COMMONWEALTH OF AUSTRALIA

Therapeutic Goods Act 1989

MEDICAL DEVICE STANDARDS ORDER NO. 1

Medical Device Standards for Clinical Evidence

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 item 1 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 specified in column 2 of items 2 and 3 of the Schedule constitute a medical device standard for cardiac valve prosthesis and intraocular lenses respectively, and

(c) medical devices of those kinds that comply with the appropriate standard are to be treated as complying with those parts of the essential principles specified in column 4 of the relevant item of the 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 Item No.	2 Medical Device Standard	3 Conditions	4 Essential Principle
1	AS EN 540-2002 identical to: EN 540: 1993 *Clinical investigation of medical devices for human subjects* OR AS ISO 14155-2002 identical to: ISO 14155:1996 *Clinical investigation of medical devices*		14
2	ISO 5840:1996 *Cardiovascular implants – Cardiac valve prostheses* clause 9	Applicable to cardiac valve prosthesis only.	1(a)
3	ISO 11979-7:2001 *Ophthalmic implants – Intraocular lenses -- Part 7: Clinical investigations*	Applicable to intraocular lenses only.	1(a)