

SLOVENSKI STANDARD

SIST EN ISO 22794:2010

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SIST EN ISO 22794:2007

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Dentistry - Implantable materials for bone filling and augmentation in oral and maxillofacial surgery - Contents of a technical file (ISO 22794:2007, corrected version 2009-01-15)

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Zahnheilkunde - Implantierbare Materialien zum Auffüllen von Knochendefekten und zur Augmentation bei oralen und maxillofazialen Eingriffen - Inhalt der Technischen Dokumentation (ISO 22794:2007, korrigierte Fassung 2009-01-15)

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Art dentaire - Matériaux implantables de comblement et de reconstruction osseuse en chirurgie orale et maxillofaciale - Contenu d'un dossier technique (ISO 22794:2007, version corrigée 2009-01-15)

Ta slovenski standard je istoveten z: EN ISO 22794:2009

ICS:

11.060.15 Zobni implantati Dental implants

SIST EN ISO 22794:2010

en

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 22794

August 2009

ICS 11.060.15

Supersedes EN ISO 22794:2007

English Version

**Dentistry - Implantable materials for bone filling and
augmentation in oral and maxillofacial surgery - Contents of a
technical file (ISO 22794:2007, corrected version 2009-01-15)**

Art dentaire - Matériaux implantables de comblement et de
reconstruction osseuse en chirurgie orale et maxillofaciale -
Contenu d'un dossier technique (ISO 22794:2007, version
corrigée 2009-01-15)

Zahnheilkunde - Implantierbare Materialien zum Auffüllen
von Knochendefekten und zur Augmentation bei oralen und
maxillofazialen Eingriffen - Inhalt der Technischen
Dokumentation (ISO 22794:2007, korrigierte Fassung 2009-
01-15)

This European Standard was approved by CEN on 3 August 2009.

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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 CEN Management Centre has the same status as the official versions.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

The text of ISO 22794:2007, corrected version 2009-01-15 has been prepared by Technical Committee ISO/TC 106 "Dentistry" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 22794:2009 by 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 January 2010, and conflicting national standards shall be withdrawn at the latest by January 2010.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

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The text of ISO 22794:2007, corrected version 2009-01-15 has been approved by CEN as a EN ISO 22794:2009 without any modification. [SIST EN ISO 22794:2010](https://standards.iteh.ai/catalog/standards/sist/e362bdbb-908b-41e9-953d-0969e6aaca6b/sist-en-iso-22794-2010)

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INTERNATIONAL STANDARD

ISO
22794

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2007-07-15

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2009-01-15

Dentistry — Implantable materials for bone filling and augmentation in oral and maxillofacial surgery — Contents of a technical file

*Art dentaire — Matériaux implantables de comblement et de
reconstruction osseuse en chirurgie orale et maxillofaciale — Contenu
d'un dossier technique*

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 22794 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 8, *Dental implants*.

In this corrected version of ISO 22794:2007 changes have been made to the list of Normative references (Clause 2) and to the Bibliography. Consequently cross-references in subclauses 5.2, 5.5.5, 5.7, 5.8 and 5.9.2 have been altered.

Further, new subclauses 5.5.3 and 5.5.4 have been designated with the former 5.5.3 becoming 5.5.5.

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Introduction

Different materials used for the preservation of masticatory function, such as dental restorative materials and dental implants are subject to standards and regulations, either in existence or in preparation, designed to evaluate the performance of these products.

Implantable materials for bone filling and augmentation in oral and maxillofacial surgery are not covered by the procedures for evaluating and testing dental restorative materials and dental implants; it is necessary to develop a new standard for these materials.

The aim of this International Standard is to define the content of a technical file that demonstrates safety and effectiveness of bone filling and augmentation materials used in oral and maxillofacial surgery.

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