National Standards Authority of Ireland

IRISH STANDARD

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# 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

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EUROPEAN STANDARD

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**EN 12442-3**

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English version

# 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

Tissus animaux et leurs dérivés utilisés dans la fabrication des dispositifs médicaux - Partie 3: Validation de l'élimination et/ou de l'inactivation des virus et autres agents transmissibles

Tierische Gewebe und deren Derivate, die zur Herstellung von Medizinprodukten eingesetzt werden - Teil 3: Validierung der Abreicherung und/oder Inaktivierung von Viren und übertragbaren Krankheitserregern

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 12442-2 | Animal tissues and their derivatives utilized in the manufacture of medical devices - Part 2: Controls on sourcing, collection and handling. |

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

It is important to be aware that the exposure to a properly validated and accurately controlled method of inactivation is not the only factor associated with demonstrating product safety. Attention has also to be given to a number of factors including sourcing, collecting, handling, storage, processing, testing of tissues and/or cells of animal origin, and to the control of the environment in which the product is manufactured, assembled and packaged. The manufacturer should consider the fact that each manufacturing phase can contribute to

contamination as well as elimination and/or inactivation of viruses and transmissible agents.

For the safety of medical devices there are two complementary approaches (see EN 12442-1) that can be adopted to control the potential contamination of tissues. These typically are:

a) selecting source material for minimal contamination with agents (see EN 12442-1 and EN12442-2);

b) testing the ability of the production processes to remove or inactivate agents (this standard, EN 12442-3).

Requirements for the quality system for the design, production, installation and servicing are given in the EN ISO 9000 and EN 46000 series of standards. These standards refer to certain manufacturing processes as 'special' if the results cannot be fully verified by subsequent inspection and testing of the product. The elimination and/or inactivation of viruses and transmissible agents is an example of a special process because process efficacy cannot be verified by inspection and testing of the product. For this reason, the following need to be considered in particular:

- definition of the process(es) and materials to be used;

- adequate inactivation validation before routine use;

- performance monitoring of the process during manufacture;

- appropriate equipment maintenance;

- staff training, etc.

Since many instances of contamination in the past have occurred with viruses, whose presence was not known or even suspected at the time of manufacture, an evaluation of the process can provide a measure of confidence that a wide range of viruses including unknown, harmful viruses, may be eliminated. Similar principles may apply to transmissible agents.

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 specifies requirements for the validation of elimination and/or inactivation of viruses and/or transmissible agents during the manufacture of medical devices (excluding in-vitro diagnostic medical devices) utilizing materials of animal origin. It is not applicable to bacteria, moulds and yeasts.

NOTE 1: Analysis and management of risk and 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 extremely important (see EN 12442-1 and EN 12442-2).