

Australia New Zealand Therapeutic Products Authority (Conformity Assessment Standards) Order No 1 2007

Conformity Assessment Standard for Quality Management Systems and Quality Assurance Techniques for 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 a standard published by a standards organisation in column 2 of an item in Schedule 1, constitute a conformity assessment standard for quality management systems for the manufacture of all kinds of medical devices that require conformity assessment, subject to the conditions (if any) set out in column 3 of that item in Schedule 1; and
- (b) that the matters specified in the relevant parts of a standard published by a standards organisation in column 2 of an item in Schedule 2 constitute a conformity assessment standard for quality assurance techniques for the manufacture of kinds of medical devices that are intended by the manufacturer to be supplied in a sterile state, subject to the conditions (if any) set out in column 3 of that item of Schedule 2; and
- (c) that quality management systems and quality assurance techniques of those kinds that comply with the conformity assessment standard specified in column 2 of an item in Schedule 1 or 2 are to be treated as complying with those parts of the conformity assessment procedures specified in column 4 of the relevant item of the respective Schedule.

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

Dated 2007

Managing Director of the Australia New Zealand Therapeutic Products
Authority

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>AS ISO 13485-2003 identical to: ISO 13485:2003 <i>Medical devices – Quality management systems – Requirements for regulatory purposes</i></p> <p>Any reference to regulatory requirements is a reference to the Australia New Zealand Therapeutic Products Regulatory Scheme (Medical Devices) Rule 2007</p>		Part 2, clause 2.04
2	<p>AS ISO 13485-2003 Identical to: ISO 13485:2003 <i>Medical devices – Quality management systems – Requirements for regulatory purposes</i></p> <p>But excluding clause 7.3 - Design and Development</p> <p>Any reference to regulatory requirements is a reference to the Australia New Zealand Therapeutic Products Regulatory Scheme (Medical Devices) Rule 2007</p>		Part 5, clause 5.04

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)
3	<p>AS ISO 13485-2003 identical to: ISO 13485:2003 <i>Medical devices – Quality management systems – Requirements for regulatory purposes</i></p> <p>But excluding clause 7.3 - Design and Development and clause 7.5.2 - Validation of processes for production and service provision</p> <p>Any reference to regulatory requirements is a reference to the Australia New Zealand Therapeutic Products Regulatory Scheme (Medical Devices) Rule 2007</p>		Part 6, clause 6.04

Schedule 2

1	2	3	4
Item No.	Conformity Assessment Standard	Conditions	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 ISO 11135: 2007 <i>Sterilization of health care products – Ethylene Oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.</i></p>	For use in the validation and routine control of ethylene oxide sterilization processes for medical devices.	<p>Part 2, clause 2.04(2) Part 5, clause 5.04(2)</p>
2	<p>AS ISO/NZS 11137-2006 identical to: ISO 11137: 2006 <i>Sterilization of health care products – Radiation - Part 1: Requirements for validation and routine control – Radiation sterilization.</i></p> <p>AND</p> <p>AS ISO/NZS 11137 – 2:2006 <i>Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose.</i></p> <p>AND</p> <p>AS ISO/NZS 11137 – 3:2006 <i>Sterilization of health care products – Radiation – Part 3: Guidance on dosimetric aspects.</i></p>	For use in the validation and routine control of radiation sterilization processes for medical devices.	<p>Part 2, clause 2.04(2) Part 5, clause 5.04(2)</p>
3	<p>EN ISO 17665-1: 2006 <i>Sterilization of health care products-Moist heat-Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices</i></p>	For use in the validation and routine control of steam sterilization processes for medical devices.	<p>Part 2, clause 2.04(2) Part 5, clause 5.04(2)</p>

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4	<p>ISO 13408 -1:1998: <i>Aseptic processing of health care products – Part 1: General requirements.</i></p> <p>OR</p> <p>EN 13824: 2004: <i>Sterilization of medical devices: Aseptic processing of liquid medical devices – Requirements.</i></p> <p>AND</p> <p>ISO 13408-2:2003: <i>Aseptic processing of health care products – Part 2: Filtration.</i></p> <p>AND</p> <p>ISO 13408-3:2006: <i>Aseptic processing of health care products – Part 3: Lyophilization.</i></p> <p>AND</p> <p>ISO 13408-4:2003: <i>Aseptic processing of health care products – Part 4: Clean-in-place technologies.</i></p> <p>AND</p> <p>ISO 13408-5:2006: <i>Aseptic processing of health care products – Part 5: Sterilization in place.</i></p> <p>AND</p> <p>ISO 13408-6:2005: <i>Aseptic</i></p>	<p>For use in the validation and routine control of aseptic processes for medical devices, together with applicable part(s) 2, 3 4, 5 and 6 of ISO 13408</p>	<p>Part 2, clause 2.04(2)</p> <p>Part 5, clause 5.04(2)</p>

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	<i>processing of health care products – Part 6: Isolator systems.</i>		
5	ISO 14937:2000 <i>Sterilization of health care products – General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices</i>	For use in the validation of sterilization by a method not specified in another standard.	Part 2, clause 2.04(2) Part 5, clause 5.04(2)
6	AS ISO 14160-2002 identical to: ISO 14160: 1998 identical to: EN ISO 14160: 1998 <i>Sterilization of single-use medical devices incorporating materials of animal origin – Validation and routine control of sterilization by liquid chemical sterilants</i>	For use in the validation of sterilization processes for medical devices using liquid chemical sterilants.	Part 2, clause 2.04(2) Part 5, clause 5.04(2)