SLOVENSKI STANDARD
SIST EN 1641:2000

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Zobozdravstvo - Medicinski pripomoļ ki za zobozdravstvo - Materiali

Dentistry - Medical devices for dentistry - Materials

Zahnheilkunde - Medizinprodukte für die Zahnheilkunde - Werkstoffe

Art dentaire - Dispositifs pour l'art dentaire - Produits

Ta slovenski standard je istoveten z: **EN 1641:1996**

ICS:

11.060.10 Zobotehniļ ni materiali Dental materials

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English version

Dentistry - Medical devices for dentistry - Materials

Art dentaire - Dispositifs pour l'art dentaire - Produits

Zahnheilkunde - Medizinprodukte für die Zahnheilkunde - Werkstoffe

This European Standard was approved by CEN on 1996-07-04. 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, 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

Foreword

This standard has been prepared by Technical Committee CEN/TC 55 'Dentistry', the secretariat of which is held by DIN.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association and supports essential requirements of the EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this standard.

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of an identical text or by endorsement, at the latest by February 1997, and conflicting national standards shall be withdrawn at the latest by February 1997.

According to the CEN/CENELEC Internal Regulations, the national standards organisations of 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.

There are three levels of European Standards dealing with medical devices used in dentistry. These are as follows:

Level 1: General requirements for medical devices;
Level 2: Particular requirements for families of medical devices used in dentistry;
Level 3: Specific requirements for types of medical devices used in dentistry.

There are no level 1 standards written exclusively in respect of medical devices used in dentistry.

This standard is a level 2 standard and details requirements that apply to those materials used in the practice of dentistry for the restoration of the form and function of the dentition (For dental implants see EN 1642). It also indicates that there are additional requirements in the level 3 standards. Where available, these are included as normative references. To cover all the requirements for a particular product, it is necessary to use a standard of the lowest available level.

If a restorative material incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in Article 1 of Directive 65/65/EEC [2], and whose action in combination with the device can result in its bioavailibility, the safety, quality and usefulness of the substance must be verified, taking account of the intended purpose of the device,

by analogy with the appropriate methods specified in Directive 75/318/EEC [3], as last amended by Directive 89/341/EEC [4].

In the informative annex A a reference for guidance on the classification of medical devices used in dentistry [5] is given.

1 Scope

This European Standard specifies general requirements for materials used in the practice of dentistry for the restoration of the form and function of the dentition and which are medical devices. For the purposes of this standard these materials are defined as restorative materials. Dental implants are specifically excluded and described in EN 1642. This standard includes requirements for intended performance, design attributes, components, sterilization, packaging, marking, labelling, and information supplied by the manufacturer.

Tests for demonstrating compliance with this standard are contained in the level 3 standards, if appropriate.

2 Normative references

This European Standard incorporates by dated or undated reference provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN 540	Clinical investigation of medical devices for human subjects
EN 980	Graphical symbols for use in the labelling of medical devices
prEN 1041	Information supplied by the manufacturer with medical devices
EN 1642	Dentistry - Medical devices for dentistry - Dental implants
EN 21942-1	Dental vocabulary - Part 1: General and clinical terms
EN 21942-2	Dental vocabulary - Part 2: Dental materials
EN 21559	Dentistry - Alloys for dental amalgam
EN 21560	Dentistry - Dental mercury
EN 21561	Dental inlay casting wax
EN 21563	Dental alginate impression material
EN 21564	Dentistry - Agar impression material
EN 23107	Dental zinc oxide/eugenol cements and zinc oxide non-eugenol cements
EN 24049	Dentistry - Resin-based filling materials

EN 24823	Dental elastomeric impression materials
EN 26871	Dentistry - Dental base metal casting alloys
EN 26873	Dentistry - Dental gypsum products
EN 26874	Dental resin-based pit and fissure sealants
EN 26876	Dentistry - Dental root canal sealing materials
EN 27491	Dentistry - Dental materials - Determination of colour stability of dental polymeric materials
EN 29333	Dental brazing materials
EN 29917	Dental water based cements
EN 30139-1	Dentistry - Resilient lining materials for removable dentures - Part 1: Short-term materials
EN 30993-1	Biological evaluation of medical devices - Part 1: Guidance on selection of tests
EN 30993-3	Biological evaluation of medical devices - Part 3: Test for genotoxicity, carcinogenicity and reproductive toxicity
EN 30993-4	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood
EN 30993-5	Biological evaluation of medical devices - Part 5: Tests for cytotoxicity - In vitro methods
EN 30993-6	Biological evaluation of medical devices - Part 6: Test for local effects after implantation
EN 28601	Data elements and interchange formats - Information interchange - Representation of dates and times
EN ISO 1562	Dentistry - Dental casting gold alloys
EN ISO 1567	Dentistry - Denture base polymers
EN ISO 1942-5	Dental vocabulary - Part 5: Terms associated with testing
EN ISO 3336	Dentistry - Synthetic polymer teeth
EN ISO 4824	Dentistry - Ceramic denture teeth
ISO 6872	Dental ceramic
prEN ISO 7405	Biological evaluation of dental materials
EN ISO 8891	Dental casting alloys with noble metal content of 25% up to but not including 75%
EN ISO 9693	Dental ceramic fused to metal restorative materials
EN ISO 10477	Dentistry - Polymer based crown and bridge materials
EN ISO 10993-10	Biological evaluation of medical devices - Part 10: Tests for irritation and sensitization
EN ISO 10993-11	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

3 Definitions

For the purposes of this standard the definitions of EN 21942-1, EN 21942-2, EN ISO 1942-5 and the following definition apply:

restorative material

Material used in restorative dentistry including, for example, impression and other materials used transiently in the mouth, denture teeth and denture base resins, casting alloys, filling and lining materials.

4 Requirements

4.1 General

4.1.1 Restorative materials shall comply with the requirements which are applicable to them bearing in mind the intended purpose of the device concerned. Conformity with these requirements shall be considered to be met by demonstrating compliance with the following subclauses, if appropriate.

4.1.2 For dental materials a risk analysis shall be carried out and documented.

NOTE: EN 1441[6] describes a procedure for carrying out and documenting a risk analysis of medical devices.

4.2 Chemical and physical properties

4.2.1 Composition

Restorative materials shall satisfy the compositional requirements as specified in the following standards, if appropriate:

EN 21559, EN 21560, EN 23107, EN 26871, EN 29333, EN 29917, EN ISO 1562, EN ISO 1567, EN ISO 4824, ISO 6872, EN ISO 8891, EN ISO 9693.

4.2.2 Biocompatibility

Restorative materials shall be assessed for biocompatibility in respect of the particular application using the method of selection and test methods given in EN 30993-1 and the appropriate test methods in EN 30993-3, EN 30993-4, EN 30993-5, EN 30993-6, EN ISO 10993-10, EN ISO 10993-11, and prEN ISO 7405.

4.2.3 Material properties

The chemical and physical properties of restorative materials shall be determined in accordance with the test methods as specified in the following standards, if appropriate:

EN 21559, EN 21560, EN 21561, EN 21563, EN 21564, EN 23107, EN 24049, EN 24823, EN 26871, EN 26873, EN 26874, EN 26876, EN 27491, EN 29333, EN 29917, EN ISO 1562, EN ISO 1567, EN ISO 3336, EN ISO 4824, ISO 6872, EN ISO 8891, EN ISO 9693, EN ISO 10477.

4.3 Control of contamination

4.3.1 Restorative materials shall be designed and manufactured under conditions to minimize microbial or other contamination, if appropriate.

4.3.2 Packaging systems for restorative materials supplied non-sterile shall maintain the level of cleanliness of the materials during transport and storage.

4.4 Restorative materials used in combination

Restorative materials intended for use in combination shall meet the requirements as specified in the following standards, if appropriate:

EN 21559, EN 21560, EN 21563, EN 21564, EN 24823, EN 26871, EN 28333, EN ISO 1562, EN ISO 1567, EN ISO 3336, EN ISO 8891, EN ISO 9693, EN ISO 10477.

Restrictions on use shall be indicated on the label or instructions for use associated with the material.

4.5 Clinical investigation

Clinical investigation of restorative materials, if appropriate, shall be conducted in accordance with EN 540.

4.6 Marking, labelling and information supplied by the manufacturer

4.6.1 General

Information required for the safe use of restorative materials shall be provided by the manufacturer in accordance with EN 980, prEN 1041, relevant product standards and 4.6.2, 4.6.3 and 4.6.4.

4.6.2 Symbols

Marking, labelling and instructions for use of restorative materials shall, if appropriate, include information in the form of symbols as specified in the following standards:

EN 980, EN 21560.

4.6.3 Labelling

4.6.3.1 The label shall include the following minimum information:

a) name or registered trade mark and address of the manufacturer. In the case of imported restorative materials the name and address of the authorised representative of the manufacturer in the EU;

b) description of the contents, including name, quantity, form (e.g. powder, liquid, paste), shade where appropriate, and the principal chemical constituents in order to identify the type of material;

c) batch code, preceded by the word 'LOT' or the symbol LOT ; or the serial number preceded by SN; related to the records of raw materials, manufacture and packaging;

d) "use by" date expressed in accordance with EN 2860, if appropriate;

e) the words 'exclusively for clinical investigations', if the restorative material is intended for clinical investigations;

f) special storage and/or handling conditions;

g) warnings and/or precautions to take.

4.6.3.2 If it is not practicable for all the above information to be included on the label of the primary container, the relevant information shall be provided on the outer packaging or included in the instructions for use.

4.6.4 Instructions for use

The instructions for use shall include the following minimum information:

a) details referred to in 4.6.3.1 with the exception of c) and d);

b) intended purpose of the restorative material and any undesirable side effects;

c) sufficient details of its characteristics to indentify the correct equipment and procedures to be used in order to obtain a safe combination if the restorative material is intended to be used in combination with other restorative materials or devices;

d) information to avoid risks in connection with the use of the restorative material, if appropriate;

e) details of any further treatment or handling needed for the proper use of the restorative material. These should include, if applicable, details of application, method of preparation, proportioning, mixing or trituration, working time, setting time, recommended fusion, casting or curing procedures and method of finishing;

f) information on the environmental conditions which may adversely effect the materials such as temperature, humidity or ambient light, and the disposal of waste, if precautions are necessary.