INTERNATIONAL STANDARD

ISO 24234

Second edition
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Dentistry — Dental amalgam

Médecine bucco-dentaire — 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).

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 meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 106, *Dentistry*, Subcommittee SC 1, *Filling and Restorative Materials*.

This second edition cancels and replaces the first edition (ISO 24234:2004), which has been technically revised. It also incorporates the amendment ISO 24234:2004/Amd, 1. The following changes have been made.

— The title of this International Standard has been changed to reflect the content and requirements more accurately.

— The supply of dental mercury in units of greater mass (bulk dental mercury) is no longer within the scope of this International Standard. Through this restriction on the supply of dental mercury for a product to comply with this International Standard (introduced by ISO/TC 106 SC1), a general concern about the environmental impact from the sale of mercury in bulk volumes (for all applications) is addressed.

— As a consequence of the removal of dental mercury supplied in bulk quantities from the scope of this International Standard, requirements for freedom from contamination (by water, oil and foreign bodies) and free pouring of dental mercury are no longer present in this International Standard.

— The values for the requirements on the dimensional change during hardening and the compressive strength at 1 h and 24 h have been revised. "Permitted dimensional change during hardening" is changed from (- 0,10 to +0,20) % to (−0,10 to +0,15) %. Furthermore, the "Minimum compressive strength at 1h" is increased from 80 to 100 MPa, and the "Minimum compressive strength at 24 h" is increased from 300 to 350 MPa.

— Provisions for packaging and marking have been revised.

— Markings required for mercury safety warnings and precautions have been revised.

— Normative annexes on procedures for corrosion testing have been removed from this International Standard and are now contained in a new International Technical Specification, ISO/TS 17988: *Dentistry — Corrosion test methods for dental amalgam.*

Introduction

Dental amalgam alloy and dental mercury are the essential and only components of dental amalgam restorative material. This International Standard 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 and the requirements for packaging and marking (including those for dental mercury), of which this International Standard is the second edition.

Specific qualitative and quantitative test methods for demonstrating freedom from unacceptable biological hazard are not included in this International Standard but it is recommended that, for the assessment of possible biological hazards, reference should be made to ISO 10993 and ISO 7405.

To enhance the safety of dentists and support staff, and minimize the consequence that might result from the accidental damage to containers during shipping, the scope is limited solely to dental mercury that is supplied pre-capsulated or in pre-dosed sachets. Both are limited to a mass sufficient for one mix.

Safety precautions relating to marking, labelling, and packaging have been strengthened in this revision.

Restricting the scope to dental amalgam alloys with copper contents above 12 % by mass (i.e. “high copper” dental amalgam alloy) was considered, because it is reported that restorations made with such alloys, as a group, have a better long term survival rate than those made with traditional alloys (i.e. “low copper” dental amalgam alloy). This was rejected since there are a few products with a low copper content that produce restorations that are as durable as those produced using some of the high copper products. (Factors other than the percentage of copper are important.) Also, it was felt that excluding products from compliance should not be done by a change to the composition requirement; it should be on the basis of a revision to the requirements for the properties that determine performance.

Inclusion of a requirement for corrosion resistance was considered. However, it was agreed that the data available were insufficient to set a corrosion requirement in this edition of this International Standard. 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 should be made to ISO/TS 17988.

In the first edition of this International Standard (and before that in ISO 1559) a compression strength test was used to determine the resistance to fracture of dental amalgam. Such a test, with a compressive strength requirement, continues to be used in this edition. However, the Working Group recognizes that dental amalgam, is in effect, a brittle material and it is evaluating a suitable test procedure that produces tensile forces to initiate fracture in a way that replicates the clinical process. At this time, the work has not reached the point at which this test (with a requirement) can be included in this revision of the International Standard. When evaluation is completed, consideration will be given to adding a requirement for fracture resistance that utilizes this test. This will be in the form of a Technical Amendment.

Requirements and test methods for the capsules used for pre-capsulated products are contained in ISO 13897.

Dentistry — Dental amalgam

1 Scope

This International Standard specifies the requirements and test methods for dental amalgam alloys that are suitable for the preparation of dental amalgam, together with the requirements and test methods for that dental amalgam and the requirements for packaging and marking (including those for dental mercury).

It is applicable to dental amalgam alloys supplied in the form of a free-flowing powder in bulk, or a powder compressed to form a tablet, or a powder in a capsule (i.e. pre-capsulated).

With respect to dental mercury, the scope is limited solely to dental mercury which is supplied pre-capsulated or in pre-dosed sachets. Both are limited to a mass sufficient for one mix. The mass of dental mercury in one capsule or sachet shall be sufficient to produce a homogeneous plastic mix, appropriate for a small or medium sized restoration in a single tooth. This International Standard is not applicable to mercury supplied in masses greater than this in a single primary container (i.e. dental mercury in bulk). Dental mercury supplied in bulk volumes will not conform to this International Standard.

This International Standard does not exclude the supply of dental amalgam alloy or dental mercury separately.

This International Standard is not applicable to 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.

NOTE Dental mercury is at least 99,99 % pure, and as such, it is a metallic element of high commercial purity, and not an alloy

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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 6344-1, *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 13897, *Dentistry — Amalgam capsules*

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