# Hambaraviaparatuur. Elavhõbeda- ja sulamisegistid ning -dosaatorid

Wal. Dental equipment - Mercury and alloy mixers and dispensers



# **EESTI STANDARDI EESSÕNA**

# **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN ISO 8282;1999 sisaldab Euroopa standardi EN ISO 8282:1997 ingliskeelset teksti.

This Estonian standard EVS-EN ISO 8282:1999 consists of the English text of the European standard EN ISO 8282:1997.

Käesolev dokument on jõustatud 12.12.1999 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.

This document is endorsed on 12.12.1999 with the notification being published in the official publication of the Estonian national standardisation organisation.

Standard on kättesaadav Eesti standardiorganisatsioonist.

The standard is available from Estonian standardisation organisation.

#### Käsitlusala:

Standard esitab nõuded ja testimismeetodid seadmetele, mida kasutatakse hambaravis kasutatava amalgaami ja/või elavhõbeda doseerimiseks. Standard hõlmab seadmeid, mis doseerivad sulami ja elavhõbeda täpseid portsjoneid ning segavad ka amalgaami ühe katkematu toiminguna.

# Scope:

**ICS** 11.060.20

**Võtmesõnad:** amalgaamid, dosaatorid, hambaraviaparatuur, kasutamisjuhised, liigitus, märgistus, pakendamine, segistid, stomatoloogia, tehnilised andmed, testimine

March 1997

ICS 11.060.20

Descriptors: Dentistry, mixers, dispensers.

#### **English version**

# Dental equipment

Mercury and alloy mixers and dispensers (ISO 8282:1994)

Matériels dentaires - Mélangeurs et distributeurs de mercure et d'alliage (ISO 8282:1994)

Zahnärztliche Ausrüstung – Mischgeräte und Dosierer für Quecksilber und Legierungen zur Herstellung von Amalgam (ISO 8282:1994)

This European Standard was approved by CEN on 1997-02-28.

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.

The European Standards exist 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, the Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

CEN

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

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

EN ISO 8282:1997

#### **Foreword**

International Standard

ISO 8282:1994 Dental equipment - Mercury and alloy mixers and dispensers,

which was prepared by ISO/TC 106 'Dentistry' of the International Organization for Standardization, has been adopted by Technical Committee CEN/TC 55 'Dentistry' as a European Standard.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, and conflicting national standards withdrawn, by September 1997 at the latest.

In accordance with the CEN/CENELEC Internal Regulations, the following countries are bound to implement this European Standard:

Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

#### **Endorsement notice**

The text of the International Standard ISO 8282:1994 was approved by CEN as a European Standard without any modification.

NOTE: Normative references to international publications are listed in Annex ZA (normative).

# 1 Scope

This International Standard specifies requirements and test methods for devices used for dispensing dental amalgam alloys and/or mercury. It includes the dispensing portion of devices which dispense the correct portions of alloy and mercury as well as mix the amalgam in a single, continuous operation.

It does not specify requirements and test methods for the efficacy of mixing.

#### 2 Normative reference

The following standard contains provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the edition indicated was valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the standard indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 1560:1985, Dental mercury.

# 3 Classification

Dispensers covered by this International Standard shall be classified as follows:

Type 1	Alloy dispensers
Category 1	Powder
Category 2	Tablet
Type 2	Mercury dispensers
<b>Type 2</b> Category 1	<b>Mercury dispensers</b> Fixed volume

Туре 3	Combination alloy/mercury dispensers
Category 1	Alloy powder
Category 2	Alloy tablet
Category 3	Adjustable volume alloy and/or mercury
Type 4	Dispensing and mixing devices

## 4 Requirements

#### 4.1 Construction

Dispensers shall not exhibit any defects such as cracks or missing adhesive which could lead to failure of the dispenser during normal usage resulting in a sudden release of mercury or alloy.

Dispensers shall be made of materials that do not react with or contaminate the alloy or mercury. No deterioration of the surface of the reservoir shall be visible after the test and no visible change in the alloy or mercury is acceptable.

Testing shall be in accordance with 6.1 and 6.2.

#### 4.2 Adjustment

Adjustable dispensers shall be provided with a means of ensuring that the adjustment will not change during normal use.

Testing shall be in accordance with 6.1

### 4.3 Mercury leakage

Mercury dispensers shall not exhibit a static leakage exceeding 1 mg.

NOTE 1 While 1 mg leakage is currently acceptable, the goal is to reach zero leakage in the near future.