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Medical devices Essential Principles checklist

Manufacturer name

Product name

ID

Notes on what to include in each column

Applicable/Not applicable – respond with 'A' or 'NA' for the device. If not applicable (NA) include justification.

Medical Device Standards applied by manufacturer - only include standards published by the TGA as Medical Device Standard Orders or Conformity Assessment Standard Order.

Other standards or procedures applied by manufacturer – include: EN, ISO, international or local standards or company procedures identified by number or title.

Evidence of compliance or reason for non-applicability – include direct reference to documents such as: study results, test reports, design outputs identified by number or title within the Quality System.

Note: [Therapeutic Goods Act 1989](#) (the Act) and [Therapeutic Goods \(Medical Devices\) Regulations 2002](#) (the Regulations).

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Schedule 2	Essential Principle from the Regulations	Applicable/Not applicable	Medical Device Standards applied by manufacturer	Other standards or procedures applied by manufacturer	Evidence of compliance or reason for non-applicability
Part 1.	General principles				
1.	<p>Use of medical devices not to compromise health and safety A medical device is to be designed and produced in a way that ensures that:</p> <p>(a) the device will not compromise the clinical condition, or safety of a patient, or the safety and health of the user or any other person, when the device is used on a patient under the conditions and for the purposes for which the device was intended and, if applicable, by a user with appropriate technical knowledge, experience, education or training; and</p> <p>(b) any risks associated with the use of the device are:</p> <p>(i) acceptable risks when weighed against the intended benefit to the patient; and</p> <p>(ii) compatible with a high level of protection of health and safety.</p>				
2.	<p>Design and construction of medical devices to conform with safety principles</p> <p>(1) The solutions adopted by the manufacturer for the design and construction of a medical device must conform with safety principles, having regard to the generally acknowledged state of the art.</p> <p>(2) Without limiting subclause (1), in selecting appropriate solutions for the design and construction of a medical device so as to minimise any risks associated with the use of the device, the manufacturer must:</p> <p>(a) first, identify hazards and associated risks arising from the use of the device for its intended purpose, and foreseeable misuse of the device; and</p> <p>(b) second, eliminate, or reduce, these risks as far as possible by adopting a policy of inherently safe design and construction; and</p> <p>(c) third, if appropriate, ensure that adequate protection measures are taken, including alarms if necessary, in relation to any risks that cannot be eliminated; and</p> <p>(d) fourth, inform users of any residual risks that may arise due to any shortcomings of the protection measures adopted.</p> <p>(3) In paragraph (2) (d): residual risk, for a medical device, means the risk remaining after the measures described in paragraphs (2) (a), (b) and (c) have been applied.</p>				

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Ensheng Dong



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