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ICS 11.120.01

ANIMAL TISSUES AND THEIR DERIVATIVES UTILIZED IN THE MANUFACTURE OF MEDICAL DEVICES - PART 1: ANALYSIS AND MANAGEMENT OF RISK

National Standards
Authority of Ireland
Dublin 9
Ireland

Tel: (01) 807 3800
Tel: (01) 807 3838

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English version

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

Tissus animaux et leurs dérivés utilisés dans la fabrication des dispositifs médicaux - Partie 1: Analyse et gestion des risques

Tierische Gewebe und deren Derivate, die zur Herstellung von Medizinprodukten eingesetzt werden - Teil 1: Analyse und Handhabung von Risiken

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

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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of an identical text or by endorsement, at the latest by March 2000, and conflicting national standards shall be withdrawn at the latest by March 2000.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 12442-2	Animal tissues and their derivatives utilized in the manufacture of medical devices - Part 2: Controls on sourcing, collection and handling
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

Certain 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 an aid to the manufacturing stages of production (e.g. tallow).

EN 1441 is a general standard which specifies a procedure for the manufacturer to investigate, using available information, the safety of a medical device, including in vitro diagnostic devices or accessories, by identifying hazards and estimating the risk associated with the device. EN 12442-1 provides additional requirements and guidance for the evaluation of medical devices manufactured utilizing animal tissues or derivatives which are non-viable or rendered non-viable.

This Part of EN 12442 can only be used in combination with EN 1441 and is not a “stand-alone” standard.

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

1 Scope

1.1 This Part of EN 12442 applies to medical devices (excluding in-vitro diagnostic medical devices) manufactured utilizing animal tissue or products derived from animal tissue, which are non-viable or have been rendered non-viable. It specifies, in conjunction with EN 1441, a procedure to investigate, using available information, the safety of such devices by identifying hazards and estimating the risks associated with the device (risk analysis).

1.2 This Part of EN 12442 is intended to provide requirements and guidance on risk analysis related to the typical hazards of medical devices manufactured utilizing animal tissues or derivatives such as

a) contamination by bacteria, moulds or yeasts;
b) contamination by viruses or transmissible agents such as pathogenic entities, or agents causing spongiform encephalopathies, prions and similar entities (e.g. BSE, scrapie);
c) undesired pyrogenic, immunological or toxicological reactions.

1.3 This Part of EN 12442 does not stipulate levels of acceptability which, because they are determined by a multiplicity of factors, cannot be set down in such a standard.

1.4 In addition, this Part of EN 12442 is intended to provide requirements and guidance on risk management.

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

NOTE: There are materials which do not fall under the scope of this standard because these are not derived from animals. In this standard a specific definition of animal has been given.

1.6 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.

1.7 The principles of this Part of EN 12442 may also be applied by analogy to medical devices manufactured utilizing material derived from a non-vertebrate organism, in cases where the risks addressed in this standard are relevant.