



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

FACT SHEET

**Differences between the Australian and European Union Regulatory Systems (1) –
Fundamental Differences and Classification**

December 2004 - Draft

The revised medical devices regulatory framework for Australia, introduced in October 2004, 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 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); and
 - *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. Fundamental Differences

Fundamental differences of the Australian and the EU regulatory systems are:

- Europe has two directives that cover medical devices the Medical Device Directive (MDD) and the Active Implantable Medical Device Directive (AIMDD), Australia regulates both Medical Devices and AIMD's under the same legislation (*The Therapeutic Goods Act 1989* (the Act),
- Australia requires a manufacturer to sign a declaration that their products meet Australian requirements and the EU requires a manufacturer to sign a declaration that their product meets the EU requirements,
- The person responsible for placing the product on the market and certifying that the manufacturer has met Australia's requirements in Australia is the Sponsor. In the EU there is an Authorised Representative,
- The Australian Register of Therapeutic Goods (ARTG) is the register of information about therapeutic goods for human use that may be imported, supplied in, or exported from Australia. With few exceptions (exemptions by regulation or by application) all Medical Devices must be included in the ARTG before supply in Australia. There is no such EU requirement or equivalent register. However, the EU has a European Database on Medical Devices (EUDAMED) register which is a register only of Notified Body Certificates and is not a mandatory requirement for supply, and
- there are a few differences in classification (see Section 4 of this Fact Sheet).

3. Classes of Devices

Australia has five classes of medical devices covered by the Act. The EU has five classes of medical devices, four covered by the MDD and one by the AIMD Directive. The *In Vitro*

Diagnostic Directive (IVDD) is now implemented and these are also medical devices – however this directive is not part of this comparison document.

AUSTRALIA	EUROPEAN UNION
Class I	Class I
Class IIa	Class IIa
Class IIb	Class IIb
Class III	Class III
Class AIMD	AIMD –covered by AIMD Directive 90/385/EEC

4. Classification:

The classification rules determine the class of the medical device for the purpose of selecting a Conformity Assessment Procedure. The main differences in the classification rules between Australia and the EU are (reference Schedule 2, 3.3 of the MD Regulations and Annex IX Medical Devices Directive and AIMD Directive):

- The definition of the Central Circulatory System in Australia includes the aortic arch, thoracic aorta, abdominal aorta and the common iliac veins and arteries - these are not included in the EU definition. This means that a few Class IIb products in the EU are Class III products in Australia eg implantable abdominal aortic aneurysm grafts.
- Devices for disinfecting and cleaning, Australia - Rule 5.3 – Class IIb, EU - Rule 15 – Class IIa.
- Australia - Rule 5.5 - Devices containing tissues, cells or substances of microbial or recombinant origin are Class III. EU – under various rules these may or may not be Class III.
- Australia - Rule 5.7 - Active Implantable Medical Device (AIMD) - an AIMD is Class AIMD, an implantable accessory to an active implantable device is Class III, An active device that is to be used to control or monitor, or directly influence, the performance of an active implantable device is Class III. EU - all AIMD's and their implantable accessories are covered by the AIMD Directive.
- Australia - Rule 5.8 - devices manufactured in Australia for export only, but not sold in Australia are treated as Class I. No EU equivalent.

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, 1989*, the *Therapeutic Goods (Medical Devices) Regulations, 2002*, and the European Union's Medical Device Directives.

Further information

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