SLOVENSKI STANDARD
SIST EN ISO 22803:2006

01-februar-2006

Zobozdravstvo ï Membranski materiali za vodeno obnavljanje tkiva v ustni in maksilofacialni kirurgiji ï Vsebina tehniļne mape (ISO 22803:2004)

Dentistry - Membrane materials for guided tissue regeneration in oral and maxillofacial surgery - Contents of a technical file (ISO 22803:2004)

Zahnheilkunde - Membranmaterialien für die gesteuerte Geweberegeneration bei oralen und maxillofazialen Eingriffen - Inhalt der Technischen Dokumentation (ISO 22803:2004)

Art dentaire - Membranes pour régénération de tissus en chirurgie buccale et maxillo-faciale - Contenu du dossier technique (ISO 22803:2004)

Ta slovenski standard je istoveten z: **EN ISO 22803:2005**

ICS:

11.060.15	Zobni implantati	Dental implants

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EUROPEAN STANDARD

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English Version

Dentistry - Membrane materials for guided tissue regeneration in oral and maxillofacial surgery - Contents of a technical file (ISO 22803:2004)

Art dentaire - Membranes pour régénération de tissus en chirurgie buccale et maxillo-faciale - Contenu du dossier technique (ISO 22803:2004)

Zahnheilkunde - Membranmaterialien für die gesteuerte Geweberegeneration bei oralen und maxillofazialen Eingriffen - Inhalt der Technischen Dokumentation (ISO 22803:2004)

This European Standard was approved by CEN on 7 October 2005.

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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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, 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

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Foreword

The text of ISO 22803:2004 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 22803:2005 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 May 2006, and conflicting national standards shall be withdrawn at the latest by May 2006.

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

Endorsement notice

The text of ISO 22803:2004 has been approved by CEN as EN ISO 22803:2005 without any modifications.

INTERNATIONAL STANDARD

ISO 22803

First edition
2004-09-01

Dentistry — Membrane materials for guided tissue regeneration in oral and maxillofacial surgery — Contents of a technical file

Art dentaire — Membranes pour régénération de tissus en chirurgie buccale et maxillo-faciale — Contenu du dossier technique

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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
Web www.iso.org

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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 22803 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 8, *Dental implants*.

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.

Membrane materials for periodontal tissue reconstruction in oral and maxillofacial surgery are not covered by the procedures for evaluating and testing dental restorative materials and dental implants, thus it is necessary to develop a new International 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 membrane materials used in oral and maxillofacial surgery.

Dentistry — Membrane materials for guided tissue regeneration in oral and maxillofacial surgery — Contents of a technical file

1 Scope

This International Standard gives the requirements for a technical file on the evaluation of the chemical, physical, mechanical, biological and clinical aspects and behaviour of membrane materials, whether resorbable, partially resorbable or non-resorbable, which are used

— for guided tissue regeneration in oral and maxillofacial surgery to correct a morphological defect or abnormality,

— in contact with teeth and/or dental implants,

— for prevention of epithelial migration in periodontal surgery,

— for the augmentation of bone prior to the planned insertion of dental implants,

— and/or for augmentation of bone for stabilization of dental prostheses.

This International Standard is not applicable to materials whose primary intended use is to deliver a medicinal product, autografts and allografts, or materials intended to act through pharmacological, immunological or metabolic means.

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, *Dentistry — Vocabulary*[1)]

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing*

ISO 10993-7, *Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals*

ISO 11134, *Sterilization of health care products — Requirements for validation and routine control — Industrial moist heat sterilization*

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

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

ISO 11607, *Packaging for terminally sterilized medical devices*

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

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*

1) Revision of ISO 1942-1:1989, ISO 1942-2:1989, ISO 1942-3:1989, ISO 1942-4:1989 and ISO 1942-5:1989.