Dentistry - Contents of technical file for dental implant systems

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NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 10451:2010 sisaldab Euroopa standardi EN ISO 10451:2010 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 10451:2010 consists of the English text of the European standard EN ISO 10451:2010.
Standard on kinnitatud Eesti Standardikeskuse 30.09.2010 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 30.09.2010 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 15.06.2010.	Date of Availability of the European standard text 15.06.2010.
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Dentistry - Contents of technical file for dental implant systems (ISO 10451:2010)

Médecine bucco-dentaire - Contenu du dossier technique pour les systèmes d'implants dentaires (ISO 10451:2010)

Zahnheilkunde - Inhalt der Technischen Dokumentation für Dentalimplantatsysteme (ISO 10451:2010)

This European Standard was approved by CEN on 26 May 2010.

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Foreword

This document (EN ISO 10451:2010) 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of an identical text or by endorsement, at the latest by December 2010, and conflicting national standards shall be withdrawn at the latest by December 2010.

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 10451:2010 has been approved by CEN as a EN ISO 10451:2010 without any modification.

Introduction

Legal/regulatory requirements on the documentation of the design, manufacture and performance of dental implants are developing in various ways in different countries and international regions. As the dental implant industry is already active on a global basis, and is becoming more so, concern is growing as to the need for international and mutually recognized standards for documentation of the design and the performance of such devices.

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1 Scope

This International Standard specifies requirements for the contents of a technical file to demonstrate the fulfilment of regulatory requirements for a dental implant and any prefabricated part thereof that remains in the mouth after surgery.

This International Standard is not applicable to instruments and other parts specifically made for the dental implant system but which do not remain in the mouth. However, documentation relating to these components may be included in the technical file.

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.

ISO 129-1, *Technical drawings — Indication of dimensions and tolerances — Part 1: General principles*

ISO 1942, *Dentistry — Vocabulary*

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

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

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

ISO 10993-7, *Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals*

ISO 10993-9, *Biological evaluation of medical devices — Part 9: Framework for identification and quantification of potential degradation products*

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/TS 11135-2, *Sterilization of health care products — Ethylene oxide — Part 2: Guidance on the application of ISO 11135-1*

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 11137-2, *Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose*

ISO 11137-3, *Sterilization of health care products — Radiation — Part 3: Guidance on dosimetric aspects*

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

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

ISO 14155-1, *Clinical investigation of medical devices for human subjects — Part 1: General requirements*

ISO 14155-2, *Clinical investigation of medical devices for human subjects — Part 2: Clinical investigation plans*

ISO 14405-2, *Geometrical product specifications (GPS) — Dimensional tolerancing — Part 2: Dimensions other than linear sizes*

ISO 14801, *Dentistry — Implants — Dynamic fatigue test for endosseous dental implants*

ISO 14937, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

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

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*

ISO/TS 22911, *Dentistry — Preclinical evaluation of dental implant systems — Animal test methods*

3 Terms and definitions

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

3.1
coating
layer of material used to cover or partially cover a surface of an implant or part of an implant system

3.2
dental implant system
device that consists of integrated components including the ancillary instruments and specific equipment necessary for the clinical and laboratory preparation and placement of the implant, and for the construction and insertion of the dependent prosthesis

3.3
technical file
documentation provided by the manufacturer containing the basic available information on a device or indicating its location

3.4
water sorption
gain in water content, per volume, of an initially dry specimen after immersion in water for a given time