

Australia New Zealand Therapeutic Products Authority Medical Device Standards Order No 1 of 2007

Medical Device Standards for Clinical Evidence

The Australia New Zealand Therapeutic Products Authority for the purposes of section 2.08 of the Australia New Zealand Therapeutic Products Regulatory Scheme (Medical Devices) Rule 2007, DETERMINE:

- (a) that the matters in the relevant standards published by the standards organisations that are 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) that the matters in the relevant standards or parts of those standards published by the International Organisation for Standardization 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) 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 specified in column 4 of the relevant item of the Schedule.

This Order commences on the day it is published in the Australia New Zealand Therapeutic Products Authority Internet site.

Dated 2007

Managing Director of the Australia New Zealand Therapeutic Products
Authority

Schedule

1 Item No.	2 Medical Device Standard	3 Conditions	4 Essential Principle (as set out in Schedule 1 of the Australia New Zealand Therapeutic Products Regulatory Scheme (Medical Devices) Rule 2007)
1	AS ISO 14155-1: 2004 identical to: ISO 14155-1: 2003 <i>Clinical investigation of medical devices for human subjects – General requirements</i>		4.01
2	ISO 5840: 2005 <i>Cardiovascular implants – Cardiac valve prostheses clause 7.4</i>	Applicable to cardiac valve prosthesis only.	1.01(a)
3	ISO 11979-7:2006 <i>Ophthalmic implants – Intraocular lenses -- Part 7: Clinical investigations</i>	Applicable to intraocular lenses only.	1.01(a)