**COMMONWEALTH OF AUSTRALIA**

***Therapeutic Goods Act 1989***

# MEDICAL DEVICE STANDARDS ORDER (STANDARDS FOR MEDICAL DEVICES REQUIRED TO BE STERILE) 2007

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

(1) REVOKE "Medical Device Standards Order No.3 – *Medical Device Standards for Medical Devices required to be Sterile"* made on 20 February 2003, AND

(2) DETERMINE:

(a) that the matters in the relevant standards published by the standards organisations that are specified in column 2 of an item in Schedule 1 constitute a medical device standard for 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 1; and

(b) that the matters in the relevant standards published by the standards organisations that are specified in column 2 of an item in Schedule 2 constitute a medical device standard for kinds of medical devices that are intended by the manufacturer to be sterilized before they are used, subject to the conditions (if any) set out in column 3 of that item of Schedule 2; and

(c) that medical devices of those kinds that comply with the appropriate standard specified in column 2, subject to compliance with conditions (if any) set out in column 3, of the relevant Schedule are to be treated as complying with those parts of the essential principles set out in the Therapeutic Goods (Medical Devices) Regulations 2002 that are specified in column 4 of the relevant item of the relevant Schedule.

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 – Standards for applicable medical devices intended by the manufacturer to be supplied in a sterile state.**

| 1<br>Item No. | 2<br>Medical Device Standard | 3<br>Conditions | 4<br>Essential Principle |
|---|---|---|---|
| 1 | AS EN 556-1: 2002<br>identical to:<br>EN 556-1: 2001 *Sterilization of medical devices — Requirements for medical devices to be designated "STERILE" — Part 1: Requirements for terminally sterilized medical devices*<br><br>OR<br><br>EN 556-2: 2003 *Sterilization of medical devices – Requirements for medical devices to be designated "STERILE" – Part 2: Requirements for aseptically processed medical devices*<br><br>AND<br><br>EN ISO 11607-1: 2006 *Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems.*<br><br>AND<br><br>EN ISO 11607-2: 2006 *Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes.* | For terminally sterilized medical devices AS EN 556-1: 2002 or EN 556-1: 2001 must be complied with.<br><br>For aseptically processed medical devices EN556-2: 2003 must be complied with. | Schedule 1, subclause 8.3(2) |
| 2 | EN ISO 11135-1: 2007<br>*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 1, subclause 8.3(3) |

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|---|---|---|---|
| 3 | AS ISO/NZS 11137-1: 2006<br>identical to:<br>ISO 11137: 2006<br>*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>*Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose.*<br><br>AND<br><br>AS/NZS ISO 11137-3: 2006<br>*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 1 subclause 8.3(3) |
| 4 | EN ISO 17665-1: 2006<br>*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, together with microbiological validation demonstrating compliance with AS EN 556.1: 2002. | Schedule 1 subclause 8.3(3) |
| 5 | AS ISO 14160: 2002<br>identical to:<br>EN ISO 14160: 1998<br>identical to:<br>ISO 14160: 1998<br>*Sterilization of single-use medical devices incorporating materials of animal origin – Validation and routine control of sterilization by liquid chemical sterilants* | For use in the validation of sterilization by liquid chemical sterilants for medical devices. | Schedule 1 subclause 8.3(3) |
| 6 | EN ISO 11737-1: 2006<br>*Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microrganisms on products* | For use in the bioburden determination of medical devices for all sterilization methods for medical devices. | Schedule 1 subclause 8.3(3) |

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|---|---|---|---|
| 7 | EN ISO 11737-2: 2000 *Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the validation of a sterilization process* | For use in the validation of sterilization processes for medical devices. | Schedule 1 subclause 8.3(3) |
| 8 | 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.*<br><br>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: 2003 *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.* | For use in the manufacture of medical devices that are aseptically prepared, rather than terminally sterilized, together with the applicable Part(s) 2, 3, 4, 5, 6 of ISO 13408 set out in Column 2 | Schedule 1 subclause 8.3(3) |

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|---|---|---|---|
| 9 | ISO 14937: 2000<br>*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* | 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 2, 3, 4 and 5 of this Schedule. | Schedule 1, subclause 8.3(3) |
| 10 | EN ISO 17664: 2004<br>*Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices* | For use in circumstances where the manufacturer intends that a medical device is suitable to be resterilized | Schedule 1, clause 13.4 items 12 or 13 |
| 11 | TGA Guidelines for sterility testing of Therapeutic Goods – 2006<br><br>This will need to be defined in the document as this has no legal status | To be used when an end-point sterility test is required to support product release. | Schedule 1, subclause 8.3(3) |

**Schedule 2 – Standards for medical devices intended by the manufacturer to be sterilized before they are used.**

| 1<br>Item No. | 2<br>Medical Device Standard | 3<br>Conditions | 4<br>Essential Principle |
|---|---|---|---|
| 1 | EN ISO 11607-1: 2006<br>*Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems.*<br><br>AND<br><br>EN ISO 11607-2: 2006<br>*Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes.* | | Schedule 1, subclause 8.4(2) |
| 2 | EN ISO 17664: 2004:<br>*Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices.* | Reprocessing instructions specified by the manufacturer should also demonstrate compliance with AS EN 556-1: 2002 | Schedule 1, subclause 13.4(3), item 13 |