



## Medical Devices Essential Principles Checklist

Manufacturers must demonstrate their medical device complies with the Essential Principles. Manufacturers must generate, collate, assess, and maintain scientific and clinical evidence that shows that their devices comply with the Essential Principles. The evidence must be relevant to the device's intended purpose and must be objective, sufficient, and robust.

- The [Essential Principles Checklist](#) is a template that may help you:
  - identify the safety and performance requirements that apply to your device
  - document a rationale for any of the safety and performance requirements that aren't relevant
  - summarise the evidence you hold in support of each of the relevant safety and performance requirements
- Completing the checklist could help you:
  - apply for an Australian conformity assessment certificate
  - comply with regulations as part of a post-market review or investigation
  - to determine if you have considered and addressed all the requirements with supporting evidence

### Instructions

- Complete this checklist for each new medical device conformity assessment application
- Provide an updated checklist if applicable, for change applications relating to your medical device.
- The checklist must be applicable to the subject medical devices or may be completed for a family or group of devices.
- Complete the checklist as outlined in the table instructions below

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### Table instructions

Reference to Therapeutic Goods (Medical Devices) Regulations 2002 Schedule 1, Part number and title		Applicable	Not applicable <i>Justification must be provided below</i>	Medical Devices / IVD standard or other procedure applied	Evidence of compliance <i>Include direct reference to documents within the manufacturer's quality system</i>
EP Reg.#	<i>Title of the Essential Principle</i>				
EP.# Reg.#	The Essential Principle requirement is contained here.	<input type="checkbox"/> Tick this box if the Essential Principle requirement is applicable to the device / family of devices. Complete the two columns on the right.	<input type="checkbox"/> Tick this box if the Essential Principle requirement is not applicable to your device / family of devices. Then provide justification.	List here the standards / procedures applied with justification (include number / title / version). These include (but are not limited to): <ul style="list-style-type: none"> <li>• EN ISO international, local standards</li> <li>• company procedures</li> <li>• TGA Medical Device Standard Order</li> <li>• TGA Conformity Assessment Standard Order</li> <li>• TGA Guidance document</li> </ul>	This column is to contain direct reference to documents within the manufacturer's quality system such as: <ul style="list-style-type: none"> <li>• study results</li> <li>• test reports</li> <li>• design outputs</li> </ul> identified by number / title / version

# Medical Devices Essential Principles Checklist

**Lei Huang**



**Medical Devices Essential Principles Checklist:**

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