



# SLOVENSKI STANDARD

## SIST EN 1642:2012

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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

Médecine bucco-dentaire - Dispositifs médicaux pour la médecine bucco-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

Médecine bucco-dentaire - Dispositifs médicaux pour la  
médecine bucco-dentaire - Implants dentairesZahnheilkunde - Medizinprodukte für die Zahnheilkunde -  
Dentalimplantate

This European Standard was approved by CEN on 20 September 2011.

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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 CEN-CENELEC Management Centre has the same status as the official versions.

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## Foreword

This document (EN 1642:2011) 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of an identical text or by endorsement, at the latest by April 2012, and conflicting national standards shall be withdrawn at the latest by April 2012.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 1642:2009.

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.

The following changes were made:

a) normative references:

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1) addition of new relevant product standards, issued after 2004: EN 1641, EN ISO 11135-1, EN ISO 11137-1, EN ISO 11607-1, EN ISO 11607-2, EN ISO 14801, EN ISO 14971, EN ISO 22794, EN ISO 22803;

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2) deletion of the following withdrawn standards: EN 550, EN 552, EN ISO 14727;

b) 4.5 Clinical evaluation: clarification of requirement for a clinical evaluation;

c) 4.6.4 Instructions for use: clarification of requirement that information may be provided in an electronic format;

d) Annex ZA: actualisation of the annex.

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

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## 1 Scope

This European Standard specifies general requirements for dental implants and accessories. 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

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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, *Symbols for use in the labelling of medical devices*

EN 1041, *Information supplied by the manufacturer of medical devices*

EN 21942-1:1991, *Dental vocabulary — Part 1: General and clinical terms (ISO 1942-1:1989)*

EN 21942-2:1992, *Dental vocabulary — Part 2: Dental materials (ISO 1942-2:1989)*

EN ISO 1942-5:1994, *Dental vocabulary — Part 5: Terms associated with testing (ISO 1942-5:1989)*

EN ISO 7405, *Dentistry — Evaluation of biocompatibility of medical devices used in dentistry (ISO 7405:2008)*

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 11135-1, *Sterilization of health care products — Ethylene oxide — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11135-1:2007)*

EN ISO 11137-1, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006)*

EN ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2006)*

EN ISO 11607-2, *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2006)*

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 14155-2:2003)*

EN ISO 14801, *Dentistry — Implants — Dynamic fatigue test for endosseous dental implants (ISO 14801:2007)*

EN ISO 14971, *Medical devices — Application of risk management to medical devices (ISO 14971:2007)*

EN ISO 22794, *Dentistry — Implantable materials for bone filling and augmentation in oral and maxillofacial surgery — Contents of technical file (ISO 22794:2007)*

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EN ISO 22803, *Dentistry — Membrane materials for guided tissue regeneration in oral and maxillofacial surgery — Contents of technical file (ISO 22803:2004)*

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

**3 Terms and definitions**

For the purposes of this document, the terms and definitions given in EN 21942-1:1991, EN 21942-2:1992, EN ISO 1942-5:1994 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 or to provide orthodontic anchorage

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** Risk management shall be carried out and documented. This shall include a risk analysis in accordance with EN ISO 14971.

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**4.2 Design and properties****4.2.1 Materials**

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

**4.2.2 Contents of technical file**

The contents of the manufacturer's technical file shall be in accordance with EN ISO 10451, EN ISO 22794 and EN ISO 22803, if applicable.

**4.2.3 Biocompatibility**

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.

Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction.

NOTE Further information is given in Annex I of Council Directive 67/548/EEC of 27 June 1967.

**4.2.4 Biophysical properties and modelling**

Dental implants, other than those designed to provide orthodontic anchorage, shall be assessed for mechanical stability by fatigue testing according to EN ISO 14801.

NOTE The stability of dental implants designed to provide orthodontic anchorage shall be assessed by mechanical tests with regard to the properties required for the intended purpose.



### 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 ISO 11135-1 shall apply;
- b) If dental implants are to be sterilized by irradiation, EN ISO 11137-1 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.

Packaging systems for dental implants supplied sterile shall be in accordance with EN ISO 11607-1 and EN ISO 11607-2.

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#### 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 ISO 22442-1 [5].

### 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 10451 specifies requirements for the contents of a technical file to prefabricated parts connecting a dental suprastructure to a transgingival implant.

### 4.5 Clinical investigation and evaluation

A clinical investigation shall be conducted for all types of dental implants in accordance with EN ISO 14155-1 and EN ISO 14155-2, unless it is duly justified and documented to rely on existing clinical data.

A clinical evaluation shall be conducted and reported for all dental implants.