AS EN 12442.1—2003
EN 12442-1:2000

Australian Standard™

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

Part 1: Analysis and management of risk

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

The objective of this Standard is to specify a procedure to investigate, using available information, the safety of medical devices by identifying hazards and estimating the risks associated with the device (risk analysis). This Standard 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.

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
12442-2	Part 2: Controls on sourcing, collection and handling	12442.2	Part 2: Controls on sourcing, collection and handling
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

This Part of AS EN 12442 references EN 1441:1997 *Medical Devices—Risk Analysis*, which can be obtained from Standards Australia.

CONTENTS

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.

AUSTRALIAN STANDARD

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

Part 1: Analysis and management of risk

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.