



**International**

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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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**ISO 10451**

**Third edition  
2026-03**

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Published in Switzerland

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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.

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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.