

COMMONWEALTH OF AUSTRALIA

Therapeutic Goods Act 1989

CONFORMITY ASSESSMENT STANDARDS ORDER (STANDARD FOR QUALITY MANAGEMENT SYSTEMS AND QUALITY ASSURANCE TECHNIQUES) 2007

I, RITA MACLACHLAN, delegate of the Minister for Health and Ageing for the purposes of section 41DC of the *Therapeutic Goods Act 1989* and acting under that section, HEREBY:

(1) REVOKE “Conformity Assessment Standards Order No. 1 - *Conformity Assessment Standard for Quality Management Systems and Quality Assurance Techniques*” made on 21 September 2005; AND

(2) 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 of 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 standard are to be treated as complying with those parts of the conformity assessment procedures set out in the Therapeutic Goods (Medical Devices) Regulations 2002 that are specified in column 4 of the relevant item of the respective Schedules.

This Order commences on the day after it is registered in the Federal Register of Legislative Instruments.

Dated this _____ day of _____ 2007

Rita MacLachlan
Delegate of the Minister for Health and Ageing

SCHEDULE 1

1 Item No.	2 Conformity Assessment Standard	3 Conditions	4 Conformity Assessment Procedure
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 Therapeutic Goods Act 1989 and the Therapeutic Goods (Medical Devices) Regulations 2002.</p>		<p>Schedule 3 Part 1, clause 1.4</p>
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 <i>Therapeutic Goods Act 1989</i> and Therapeutic Goods (Medical Devices) Regulations 2002.</p>		<p>Schedule 3 Part 4, clause 4.4</p>

Schedule 1

1 Item No.	2 Conformity Assessment Standard	3 Conditions	4 Conformity Assessment Procedure
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 <i>Therapeutic Goods Act 1989</i> and the Therapeutic Goods (Medical Devices) Regulations 2002.</p>		<p>Schedule 3 Part 5, clause 5.4</p>

SCHEDULE 2

1 Item No.	2 Conformity Assessment Standard	3 Conditions	4 Conformity Assessment Procedure
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>	<p>For use in the validation and routine control of ethylene oxide sterilization processes for medical devices.</p>	<p>Schedule 3 Part 1, subparagraph 1.4(5)(d)(i)</p> <p>AND</p> <p>Schedule 3 Part 4, subparagraph 4.4(5)(c)(i)</p>
2	<p>AS ISO/NZS 11137: 2006 identical to: ISO 11137-1: 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>	<p>For use in the validation and routine control of radiation sterilization processes for medical devices.</p>	<p>Schedule 3 Part 1, subparagraph 1.4(5)(d)(i)</p> <p>AND</p> <p>Schedule 3 Part 4, subparagraph 4.4(5)(c)(i)</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>	<p>For use in the validation and routine control of steam sterilization processes for medical devices.</p>	<p>Schedule 3 Part 1, subparagraph 1.4(5)(d)(i)</p> <p>AND</p> <p>Schedule 3 Part 4, subparagraph 4.4(5)(c)(i)</p>

1 Item No.	2 Conformity Assessment Standard	3 Conditions	4 Conformity Assessment Procedure
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 processing of health care products – Part 6: Isolator systems.</i></p>	<p>For use in the validation and routine control of aseptic processing, together with applicable part(s) 2, 3 4, 5 and 6 of ISO 13408.</p>	<p>Schedule 3 Part 1, subparagraph 1.4(5)(d)(i)</p> <p>AND</p> <p>Schedule 3 Part 4, subparagraph 4.4(5)(c)(i)</p>

1 Item No.	2 Conformity Assessment Standard	3 Conditions	4 Conformity Assessment Procedure
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.	Schedule 3 Part 1, subparagraph 1.4(5)(d)(i) AND Schedule 3 Part 4, subparagraph 4.4(5)(c)(i)
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.	Schedule 3 Part 1, subparagraph 1.4(5)(d)(i) AND Schedule 3 Part 4, subparagraph 4.4(5)(c)(i)