Dentistry - Dental amalgam (ISO 24234:2015)

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NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 24234:2015 sisaldab Euroopa standardi EN ISO 24234:2015 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 24234:2015 consists of the English text of the European standard EN ISO 24234:2015.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 06.05.2015.	Date of Availability of the European standard is 06.05.2015.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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English Version

Dentistry - Dental amalgam (ISO 24234:2015)

Médecine bucco-dentaire - Amalgame dentaire (ISO 24234:2015)

Zahnheilkunde - Dentale Amalgame (ISO 24234:2015)

This European Standard was approved by CEN on 3 January 2015.

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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

This document (EN ISO 24234:2015) 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of an identical text or by endorsement, at the latest by November 2015, and conflicting national standards shall be withdrawn at the latest by November 2015.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 24234:2004.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 24234:2015 has been approved by CEN as EN ISO 24234:2015 without any modification.

Contents

Page

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*

