AS EN 12442.2—2003
EN 12442-2:2000

Australian Standard™

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

Part 2: Controls on sourcing, collection and handling

Standards Australia

This Australian Standard was prepared by Committee HE-012, Surgical Implants. It was approved on behalf of the Council of Standards Australia on 28 May 2003 and published on 30 June 2003.

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Australian Dental Association

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Australian Orthopaedic Association

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PREFACE

This Standard was prepared by the Australian members of the Joint Standards Australia/ Standards New Zealand Committee HE-012, Surgical Implants. After consultation with stakeholders in both countries, Standards Australia and Standards New Zealand decided to develop this Standard as an Australian, rather than an Australian/New Zealand Standard.

This Standard is identical with and has been reproduced from EN 12442-2:2000, *Animal tissues and their derivatives utilized in the manufacture of medical devices—Part 2: Controls on sourcing, collection and handling.*

The objective of this Standard is to specify 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.

The terms 'normative' and 'informative' are used to define the application of the annex to which they apply. A normative annex is an integral part of a standard, whereas an informative annex is only for information and guidance.

As this Standard is reproduced from a European Standard, the following applies:

(a) Its number does not appear on each page of text and its identity is shown only on the cover and title page.

(b) In the source text 'this European Standard' should read 'this Australian Standard'.

(c) A full point substitutes for a comma when referring to a decimal marker.

References to European Standards should be replaced by references to Australian or Australian/New Zealand Standards as follows:

Reference to European Standard		*Australian Standard*	
EN		AS EN	
12442	Animal tissues and their derivatives utilized in the manufacture of medical devices	12442	Animal tissues and their derivatives utilized in the manufacture of medical devices
12442-1	Part 1: Analysis and management of risk	12442.1	Part 1: Analysis and management of risk
12442-3	Part 3: Validation of the elimination and/or inactivation of viruses and transmissible agents	12442.3	Part 3: Validation of the elimination and/or inactivation of viruses and transmissible agents

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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.

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

Part 2: Controls on sourcing, collection and handling

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: