

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	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 OR ISO 14971:2007 <i>Medical Devices – Application of Risk Management to Medical Devices</i> Clauses 1 to 9 inclusive	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.	1.01 (b) and 1.02 (2)