Nederlandse

2e Ontwerp

norm

NEN-EN-ISO 22442-2

Medical devices utilizing animal tissues and their derivatives - Part 2: Controls on sourcing, collection and handling (ISO/DIS 22442-2:2006,IDT)

Publicatie uitsluitend voor commentaar

juni 2006
ICS 11.100.20

Vervangt NEN-EN-ISO 22442-2:2005 Ontw. Zal vervangen NEN-EN 12442-2:2000

Als Europees normontwerp is gepubliceerd: prEN ISO 22442-2:2006,IDT

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Normcommissie 301 082 "Biocompatibiliteit en biologisch onderzoek"

NEN

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

DRAFT
prEN ISO 22442-2

May 2006

ICS

Will supersede EN 12442-2:2000

English Version

Medical devices utilizing animal tissues and their derivatives - Part 2: Controls on sourcing, collection and handling (ISO/DIS 22442-2:2006)

Tissus animaux et leurs dérivés utilisés dans la fabrication des dispositifs médicaux - Partie 2: Contrôles de l'origine, de la collecte et du traitement (ISO/DIS 22442-2:2006)

Tierische Gewebe und deren Derivate nutzende Medizinprodukte - Teil 2: Kontrollen der Gewinnung, Sammlung und Handhabung (ISO/DIS 22442-2:2006)

This draft European Standard is submitted to CEN members for second parallel enquiry. It has been drawn up by the Technical Committee CEN/TC 316.

If this draft becomes a European Standard, 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.

This draft European Standard was established by CEN 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 Management Centre has the same status as the official versions.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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

Ref. No. prEN ISO 22442-2:2006: E

Foreword

This document (prEN ISO 22442-2:2006) has been prepared by Technical Committee ISO/TC 194 "Biological evaluation of medical devices" in collaboration with Technical Committee CEN/TC 316 "Medical devices utilizing tissues", the secretariat of which is held by IBN.

This document is currently submitted to the second parallel Enquiry.

This document will supersede EN 12442-2:2000.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

Endorsement notice

The text of ISO 22442-2:2006 has been approved by CEN as prEN ISO 22442-2:2006 without any modifications.

DRAFT INTERNATIONAL STANDARD ISO/DIS 22442-2.2

ISO/TC **194**/SC **1** Secretariat: **DIN**

Voting begins on: **2006-05-25**

Voting terminates on: **2006-07-25**

Medical devices utilizing animal tissues and their derivatives —

Part 2:

Controls on sourcing, collection and handling

Tissus animaux et leurs dérivés utilisés dans la fabrication des dispositifs médicaux —

Partie 2: Contrôles de l'origine, de la collecte et du traitement

ICS 11.100.20

ISO/CEN PARALLEL ENQUIRY

The CEN Secretary-General has advised the ISO Secretary-General that this ISO/DIS covers a subject of interest to European standardization. **In accordance with the ISO-lead mode of collaboration as defined in the Vienna Agreement, consultation on this ISO/DIS has the same effect for CEN members as would a CEN enquiry on a draft European Standard.** Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month FDIS vote in ISO and formal vote in CEN.

In accordance with the provisions of Council Resolution 15/1993 this document is circulated in the English language only.

Conformément aux dispositions de la Résolution du Conseil 15/1993, ce document est distribué en version anglaise seulement.

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Contents

Page

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 22442-2 was prepared by Technical Committee ISO/TC 194, *Biological evaluation of medical devices*, Subcommittee SC 1, and by Technical Committee CEN/TC 316, *Medical devices utilizing tissues* in collaboration.

ISO 22442 consists of the following parts, under the general title *Medical devices utilizing animal tissues and their derivatives*:

— *Part 1: Application of risk management*

— *Part 2: Controls on sourcing, collection and handling*

— *Part 3: Validation of the elimination and/or inactivation of viruses and Transmissible Spongiform Encephalopathy (TSE) agents*

Introduction

Certain medical devices may utilize materials of animal origin.

Animal tissues and their derivatives are used in the design and manufacture of medical devices to provide performance characteristics that were chosen for advantages over non-animal based materials. The range and quantities of materials of animal origin in medical devices vary. These materials may comprise a major part of the device (e.g. bovine/porcine heart valves, bone substitutes for use in dental or orthopaedic applications, haemostatic devices), a product coating or impregnation (e.g. collagen, gelatine, heparin), or an aid to the device manufacturing process (e.g. tallow derivatives such as oleates and stearates, fetal calf serum, enzymes, culture media).

Tissues and derivatives for use in medical devices are typically obtained by the manufacturer from a range of sources such as animal herds or flocks and commercial harvesting (including fishing). Some specialized industries also process materials of animal origin to manufacture a finished product (e.g. gelatine) which is incorporated as a raw material into the finished medical device by the manufacturer.

NOTE To show compliance with this International Standard, its specified requirements should be fulfilled. The guidance given in the NOTES and in Informative Annexes is not normative and is not provided as a checklist for auditors.

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