AS EN 12442.3—2003
EN 12442-3:2000

Australian Standard™

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

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 12442-3:2000, *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.*

The objective of this Standard is to specify 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.

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

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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 AS 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 AS EN 12442.1 and AS EN 12442.2);

b) testing the ability of the production processes to remove or inactivate agents (this Standard, AS 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.

AUSTRALIAN STANDARD

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

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).

NOTE 2: EN 550, EN 552, EN 554, ISO 14160 and EN 1174 may be relevant for bacteria, moulds and yeast (see Bibliography).

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 (e.g. EN ISO 9001 and EN 46001 or EN ISO 9002 and EN 46002, see Bibliography) which may be used to control all stages of manufacture. It is not a requirement of this standard to apply a complete quality system during manufacture but certain elements of such a system are required and these are addressed at appropriate places in the text.

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.