COMMONWEALTH OF AUSTRALIA

Therapeutic Goods Act 1989

MEDICAL DEVICE STANDARDS ORDER (STANDARDS FOR RISK MANAGEMENT) 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, HEREBY:

(1) REVOKE "Medical Device Standards Order No 2 – *Medical Device Standards for Risk Management"* made on 20 February 2003, AND

(2) DETERMINE

(a) that the matters specified in the relevant standards or parts of those standards published by the standards organisations that are specified in column 2 of an item 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 medical devices of those kinds that comply with the 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 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 19th day of May 2008

Signed

Larry Kelly
Delegate of the Minister for Health and Ageing

Schedule

1 Item No.	2 Medical Device Standard	3 Conditions	4 Essential Principle
1	EN ISO 14971:2000 *Medical Devices – Application of Risk Management to Medical Devices* Clauses 1 to 9 inclusive OR ISO 14971:2000 *Medical Devices – Application of Risk Management to Medical Devices* Clauses 1 to 9 inclusive (Note: EN ISO 14971:2000 is identical to ISO 14971:2000) OR EN ISO 14971:2007 *Medical Devices – Application of Risk Management to Medical Devices* Clauses 1 to 9 inclusive OR ISO 14971:2007 *Medical Devices – Application of Risk Management to Medical Devices* Clauses 1 to 9 inclusive (Note: EN ISO 14971:2007 is identical to ISO 14971:2007)	To be used as a method to identify the risk associated with the use of the device, but not to be used as a specific means to implement the reduction of risks. EN ISO 14971:2000 and ISO 14971:2000 will not constitute a medical device standard for essential principles 1(b) and 2(2) after 31 March 2010.	Schedule 1, paragraph 1(b) and subclause 2(2)