



**SLOVENSKI STANDARD
SIST EN ISO 11143:2000**

01-julij-2000

Dental equipment - Amalgam separators (ISO 11143:1999)

Dental equipment - Amalgam separators (ISO 11143:1999)

Zahnärztliche Ausrüstung - Amalgamabscheider (ISO 11143:1999)

Matériel dentaire - Séparateurs d'amalgame (ISO 11143:1999)

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ICS:

11.060.20 Z[à[ç @ ã } æ] ! ^ { æ Dental equipment

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NORME EUROPÉENNE
EUROPÄISCHE NORM

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English version

Dental equipment - Amalgam separators (ISO 11143:1999)

Matériel dentaire - Séparateurs d'amalgame (ISO
11143:1999)

Zahnärztliche Ausrüstung - Amalgamabscheider (ISO
11143:1999)

This European Standard was approved by CEN on 15 November 1999.

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

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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

Foreword

The text of the International Standard ISO 11143:1999 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of an identical text or by endorsement, at the latest by June 2000, and conflicting national standards shall be withdrawn at the latest by June 2000.

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

NOTE FROM CEN/CS: The foreword is susceptible to be amended on reception of the German language version. The confirmed or amended foreword, and when appropriate, the normative annex ZA for the references to international publications with their relevant European publications will be circulated with the German version.

Endorsement notice

The text of the International Standard ISO 11143:1999 was approved by CEN as a European Standard without any modification.

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INTERNATIONAL
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First edition
1999-12-01

Dental equipment — Amalgam separators

Matériel dentaire — Séparateurs d'amalgame

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ISO 11143:1999(E)**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 3.

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 International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 11143 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 6, *Dental equipment*.

Annex C forms a normative part of this International Standard. Annexes A, B and D are for information only.

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Introduction

Amalgam separators are items of dental equipment designed to retain amalgam particles carried by the waste water from the dental treatment centre, so as to reduce the number of amalgam particles and therefore the mass of amalgam entering the sewage system.

Separation of the amalgam particles may be effected by the use of a centrifuge, filtration, sedimentation or a combination of any of these methods.

It is recognized that the test sample used to assess the efficiency of an amalgam separator should have a particle size distribution which reflects the actual situation in dental treatment centres. The test sample used in this International Standard is based on investigations that have been carried out to determine the particle size distribution of amalgam particles in waste water from dental treatment centres (see annex D).

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Dental equipment — Amalgam separators

1 Scope

This International Standard specifies requirements for amalgam separators used in connection with dental equipment in the dental treatment centre. It specifies the efficiency of the amalgam separators in terms of the level of retention of amalgam based on a laboratory test and the test procedure for determining this efficiency. It also includes requirements for the safe functioning of the separator, marking, instructions for use, operation and maintenance.

All tests described in this International Standard are type tests.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 1559:1995, *Dental materials — Alloys for dental amalgam*.
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ISO 3585, *Borosilicate glass 3.3 — Properties*.

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

ISO 9687, *Dental equipment — Graphical symbols*.

ISO 10076:1991, *Metallic powders — Determination of particle size distribution by gravitational sedimentation in a liquid and attenuation measurement*.

IEC 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety*.

IEC 61010-1:1990, *Safety requirements for electrical equipment for measurement, control and laboratory use — Part 1: General requirements*.

3 Terms and definitions

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

3.1

amalgam separator

item of dental equipment designed to remove amalgam particles from the waste water from the dental treatment centre, so as to reduce the number of amalgam particles and therefore the mass (amount) of amalgam entering the sewage system

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NOTE The amalgam separator may comprise any auxiliary units required for admission of water and the connecting lines inside the separator, but it does not include the supply and drainage pipes or tubes.

3.2**collecting container**

that part of the amalgam separator for retention of separated amalgam waste for the purpose of disposal

3.3**dental treatment centre**

combination of units, consisting as a minimum of the dental unit and the dental chair combination, which enable the dentist to perform patient therapy

3.4**efficiency of amalgam separator**

mass percentage of the specified amalgam sample retained by the amalgam separator

3.5**maximum filling level**

level defined by the maximum collecting capacity of the collecting container of the amalgam separator at which the efficiency is unaffected

3.6**warning level**

level, below the maximum filling level, at which the collecting container should be emptied or replaced

3.7**warning signal**

auditory or visual sign, signal and/or other kind of indicator, or a combination thereof, indicating an adverse condition likely to cause reduction of efficiency if unattended

3.8**alarm signal**

auditory or visual sign, signal and/or other kind of indicator, or a combination thereof, indicating an adverse condition affecting the efficiency of the amalgam separator

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For the purposes of this International Standard, amalgam separator systems are classified according to the method of separation into the following types:

- Type 1: Centrifugal system
- Type 2: Sedimentation system
- Type 3: Filter system
- Type 4: Any combination of types 1, 2 and 3.

This classification is applicable to all amalgam separators, irrespective of whether the amalgam separator is included in every dental treatment centre or built as a central amalgam separator for one or several dental treatment centres.