SLOVENSKI STANDARD
SIST EN ISO 20749:2018

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Nadomešča:

SIST EN ISO 24234:2015

Zobozdravstvo - Pripravljeni zobni amalgam (ISO 20749:2017)

Dentistry - Pre-capsulated dental amalgam (ISO 20749:2017)

Zahnheilkunde - Vorgefertigte Amalgamkapseln (ISO 20749:2017)

Médecine bucco-dentaire - Amalgame dentaire en capsules prédosées (ISO 20749:2017)

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Dentistry - Pre-capsulated dental amalgam (ISO 20749:2017)

Médecine bucco-dentaire - Amalgame dentaire en capsules prédosées (ISO 20749:2017)

Zahnheilkunde - Gekapseltes zahnärztliches Amalgam (ISO 20749:2017)

This European Standard was approved by CEN on 22 July 2018.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

The text of ISO 20749:2017 has been prepared by Technical Committee ISO/TC 106 "Dentistry" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 20749:2018 by 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of an identical text or by endorsement, at the latest by March 2019, and conflicting national standards shall be withdrawn at the latest by March 2019.

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Endorsement notice

The text of ISO 20749:2017 has been approved by CEN as EN ISO 20749:2018 without any modification.

INTERNATIONAL STANDARD

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Dentistry — Pre-capsulated dental amalgam

Médecine bucco-dentaire — Amalgame dentaire en capsules prédosées

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ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

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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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on 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 the following URL: www.iso.org/iso/foreword.html.

This document was prepared by ISO/TC 106, *Dentistry*, Subcommittee SC 1, *Filling and restorative materials*.

Introduction

This is the first edition of this document. Its scope is limited solely to dental amalgam alloy and dental mercury that are supplied pre-capsulated in masses that are sufficient to produce a mass of dental amalgam that is considered to be suitable for a single small or medium size restoration in a single tooth.

Dental amalgam alloy and dental mercury are the essential and only components of dental amalgam restorative material. This document specifies the requirements and the test methods for dental amalgam alloy that is suitable for the preparation of dental amalgam, together with those for the set dental amalgam, those for the capsules themselves and the requirements for packaging and marking.

This document has been developed in response to the UNEP Minamata Convention on Mercury. The objective of the Minamata Convention is to reduce anthropogenic mercury pollution by restricting the use of mercury, products containing mercury and materials that release mercury during use. In this convention, dental amalgam is classified as a "mercury-added product", for which parties to the agreement are to adopt two or more measures from a list of nine. One of these is "restricting the use of dental amalgam to its encapsulated form". In some countries, the term *encapsulated* has been interpreted as the *pre-capsulated* form alone. Given the increased vigilance on the use of dental amalgam products since 2013, when the Minamata Agreement was signed, this document will enable countries that do not allow the use of products other than those that are pre-capsulated to adopt an ISO standard on dental amalgam. Not all of the membership of the UN has signed the Minamata Convention and in non-signatory countries, dental amalgam products outside the scope of this document, but within the scope of ISO 24234, will continue to be marketed. Thus, both standards are required to provide full global coverage for compliance.

Although this document is based on ISO 24234, there have been significant technical changes. Also, the requirements for the capsule that were in ISO 13897 have been transferred to this document, treating a product that falls within the scope as an entity. This document differs technically from ISO 24234 in the following respects:

— The scope of this document is restricted to pre-capsulated products alone.

— A requirement for packaging and capsule to be free from contamination is present.

— The requirement concerning foreign matter in the dental amalgam alloy powder has been removed.

— A requirement for loss of mass from the capsule during mixing has been added.

— A requirement for the yield of dental amalgam from a capsule replaces the requirement for the masses of dental mercury and dental amalgam powder present before mixing.

— A requirement for the consistency in the ratio of dental mercury to dental amalgam alloy powder in capsules has been changed radically. Determination of the effect of variation in this ratio upon properties replaces weighing the dental mercury and the dental amalgam alloy powder.

— Requirements for the capsule have been introduced and revised technically.

A decision was taken not to alter requirements upon which capsulation has no bearing, these being:

— the requirements on chemical composition and purity of the dental amalgam alloy;

— the requirements for the properties of dental amalgam;

— the requirement for the appearance of dental amalgam before setting.

As with ISO 24234, the inclusion of a requirement for corrosion resistance was considered. However, it was agreed that the data available were insufficient to set a corrosion resistance requirement in this edition of this document. A requirement for the corrosion resistance will be set and incorporated at the earliest possible date. It is recommended that in assessing corrosion resistance of a dental amalgam product (relative to other dental amalgam products), reference can be made to ISO/TS 17988.

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 and dental mercury in quantities suitable for the creation of a single dental restoration.

This document specifies the requirements and test methods for dental amalgam alloys that are suitable for the preparation of dental amalgam and the capsule, together with the requirements and test methods for that dental amalgam and the requirements for packaging and marking.

This document is not applicable to dental amalgam alloys supplied as a free-flowing powder in bulk quantities or as powder compressed into tablets, or to dental mercury supplied in sachets or bulk quantities.

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.

Specific qualitative and quantitative test methods for demonstrating freedom from unacceptable biological hazard are not included in this document. For the assessment of possible biological hazards, reference can be made to ISO 10993-1 and ISO 7405.

The scope of 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 within the scope of 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 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 6344-1, *Coated abrasives — Grain size analysis — Part 1: Grain size distribution test*

ISO 7488, *Dental amalgamators*

ISO 13565-2, *Geometrical Product Specifications (GPS) — Surface texture: Profile method; Surfaces having stratified functional properties — Part 2: Height characterization using the linear material ratio curve*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

Globally Harmonized System of Classification and Labelling of Chemicals (GHS). United Nations, New York and Geneva, 5th Revised Edition, 2013, ISBN 978-92-1-117067-2

