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)

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

ICS:

11.060.10	Zobotehnični materiali	Dental materials

SIST EN ISO 20749:2023 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 20749

July 2023

ICS 11.060.10

Supersedes EN ISO 20749:2018

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 COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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

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of an identical text or by endorsement, at the latest by January 2024, and conflicting national standards shall be withdrawn at the latest by January 2024.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

This document supersedes EN ISO 20749:2018.

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Endorsement notice

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).

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.