# INTERNATIONAL STANDARD



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# Dentistry — Contents of technical file for dental implant systems

Médecine bucco-dentaire — Contenu du dossier technique pour les systèmes d'implants dentaires



Reference number ISO 10451:2010(E)

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# Foreword

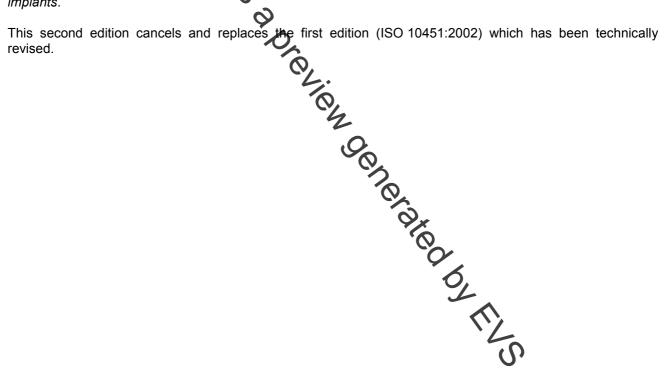
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ISO 10451 was prepared by Technica Committee ISO/TC 106, Dentistry, Subcommittee SC 8, Dental implants.



# 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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# Dentistry — Contents of technical file for dental implant systems

# 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 fig.

# 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 of the references.

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 Evaluation and testing within a risk management process

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

ISO 10993-9, Biological evaluation of medical devices — Part 9: Framework for identification and guantification 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 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 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