National Standards Authority of Ireland

IRISH STANDARD

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ICS 11.120.01

ANIMAL TISSUES AND THEIR DERIVATIVES UTILISED IN THE MANUFACTURE OF MEDICAL DEVICES - PART 2: CONTROLS ON SOURCING, COLLECTION AND HANDLING

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English version

Animal tissues and their derivatives utilized in the manufacture of medical devices - 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

Tierische Gewebe und deren Derivate, die zur Herstellung von Medizinprodukten eingesetzt werden - Teil 2: Kontrollen der Gewinnung, Sammlung und Handhabung

This European Standard was approved by CEN on 20 April 2000.

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 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 Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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Foreword

This European Standard has been prepared by Technical Committee CEN/TC 316 "Medical devices utilizing tissues", the secretariat of which is held by IBN.

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of an identical text or by endorsement, at the latest by March 2000, and conflicting national standards shall be withdrawn at the latest by March 2000.

This European Standard 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).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this standard.

This Part of EN 12442 has been considered by CEN/TC 316 as one of a series of European Standards concerned with the development of European Standards for medical devices manufactured utilizing tissues or derivatives of animal origin, non-viable or rendered non-viable. These standards are:

EN 12442-1 Animal tissues and their derivatives utilized in the manufacture of medical devices - Part 1: Analysis and management of risk.

EN 12442-3 Animal tissues and their derivatives utilized in the manufacture of medical devices - Part 3: Validation of the elimination and/or inactivation of viruses and transmissible agents.

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

Introduction

Medical devices may contain materials of animal origin.

The use of animal tissues and derivatives will give performance characteristics expected to be superior to non-animal based materials such as metal, plastics or textiles. 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, catgut sutures, haemostatic devices), a product coating or impregnation (e.g. heparin, gelatin, collagen), or aid the manufacturing stages of production (e.g. tallow).

Tissues 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. gelatin) which is incorporated as a raw material into the finished medical device by the manufacturer.

NOTE: To show compliance with this standard, its specified requirements should be fulfilled. The guidance given in the Notes and in informative Annexes is not obligatory and is not provided as a checklist for auditors.

1 Scope

1.1 This Part of EN 12442 specifies requirements for controls on the sourcing, collection and handling (which includes storage and transport) of animals and tissues for the manufacture of medical devices utilizing materials of animal origin other than in vitro diagnostic medical devices.

NOTE 1: Requirements for the risk analysis of the use of materials of animal origin in medical devices are described in EN 12442-1.

NOTE 2: Conventional processes used for sterilization, when used for the treatment of animal tissues for medical devices, have not been shown to be completely effective in inactivating the causative agents of spongiform encephalopathies. Selective sourcing is thus extremely important. Manufacturers should refer to EN 12442-3 for information on the validation of the elimination and/or inactivation of viruses and transmissible agents.

1.2 This Part of EN 12442 does not cover the utilization of human tissues in medical devices.

1.3 This Part of EN 12442 does not describe a quality assurance system for the control of all stages of manufacture.

NOTE: Attention is drawn to the standards for quality systems (see EN ISO 9001 and EN 46001 or EN ISO 9002 and EN 46002) which relate to all stages of manufacture. It is not a requirement of this standard to have a complete quality system during manufacture but certain elements of such a system are required.

1.4 This Part of EN 12442 does not consider the effect of any method of elimination and/or inactivation on the suitability of the medical device for its intended use.

2 Normative References

This European standard incorporates, by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references, the latest edition of the publication referred to applies (including amendments).

EN 12442-1:2000 Animal tissues and their derivatives utilized in the manufacture of medical devices – Part 1: Analysis and management of risk.

EN 12442-3:2000 Animal tissues and their derivatives utilized in the manufacture of medical devices – Part 3: Validation of the elimination and/or inactivation of viruses and transmissible agents.

3 Terms and definitions

For the purposes of this Part of EN 12442 the following terms and definitions apply: