



SLOVENSKI STANDARD
SIST EN 21560:2000
01-januar-2000

Zobozdravstvo - Dentalno živo srebro (ISO 1560:1985)

Dentistry - Dental mercury (ISO 1560:1985)

Zahnheilkunde - Zahnärztliches Quecksilber (ISO 1560:1985)

Art dentaire - Mercure a usage dentaire (ISO 1560:1985)

Ta slovenski standard je istoveten z: EN 21560:1991

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EUROPEAN STANDARD

EN 21560:1991

NORME EUROPEENNE

EUROPAISCHE NORM

August 1991

UDC 615.465-034.791:616.314-083.27:610.1:62-777

Descriptors: Dentistry, dental materials, amalgams,
specifications, tests, packing, marking

English version

Dentistry - Dental mercury (ISO 1560:1985)

Art dentaire - Mercure à usage dentaire Zahnheilkunde - Zahnärztliches
(ISO 1560:1985) Quecksilber (ISO 1560:1985)

This European Standard was approved by CEN on 1991-08-20 and is identical to the ISO standard as referred to.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

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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.

CEN members are the national standards bodies of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart 36, B-1050 Brussels

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Ref. No. EN 21560:1991 E



FOREWORD

This European Standard has been taken over by CEN/TC 55 "Dental products" from the work of ISO/TC 106 "Dentistry" of the International Organization for standardization (ISO).

CEN/TC 55 decided to submit this document to the Unique Acceptance Procedure (UAP). The Result was positive.

In accordance with the CEN/CENELEC Internal Regulations, the following countries are bound to implement this European Standard: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom

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The text of the International Standard ISO 1560:1985 was approved by CEN as a European standard without any modification.

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International Standard



1560

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION

Dental mercury

Mercure à usage dentaire

Second edition — 1985-04-15

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UDC 616.314 : 546.49

Ref. No. ISO 1560-1985 (E)

Descriptors : dentistry, dental materials, amalgams, mercury, specifications, tests, packing, marking.

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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

International Standard ISO 1560 was prepared by Technical Committee ISO/TC 106, *Dentistry*, in collaboration with the following international organisation: FDI (International Dental Federation).

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ISO 1560 was first published in 1975. This second edition cancels and replaces the first edition, the following clauses of the previous edition have been technically revised: clauses 2, 3, 4 and 5.

Dental mercury

0 Introduction

In this revision of ISO 1560-1975, the requirement that the mercury shall, on distillation, contain not more than 0,2 % by mass of non-volatile matter has been eliminated on account of the hazard the specified procedure created during the compliance test.

The procedure has not been replaced because it was decided by the Technical Committee responsible for this International Standard that visual inspection, together with behaviour on pouring, were adequate criteria for establishing the purity of mercury intended for dental purposes.

A requirement that labels on the containers shall bear a hazard warning has been introduced.

1 Scope and field of application

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

It does not specify requirements for sampling and the method of procurement, and the amount of mercury needed for testing should be the subject of agreement between interested parties.

2 References

ISO 3696, *Water for laboratory use — Specifications.*¹⁾

ISO 3864, *Safety colours and safety signs.*

ISO 4793, *Laboratory sintered filters — Porosity grading, classification and designation.*

3 Requirements

3.1 Condition

When the container from the supplier is first opened, the mercury shall be free from contamination by oil, water, dirt or other materials. However, oxide scum shall not be a disqualifying factor. After having been filtered and shaken as prescribed in 4.1, the mercury shall have a bright, mirror-like surface which does not readily form scum in air.

3.2 Pouring

When prepared according to the procedure in 4.1, the mercury shall be capable of being poured freely and completely without tailing. However, small droplets not coalesced with the bulk after shaking shall not be construed as evidence of non-compliance with this clause.

4 Test methods

4.1 Preparation of sample

Filter approximately 15 g (1 ml) of the mercury through a sintered glass filter having a pore size in the range of 16 to 40 μm (porosity grade P 40 as defined in ISO 4793). Apply a slight vacuum if necessary.

Take a small flask (100 ml is a suitable capacity) made of borosilicate or similar glass and having an accurately fitting ground glass stopper or a polytetrafluoroethylene lined screw cap. Clean the flask and stopper in a manner appropriate to the techniques of analytical chemistry, rinse thoroughly with water complying with ISO 3696 grade 3, dry at 100 °C and allow to cool. Transfer the filtered sample of mercury to the flask, place the stopper or cap securely in place (do not use grease) and shake the flask vigorously for 5 s.

1) At present at the stage of draft.

ISO 1560-1985 (E)

4.2 Visual inspection

Inspect the sample visually for compliance with the requirements of 3.1 and 3.2.

5 Packaging and marking

5.1 Packaging

The containers with their closures shall be air-tight and made of materials which do not react with the mercury and have no permanent deleterious effect on it. Their strength shall be sufficient to contain and protect the mercury under normal conditions of transport and handling.

5.2 Marking

- a) Each container or package of capsules shall be marked with the supplier's name and a serial number, or a combination of letters and numbers, which refer to the supplier's records for the particular lot or batch of mercury.
- b) The date of final processing and/or cleaning before packing (year and month) shall be indicated on the container or package of capsules either as a separate item or as a part of the lot number.
- c) The minimum net mass of the contents shall be marked in grams or kilograms on each container.

- d) The label for each container of mercury shall bear the words "DANGER-POISON" or equivalent, and the symbol according to the national legislation of the country concerned.

Any package used for the shipment of dental mercury shall also bear these warnings or similar as required by legislation governing the transportation of dangerous goods.

NOTE — If there is no national symbol, the following one may be used.



The symbol should be a triangle with a skull and cross-bones, both in black with a yellow background. This is in accordance with ISO 3864.

These hazard warnings should be printed on a package insert or on a tag attached to the container rather than on the container itself.

These hazard warnings are minimum requirements and are not intended to replace any national or regional requirements that are more demanding.

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