Dental implant systems - Contents of technical file

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EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN ISO 10451:2002 sisaldab Euroopa standardi EN ISO 10451:2002 ingliskeelset teksti. Käesolev dokument on jõustatud 06.08.2002 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN ISO 10451:2002 consists of the English text of the European standard EN ISO 10451:2002. This document is endorsed on 06.08.2002 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: This International Standard specifies requirements for te contents of a technical file to demonstrate the fulfiment of regulatory requirements for a dental implant and any prefabricated part thereof which remains in the mouth after surgery.	**Scope:** This International Standard specifies requirements for te contents of a technical file to demonstrate the fulfiment of regulatory requirements for a dental implant and any prefabricated part thereof which remains in the mouth after surgery.

ICS 11.060.10

Võtmesõnad: classification systems, classifications, contents, dental implants, dental materials, dentistry, general section, implants (surgical), materials, medical equipment, prefabricated, products documentation, specifications, surveys

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Dental implant systems

Contents of technical file
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Systèmes d'implants dentaires – Contenu du dossier technique (ISO 10451 : 2002)

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

This European Standard was approved by CEN on 2002-02-15.

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.

The European Standards exist 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, the Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

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

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Foreword

International Standard

ISO 10451 : 2002 Dental implant systems – Contents of technical file,

which was prepared by ISO/TC 106 'Dentistry' of the International Organization for Standardization, has been adopted by Technical Committee CEN/TC 55 'Dentistry', the Secretariat of which is held by DIN, as a European Standard.

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

In accordance with the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard:

Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 10451 : 2002 was approved by CEN as a European Standard without any modification.

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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.

1 Scope

This International Standard specifies requirements for the contents of a technical file to demonstrate the fulfilment of regulatory requirements for a dental implant and any prefabricated part thereof which remains in the mouth after surgery.

This International Standard is not applicable to instruments and other parts specifically made for the dental implant system but which do not remain in the mouth. However, documentation relating to these components may be included in the technical file.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 1942-1, *Dental vocabulary — Part 1: General and clinical terms*

ISO 7405, *Dentistry — Preclinical evaluation of biocompatibility of medical devices used in dentistry — Test methods for dental materials*

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

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

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

3 Terms and definitions

For the purposes of this International Standard, the terms and definitions given in ISO 1942-1 and the following apply.

3.1
safety
freedom from unacceptable risk of harm

3.2
coating
layer of material used to cover or partially cover a surface of an implant