



SLOVENSKI STANDARD
SIST EN ISO 10451:2002
01-november-2002

G]ghYa `ncVb] \ `j gUX_cj `f]a d`UbUHL!`J gYV]bUHM b] bY`a UdY`f]GC`%\$(.&\$ \$&L

Dental implant systems - Contents of technical file (ISO 10451:2002)

Dentalimplantatsysteme - Inhalt der Technischen Dokumentation (ISO 10451:2002)

Systemes d'implants dentaires - Contenu du dossier technique (ISO 10541:2002)

Ta slovenski standard je istoveten z: EN ISO 10451:2002

[SIST EN ISO 10451:2002](https://standards.iteh.ai/catalog/standards/sist/2298e6bc-8474-4432-9533-d4c6c21fc883/sist-en-iso-10451-2002)

<https://standards.iteh.ai/catalog/standards/sist/2298e6bc-8474-4432-9533-d4c6c21fc883/sist-en-iso-10451-2002>

ICS:

11.060.15 Zobni implantati Dental implants

SIST EN ISO 10451:2002 **en**

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 10451:2002

<https://standards.iteh.ai/catalog/standards/sist/2298e6bc-8474-4432-9533-d4c6c21fc883/sist-en-iso-10451-2002>

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 10451

February 2002

ICS 11.060.10

English version

**Dental implant systems - Contents of technical file (ISO
10451:2002)**

Systèmes d'implants dentaires - Contenu du dossier
technique (ISO 10541:2002)

Dentalimplantatsysteme - Inhalt der Technischen
Dokumentation (ISO 10451:2002)

This European Standard was approved by CEN on 15 February 2002.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

[SIST EN ISO 10451:2002](https://standards.iteh.ai/catalog/standards/sist/2298e6bc-8474-4432-9533-d4c6c21fc883/sist-en-iso-10451-2002)

<https://standards.iteh.ai/catalog/standards/sist/2298e6bc-8474-4432-9533-d4c6c21fc883/sist-en-iso-10451-2002>



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

EN ISO 10451:2002 (E)

CORRECTED 2002-04-17

Foreword

This document (ISO 10451:2002) has been prepared by Technical Committee ISO/TC 106 "Dentistry" in collaboration with Technical Committee CEN/TC 55 "Dentistry", the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by August 2002, and conflicting national standards shall be withdrawn at the latest by August 2002.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

iTeh STANDARD PREVIEW
(standard not published)
Endorsement notice

The text of the International Standard ISO 10451:2002 has been approved by CEN as a European Standard without any modifications.

NOTE Normative references to International Standards are listed in annex ZA (normative).

Annex ZA (normative)

Normative references to international publications with their relevant European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

NOTE Where an International Publication has been modified by common modifications, indicated by (mod.), the relevant EN/HD applies.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN</u>	<u>Year</u>
ISO 1942-1	1989	Dental vocabulary – Part 1: General and clinical terms	EN 21942-1	1991
ISO 7405	1997	Dentistry – Preclinical evaluation of biocompatibility of medical devices used in dentistry – Test methods for dental materials	EN ISO 7405	1997
ISO 8601	1988	Data elements and interchange formats – Information interchange – Representation of dates and times (including technical corrigendum 1:1991)	EN 28601	1992
ISO 10993-1	1997	Biological evaluation of medical devices – Part 1: Evaluation and testing	EN ISO 10993-1	1997
ISO 14971	2000	Medical devices - Application of risk management to medical devices	EN ISO 14971	2000

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 10451:2002

<https://standards.iteh.ai/catalog/standards/sist/2298e6bc-8474-4432-9533-d4c6c21fc883/sist-en-iso-10451-2002>

INTERNATIONAL
STANDARD

ISO
10451

First edition
2002-02-15

**Dental implant systems — Contents of
technical file**

Systèmes d'implants dentaires — Contenu du dossier technique

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN ISO 10451:2002](https://standards.iteh.ai/catalog/standards/sist/2298e6bc-8474-4432-9533-d4c6c21fc883/sist-en-iso-10451-2002)

[https://standards.iteh.ai/catalog/standards/sist/2298e6bc-8474-4432-9533-
d4c6c21fc883/sist-en-iso-10451-2002](https://standards.iteh.ai/catalog/standards/sist/2298e6bc-8474-4432-9533-d4c6c21fc883/sist-en-iso-10451-2002)



Reference number
ISO 10451:2002(E)

© ISO 2002

ISO 10451:2002(E)

PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

iTeh STANDARD PREVIEW (standards.iteh.ai)

[SIST EN ISO 10451:2002](https://standards.iteh.ai/catalog/standards/sist/2298e6bc-8474-4432-9533-d4c6c21fc883/sist-en-iso-10451-2002)

<https://standards.iteh.ai/catalog/standards/sist/2298e6bc-8474-4432-9533-d4c6c21fc883/sist-en-iso-10451-2002>

© ISO 2002

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.ch
Web www.iso.ch

Printed in Switzerland

Contents

	Page
Foreword.....	iv
Introduction.....	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Requirements	2
4.1 General.....	2
4.2 Intended use.....	2
4.3 Design characteristics	2
4.4 Properties of the constituent materials.....	2
4.5 Properties of the final product	4
4.6 Manufacturing process	4
4.7 Quality control of the implant manufacturing process.....	4
4.8 Control of infection and microbial contamination	4
4.9 Risk assessment.....	4
4.10 Clinical evaluation	5
4.11 Packaging.....	5
4.12 Label.....	5
4.13 Instructions for use	6
Bibliography.....	7

[SIST EN ISO 10451:2002](https://standards.iteh.ai/catalog/standards/sist/2298e6bc-8474-4432-9533-d4c6c21fc883/sist-en-iso-10451-2002)

<https://standards.iteh.ai/catalog/standards/sist/2298e6bc-8474-4432-9533-d4c6c21fc883/sist-en-iso-10451-2002>