



SLOVENSKI STANDARD SIST EN ISO 20749:2023

01-oktober-2023

Nadomešča:
SIST EN ISO 20749:2018

Zobozdravstvo - Pripravljeni zobni amalgam (ISO 20749:2023)

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

Zahnheilkunde – Dentalamalgam in Kapseln (ISO 20749:2023)

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

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Ta slovenski standard je istoveten z: **EN ISO 20749:2023**

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11.060.10 Zobotehnični materiali Dental materials

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NORME EUROPÉENNE

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of an identical text or by endorsement, at the latest by January 2024, and conflicting national standards shall be withdrawn at the latest by January 2024.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

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Endorsement notice

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The text of ISO 20749:2023 has been approved by CEN as EN ISO 20749:2023 without any modification.

INTERNATIONAL
STANDARD

ISO
20749

Second edition
2023-06

**Dentistry — Pre-capsulated dental
amalgam**

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

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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).

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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;

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- 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.

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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.

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