SLOVENSKI STANDARD
SIST EN ISO 24234:2005

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Nadomeģļ a:
SIST EN 21560:2000

Zobozdravstvo - Živo srebro in zlitine za zobni amalgam (ISO 24234:2004)

Dentistry - Mercury and alloys for dental amalgam (ISO 24234:2004)

Zahnheilkunde - Quecksilber und Legierungen für zahnärztliche Amalgame (ISO 24234:2004)

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Art dentaire - Mercure et alliages pour amalgame dentaire (ISO 24234:2004)

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Ta slovenski standard je istoveten z: EN ISO 24234:2004

ICS:

11.060.10	Zobotehniļ ni materiali	Dental materials

SIST EN ISO 24234:2005 **en**

2003-01.Slovenski inštitut za standardizacijo. Razmnoževanje celote ali delov tega standarda ni dovoljeno.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 24234

October 2004

ICS 11.060.10

Supersedes EN 21560:1991

English version

Dentistry - Mercury and alloys for dental amalgam (ISO 24234:2004)

Art dentaire - Mercure et alliages pour amalgame dentaire (ISO 24234:2004)

Zahnheilkunde - Quecksilber und Legierungen für zahnärztliche Amalgame (ISO 24234:2004)

This European Standard was approved by CEN on 16 August 2004.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

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Foreword

This document (EN ISO 24234:2004) 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of an identical text or by endorsement, at the latest by April 2005, and conflicting national standards shall be withdrawn at the latest by April 2005.

This document supersedes EN 21560:1991.

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

Endorsement notice

The text of ISO 24234:2004 has been approved by CEN as EN ISO 24234:2004 without any modifications.

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INTERNATIONAL STANDARD

ISO 24234

First edition
2004-10-15

Dentistry — Mercury and alloys for dental amalgam

Art dentaire — Mercure et alliages 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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 24234 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 1, *Filling and restorative materials*.

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This International Standard cancels and replaces ISO 1559:1995, ISO 1559:1995/Cor.1:1997 and ISO 1560:1985.

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A number of technical revisions have been made as improvements or as a consequence of combining the International Standards that have been replaced.

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— The scope of this International Standard applies to alloys for dental amalgam and dental mercury, whether provided individually or together.

— The clause permitting a deviation in the composition of alloys for amalgam has been removed.

— Guidance on biocompatibility assessment has been introduced.

— A limit on the presence of large alloy particles has been introduced.

— The requirement for loss of mercury from predosed capsules has been removed, since it is a requirement in ISO 13897.

— The values for the requirements on creep, dimensional change and compressive strength at 1 h have been revised.

— The criterion for compliance with the compressive strength requirements has been revised.

— Provisions for packaging and marking have been revised.

— Markings required for mercury safety warnings and precautions have been revised to conform to ISO requirements and the United Nations *Globally Harmonized System of Classification and Labelling of Chemicals* (GHS). They are no longer dependent upon national or regional requirements.

— Procedures for corrosion testing have been added as normative annexes.

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Introduction

Dental amalgam alloy and mercury are the essential and only components of dental amalgam restorative material. This International Standard combines the requirements and the test methods for the alloy with those for the mercury in a single standard, of which this is the first edition. Formerly, these were contained in two separate standards.

Specific qualitative and quantitative requirements for freedom from biological hazard are not included in this International Standard, but it is recommended that, in assessing possible biological hazards, reference be made to ISO 10993-1 and ISO 7405.

To enhance the safety of dentists and support staff, it would have been preferred to limit the scope solely to the use of predosed capsules of alloy and mercury. It is, however, recognised and accepted that both amalgam alloy and mercury are supplied in bulk form in some parts of the world where, for economic reasons, this is necessary for the provision of dental treatment. Therefore requirements for these products are included in this International Standard. Safety precautions relating to marking, labelling and packaging have been strengthened in this revision.

Inclusion of a requirement for corrosion resistance was considered, using the procedures for corrosion testing given in ISO/TS 17576. However it was decided that the data available were insufficient to justify a corrosion requirement in this International Standard, and as a consequence the test methods alone are given, as normative annexes. A requirement for the corrosion resistance will be set and incorporated at the earliest possible date.

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Dentistry — Mercury and alloys for dental amalgam

WARNING — The use of this International Standard may involve hazardous materials, operations and equipment. This International Standard does not purport to address all of the safety problems associated with its use. It is the responsibility of the user of this International Standard to establish appropriate safety and health practices and to determine the applicability or regulatory limitations prior to use.

1 Scope

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

It is applicable to alloys supplied in the form of either a powder in bulk, or a powder compressed to form a tablet, or a powder in predosed capsules.

It is applicable to dental mercury supplied either in bulk quantities, or in predosed sachets, or in predosed capsules.

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

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This International Standard is not applicable to alloys intended for use with liquid metals that are not mercury, nor is it applicable to liquid metal alloys.

2 Normative references

The following referenced documents are indispensable for the application 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, *ISO system of limits and fits — Part 2: Table of standard tolerance grades and limit deviations for holes and shafts*

ISO 3310-1, *Test sieves — Technical requirements for testing — Part 1: Test sieves of metal wire cloth*

ISO 3585, *Borosilicate glass 3.3 — Properties*

ISO 3696:1987, *Water for analytical laboratory use — Specification and test methods*

ISO 3864-2, *Graphical symbols — Safety colours and safety signs — Part 2: Design principles for product safety labels*

ISO 4793:1980, *Laboratory sintered (fritted) filters — Porosity grading, classification and designation*

ISO 6344-1:1998, *Coated abrasives — Grain size analysis — Part 1: Grain size distribution test*

ISO 7488, *Dental amalgamators*

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ISO 8282, *Dental equipment — Mercury and alloy mixers and dispensers*

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*

Globally Harmonized System of Classification and Labelling of Chemicals (GHS). United Nations, New York and Geneva, 2003, ISBN 92-1-116840-6

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
alloy for dental amalgam
alloy in fine particles, composed mainly of silver, tin and copper, which when mixed with mercury produces a dental amalgam

3.2
predosed capsule
capsule, as-supplied, containing measured amounts of alloy powder and mercury for dental amalgam, separated in such a way that premature combination is prevented

NOTE The separating barrier is broken immediately prior to mixing or breaks during mixing, allowing the alloy and mercury to come into contact.

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3.3
amalgam alloy tablet
quantity of dental amalgam alloy powder that has been compressed to form a single entity for the purpose of providing a predosed quantity of the alloy.

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NOTE During mixing, the tablet is intended to break apart, forming a fine powder.

3.4
tailing
phenomenon which occurs when mercury that contains impurities moves over a clean surface, tending to leave behind a portion of the liquid, forming an elongated tail as if it were sticking to that surface

3.5
primary container
container or package that is in direct contact with the material

3.6
dental mercury sachet
measured quantity of dental mercury supplied in a sachet that is suitable for a reusable mixing capsule

NOTE The sachet is broken immediately prior to mixing, or breaks during mixing, allowing the mercury to come into contact with the alloy

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