 |
| 6.4.1 Principle..... | 9 |
| 6.4.2 Test sample..... | 9 |
| 6.4.3 Apparatus..... | 9 |
| 6.4.4 Test procedure..... | 9 |
| 6.4.5 Treatment of the results..... | 10 |
| 6.4.6 Report..... | 10 |
| 6.5 Yield of amalgam from the capsule..... | 11 |

ISO 20749:2023(E)

| | | |
|----------|--|-----------|
| 6.5.1 | Principle..... | 11 |
| 6.5.2 | Test sample..... | 11 |
| 6.5.3 | Apparatus..... | 11 |
| 6.5.4 | Test procedure..... | 11 |
| 6.5.5 | Treatment of the results..... | 12 |
| 6.5.6 | Report..... | 12 |
| 6.6 | Consistency of the dental amalgam from capsule to capsule..... | 13 |
| 6.6.1 | Principle..... | 13 |
| 6.6.2 | Test sample..... | 13 |
| 6.6.3 | Apparatus..... | 13 |
| 6.6.4 | Test piece production..... | 14 |
| 6.6.5 | Procedure..... | 14 |
| 6.6.6 | Microhardness measurement..... | 15 |
| 6.6.7 | Treatment of the results..... | 15 |
| 6.6.8 | Report..... | 16 |
| 6.7 | Properties of the dental amalgam..... | 16 |
| 6.7.1 | Principle..... | 16 |
| 6.7.2 | Mould for the preparation of test pieces for determining creep, dimensional change during hardening and compressive fracture stress..... | 16 |
| 6.7.3 | Test sample..... | 21 |
| 6.7.4 | Test piece production..... | 21 |
| 6.7.5 | Procedure for the determination of creep..... | 23 |
| 6.7.6 | Procedure for the determination of dimensional change during hardening..... | 24 |
| 6.7.7 | Procedure for the determination of compressive fracture stress..... | 26 |
| 6.8 | Appearance of the mixed dental amalgam before setting..... | 28 |
| 6.8.1 | Principle..... | 28 |
| 6.8.2 | Apparatus..... | 28 |
| 6.8.3 | Procedure..... | 28 |
| 6.8.4 | Treatment of the results..... | 29 |
| 6.8.5 | Report..... | 29 |
| 6.9 | Corrosion resistance of the dental amalgam..... | 29 |
| 6.9.1 | Principle..... | 29 |
| 6.9.2 | Test sample..... | 29 |
| 6.9.3 | Procedure..... | 30 |
| 6.9.4 | Treatment of results..... | 30 |
| 6.9.5 | Report..... | 30 |
| 6.10 | Length tolerance for the capsule..... | 31 |
| 6.10.1 | Principle..... | 31 |
| 6.10.2 | Test sample..... | 31 |
| 6.10.3 | Apparatus..... | 31 |
| 6.10.4 | Procedure..... | 31 |
| 6.10.5 | Treatment of results..... | 31 |
| 6.10.6 | Report..... | 31 |
| 7 | Test report..... | 32 |
| 8 | Marking and labelling..... | 32 |
| 8.1 | Information..... | 32 |
| 8.2 | Labelling of the package for dental mercury..... | 33 |
| 8.3 | Labelling of the outer surface of package or container used for shipping..... | 33 |
| 8.4 | Instructions for use..... | 34 |
| 8.5 | Precautionary notes..... | 34 |
| | Bibliography..... | 35 |

Foreword

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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).

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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;

ISO 20749:2023(E)

- 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

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