



**Australian Government**  
**Department of Health and Ageing**  
**Therapeutic Goods Administration**

**FACT SHEET**  
**Differences between the Australian and European Union Regulatory Systems (2) – Essential Principles**  
**April 2005 – Draft**

The revised medical devices regulatory framework for Australia has been implemented in response to the initiatives of the Global Harmonisation Task Force (GHTF) to harmonise medical device regulatory requirements. The resulting regulatory framework has many similarities with that adopted by the European Union (EU). However while similar, the two systems do have some differences.

This Fact Sheet is one of a series that covers the differences between the Australian and European Union (EU) Regulatory Systems.

Readers of this Fact Sheet will need to have a good knowledge of:

- The European Union's Medical Device Directives (EU MDD):
  - The EU Directive 93/42/EEC (Medical Device Directive),
  - The EU Directive 90/385/EEC (Active Implantable Medical Device Directive), and
- The Australian legislation for medical devices implemented in October 2002:
  - *The Therapeutic Goods Act 1989* (the Act),
  - *Therapeutic Goods (Medical Devices) Regulations, 2002* (the MD Regulations).

**1. Scope**

This Fact Sheet has been created primarily to assist:

- Australian manufacturers of medical devices who wish to affix the CE mark and export their medical devices to the European Union,
- Australian sponsors who wish to import CE marked medical devices into the Australian market, and
- Overseas manufacturers who wish to have their manufacturing quality systems audited to the Australian regulatory requirements.

**2. Essential Principles – General**

The Australian Essential Principles were aligned with those of the GHTF at the time of drafting of the legislation.

**References** - Schedule 1 of the MD Regulations - Essential Principles, Annex I of the Medical Devices and AIMD Directives – Essential Requirements.

The Table below shows whether the Australian Essential Principles (EP) are similar to the EU Essential Requirements (ER).

Australian Essential Principle	Does the EU have a similar requirement? Yes or No
<b>Schedule 1 of the MD Regulations, Part 1 – General Principles</b>	
EP 1 – Use of medical devices not to compromise health and safety.	Yes
EP 2 – Design and construction of medical devices to conform with safety principles.	No - EP 2, 2a – states that the manufacturer must – identify hazards and risks arising from the use of the device and foreseeable misuse of the device. There is no corresponding paragraph in the EU Essential Requirements.
EP 3 – Medical devices to be suitable for intended purpose.	Yes
EP 4 – Long – term safety.	Yes
EP 5 – Medical devices not to be adversely affected by transport or storage.	Yes
EP 6 – Benefits of medical devices to outweigh any side effects.	Yes

Schedule 1 of the MD Regulations, Part 2 – Principles about design and construction.		EP 9 – Construction and environmental properties	
<b>EP 7 – Chemical, physical and biological properties</b>		EP 9.1 – Medical devices intended to be used in combination with other devices or equipment.	Yes
EP 7.1 – Choice of materials.	Yes	EP 9.2 Minimisation of risks associated with use of medical devices.	Yes
EP 7.2 – Minimisation of risks associated with contaminants and residues.	Yes	EP 10 – Medical devices with a measuring function.	No – Aust - EP – 10.1 – measurements must be expressed in Australian legal units of measurement; or, if the device measures a physical quantity which is not prescribed under the <i>National Measurement Act 1960</i> , the units used are to be approved by the Secretary of the Department of Health and Ageing.
EP 7.3 – Ability to be used safely with materials etc.	Yes		In the EU – ER - 10.1 states that the measurements must be expressed in legal units conforming to the provisions of the Council Directive 80/181/EEC.
EP 7.4 – Verification of incorporated substance.	Yes		Aust - EP - 10.2 currently provides that the sponsor must ensure information provided with the medical device allows the sponsor to be identified. From 4 October 2007 the sponsors name and address must be provided with the device so that the user can readily identify the sponsor and must be located either on the device, on packaging for the device, outer packaging or a leaflet (EP - 13.2).
EP 7.5 – Minimisation of risks associated with leaching substances.	No - the concept of leaking in the EU is replaced by Egress in Australia.		EU ER - 13.3 & 13.6 requires the manufacturer to place the name or address of either the person responsible or the authorised representative of the manufacturer or the importer established within the Community to be on the label or outer package
EP 7.6 – Minimisation of risks associated with ingress or egress of substances.	Egress and ingress in Australia is Essential Principle 7.6, Essential Principle 7.5 clarifies the concern around toxic substances being leached from materials.  This addressed in the EU through a combination of Essential Requirements 7.1 & 7.5.		
<b>EP 8 – Infection and microbial contamination</b>			
EP 8.1 – Minimisation of risk of infection and contamination.	Yes		
EP 8.2 – Control of animal, microbial or recombinant tissues, cells and other substances.	No - the equivalent requirement in the EU only includes devices that contain animal origin.		
EP 8.3 – Medical devices to be supplied in a sterile state.	Yes		
EP 8.4 – Medical devices to be supplied in a non-sterile state.	Yes		
EP 8.5 – Distinction between medical devices supplied in sterile and non-sterile state.	Yes		

	or instructions for use.		
EP 11 – Protection against radiation.	Yes		or plasma, must indicate on the label that the device contains a human blood derivative.
EP 12 – Medical devices connected to or equipped with an energy source.	Yes		Australia only has this requirement for instructions for use.
<b>EP 13 – Information to be provided with medical devices</b>			It is worth noting that the EU states under ER 9.1 that any restrictions on use must be indicated on the label or in the instructions for use. (This requirement is covered in Australia by Instructions for Use requirements EP - 13.4, 3 and 5).
EP 13.1 – Information to be provided with medical devices – general.	No – EP - 13.1 Australia has the requirement for the label to at least be in English.  The EU has no requirement for the label to be in English, however the EU are able to stipulate which language is appropriate for the country of supply.  EP 13.1 – Australia requires any numbers, letters, symbols used to be legible and at least 1 millimetre high.  In the EU this requirement is addressed in the relevant harmonised standard.		
EP 13.2 – Information to be provided with medical devices – location.	Yes		
EP 13.3 – Information to be provided with medical devices – particular requirements.	No - In Australia and EU if applicable a use by date is required.  Australia requires either the date of manufacture or a date up to when the device can be safely used. It must be clear which is the month and year.  In the EU there must be a date of manufacture for an active implantable medical device. The EU also requires the year of manufacture if the device doesn't have a use by date, for an active device.		
EP 13.4 – Instruction for use.	Yes, except the EU (ER 13.3) also has the requirement that devices incorporating a medicine derived from human blood		
		EP 14 – Clinical evidence.  Every medical device required evidence, appropriate for the use and classification of the device, demonstrating that the device complies with the applicable provisions of the essential principles.	In the EU (ER 14) Clinical data is required in accordance with Annex X of the Medical Device Directives.

### 3. Essential Principles for Active Implantable Medical Devices (AIMD's).

References Schedule 1 of the MD Regulations (Essential Principals), EU - AIMD Directive 90/385/EEC.

- AIMD's are expected to meet Australia's Essential Principles for medical devices. At the time of drafting of the legislation it was determined that all AIMD Directive Essential requirements where addressed by the existing GHTEF Essential Principles which Australia adopted.
- The following are examples where the EU requirements for AIMD's have been incorporated into the Australian Essential Principles.
- Essential Principle 12.13 was added to the MD Regulations to include the unique requirement for AIMD's that they be able to display a code which can be used to identify a device.
- The EU requirement for implantable devices to be repackaged in a non-reusable pack to ensure they are sterile when placed on the market is met by the Australian requirement for appropriate packaging. Australia - Essential Principle 3, 8.1 and 8.3 and EU – AIMDD 7.

**Disclaimer**

This document is provided for guidance only. It should not be relied upon to address every aspect of relevant legislation. Please refer to the *Therapeutic Goods Act*, and the *Therapeutic Goods (Medical Devices) Regulations, 2002* for legislative requirements.

**Further information**

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