

Differences between the Australian and European Union medical device regulatory requirements

 This section contains information about the differences between the Australian and European Union (EU) regulatory requirements.	
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Overview

The medical devices regulatory framework in Australia, introduced in October 2002, has been implemented to align with the Global Harmonisation Task Force (GHTF) regulatory model. The regulatory framework has many similarities with that adopted by the European Union (EU). However while similar, the two systems do have some differences.

This guidance document has been created primarily to assist:

- Australian manufacturers who export medical devices to the EU or who intend to export to the EU
- Australian sponsors who wish to import CE marked medical devices into the Australian market
- Overseas manufacturers who wish to manufacture for both the European and Australian markets.

Regulatory frameworks

Australia regulates medical devices under the:

- *Therapeutic Goods Act 1989* (the Act)
- Therapeutic Goods (Medical Devices) Regulations, 2002 (the Regulations).

The EU has multiple directives to cover medical devices:

- Medical Device Directive (MDD) 93/42/EEC
- Active Implantable Medical Device Directive (AIMDD) 90/385/EEC.

EU Directive 2007/47/EC, introduced on 5 September 2007 in the European Parliament, made significant amendments to the MDD and AIMDD. Manufacturers have until 21 March 2010 to comply with the changes introduced by the new Directive. This document takes account of the changes introduced by the Directive 2007/47/EC.

In vitro diagnostic devices

The regulatory frameworks for in vitro diagnostic devices (IVDs) are different in Australia and the EU. In the EU, IVDs are covered by the IVD Directive 98/79/EC. In Australia, IVDs are not currently regulated as medical devices and have distinct regulatory requirements. See <http://www.tga.gov.au/ivd/current.htm> for details. However, a new regulatory framework for IVDs is under development in Australia. See <http://www.tga.gov.au/ivd/forthcoming.htm> for more details.

Specific differences between Australia and the EU in relation to IVDs are not covered in this document.

Australian Register of Therapeutic Goods (ARTG) vs. CE marking

The ARTG is the register of information about therapeutic goods for human use that may be imported, supplied in, or exported from Australia. All medical devices, including Class I, must have marketing authorisation from the TGA via inclusion on the ARTG before supply in Australia. There are limited exceptions specified in the legislation, such as for experimental use. These exceptions are detailed in Schedule 4 of the Regulations.

In the EU, the manufacturer must affix the CE marking to medical devices prior to supply. Marketing authorisation is achieved in the EU when the manufacturer affixes the CE marking

to the medical device. CE marking does not indicate marketing authorisation in Australia. The authorised representative of the manufacturer of Class I medical devices exported to the EU must register details with their EU Competent Authority. For higher class devices, the manufacturer's Notified Body must register details with their designating Competent Authority. The EU Competent Authorities utilise a centralised databank (EUDAMED) to store and share the above information as well as data relating to certificates, data obtained in accordance with vigilance procedures and data related to clinical investigations. The Directive 2007/47/EC requires the databank to be fully operational by 5 September 2012.

Global Medical Device Nomenclature (GMDN) system

GMDN codes are used internationally by regulatory bodies to identify medical devices.

In Australia, GMDN codes are included on all:

- entries in the ARTG
- *TGA Conformity Assessment Certificates*
- Australian Declarations of Conformity.

In the EU, the adoption of GMDN codes has not been implemented to the same extent as in Australia. CE certificates are sometimes issued by EU Notified Bodies without reference to GMDN codes. This may change as the EU prepares for the EUDAMED databank to become fully operational in September 2012.

Declarations of conformity

In the EU, manufacturers make a Declaration of Conformity (DoC) under the MDD or AIMDD. This is a formal statement signed by an authorised representative of the manufacturer. The DoC states that the device (including the name, type or model of the device) has been verified in accordance with the relevant conformity assessment procedure and meets the requirements of the MDD or AIMDD

In Australia, the conformity assessment procedures require the manufacturer to make a DoC in accordance with the Australian requirements. The Australian DoC, made under the relevant clause of Schedule 3 of the Regulations must:

- include the GMDN code and classification of the devices
- indicate the Unique Product Identifier for each Class III and AIMD device

Australian sponsor vs. European authorised representative

In Australia, the person responsible for including the devices in the ARTG and placing the devices on the market is the sponsor. Sponsors take responsibility for the supply or export of a medical device in or from Australia.

In the EU, if the manufacturer does not have a registered place of business in a member state, the manufacturer must designate a single authorised representative in the EU responsible for placing the devices on the market. The authorised representative has the mandate to act, and be contacted in lieu of the manufacturer, in relation to meeting the obligations imposed by the MDD or AIMDD for all classes of devices. The authorised representative must be identified in the labelling supplied with the device.

Please note: Directive 2007/47/EC clarifies that manufacturers outside the EU require a single authorised representative who is established in the EU

Sponsor/authorised representative details to be supplied with the device

In Australia, the information provided with the medical device must allow both the sponsor and manufacturer to be identified. The sponsor's name and address must be provided with the device in accordance with Regulation 10.2 of the Regulations and must be located either:

- on the device itself, unless it is not physically practicable to do so, or
- on the packaging of the device, unless it is not physically practicable to do so, or
- in documents supplied with the device.

In the EU, Essential Requirements 13.3 & 13.6 require the manufacturer to place the name and address of either the person responsible or the authorised representative of the manufacturer or the importer established within the EU to be on the label or outer package or instructions for use.

Retention of records

In Australia, the manufacturer must keep all manufacturing records for at least 5 years from the last date of manufacture or the lifetime of the device, whichever is longer. However, distribution records relating to Class AIMD, Class III or implantable Class IIb medical devices must be retained for inspection by the TGA for 10 years.

Similarly, the EU directives require the retention of manufacturing records for 5 years from the last date of manufacture or the lifetime of the device, whichever is longer. However, for implantable devices, records must be kept for at least 15 years from the last date of manufacture.

Please note:

Directive 2007/47/EC introduces the requirement that manufacturing records of implantable devices must be kept for at least 15 years from the last date of manufacture.

EU Essential Requirements modified by Directive 2007/47/EC

The Australian Essential Principles (EPs) are specified in Schedule 1 of the Regulations. The EU Essential Requirements (ERs) are specified in Annex I of the MDD. The following table compares the Australian EPs with the recent changes to the EU ERs introduced by Directive 2007/47/EC.

EU Essential Requirements modified by Directive 2007/47/EC	Australian Essential Principles
<p>ER 1.</p> <p><i>Directive 2007/47/EC introduces more explicit requirements to ER 1:</i></p> <p>i.e., reduce risk of use error due to ergonomic features of the device and consider the technical knowledge, experience, education and training of intended users while designing the device.</p>	<p>Australian EP 1 addresses the need to consider technical knowledge, experience, education or training of users.</p> <p>Australian EP 2a requires identification of hazards and risks arising from the use and foreseeable misuse of the device. The manufacturer must minimise any risks associated with the use of the device.</p>

EU Essential Requirements modified by Directive 2007/47/EC	Australian Essential Principles
<p>ER 6(a) (and ER 14).</p> <p><i>Directive 2007/47/EC</i> added ER 6(a):</p> <p>“demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X”.</p> <p>Previously this requirement was addressed in ER 14. Now ER 14 is removed.</p>	<p>This requirement is addressed by EP 14</p>
<p>ER 7.1.</p> <p><i>Directive 2007/47/EC</i> clarifies requirements in ER 7.1:</p> <p>“particular attention must be paid to: where, appropriate, the results of biophysical or modelling research whose validity has been demonstrated beforehand”.</p>	<p>This requirement is not explicitly covered in the Australian EPs. However, EP 7.1(a) requires that “particular attention must be given to the chemical and physical properties of the materials used in the device”. Moreover, <i>ISO 10993-1: Biological evaluation of medical devices - Part 1 Evaluation and testing</i> which is included in the <i>Medical Device Standards Order (Standards for Biological Safety Of Medical Devices) 2008</i> refers to the consideration of physical characteristics and properties in the selection of materials.</p>
<p>ER 7.5.</p> <p><i>Directive 2007/47/EC</i> added the additional requirement to ER 7.5:</p> <p>“special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Annex 1 to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations, packaging and labelling of dangerous substances”.</p>	<p>This is addressed in Australia by the general risk management requirements of EP 2. Users must be informed of any residual risks remaining after design-based risk removal or risk reduction is employed.</p>
<p>ER 7.5. (phthalates)</p> <p><i>Directive 2007/47/EC</i> also added:</p> <p>“If parts of a device (or a device itself) intended to administer and/or remove medicines, body liquids or other substances to or from the body, or devices intended for transport and storage of such body fluids or substances, contain phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction, of category 1 or 2, in accordance with Annex I to Directive 67/548/EEC, these devices must be labelled on the device itself and/or on the packaging for</p>	<p>There are no specific labelling requirements for medical devices containing phthalates in Australia. However, the general requirements of EP 2 apply (see above).</p>

EU Essential Requirements modified by <i>Directive 2007/47/EC</i>	Australian Essential Principles
<p>each unit or, where appropriate, on the sales packaging as a device containing phthalates.</p> <p>If the intended use of such devices includes treatment of children or treatment of pregnant or nursing women, the manufacturer must provide a specific justification for the use of these substances with regard to compliance with the essential requirements, in particular of this paragraph, within the technical documentation and, within the instructions for use, information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures.”</p>	
<p>ER 12.1(a)</p> <p><i>Directive 2007/47/EC</i> introduced additional requirements to ER12.1(a):</p> <p>“for devices which incorporate software, or which are medical software in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification”.</p>	<p>The software development lifecycle is not explicitly addressed in the Australian EPs. EP 12.1 addresses other requirements for medical devices incorporating electronic programmable systems.</p> <p>See Section – Active medical devices for more details on medical device software requirements.</p>

Other differences between Australian EPs and EU ERs

Australian Essential Principles	EU Essential Requirements
EP 7.4 – Verification of incorporated substance.	Please see <i>Medical devices incorporating a medicinal substance</i> later in this Section for more details.
EP 7.5 – Minimisation of risks associated with leaching substances. and EP 7.6 – Minimisation of risks associated with ingress or egress of substances.	Risks associated with leaching, egress or ingress of material or substances are addressed by the combination of the EU MDD ERs 7.1, 7.5 and 7.6.
EP 8.2 – Control of animal, microbial or recombinant tissues, cells and other substances.	Please see <i>Medical devices containing substances of animal origin</i> and <i>Medical devices containing tissues, cells or substances of microbial or recombinant origin</i> later in this Section for more details

Australian Essential Principles	EU Essential Requirements
<p>EP 10 – Medical devices with a measuring function.</p> <p>The Australian EP 10.1(3) requires that 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 TGA.</p>	<p>In the EU, ER 10.3 states that the measurements must be expressed in legal units conforming to the provisions of the Council Directive 80/181/EEC.</p>
<p>EP 13.1 – Information to be provided with medical devices – general.</p> <p>The Australian EP 13.1(3) requires that the information must be provided in English and may also be provided in any other language.</p> <p>The Australian EP 13.1(5) requires that any number, letter, symbol, or letter or number in a symbol, used in the information to be legible and at least 1 millimetre high.</p>	<p>Article 4 (4) of the MDD allows individual Member States to require the information made available to the user and the patient in accordance with ER 13, to be in a national language.</p> <p>In the EU the equivalent dimensional requirements are addressed in the standard <i>EN1041 – 2008: Information supplied by the manufacturer of medical devices</i>.</p>
<p>EP 13.3 – Information to be provided with medical devices – particular requirements.</p> <p>Australian EP 13.3, items 12 & 13 require that the label displays either a date up to which the device can be safely used (if applicable) or the date of manufacture of the device.</p>	<p>In the EU, a use by date by which the device should be used (where appropriate) is required (ER 13.3 (e)).</p> <p>Active devices in the EU require the year of manufacture if the device doesn't have a use by date (ER 13.3 (i)).</p>
<p>EP 13.4 – Instructions for use must include:</p> <p>Item 18</p> <p>For a device that is intended by the manufacturer to be installed with, or connected to, another medical device or other equipment so that the device can operate as required for its intended purpose — sufficient information about the device to enable the user to identify the appropriate other medical device or equipment that will ensure a safe combination</p>	<p>The EU has an equivalent requirement under ER 9.1: any restrictions on use, in relation to other devices or equipment, must be indicated on the label or in the instructions for use.</p>
<p>EP 13.4 – Instructions for use must include:</p> <p>Item 25</p> <p>Information about any medicine (including any stable derivative of human blood or blood plasma) that is incorporated, or is intended to be incorporated, into the device as an integral part of the device</p>	<p>EU ER 13.3 (n) requires that devices incorporating human blood derivative must indicate this on the label. Including this information in separate instructions for use is insufficient in the EU.</p>

Devices with different requirements in Australia and the EU

Hip, Knee and shoulder joint replacements

Hip, knee and shoulder joint replacements are classified as Class IIb in Australia (Schedule 2, Part 3.4(2) of the Regulations).

EU Directive 2005/50/EC of 11 August 2005 changed the classification of implantable component parts of total hip, knee and shoulder replacements from Class IIb to Class III. Hip, knee and shoulder joint replacements that have followed the Annex II conformity assessment procedures must undergo a design dossier examination (Annex II.4) to be placed on the EU market after 1 September 2009. Devices currently approved under Annex VI in conjunction with Annex III have until 1 September 2010 to upgrade the Annex VI conformity assessment certificate to Annex IV or Annex V of the MDD (Annex VI is not acceptable for Class III devices).

If manufacturers do not upgrade their CE certification to cover Class III devices, Notified Bodies may exclude these devices from the certification. If this happens, the manufacturer may not have appropriate conformity assessment evidence for supplying the hip, knee and shoulder joint replacements as Class IIb devices in Australia. If this occurs the manufacturer has the following options:

- Do not supply the device in Australia
- Obtain MRA certification (available only to EU manufacturers) for the Australian Class IIb devices
- Obtain a *TGA Conformity Assessment Certificate*.

Devices intended for direct contact with the central nervous system

In the EU, transient devices intended specifically for use in direct contact with the central nervous system are Class III (Annex IX, Rule 6 of the MDD). 'Central nervous system' means the system in a human being comprising the brain, meninges and spinal cord.

There is no equivalent rule to this in Australia. Therefore, these devices may be classified as Class I, Class IIa or Class IIb (Schedule 2, Part 3.2 of the Regulations) in Australia based on the intended purpose.

Please note: Directive 2007/47/EC amended the MDD to classify transient devices intended specifically for use in direct contact with the central nervous system as Class III.

Definition of central circulatory system

In Australia, the definition of the central circulatory system extends beyond the current EU MDD definition to include the common iliac arteries. This means that some devices classified as Class III in Australia (Schedule 2, Parts 3.2(3), 3.3(4)(a) and 3.4(4)(a) of the Regulations) will have a lower classification in the EU.

In the EU, implantable or long-term surgically invasive devices will usually be Class IIb (Rule 8 of Annex IX of the MDD) and transient or short-term surgically invasive devices will usually be Class IIa (Annex IX, Rules 6 and 7 of the MDD), if intended to be used in the common iliac arteries.

Depending on the conformity assessment procedures performed by the manufacturer in Europe, additional conformity assessment may be required to be done by the TGA before including the device in the ARTG. The EU Annex III Type Examination and Annex V Production Quality Assurance procedures for a Class IIb device are also sufficient for a Class III device. However, the EU Annex II Full Quality Assurance procedures for a Class IIb device are insufficient for a Class III device.

Please note:

Directive 2007/47/EC adds the following vessels to the 'central circulatory system':

- *arcus aorta*
- *aorta descendens to the bifurcatio aortae.*

This means that the devices in contact with these blood vessels are Class III in Europe now, which is the same classification as in Australia.

However, the EU definition of 'central circulatory system' was not extended to include the common iliac arteries, which are included in the Australian definition.

Devices for recording X-ray images

In Australia, non-active devices that are intended by the manufacturer to be used to record X-ray diagnostic images are classified as Class IIa (Schedule 2, Part 5.4 of the Regulations). This Classification Rule captures X-ray films, but not digital image receptors as they are active medical devices. Digital receptors which capture X-ray images are classified as Class I in Australia (Schedule 2, Part 4.1 of the Regulations).

However, in the EU, all the devices that are specifically intended for recording of X-ray diagnostic images are Class IIa. This means that in the EU, X-ray films and digital image receptors are both Class IIa medical devices.

Please note: Directive 2007/47/EC replaced the wording 'non-active devices' with 'devices' in Annex IX, Rule 16 of the MDD in order to capture digital image receptors.

Active implantable medical devices and accessories

In Australia, active implantable medical devices (AIMD) are classified as Class AIMD (Schedule 2 Rule 5.7(1) of the Regulations). Accessories to AIMDs are classified in their own right and accessories may be Class I, Class I sterile, Class I measuring, Class IIa, Class IIb or Class III depending on the intended purpose.

Implantable accessories to AIMDs are Class III (Schedule 2 Rule 5.7(2) of the Regulations). This means implantable pacing leads (Class III) are classified differently to the implantable pulse generator (Class AIMD). Active medical devices intended for controlling, monitoring, or directly influencing the performance of active implantable medical devices are also classified as Class III in Australia (Schedule 2 Rule 5.7(3) of the Regulations). This means devices which are not implanted such as pacemaker programmers and external cochlea implant speech processors are Class III, and are classified differently to the implantable pulse generator which is Class AIMD.

In the EU, the AIMD Directive (AIMDD) does not include a device classification scheme. All AIMDs and AIMD accessories are covered under the AIMDD and are treated in an equivalent manner to Class III medical devices in the EU MDD. The requirements for lower risk AIMD accessories are therefore less burdensome in Australia than in the EU.

AIMDs must meet the Australian Essential Principles for medical devices. All of the EU AIMD Directive 90/385/EEC Essential Requirements are addressed in the Australian Essential Principles, including the following:

- AIMD Directive Essential Requirement 12 requires that AIMDs incorporate an identifying code that can be read without the need for surgery. This is equivalent to Essential Principle 12.13.
- AIMD Directive Essential Requirement 7 requires implantable devices to be presented in a non-reusable pack to ensure they are sterile when placed on the market. This is equivalent to Australian Essential Principles 3, 8.1 and 8.3.

Medical devices that are considered machinery

In Europe, medical devices that are also considered ‘machinery’ within the meaning of Article 2(a) of Directive 2006/42/EC on Machinery will be required to meet the essential health & safety requirements of Annex I to that Directive as well as the Essential Requirements of the MDD.

In Australia, the medical devices regulatory framework does not impose additional requirements for medical devices that are also considered machinery. This does not preclude, however, some requirements to comply with State based regulations where they exist, eg for devices containing pressure vessels or devices emitting ionising or non-ionising radiation.

Please note: Directive 2007/47/EC included additional requirements for medical devices that are considered machinery

Medical devices that are considered personal protective equipment

In Europe, medical devices that are also considered personal protective equipment within the meaning of Article 1(2) of Directive 89/686/EEC on Personal Protective Equipment will be required to meet the basic health & safety requirements of Annex II to that Directive as well as the Essential Requirements of the MDD.

In Australia, medical devices that are intended by the manufacturer to be also used as personal protective equipment have no additional requirements.

Please note: Non-sterile protective or safety apparel or equipment used in the home or for occupational or recreational use is excluded from the jurisdiction of the Act. Please see Therapeutic Goods (Excluded Goods) Order No. 1 of 2008 for more details < <http://www.tga.gov.au/legis/tgeg0801.htm>>.

Please note: Directive 2007/47/EC included additional requirements for medical devices that are considered personal protective equipment.

Medical devices intended for disinfecting, cleaning, etc

In Australia a medical device that is intended to specifically be used for disinfecting another medical device is Class IIb (Schedule 2, Part 5.3(2) of the Regulations). These devices include sterilants, sterilisers, and instrument grade disinfectants intended to disinfect both invasive and non-invasive devices.

In the EU, all devices intended specifically to be used for disinfecting medical devices are Class IIa unless they are specifically to be used for disinfecting invasive devices, in which case they are Class IIb (Annex IX, Rule 15 of the MDD).

Please note:

Directive 2007/47/EC amended the MDD to classify the devices intended specifically to be used for disinfecting invasive devices as Class IIb. These devices are also Class IIb in Australia.

However, devices intended specifically to be used for disinfecting non-invasive devices are Class IIa in the EU but are Class IIb in Australia.

Medical gas and connection systems

In Australia, medical gas pipeline systems are considered fixed building installations and outside the scope of the medical device legislation (see Therapeutic Goods (Excluded Goods) Order No.1 of 2008). However, the installation of medical gas pipeline and connection systems (including labeling and colour coding of connections) should comply with AS 2896-1998: *Medical gas systems - Installation and testing of non-flammable medical gas pipeline systems*.

Bottled medical gases are classified as medicines in Australia, and outside the scope of the medical device legislation. However, bottled medical gases supplied in Australia must comply with AS 4484-2004: *Gas cylinders for industrial, scientific, medical and refrigerant use - Labelling and colour coding*.

Medical devices intended for connection to Australian medical gas systems are required to be compatible with these systems (as per Essential Principle 9.1).

In the EU, the international standard *ISO 7396 – Medical gas pipeline systems* is the harmonised standard under the MDD and the requirements of labelling & colour coding of connection systems and bottled medical gas will be different to that of Australia and may vary depending on the country.

Devices with radio communication transmitters and/or that connect to telecommunications networks

In Australia, medical devices that connect to a public telecommunications network must comply with the Australian Communications and Media Authority (ACMA) A-Tick requirements. Medical devices with radio communication transmitters (e.g. Bluetooth devices) must comply with the ACMA spectrum licensing and C-Tick requirements. Further details are available in the **Section - Active medical devices**.

The EU radio spectrum and telecommunications requirements (e.g. Radio & Telecommunications Terminal Equipment (R&TTE) Directive 1999/5/EC) are different to those in Australia.

Medical devices that connect to public mains electricity networks

The Australian mains electricity supply operates at 230 volts, 50 Hz. All electrical equipment, including medical devices, connect to the mains electricity supply using a plug with active

and neutral pins partially insulated and with Australian-specific pin configuration as required by *AS/NZS 3112 - Approval and test specification - Plugs and socket-outlets*. For more details, please see **Section - Active medical devices**.

In the EU, the requirements will be different to that of Australia and will vary depending on the country.

Medical devices incorporating a medicinal substance

In Australia, medicinal substances that are incorporated, or intended to be incorporated in the device must meet the Australian regulatory requirements for medicines. Manufacturers of these devices must obtain a *TGA Conformity Assessment Certificate*.

In the EU, for devices incorporating a medicinal substance, the Notified Body has to consult with one of the Competent Authorities, or the European Medicines Agency (EMA) to verify compliance with Annex 1 of Directive 2001/83/EC. For devices incorporating human blood derivatives, the Notified Body is required to consult the EMA.

Any stable derivative of human blood or human plasma is considered a medicine in both the EU and Australia.

See **Section – Medical devices incorporating a medicine** for more details.

Please note: Directive 2007/47/EC included the option for the Notified Body to consult with the EMA (European Medicines Agency) or one of the Competent Authorities.

Medical devices containing substances of animal origin

In the EU, medical devices containing substances of animal origin must comply with Transmissible Spongiform Encephalopathy (TSE) Directive 2003/32/EC.

Manufacturers need to obtain a *TGA Conformity Assessment Certificate* to supply these devices in Australia. The Australian regulatory framework requires demonstration of compliance with risk management procedures, controls on sourcing, collection and handling of animal origin materials and validation of inactivation processes for viruses and transmissible agents. See **Section - Medical devices containing materials of animal, microbial or recombinant origin** for details.

Catgut sutures

Catgut sutures are absorbable sutures manufactured from animal intestinal tissue, commonly bovine or ovine. Catgut sutures are no longer supplied in the EU. In Australia, catgut sutures are classified as Class III medical devices because they contain substances of animal origin. The supply of animal material must only be sourced from countries that have not reported indigenous cases of Bovine Spongiform Encephalopathy (BSE), unless it can be justified otherwise.

As manufacturers of catgut sutures are not able to obtain valid CE certification, the TGA assessment of the conformity assessment procedures cannot be abridged and an on-site audit of the manufacturing facilities will be required.

Medical devices containing gelatine and collagen

There are differences between the EU and Australia in terms of requirements for bovine-bone derived gelatine and collagen used with medical devices.

In the EU, collagen and gelatine used for the manufacturing of medical devices shall meet at least the requirements as fit for human consumption (Article 1.3, TSE Directive 2003/32/EC).

In Australia, bovine derived gelatine and collagen raw material (bone) must not be sourced from high risk countries. See *Supplementary requirements for therapeutic goods for minimising the risk of TSEs* <<http://www.tga.gov.au/docs/html/tsesupp.htm>> for more details.

Medical devices containing tissues, cells or substances of microbial or recombinant origin

In Australia, medical devices containing tissues, cells or substances of microbial or recombinant origin are Class III (Schedule 2, Part 5.5 of the Regulations). Manufacturers of these devices must obtain a *TGA Conformity Assessment Certificate*.

There is currently no distinction in the EU regarding such devices and they are classified according to the other rules on the basis of the intended purpose. This means that some devices classified as Class III in Australia will have a lower classification in the EU. Generally, implantable or long term surgically invasive devices will be Class IIb and transient or short term surgically invasive devices will be Class IIa, but some devices that are Class I in the EU may contain substances of microbial or recombinant origin.

Medical devices containing mercury

In Australia, there are no additional requirements for medical devices containing mercury.

In the EU, Directive 2007/51/EC imposes restrictions on the marketing of certain measuring devices containing mercury. Mercury-In-Glass fever thermometers may no longer be placed on the market. Mercury sphygmomanometers may no longer be placed on the market for sale to the general public, but may still be available for healthcare professionals.

Medical devices containing nanomaterials

Some medical devices contain nanomaterials (e.g. some dental materials).

The European Commission has endorsed the *precautionary principle* in relation to medical devices containing nanomaterials. The manufacturer should therefore incorporate the *precautionary principle* into their risk management system for these devices. This is likely to require explicit consideration of the uncertainty associated with the potential hazards posed by nanomaterials.

The TGA position is consistent with that of other Australian Government agencies and with the EU position. The *precautionary principle* is consistent with the Australian approach to nanomaterials, and with the requirement for manufacturers to implement a comprehensive risk management system. The hazards posed by nanomaterials must be addressed within that framework. However, at this time, the *precautionary principle* has not been formally endorsed in Australia in relation to nanomaterials.

Reprocessing of single-use medical devices

In Australia, reprocessed single-use medical devices are treated as new distinct medical devices with a new manufacturer (usually the organisation performing the reprocessing) who is responsible for conformity assessment of the recycled devices. Full compliance with the Essential Principles must be demonstrated and an appropriate conformity assessment procedure must be performed. See **Section - Reuse of single use devices** for more details.

It appears that recycled medical devices are not currently CE certified under the MDD. This means that overseas manufacturers would need to obtain a TGA conformity assessment certificate in order to supply reprocessed single-use medical devices in Australia.

Please note: Directive 2007/47/EC requires the European Commission to submit a report on medical device reprocessing by 5 September 2010 (Article 12a).

Medical devices intended for export only

Medical devices that are not supplied in Australia, but are exported from Australia are subject to regulatory requirements. These devices are treated as Class I, regardless of other rules. Devices intended for export only still need to comply with the regulatory requirements of the destination country, such as the countries of the EU.

There is no equivalent rule in the EU - these devices are classified in the same manner as other devices.

Special/particular procedure for systems and procedure packs

In the EU, the 'particular procedure' under Article 12 of the MDD can be applied for systems and procedure packs, if all products making up the system or procedure pack have the CE mark, including medical devices, medicines and non-therapeutic goods.

In Australia, the 'special procedure' requirements (Schedule 3 Clause 7.5) for products making up a system or procedure pack are different from the EU. The 'special procedure' can be applied if the manufacturer can meet the following requirements for the products included in the system or procedure pack:

- medicines, or other therapeutic goods, must have an appropriate ARTG entry
- medical devices must have undergone an appropriate conformity assessment procedure
- non-therapeutic goods are not required to have undergone conformity assessment.

There are also other requirements for applying the Australian 'special procedure'. For more details, please see **Section – Systems and procedure packs**.

Certification of sterilisation providers

In Australia, there are no requirements for certification of sterilisation providers under the regulatory framework.

Directive 2007/47/EC amended Article 12 of the MDD so that sterilisation providers, who sterilise CE marked medical devices intended to be sterilised before use in the EU are limited to use conformity assessment procedures under Annex II or V.