Dentistry - General requirements for instruments and related accessories used in dental implant placement and treatment (ISO 13504:2012)

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NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 13504:2012 sisaldab Euroopa standardi EN ISO 13504:2012 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 13504:2012 consists of the English text of the European standard EN ISO 13504:2012.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 15.07.2012.	Date of Availability of the European standard is 15.07.2012.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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Dentistry - General requirements for instruments and related accessories used in dental implant placement and treatment (ISO 13504:2012)

Médecine bucco-dentaire - Exigences générales relatives aux instruments et aux accessoires connexes utilisés en implantologie dentaire (ISO 13504:2012)

Zahnheilkunde - Allgemeine Anforderungen an bei der Implantation verwendete Instrumente und Zubehör (ISO 13504:2012)

This European Standard was approved by CEN on 14 July 2012.

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Foreword

This document (EN ISO 13504:2012) 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of an identical text or by endorsement, at the latest by January 2013, and conflicting national standards shall be withdrawn at the latest by January 2013.

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.

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Endorsement notice

The text of ISO 13504:2012 has been approved by CEN as a EN ISO 13504:2012 without any modification.

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Introduction

The use of dental implants is increasing throughout the world. Due to improved and new applications of dental implants, the need for better instruments and related accessories to be used in the placement of dental implants and the further manipulation of connecting parts in the craniofacial area is also growing. Dental implants need to be approved by local authorities.

However, instruments used in the placement of dental implants are different and need a different approval procedure. This International Standard is intended to harmonize the approval procedures and to reduce the costs caused by repeated approval and test procedures in different countries.

Materials present in instruments used in dental implant procedures have proven to be well tolerated. Potential adverse reactions cannot be totally ruled out but such reactions are to be mitigated.

However, long-term clinical experience of the use of the materials referred to in this International Standard has shown that an acceptable level of biological response can be expected when they are used in appropriate applications and when instruments are manufactured under appropriate design considerations and processes.

Due to different stainless steel standards, Annex B has been added. This gives cross-references to designations of stainless steels which are listed in other international, regional or national standards designation systems.

Dentistry — General requirements for instruments and related accessories used in dental implant placement and treatment

1 Scope

This International Standard specifies general requirements for the manufacture of instruments and related accessories used in the placement of dental implants and further manipulations of connecting parts in the craniofacial area.

It is applicable to single-use and reusable instruments, regardless of whether they are manually driven or connected to a power-driven system.

It is not applicable to the power-driven system itself, nor to the dental implant or to parts intended to be connected to the dental implant.

With regard to safety, this International Standard gives requirements for classification, intended performance, performance attributes, material selection, performance evaluation, manufacture, sterilization and information to be supplied by the manufacturer.

2 Normative references

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

ISO 1043-1, *Plastics — Symbols and abbreviated terms — Part 1: Basic polymers and their special characteristics*

ISO 1942, *Dentistry — Vocabulary*

ISO 2768-1, *General tolerances — Part 1: Tolerances for linear and angular dimensions without individual tolerance indications*

ISO 5832-2, *Implants for surgery — Metallic materials — Part 2: Unalloyed titanium*

ISO 5832-3, *Implants for surgery — Metallic materials — Part 3: Wrought titanium 6-aluminium 4-vanadium alloy*

ISO 7405, *Dentistry — Evaluation of biocompatibility of medical devices used in dentistry*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

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 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 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 17664, *Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices*

ISO 17665-1, *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 and the following apply.

3.1
transient usage
usage for less than 60 min in any one clinical procedure

3.2 Instruments

3.2.1
surgically invasive device
device which penetrates into the human body through the surface of the body, with the aid or in the context of a surgical operation

3.2.2
instrument used in dental implant placement and treatment
surgically invasive device, used with a transient usage for the preparation of bone and tissue in the craniofacial region, to be used in the placement of dental implants and the further manipulation of connecting parts

3.2.3
accessory used in dental implant placement and treatment
non-surgically invasive device, used with a transient usage in direct or indirect contact with the human body, to be used in the placement of dental implants and the further manipulation of connecting parts

3.3 Stainless steel

3.3.1
stainless steel
steel, the main alloying element of which is chromium, of at least 10,5 % (mass fraction) Cr and maximum 1,2 % (mass fraction) C, and the primary importance of which is its resistance to corrosion

3.3.2
austenitic stainless steel
corrosion-resistant steel, typically with composition of less than 0,2 % (mass fraction) C, at least 16% (mass fraction) Cr, typically about 18 % (mass fraction) Cr and over 8 % (mass fraction) Ni, which cannot be hardened by heat treatment

3.3.3
martensitic stainless steel
corrosion-resistant steel with low to medium carbon, with at least 0,1 % (mass fraction) C and between 12 % (mass fraction) and 19 % (mass fraction) Cr, which can be hardened by quenching and tempering

3.3.4
precipitation-hardening stainless steel
corrosion-resistant steel with a high strength resulting from the precipitation of intermetallic compounds (the formation of very fine intermetallic phases, carbides and Laves phases in the structure) by a final heat treatment at relatively low temperature