SLOVENSKI STANDARD
SIST EN 1642:2000

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Zobozdravstvo -Medicinski pripomočki za zobozdravstvo - Dentalni vsadki (implantati)

Dentistry - Medical devices for dentistry - Dental implants

Zahnheilkunde - Medizinprodukte für die Zahnheilkunde - Dentalimplantate

Art dentaire - Dispositifs médicaux pour l'art dentaire - Implants dentaires

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ICS:

11.060.15	Zobni implantati	Dental implants

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English version

Dentistry - Medical devices for dentistry - Dental implants

Art dentaire - Dispositifs médicaux pour l'art dentaire - Implants dentaires

Zahnheilkunde - Medizinprodukte für die Zahnheilkunde - Dentalimplantate

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.

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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of an identical text or by endorsement, at the latest by February 1997, and conflicting national standards shall be withdrawn at the latest by February 1997.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 organizations 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 dental implants (For surgically implantable dental materials included within the definition of restorative materials see EN 1641). 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.

In the informative annex A a reference for guidance on the classification of medical devices used in dentstry [3] is given.

1 Scope

This European Standard specifies general requirements for dental implants. Surgically implantable dental materials defined as restorative materials are specifically excluded and described in EN 1641. This Standard includes requirements for intended performance, design attributes, components, sterilization, packaging, marking, labelling, and information supplied by the manufacturer.

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 550	Sterilization of medical devices - Validation and routine control of ethylene oxide sterilization
EN 552	Sterilization of medical devices - Validation and routine control of sterilization on by irradiation
EN 556	Sterilization of medical devices - Requirements for medical devices to be labelled 'STERILE'
EN 980	Graphical symbols for use in the labelling of medical devices
prEN 1041	Information supplied by the manufacturer with medical devices
EN 1641	Dentistry - Medical devices for dentistry - Materials
EN 21942-1	Dental vocabulary - Part 1: General clinical terms
EN 21942-2	Dental vocabulary - Part 2: Dental materials
EN 28601	Data elements and interchange formats - Information interchange - Representation of dates and times
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 ISO 1942-5	Dental vocabulary - Part 5: Terms associated with testing
prEN ISO 7405	Biological evaluation of dental 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 21941-2, EN ISO 1942-5 and the following definition apply:

dental implant

Device designed to be placed surgically within or on the mandibular or maxillary bone to provide resistance to displacement of a dental prosthesis.

NOTE: The term dental implant includes transendodontic implants.

4 Requirements

4.1 General

4.1.1 Dental implants shall comply with the requirements which are applicable to them bearing in mind the intended purpose of the implant concerned. Conformity with these requirements shall be considered to be met by demonstrating compliance with the following subclauses, as appropriate.

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

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

4.2 Design and properties

4.2.1 Dental implants shall be manufactured from materials selected with regard to the properties required for the intended purpose.

NOTE: Further information is given in ISO/TR 10451.

4.2.2 Dental implants shall be assessed for biocompatibility 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.

4.3 Control of contamination

4.3.1 General

4.3.1.1 If dental implants are provided both in sterile and non-sterile conditions the condition in which they are supplied shall be clearly indicated.

4.3.1.2 Dental implants shall be manufactured under such conditions so as to minimize microbial or other contamination.

4.3.2 Dental implants supplied sterile

4.3.2.1 Dental implants supplied sterile shall comply with EN 556.

4.3.2.2 Sterilization processes shall be validated and routinely controlled:

a) If dental implants are to be sterilized by ethylene oxide, EN 550 shall apply;
b) If dental implants are to be sterilized by irradiation, EN 552 shall apply.

4.3.2.3 Packaging systems for dental implants supplied sterile shall be such that the implants remain sterile until the package is opened.

4.3.3 Dental implants supplied non-sterile

4.3.3.1 Packaging systems for dental implants supplied non-sterile shall maintain the level of cleanliness of the implants during transport and storage.

4.3.3.2 If dental implants are to be sterilized immediately prior to use the method of sterilization shall be given.

4.3.4 Dental implants which incorporate materials of animal origin

The tissues of animal origin shall be from an approved source and shall have undergone appropriate inactivation, conservation and test procedures.

4.4 Dental implants used in combination

Dental implants used in combination with prefabricated components and connecting systems other than any custom made superstructure such as a denture shall not impair the specified respective performance of any of the parts.

4.5 Clinical investigation

Clinical investigation of dental implants 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 dental implants 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 dental implants shall, if appropriate, include information in the form of symbols as specified in EN 980.

4.6.3 Labelling

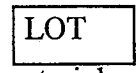
4.6.3.1 The label shall include the following minimum information:

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

b) description of the dental implant, including name, size and material(s);

c) the word 'Sterile' or the symbol 

, the method of sterilization and the recommended method of opening the pack to ensure sterile presentation at time of use, if appropriate;

d) batch code, preceded by the word 'LOT' or the symbol 

; or the serial number preceded by SN; related to the records of raw materials, manufacture, packaging and, if appropriate, sterilization;

e) "use by" date expressed in accordance with EN 28601, if appropriate;

f) indication that the dental implant is for single use;

g) the words 'exclusively for clinical investigations', if the dental implant is intended for clinical investigations;

h) special storage and/or handling conditions;

i) warnings and/or precautions to take.

4.6.3.2 If it is not practicable for all the above 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 d) and e);

b) intended purpose of the dental implant and any restrictions on use;

c) sufficient details of its characteristics to identify the correct equipment and procedures to be used in order to obtain a safe combination, if, for its intended purpose, the dental implant is used in combination with other restorative materials, devices or prefabricated components;

d) information to avoid risks in connection with implanation of the device;

e) action to be taken in the event of damage to the packaging of a dental implant supplied sterile;

f) details of any further treatment or handling needed before the dental implant can be used (in the case of dental implants provided non-sterile: instructions for final cleaning and sterilization, final assembly);

g) details allowing the dental personnel to brief the patient on the precautions to be taken. These details shall include in particular:

1) precautions to be taken in the event of changes in the performance of the dental implant;

2) information on the risks to the patient that may arise after implantation.