SLOVENSKI STANDARD
oSIST prEN ISO 10451:2025

01-januar-2025

Zobozdravstvo - Vsebina tehnične mape za sistem zobnih vsadkov (implantatov) (ISO/DIS 10451:2024)

Dentistry - Contents of technical file for dental implant systems (ISO/DIS 10451:2024)

Zahnheilkunde - Inhalt der Technischen Dokumentation für Dentalimplantatsysteme (ISO/DIS 10451:2024)

Médecine bucco-dentaire - Contenu du dossier technique pour les systèmes d'implants dentaires (ISO/DIS 10451:2024)

Ta slovenski standard je istoveten z: **prEN ISO 10451**

ICS:

11.060.15	Zobni implantati	Dental implants

oSIST prEN ISO 10451:2025	**en,fr,de**

DRAFT International Standard

ISO/DIS 10451

Dentistry — Contents of technical file for dental implant systems

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

ICS: 11.060.15

ISO/TC **106**/SC **8**

Secretariat: **ANSI**

Voting begins on:
2024-11-07

Voting terminates on:
2025-01-30

This document is circulated as received from the committee secretariat.

ISO/CEN PARALLEL PROCESSING

Reference number
ISO/DIS 10451:2024(en)

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Published in Switzerland

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 106, Dentistry, Subcommittee SC 8, Dental implants.

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

The main changes compared to the previous edition are as follows:

— Rework of the content for the Technical File considering the new European Medical Device Regulation,

— Addition of Annex A describing a list of Hazards related to Dental Implants.

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/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.

Dentistry — Contents of 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 may include:

— implant body,

— implant abutment,

— abutment screw,

— implant connecting part

— implant connecting part screw

— prosthetic screw,

— implant cover screw,

— transmucosal healing component.

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

The following devices are not included within the scope of this document:

— Dental implant 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 gives the necessary content of technical files for implantable materials for bone filling and augmentation in oral and maxillofacial surgery. ISO 22803 gives 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 the following document IMDRF/PMD WG/N49 - Definitions for Personalized Medical Devices.

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*

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 8601-1, *Date and time — Representations for information interchange — Part 1: Basic rules*

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

ISO 10993-1, *Biological evaluation of medical devices - Part 1: Evaluation and testing 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 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 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 17665-1, *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 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*

3 Terms and definitions

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