



# SLOVENSKI STANDARD SIST EN ISO 22794:2007

01-september-2007

---

NcVcnXfUj ghj c`È`JgUX]hj Yb]`a UHf]U]`nUdc`b`Yb`Y]b`dcj Y Ub`Y`\_cgh]j`i`ghb]`]b  
a U\_g]`c`ZU]U]b]`\_fi f[ ]j]È`JgYV]bUHM b] bY`a UdY`f]GC`&&+ (.&\$\$+L

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

Zahnheilkunde - Implantierbare Materialien zur Auffüllung von Knochendefekten und zur Augmentation bei oralen und maxillofazialen Eingriffen - Inhalt der Technischen Dokumentation (ISO 22794:2007)

(standards.iteh.ai)

Art dentaire - Matériaux implantables pour le remplissage et l'augmentation osseuse dans la chirurgie orale et maxillofaciale - Contenu d'un dossier technique (ISO 22794:2007)

Ta slovenski standard je istoveten z: EN ISO 22794:2007

---

**ICS:**

11.060.15      Zobni implantati      Dental implants

**SIST EN ISO 22794:2007**      en

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

SIST EN ISO 22794:2007

<https://standards.iteh.ai/catalog/standards/sist/3f56374b-12eb-4ce3-8eb1-5b18b89f6562/sist-en-iso-22794-2007>

ICS 11.060.15

English Version

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

Art dentaire - Matériaux implantables pour le remplissage et  
l'augmentation osseuse en chirurgie orale et maxillofaciale  
- Contenu d'un dossier technique (ISO 22794:2007)

Zahnheilkunde - Implantierbare Materialien zum Auffüllung  
von Knochendefekten und zur Augmentation bei oralen und  
maxillofazialen Eingriffen - Inhalt der Technischen  
Dokumentation (ISO 22794:2007)

This European Standard was approved by CEN on 20 June 2007.

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

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.



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

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

## **Foreword**

This document (EN ISO 22794:2007) 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 January 2008, and conflicting national standards shall be withdrawn at the latest by January 2008.

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

### **Endorsement notice**

The text of ISO 22794:2007 has been approved by CEN as EN ISO 22794:2007 without any modifications.

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

[SIST EN ISO 22794:2007](https://standards.iteh.ai/catalog/standards/sist/3f56374b-12eb-4ce3-8eb1-5b18b89f6562/sist-en-iso-22794-2007)

<https://standards.iteh.ai/catalog/standards/sist/3f56374b-12eb-4ce3-8eb1-5b18b89f6562/sist-en-iso-22794-2007>

---

---

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

*Art dentaire — Matériaux implantables pour le remplissage et  
l'augmentation osseuse en chirurgie orale et maxillofaciale — Contenu  
d'un dossier technique*

iTeh STANDARD PREVIEW  
(standards.iteh.ai)

SIST EN ISO 22794:2007

<https://standards.iteh.ai/catalog/standards/sist/3f56374b-12eb-4ce3-8eb1-5b18b89f6562/sist-en-iso-22794-2007>



**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 22794:2007](https://standards.iteh.ai/catalog/standards/sist/3f56374b-12eb-4ce3-8eb1-5b18b89f6562/sist-en-iso-22794-2007)

<https://standards.iteh.ai/catalog/standards/sist/3f56374b-12eb-4ce3-8eb1-5b18b89f6562/sist-en-iso-22794-2007>



**COPYRIGHT PROTECTED DOCUMENT**

© ISO 2007

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.org](mailto:copyright@iso.org)  
Web [www.iso.org](http://www.iso.org)

Published in Switzerland

## Contents

Page

Foreword.....	iv
Introduction .....	v
1 Scope .....	1
2 Normative references .....	1
3 Terms and definitions .....	2
4 Implantable materials .....	2
5 Technical file .....	3
5.1 Contents .....	3
5.2 Chemical composition .....	3
5.3 Physical properties.....	3
5.4 Intended applications, precautions, warnings and instructions .....	4
5.5 Preclinical and clinical evaluation .....	4
5.6 Manufacture.....	6
5.7 Materials of animal origin .....	6
5.8 Sterilization.....	6
5.9 Packaging.....	7
5.10 Additional information supplied by the manufacturer.....	7
Bibliography .....	8

SIST EN ISO 22794:2007

<https://standards.iteh.ai/catalog/standards/sist/3f56374b-12eb-4ce3-8eb1-5b18b89f6562/sist-en-iso-22794-2007>

## 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*.

## iTeh STANDARD PREVIEW (standards.iteh.ai)

[SIST EN ISO 22794:2007](https://standards.iteh.ai/catalog/standards/sist/3f56374b-12eb-4ce3-8eb1-5b18b89f6562/sist-en-iso-22794-2007)

<https://standards.iteh.ai/catalog/standards/sist/3f56374b-12eb-4ce3-8eb1-5b18b89f6562/sist-en-iso-22794-2007>



## 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.

## iTeh STANDARD PREVIEW (standards.iteh.ai)

[SIST EN ISO 22794:2007](https://standards.iteh.ai/catalog/standards/sist/3f56374b-12eb-4ce3-8eb1-5b18b89f6562/sist-en-iso-22794-2007)

<https://standards.iteh.ai/catalog/standards/sist/3f56374b-12eb-4ce3-8eb1-5b18b89f6562/sist-en-iso-22794-2007>