**COMMONWEALTH OF AUSTRALIA**

## *Therapeutic Goods Act 1989*

## CONFORMITY ASSESSMENT STANDARDS ORDER (STANDARD FOR QUALITY MANAGEMENT SYSTEMS AND QUALITY ASSURANCE TECHNIQUES) 2008

I, LARRY KELLY, 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 standards or 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 standards or 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 14th day of November 2008

Signed
Larry Kelly
Delegate of the Minister for Health and Ageing

## SCHEDULE 1

| 1<br>Item No. | 2<br>Conformity Assessment Standard | 3<br>Conditions | 4<br>Conformity Assessment Procedure |
|---|---|---|---|
| 1 | AS ISO 13485: 2003<br><br>OR<br><br>ISO 13485: 2003 *Medical devices – Quality management systems – Requirements for regulatory purposes.*<br><br>Any reference to regulatory requirements is a reference to the Therapeutic Goods Act 1989 and the Therapeutic Goods (Medical Devices) Regulations 2002.<br><br>(Note: AS ISO 13485: 2003 is identical to ISO 13485: 2003) | | Schedule 3 Part 1, clause 1.4 |
| 2 | AS ISO 13485: 2003<br><br>OR<br><br>ISO 13485: 2003 *Medical devices – Quality management systems – Requirements for regulatory purposes.*<br><br>But excluding clause 7.3 - Design and Development.<br><br>Any reference to regulatory requirements is a reference to the *Therapeutic Goods Act 1989* and Therapeutic Goods (Medical Devices) Regulations 2002.<br><br>(Note: AS ISO 13485: 2003 is identical to ISO 13485: 2003) | | Schedule 3 Part 4, clause 4.4 |

**Schedule 1**

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| 3 | AS ISO 13485: 2003<br><br>OR<br><br>ISO 13485: 2003 *Medical devices – Quality management systems – Requirements for regulatory purposes.*<br><br>But excluding clause 7.3 - Design and Development and clause 7.5.2 - Validation of processes for production and service provision.<br><br>Any reference to regulatory requirements is a reference to the *Therapeutic Goods Act 1989* and the Therapeutic Goods (Medical Devices) Regulations 2002.<br><br>(Note: AS ISO 13485: 2003 is identical to ISO 13485: 2003) | | Schedule 3 Part 5, clause 5.4 |

## SCHEDULE 2

| 1<br>Item No. | 2<br>Conformity Assessment Standard | 3<br>Conditions | 4<br>Conformity Assessment Procedure |
|---|---|---|---|
| 1 | EN ISO 11135-1: 2007 *Sterilization of health care products – Ethylene Oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.* | For use in the validation and routine control of ethylene oxide sterilization processes for medical devices. | Schedule 3 Part 1, subparagraph 1.4(5)(d)(i)<br><br>AND<br><br>Schedule 3 Part 4, subparagraph 4.4(5)(c)(i) |
| 2 | AS/NZS ISO 11137-1: 2006<br><br>OR<br><br>ISO 11137-1: 2006 *Sterilization of health care products – Radiation - Part 1: Requirements for validation and routine control – Radiation sterilization.*<br><br>AND<br><br>AS/NZS ISO 11137-2: 2006<br><br>OR<br><br>ISO 11137-2: 2006 *Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose.*<br><br>AND<br><br>AS/NZS ISO 11137-3: 2006<br><br>OR<br><br>ISO 11137-3: 2006 *Sterilization of health care products – Radiation – Part 3: Guidance on dosimetric aspects.* | For use in the validation and routine control of radiation sterilization processes for medical devices. | Schedule 3 Part 1, subparagraph 1.4(5)(d)(i)<br><br>AND<br><br>Schedule 3 Part 4, subparagraph 4.4(5)(c)(i) |

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|---|---|---|---|
| | (Note: AS/NZS ISO 11137: 2006 series is identical to ISO 11137: 2006 series.) | | |
| 3 | EN ISO 17665-1: 2006 *Sterilization of health care products-Moist heat-Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices* | For use in the validation and routine control of steam sterilization processes | Schedule 3 Part 1, subparagraph 1.4(5)(d)(i) AND Schedule 3 Part 4, subparagraph 4.4(5)(c)(i) |
| 4 | AS ISO 14160: 2002<br><br>OR<br><br>ISO 14160: 1998 *Sterilization of single-use medical devices incorporating materials of animal origin – Validation and routine control of sterilization by liquid chemical sterilants*<br><br>(Note: AS ISO 14160: 2002 and ISO 14160: 1998 are identical) | For use in the validation and routine control of sterilization processes for medical devices using liquid chemical sterilants. | Schedule 3 Part 1, subparagraph 1.4(5)(d)(i)<br><br>AND<br><br>Schedule 3 Part 4, subparagraph 4.4(5)(c)(i) |
| 5 | ISO 13408-1: 2008 *Aseptic processing of health care products – Part 1: General requirements.*<br><br>OR<br><br>ISO 13408-1: 1998 *Aseptic processing of health care products – Part 1: General requirements.*<br><br>OR<br><br>EN 13824: 2004 *Sterilization of medical devices: Aseptic processing of liquid medical devices – Requirements.* | For use in the validation and routine control of aseptic manufacturing processes for medical devices that are not terminally sterilized, together with the applicable Part(s) 2, 3, 4, 5, 6 of ISO 13408 as set out in column 2.<br><br>ISO 13408-1: 1998 and EN 13824: 2004 will not constitute a conformity assessment standard for the aseptic manufacturing processes of all kinds of medical devices after 30 September 2009. | Schedule 3 Part 1, subparagraph 1.4(5)(d)(i)<br><br>AND<br><br>Schedule 3 Part 4, subparagraph 4.4(5)(c)(i) |

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| | AND<br><br>ISO 13408-2: 2003 *Aseptic processing of health care products – Part 2: Filtration.*<br><br>AND<br><br>ISO 13408-3: 2006 *Aseptic processing of health care products – Part 3: Lyophilization.*<br><br>AND<br><br>ISO 13408-4: 2005 *Aseptic processing of health care products – Part 4: Clean-in-place technologies.*<br><br>AND<br><br>ISO 13408-5: 2006 *Aseptic processing of health care products – Part 5: Sterilization in place.*<br><br>AND<br><br>ISO 13408-6: 2005 *Aseptic processing of health care products – Part 6: Isolator systems.* | | |
| 6 | ISO 14937: 2000 *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* including *Technical Corrigendum 1: 2003* | For use in the validation and routine control of a sterilization process for medical devices that is not covered by the standards specified in Items 1, 2, 3 and 4 of this schedule. | Schedule 3 Part 1, subparagraph 1.4(5)(d)(i)<br><br>AND<br><br>Schedule 3 Part 4, subparagraph 4.4(5)(c)(i) |