COMMONWEALTH OF AUSTRALIA

Therapeutic Goods Act 1989

MEDICAL DEVICE STANDARDS ORDER (STANDARDS FOR MEDICAL DEVICES REQUIRED TO BE STERILE) 2008

I, LARRY KELLY, 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 or in the relevant parts of a standard published by the standards organisations or the Therapeutic Goods Administration 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 or in the relevant parts of a standard 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 2008

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

1 Item No.	2 Medical Device Standard	3 Conditions	4 Essential Principle
4	AS/NZS ISO 11137-1: 2006 OR ISO 11137-1: 2006 *Sterilization of health care products – Radiation - Part 1: Requirements for validation and routine control – Radiation sterilization.* AND AS/NZS ISO 11137-2: 2006 OR ISO 11137-2: 2006 *Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose.* AND AS/NZS ISO 11137-3: 2006 OR ISO 11137-3: 2006 *Sterilization of health care products – Radiation – Part 3: Guidance on dosimetric aspects.* (Note: AS/NZS ISO 11137: 2006 series is identical to ISO 11137: 2006 series.)	For use in the validation and routine control of radiation sterilization processes for medical devices.	Schedule 1 subclause 8.3(3)
5	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, together with microbiological validation demonstrating compliance with AS EN 556-1: 2002.	Schedule 1 subclause 8.3(3)
6	AS ISO 14160: 2002 OR	For use in the validation and routine control of sterilization by liquid chemical sterilants for medical devices.	Schedule 1 subclause 8.3(3)

1 Item No.	2 Medical Device Standard	3 Conditions	4 Essential Principle
	ISO 14160: 1998 *Sterilization of single-use medical devices incorporating materials of animal origin – Validation and routine control of sterilization by liquid chemical sterilants* (Note: AS ISO 14160: 2002 and ISO 14160: 1998 are identical)		
7	ISO 11737-1: 2006 *Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products*, including *Technical Corrigendum 1: 2007*	For use in the bioburden determination of medical devices for all sterilization processes for medical devices.	Schedule 1 subclause 8.3(3)
8	ISO 11737-2: 1998 *Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the validation of a sterilization process*	For use in the tests of sterility performed in the validation of sterilization processes for medical devices.	Schedule 1 subclause 8.3(3)
9	ISO 13408-1: 2008 *Aseptic processing of health care products – Part 1: General requirements.* OR ISO 13408-1: 1998 *Aseptic processing of health care products – Part 1: General requirements.* OR EN 13824: 2004 *Sterilization of medical devices: Aseptic processing of liquid medical devices – Requirements.* AND ISO 13408-2: 2003 *Aseptic processing of health care products – Part 2: Filtration.* AND	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. ISO 13408-1: 1998 and EN 13824: 2004 will not constitute a medical devices standard, for all kinds of medical devices that have been manufactured using an aseptic process, after 30 September 2009	Schedule 1 subclause 8.3(3)

1 Item No.	2 Medical Device Standard	3 Conditions	4 Essential Principle
	ISO 13408-3: 2006 *Aseptic processing of health care products – Part 3: Lyophilization.* AND ISO 13408-4: 2005 *Aseptic processing of health care products – Part 4: Clean-in-place technologies.* AND ISO 13408-5: 2006 *Aseptic processing of health care products – Part 5: Sterilization in place.* AND ISO 13408-6: 2005 *Aseptic processing of health care products – Part 6: Isolator systems*		
10	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 3, 4, 5 and 6 of this Schedule.	Schedule 1, subclause 8.3(3)
11	EN ISO 17664: 2004 *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
12	TGA Guidelines for sterility testing of therapeutic goods – 2006 as published on the TGA web-site at: http://www.tga.gov.au/docs/html/sterilit.htm	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 Item No.	2 Medical Device Standard	3 Conditions	4 Essential Principle
1	EN ISO 11607-1: 2006 *Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems.* AND EN ISO 11607-2: 2006 *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: *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