

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

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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.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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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of an identical text or by endorsement, at the latest by January 2008, and conflicting national standards shall be withdrawn at the latest by January 2008.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.

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

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 11134³⁾, *Sterilization of health care products — Requirements for validation and routine control — Industrial moist heat sterilization*

ISO 11135:1994, *Medical devices — Validation and routine control of ethylene oxide sterilization*

ISO 11137:1995, *Sterilization of health care products — Requirements for validation and routine control — Radiation sterilization*

ISO 11607:2003, *Packaging for terminally sterilized medical devices*

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

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

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

3) International Standard withdrawn.

ISO 14155:1996, *Clinical investigation of medical devices*

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 15223:2000, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied*

EN 1041, *Information supplied by the manufacturer with 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

3.5 resorption

progressive elimination by cellular activity and/or dissolution of a material in a biological environment

3.6 medicinal product

substance that produces its intended effect by pharmaceutical means

4 Implantable materials

The development of implantable materials shall be considered with regard to the properties required for the intended purpose, taking into account the effects of manufacture, handling, sterilization and storage. Possible