



**SLOVENSKI STANDARD
SIST EN ISO 13897:2018**

01-maj-2018

**Nadomešča:
SIST EN ISO 13897:2004**

Zobozdravstvo - Kapsule za ponovno uporabo zobnega amalgama (ISO 13897:2018)

Dentistry - Dental amalgam reusable mixing-capsules (ISO 13897:2018)

Zahnheilkunde - Wiederverwendbare Mischkapseln für zahnärztliches Amalgam (ISO 13897:2018)

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Art dentaire - Capsules réutilisables pour mélanger amalgame (ISO 13897:2018)

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ICS:

11.060.10 Zobotehnični materiali Dental materials

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EUROPEAN STANDARD

EN ISO 13897

NORME EUROPÉENNE

EUROPÄISCHE NORM

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Supersedes EN ISO 13897:2004

English Version

Dentistry - Dental amalgam reusable mixing-capsules (ISO 13897:2018)

Médecine bucco-dentaire - Capsules de mélange réutilisables pour amalgame dentaire (ISO 13897:2018)

Zahnheilkunde - Wiederverwendbare Mischkapseln für zahnärztliches Amalgam (ISO 13897:2018)

This European Standard was approved by CEN on 2 February 2018.

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European foreword

This document (EN ISO 13897:2018) 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of an identical text or by endorsement, at the latest by August 2018, and conflicting national standards shall be withdrawn at the latest by August 2018.

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INTERNATIONAL
STANDARD

ISO
13897

Second edition
2018-02

**Dentistry — Dental amalgam reusable
mixing-capsules**

*Médecine bucco-dentaire — Capsules de mélange réutilisables pour
amalgame dentaire*

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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).

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This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 6, *Dental equipment*.

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This second edition cancels and replaces the first edition (ISO 13897:2003) including Technical Corrigendum 1 (ISO 13897:2003/Cor.1:2003), which has been technically revised.

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

- the scope has been revised and is now restricted to dental amalgam reusable mixing-capsules;
- classification into two types has been deleted;
- labelling requirements have been updated.
- requirements for single-use capsules are now within the scope of ISO 20749:2017, these being:
 - the requirement for surface contamination of the package and the capsule for pre-capsulated dental amalgam alloy products;
 - loss of mass during mixing from single-use capsules;
 - the requirement for containers in which single-use capsules are supplied to prevent spillage of dental mercury leaking from faulty or damaged single-use capsules;
 - labelling requirements for pre-capsulated dental amalgam products;
 - manufacturer's instructions regarding conditions of storage and the disposal of single-use capsules in pre-capsulated dental amalgam products.

Introduction

In order to produce dental amalgam, an electrically-powered mixing machine, as described in ISO 7488 is used for mixing dental amalgam alloy powder with dental mercury. In addition, a removable mixing-capsule is used to contain the dental amalgam alloy and the dental mercury during the mixing process.

NOTE Traditionally, the mixing machine for dental amalgam has been called an amalgamator. The latter is now a deprecated term.

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