SLOVENSKI STANDARD
SIST EN 1642:2005

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Nadomeġļ a:
SIST EN 1642:2000

Zobozdravstvo - Medicinski pripomoļ ki 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

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This European Standard was approved by CEN on 17 March 2004.

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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.

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Contents

Foreword

This document (EN 1642:2004) has been prepared by 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of an identical text or by endorsement, at the latest by December 2004, and conflicting national standards shall be withdrawn at the latest by December 2004.

This document supersedes EN 1642:1996.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive 93/42/EEC.

For relationship with EU Directive 93/42/EEC, see informative annex ZA, which is an integral part of this document.

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

Introduction

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 is also indicated 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 Bibliography a reference for guidance on the classification of dental devices and accessories [4] 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 European 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 (including amendments).

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 by irradiation.*

EN 556-1, *Sterilization of medical devices — Requirements for medical devices to be designated "STERILE" — Part 1: Requirements for terminally sterilized medical devices.*

EN 980, *Graphical symbols for use in the labelling of medical devices.*

EN 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 and clinical terms.*

EN 21942-2, *Dental vocabulary — Part 2: Dental materials (ISO 1942-2:1989).*

EN 28601, *Data elements and interchange formats — Information interchange — Representation of dates and times (ISO 8601:1988 and its technical corrigendum 1:1991).*

EN ISO 1942-5, *Dental vocabulary — Part 5: Terms associated with testing (ISO 1942-5:1989).*

EN ISO 7405, *Dentistry — Preclinical evaluation of biocompatibility of medical devices used in dentistry — Test methods for dental materials (ISO 7405:1997).*

EN ISO 10451, *Dental implant systems — Contents of technical file (ISO 10451:2002).*

EN ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing (ISO 10993-1:2003).*

EN ISO 14155-1, *Clinical investigation of medical devices for human subjects — Part 1: General requirements (ISO 14155-1:2003).*

EN ISO 14155-2, *Clinical investigation of medical devices for human subjects — Part 2: Clinical investigation plans (ISO 14155-5:2003).*

EN ISO 14727, *Dental implants — Prefabricated parts connecting suprastructures to dental implants — Contents of technical file (ISO 14727:1998).*

3 Terms and definitions

For the purposes of this European Standard, the terms and definitions given in EN 21942-1, EN 21942-2, EN ISO 1942-5 and the following apply.

3.1
dental implants
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 requirements of the following subclauses, if appropriate.

4.1.2 A risk analysis shall be carried out and documented.

NOTE EN ISO 14971 [3] describes the procedures to be carried out.

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.

4.2.2 The contents of the manufacturer's Technical File shall be in accordance with EN ISO 10451 and EN ISO 14727, if applicable.

4.2.3 Dental implants shall be assessed for biocompatibility. Guidance on the selection of tests is given in EN ISO 7405 and EN ISO 10993-1. EN ISO 7405 includes usage tests specific to dental materials.

4.3 Control of contamination

4.3.1 General

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

4.3.1.2 The condition in which dental implants are supplied shall be clearly stated, i.e. sterile, non-sterile.

4.3.2 Dental implants supplied sterile

4.3.2.1 Dental implants supplied sterile shall comply with EN 556-1.

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.

NOTE Further information is given in EN 12442-1 [2].

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.

EN ISO 14727 specifies requirements for the contents of a technical file to prefabricated parts connecting a dental suprastructure to a transgingival implant.

4.5 Clinical investigation

Clinical investigation of dental implants shall be conducted in accordance with EN ISO 14155-1 and EN ISO 14155-2.

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, EN 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 STERILE, 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 LOT, 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;