International Standard

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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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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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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.

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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.

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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*

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ISO 3950, *Dentistry — Designation system for teeth and areas of the oral cavity*

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

ISO 10271, *Dentistry — Corrosion test methods for metallic materials*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Requirements and general principles for the evaluation of biological safety within a risk management process*

ISO 10993-17, *Biological evaluation of medical devices — Part 17: Toxicological risk assessment of medical device constituents*

ISO 11135, *Sterilization of health-care products — Ethylene oxide — Requirements for the 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 the 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 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 13485, *Medical devices — Quality management systems — Requirements for regulatory purposes*

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

ISO 14644-1, *Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration*

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

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

ISO 15223-1, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements*

ISO 15223-2, *Medical devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 2: Symbol development, selection and validation*

ISO 16443, *Dentistry — Vocabulary for dental implants systems and related procedure*

ISO 17664-1, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices*

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

ISO 20417, *Medical devices — Information to be supplied by the manufacturer*

ISO 22683, *Dentistry — Rotational adaptability test between implant body and implant abutment in dental implant systems*

IEC 62366-1, *Medical devices — Part 1: Application of usability engineering to medical devices*

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3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942, ISO 3950, ISO 16443, ISO 13485 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
clinical evaluation
assessment and analysis of clinical data pertaining to a medical device to verify the clinical safety and performance of the device when used as intended by the manufacturer

[SOURCE: ISO 13485:2016, 3.3]

3.2
dental implant assembly
assembly of dental implant components as recommended by the manufacturer to serve the purposes of a dental implant

[SOURCE: ISO 16443:2014, 3.2.3]

3.3
implant component coating
layer of material, different from the constitutive material of the implant component, used to cover or partially cover a defined surface of an implant body or an implant component

[SOURCE: ISO 1942:2020, 3.7.2.7]

3.4
technical documentation
manufacturer's set of data showing conformity of a device to a list of requirements of this document and which is intended to be used as part of the technical documentation required for conformity assessment procedures performed by *conformity assessment bodies* (3.2)

Note 1 to entry: See Reference [6] for an explanation of the term “conformity assessment body”.

Note 2 to entry: In Europe, notified bodies are considered as being conformity assessment bodies and every member state has a national regulatory authority (e.g. Zentralstelle der Länder für Gesundheitsschutz for Germany, Agence Nationale de Sécurité du Médicament et des Produits de Santé for France). In the United States, the Food and Drug Agency is both a regulatory authority and a conformity assessment body.

3.5
subtractive surface treatment
process that modifies a component’s surface by subtraction of material

EXAMPLE Sandblasting and acid etching are considered subtractive surface treatments.

4 Technical file content and requirements

4.1 General

The technical file should be kept up-to-date and kept for a defined period after the last device has been placed on the market.

The technical file shall contain, or reference the location of, at least the information required in 4.2 to 4.9.

NOTE Subclauses 4.2 to 4.9 are not supposed to be strictly followed as chapter headers for the technical documentation.

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