International Standard

ISO 10451

Dentistry — Contents of a technical file for dental implant systems

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

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Foreword

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This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 8, *Dental implants*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO 10451:2010), which has been technically revised.

The main changes are as follows:

— technical file has been reworked to take into account the new European Medical Device Regulation [1];

— Annex A has been added.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Legal and regulatory requirements on the documentation of the design, manufacture and performance of dental implants are developing in different ways around the world. 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 the documentation of the design and performance of such devices.

Dentistry — Contents of a technical file for dental implant systems

1 Scope

This document specifies requirements for the contents of a technical file to demonstrate the fulfilment of regulatory requirements for an endosseous dental implant that can include:

— implant body;

— implant abutment;

— abutment screw;

— implant connecting part;

— implant connecting part screw;

— prosthetic screw;

— implant cover screw;

— transmucosal healing component.

This document also specifies requirements for intended use and performance, design attributes, components, biocompatibility, manufacturing, packaging, sterilization, shelf life, marking, labelling and information supplied by the manufacturer.

This document does not apply to the following devices:

— dental implants incorporating animal or human components or bioactive characteristics;

— custom-made devices that have no pre-fabricated connection;

— implantable materials for bone filling and augmentation in oral and maxillofacial surgery;

— membrane materials for guided tissue regeneration in oral and maxillofacial surgery;

— specific instruments indicated to be used as part of a dental implant system.

NOTE 1 ISO 22794 specifies the necessary content of technical files for implantable materials for bone filling and augmentation in oral and maxillofacial surgery. ISO 22803 specifies the necessary content of technical files for membrane materials for guided tissue regeneration in oral and maxillofacial surgery. These materials require a separate technical file.

NOTE 2 ISO 13504 gives the general requirements for specific instruments indicated to be used as part of a dental implant system. These instruments require a separate technical file.

NOTE 3 Custom-made devices are defined in IMDRF/PMD WG/N49 [5].

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 1942, *Dentistry — Vocabulary*