

# **Australia New Zealand Therapeutic Products Authority Medical Device Standards Order No 2 of 2007**

---

## **Medical Device Standards for Risk Management**

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 specified in the relevant parts of the standards published by Standards Australia Ltd, Standards New Zealand and the European Committee for Standardization 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 medical device 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	<p>AS/NZS 4810.1:2000 <i>Medical devices - Risk management – Application of risk analysis</i> clauses 1 to 9 inclusive</p> <p>OR</p> <p>EN ISO 14971:2002 identical to: ISO 14971:2000 <i>Medical Devices – Application of Risk Management to Medical Devices</i> Clauses 1 to 9 inclusive</p>	<p>Provides a method to identify the risk associated with the use of the device but not the specific means to implement the reduction of risks.</p>	<p>1.01 (b) and 1.02 (2)</p>