COMMONWEALTH OF AUSTRALIA

Therapeutic Goods Act 1989

MEDICAL DEVICE STANDARDS ORDER (STANDARDS FOR CLINICAL EVIDENCE) 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 1 – *Medical Device Standards for Clinical Evidence"* made on 20th 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 items 1 and 2 in the Schedule constitute a medical device standard for all kinds of medical devices, subject to the conditions (if any) set out in column 3 of that item of the Schedule, and

(b) the matters in the relevant standards or parts of those standards published by the International Organization for Standardization specified in column 2 of items 3 and 4 of the Schedule constitute a medical device standard for cardiac valve prosthesis and intraocular lenses respectively, and

(c) 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 the Therapeutic Goods (Medical Devices) Regulations 2002 and that are specified in column 4 of the relevant item of the 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 Item No.	2 Medical Device Standard	3 Conditions	4 Essential Principle
1	AS ISO 14155-1: 2004 identical to: ISO 14155-1: 2003 *Clinical investigation of medical devices for human subjects – General requirements*		Schedule 1, clause 14
2	AS ISO 14155-2: 2004 identical to: ISO 14155-2: 2003 *Clinical investigation of medical devices for human subjects – Clinical investigation plans*		Schedule 1, clause 14
3	ISO 5840: 2005 *Cardiovascular implants – Cardiac valve prostheses* clause 7.4	Applicable to cardiac valve prosthesis only.	Schedule 1, paragraph 1(a)
4	ISO 11979-7: 2006 *Ophthalmic implants – Intraocular lenses -- Part 7: Clinical investigations*	Applicable to intraocular lenses only.	Schedule 1, paragraph 1(a)