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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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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 22794

August 2009

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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 Fasung 2009-01-15)

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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of an identical text or by endorsement, at the latest by January 2010, and conflicting national standards shall be withdrawn at the latest by January 2010.

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Endorsement notice

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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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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*

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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.

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