

# **Australia New Zealand Therapeutic Products Authority Conformity Assessment Standards Order No 2 2007**

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## **Conformity Assessment Standards for Quality Assurance Techniques for Animal Tissues and their Derivatives utilised in the Manufacture of Medical Devices**

The Australia New Zealand Therapeutic Products Authority for the purposes of section 3.10 of the Australia New Zealand Therapeutic Products Regulatory Scheme (Medical Devices) Rule 2007, DETERMINE:

- (a) that the matters specified in the relevant parts of the international standards published by the European Committee for Standardization, or those relevant parts as amended, in column 2 of an item in Schedule 1, constitute a conformity assessment standard for quality assurance techniques for controls applicable to non-viable animal tissues and their derivatives utilised in the manufacture of medical devices, subject to the conditions (if any) set out in column 3 of that item in Schedule 1; and
- (b) that quality assurance techniques of those kinds that comply with the conformity assessment standard specified in column 2 of an item in Schedule 1 are to be treated as complying with those parts of the conformity assessment procedures specified in column 4 of the relevant item of Schedule 1.

This Order commences on the day it is published in the Australia New Zealand Therapeutic Products Authority Internet site.

Dated 2007

Managing Director of the Australia New Zealand Therapeutic Products  
Authority

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### Schedule 1

1 Item No.	2 Conformity Assessment Standard	3 Conditions	4 Conformity Assessment Procedure (as set out in Schedule 3 of the Australia New Zealand Therapeutic Products Regulatory Scheme (Medical Devices) Rule 2007)
1	<p>EN 12442-1: 2000 <i>Animal tissues and their derivatives utilized in the manufacture of medical devices – Part 1: Analysis and management of risk</i></p> <p>Part 1 of this standard is amended as follows:</p> <p>Delete clause 1.1 and replace with:</p> <p>"1.1 This Part of EN 12442 applies to animal tissues and their derivatives, which are non viable or rendered non-viable, utilised in the manufacture of medical devices (excluding in vitro diagnostic medical devices). 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)."</p> <p>Delete clause 4.2.2 and replace with :</p> <p>"4.2.2 Is the animal tissue or its derivative intended to contact the patient or other persons?"</p> <p><b>AND</b></p>	<p>Full documented compliance with each standard, as amended, is required, except for:</p> <p>Clauses 4.2.4 to 4.2.21 inclusive of EN 12442-1: 2000.</p>	<p>Part 2 Clause 2.04 Sub clauses (4), (9)(c) and (7). With the sub clause (7) limited to the validation of the elimination and/or inactivation of viruses and transmissible agents.</p> <p>Part 5 Clause 5.04 Sub clauses (4) and (8)(a).</p>

1 Item No.	2 Conformity Assessment Standard	3 Conditions	4 Conformity Assessment Procedure
	<p>EN 12442-2: 2000 <i>Animal tissues and their derivatives utilized in the manufacture of medical devices – Part 2: Controls on sourcing, collection and handling</i></p> <p>Part 2 of this standard is amended as follows:</p> <p>Delete the NOTE under Clause 5 and replace with the normative statement:</p> <p>"Clauses 5, 6, 7, 8 and 9 shall be applied and documented by suppliers of animal materials, intermediaries and medical device manufacturers as relevant."</p> <p>Delete the NOTE under Clause 6.2 and replace with the normative statement:</p> <p>"For relevant species, animals shall be subject to ante-mortem veterinary inspection. Prior to certification, a post-mortem inspection shall be performed immediately after slaughter and should include:</p> <ul style="list-style-type: none"> <li>a) visual inspection;</li> <li>b) palpation of specified organs;</li> <li>c) incision of organs and lymph nodes;</li> <li>d) investigation of anomalies, for example inconsistency, colour and smell;</li> <li>e) laboratory tests, if inspections carried out in (a) to (d) are inconclusive." <p><b>AND</b></p> </li></ul>		

1 Item No.	2 Conformity Assessment Standard	3 Conditions	4 Conformity Assessment Procedure
	<p>EN 12442-3: 2000 <i>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.</i></p> <p>Part 3 of this standard is amended as follows:</p> <p>Under Annex C Delete (informative) Replace with (normative)</p> <p>In EN 12442-3: 2000, all references to Annex C are taken as being normative.</p>		

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