

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

This document is a preview generated by EVS

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-EN ISO 22794:2009 sisaldab Euroopa standardi prEN ISO 22794:2009 ingliskeelset teksti.</p> <p>Standard on kinnitatud Eesti Standardikeskuse 30.11.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.</p> <p>Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 19.08.2009.</p> <p>Standard on kättesaadav Eesti standardiorganisatsioonist.</p>	<p>This Estonian standard EVS-EN ISO 22794:2009 consists of the English text of the European standard prEN ISO 22794:2009.</p> <p>This standard is ratified with the order of Estonian Centre for Standardisation dated 30.11.2009 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.</p> <p>Date of Availability of the European standard text 19.08.2009.</p> <p>The standard is available from Estonian standardisation organisation.</p>
--	---

ICS 11.060.15

Standardite reprodutseerimis- ja levitamiseõigus kuulub Eesti Standardikeskusele

Andmete paljundamine, taastekitamine, kopeerimine, salvestamine elektroonilisse süsteemi või edastamine ükskõik millises vormis või millisel teel on keelatud ilma Eesti Standardikeskuse poolt antud kirjaliku loata.

Kui Teil on küsimusi standardite autorikaitse kohta, palun võtke ühendust Eesti Standardikeskusega:
Aru 10 Tallinn 10317 Eesti; www.evs.ee; Telefon: 605 5050; E-post: info@evs.ee

Right to reproduce and distribute Estonian Standards belongs to the Estonian Centre for Standardisation

No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying, without permission in writing from Estonian Centre for Standardisation.

If you have any questions about standards copyright, please contact Estonian Centre for Standardisation:
Aru str 10 Tallinn 10317 Estonia; www.evs.ee; Phone: +372 605 5050; E-mail: info@evs.ee

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.

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: Avenue Marnix 17, B-1000 Brussels

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.

This document supersedes EN ISO 22794:2007.

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 the United Kingdom.

Endorsement notice

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.

Contents

Page

Foreword.....	iv
Introduction.....	v
1 Scope.....	1
2 Normative references.....	1
3 Terms and definitions.....	2
4 Implantable materials.....	3
5 Technical file.....	3
5.1 Contents.....	3
5.2 Chemical composition.....	3
5.3 Physical properties.....	4
5.4 Intended applications, precautions, warnings and instructions.....	4
5.5 Preclinical and clinical evaluation.....	5
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.....	9

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.

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

1 Scope

This International Standard applies to implantable materials, whether resorbable or non-resorbable, used as dental devices for filling and augmenting bones in oral and maxillofacial surgery. Products that are essentially pure (> 90 %) hydroxyapatite are not covered by this International Standard.

Evaluation includes the physico-chemical, mechanical, biological and clinical aspects and behaviour of these implantable dental materials.

Materials such as autografts, allografts and membranes, and products for which the primary intended use is to deliver a medicinal product, are not covered by this International Standard.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 1942 ¹⁾, *Dentistry — Vocabulary*

ISO 10993-1 ²⁾, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management system*

ISO 10993-17, *Biological evaluation of medical devices — Part 17: Establishment of allowable limits for leachable substances*

ISO 11135-1 ³⁾, *Sterilization of health care products — Ethylene oxide — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11137-1 ⁴⁾, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11607-2 ⁵⁾, *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes*

1) To be published. (Revises and replaces ISO 1942 parts 1 to 5:1989)

2) To be published. (Revision of ISO 10993-1:2003)

3) Cancels and replaces ISO 11135:1994 and ISO 11135:1994/Cor.1:1994.

4) Cancels and replaces ISO 11137:1995, ISO 11137:1995/Cor.1:1997 and ISO 11137:1995/Amd.1:2001.

5) Cancels and replaces ISO 11607:2003.

ISO 13408-1, *Aseptic processing of health care products — Part 1: General requirements*

ISO 14155-1 ⁶⁾, *Clinical investigation of medical devices for human subjects — Part 1: General requirements*

ISO 14155-2 ⁶⁾, *Clinical investigation of medical devices for human subjects — Part 2: Clinical investigation plans*

ISO 14937, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

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

ISO 15223, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied*

ISO 17665-1 ⁷⁾, *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

EN 1041, *Information supplied by the manufacturer of medical devices*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 and the following apply.

3.1 biocompatibility

- a) capability of a material to fulfil its function with an appropriate response for a specific application from the receiving host;
- b) quality of being accepted in a specific living environment without adverse or unwanted side effects

3.2 biomaterial

- a) material intended to interface with the biological system to evaluate, treat, augment or replace tissue, organ or function of the organism;
- b) material specially prepared and/or presented to exhibit bioacceptability, biocompatibility or positive biocompatibility

NOTE The implantable materials referred to in this document are all biomaterials.

3.3 filling

surgical placement of a biomaterial, resorbable or non-resorbable, into an intrabony cavity during oral and maxillofacial surgery

NOTE Intrabony cavity includes extraction socket.

3.4 augmentation

surgical placement of a biomaterial, resorbable or non-resorbable, to increase the volume of bone, usually on the sinus floor or the alveolar ridges

6) Cancels and replaces ISO 14155:1996.

7) Cancels and replaces ISO 11134:1994 and ISO 13683:1997.