COMMONWEALTH OF AUSTRALIA

Therapeutic Goods Act 1989

MEDICAL DEVICE STANDARDS ORDER (STANDARDS FOR BIOLOGICAL SAFETY OF MEDICAL DEVICES) 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, DETERMINE:

(a) that the matters in the relevant standards that are specified in column 2 of an item in the Schedule constitute a medical device standard for the biological safety of a kind of medical device, subject to the conditions (if any) set out in column 3 of that item of the Schedule, and

(b) that medical devices of those kinds that comply with the appropriate standard specified in column 2 are to be treated as complying with those parts of the essential principles set out in Schedule 1 of the Therapeutic Goods (Medical Devices) Regulations 2002 and that are specified in column 4 of the relevant item of the relevant Schedule.

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

Dated this 14th day of November 2008

Larry Kelly
Delegate of the Minister for Health and Ageing

Schedule

1 Item No.	2 Medical Device Standard	3 Conditions	4 Essential Principle
1	ISO 10993-1: 2003 *Biological evaluation of medical devices - Part 1 Evaluation and testing*		Schedule 1, paragraph 7.1(b)
2	ISO 10993-3: 2003 *Biological evaluation of medical devices - Part 3 Tests for genotoxicity, carcinogenicity and reproductive toxicity*		Schedule 1, paragraph 7.1(b)
3	ISO 10993-4: 2002 *Biological evaluation of medical devices - Part 4 Selection of tests for interactions with blood* AND ISO 10993-4: 2002 *Biological evaluation of medical devices - Part 4 Selection of tests for interactions with blood Amendment 1:2006*		Schedule 1, paragraph 7.1(b)
4	ISO 10993-5: 1999 *Biological evaluation of medical devices - Part 5 Tests for in vitro cytotoxicity*		Schedule 1, paragraph 7.1(b)
5	ISO 10993-6: 2007 *Biological evaluation of medical devices - Part 6 Tests for local effects after implantation*		Schedule 1, paragraph 7.1(b)
6	ISO 10993-7: 1995 *Biological evaluation of medical devices - Part 7 Ethylene oxide sterilization residuals*		Schedule 1, paragraph 7.1(b)
7	ISO 10993-9: 1999 *Biological evaluation of medical devices - Part 9 Framework for identification and quantification of potential degradation products*		Schedule 1, paragraph 7.1(b)

1 Item No.	2 Medical Device Standard	3 Conditions	4 Essential Principle
8	ISO 10993-10:2002 *Biological evaluation of medical devices - Part 10 Tests for irritation and delayed-type hypersensitivity* AND ISO 10933-10:2002 *Biological evaluation of medical devices - Part 10 Tests for irritation and delayed- type hypersensitivity* Amendment 2006		Schedule 1, paragraph 7.1(b)
9	ISO 10993-11: 2006 *Biological evaluation of medical devices – Part 11 Tests for systemic toxicity*		Schedule 1, paragraph 7.1(b)
10	ISO 10993-12: 2007 *Biological evaluation of medical devices - Part 12 Sample preparation and reference materials*		Schedule 1, paragraph 7.1(b)
11	ISO 10993-13: 1998 *Biological evaluation of medical devices - Part 13 Identification and quantification of degradation products from polymeric medical devices*		Schedule 1, paragraph 7.1(b)
12	ISO 10993-14: 2001 *Biological evaluation of medical devices - Part 14 Identification and quantification of degradation products from ceramics*		Schedule 1, paragraph 7.1(b)
13	ISO 10993-15: 2000 *Biological evaluation of medical devices - Part 15 Identification and quantification of degradation products from metals and alloys*		Schedule 1, paragraph 7.1(b)
14	ISO 10993-16: 1997 *Biological evaluation of medical devices - Part 16 Toxicokinetic study design for degradation products and leachables*		Schedule 1, paragraph 7.1(b)
15	ISO 10993-17: 2002 *Biological evaluation of medical devices – Part 17 Establishment of allowable limits for leachable substances*		Schedule 1, paragraph 7.1(b)
16	ISO 10993-18: 2005 *Biological evaluation of medical devices – Part 18 Chemical characterization of materials*		Schedule 1, paragraph 7.1(b)