

COMMONWEALTH OF AUSTRALIA

Therapeutic Goods Act 1989

MEDICAL DEVICE STANDARDS ORDER NO. 3

Medical Device Standards for Medical Devices Required to be Sterile

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, DETERMINE:

- (a) that the matters 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 the Schedule 1, and
- (b) that the matters specified in column 2 of an item in the Schedule 2 constitute a medical device standard for kinds of medical devices that are intended by the manufacturer to be sterilised before they are used, subject to the conditions (if any) set out in column 3 of that item of Schedule 2, and
- (c) medical devices of those kinds that comply with the standard are to be treated as complying with those parts of the essential principles specified in column 4 of the relevant item of the relevant Schedule.

This Order commences on the day it is gazetted in the Commonwealth Gazette.

Dated this twentieth day of February 2003

Rita Maclachlan
Delegate of the Minister for Health and Ageing

Schedule 1

| 1 Item No. | 2 Medical Device Standard | 3 Conditions | 4 Essential Principle |
|------------------|--|--|-----------------------------|
| 1 | <p>AS EN 556.1-2002 identical to: EN 556-1: 2001 <i>Sterilization of medical devices — Requirements for medical devices to be designated “STERILE” — Part 1: Requirements for terminally sterilized medical devices</i></p> <p>AND EITHER</p> <p>EN 868-1: 1997 <i>Packaging materials and systems for medical devices which are to be sterilized – Part 1: general requirements and test methods</i></p> <p>OR</p> <p>ISO 11607: 1997 <i>Packaging for terminally sterilized medical devices</i></p> | | 8.3(2) |
| 2 | <p>AS ISO 11135-2002 identical to: ISO 11135: 1995 <i>Medical devices – Validation and routine control of ethylene oxide sterilization</i></p> <p>OR</p> <p>EN 550: 1994 <i>Sterilization of medical devices – Validation and routine control of ethylene oxide sterilization</i></p> | For the validation of ethylene oxide sterilisation procedures. | 8.3(3) |

| 1 Item No. | 2 Medical Device Standard | 3 Conditions | 4 Essential Principle |
|------------------|---|---|-----------------------------|
| 3 | AS ISO 11137-2002 identical to: ISO 11137: 1995 <i>Sterilization of health care products –Requirements for validation and routine control – Radiation sterilization</i> OR EN 552: 1994 <i>Sterilization of medical devices – Validation and routine control of sterilization by irradiation</i> | For the validation of radiation sterilisation procedures. | 8.3(3) |
| 4 | ISO 11134: 1994 <i>Sterilization of health care products – Requirements for validation and routine control – Industrial moist heat sterilization</i> OR EN 554: 1994 <i>Sterilization of medical devices – Validation and routine control of sterilization by moist heat</i> | To be used for the validation of steam sterilisation procedures, together with microbiological validation demonstrating compliance with AS EN 556.1-2002. | 8.3(3) |
| 5 | AS ISO 14160-2002 identical to: EN ISO 14160: 1998 identical to: 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> | To be used for the validation of sterilisation by liquid chemical sterilants | 8.3(3) |
| 6 | TGA Guidelines for sterility testing of Therapeutic Goods – 2002 | To be used when an end-point sterility test is required to support product release. | 8.3(3) |

Schedule 2

| 1 Item No. | 2 Medical Device Standard | 3 Conditions | 4 Essential Principle |
|------------------|--|-----------------|-----------------------------|
| 1 | EN 868-1: 1997 <i>Packaging materials and systems for medical devices which are to be sterilized – Part 1: general requirements and test methods</i> OR ISO 11607: 1997 <i>Packaging for terminally sterilized medical devices</i> | | 8.4(2) |