AUSTRALIAN MEDICAL DEVICES
GUIDANCE DOCUMENT NUMBER 22

The Essential Principles for Medical Devices

3 November 2003
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* and the *Therapeutic Goods (Medical Devices) Regulations, 2002* for legislative requirements.

FURTHER INFORMATION

The Medical Devices Information Unit of the Office of Devices, Blood and Tissues of the Therapeutic Goods Administration (TGA) can be contacted by:

Telephone: 1800 141 144
Facsimile: (02) 6232 8299
Email: cab.medical.device.information@health.gov.au
Website: www.tga.gov.au/devices/devices.htm
Mail: PO Box 100
      Woden
      ACT   2606

© Commonwealth of Australia 2003
# AMENDMENT SCHEDULE

<table>
<thead>
<tr>
<th>Version Number</th>
<th>Date of Amendment</th>
<th>Summary of Amendments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
CONTENTS

Disclaimer ..............................................................................................................................................2

Further information................................................................................................................................2

Amendment schedule ............................................................................................................................3

Introduction ............................................................................................................................................7

Part 1 General principles .......................................................................................................................8

Essential Principle 1 - Use of medical devices not to compromise health and safety ...............8
Essential Principle 1 - Comments.....................................................................................................8

Essential Principle 2 - Design and construction of medical devices to conform with safety principles ............................................................................................................................9
Essential Principle 2 - Comments....................................................................................................9

Essential Principle 3 - Medical devices to be suitable for intended purpose.............................10
Essential Principle 3 - Comments..................................................................................................10

Essential Principle 4 – Long term safety .......................................................................................11
Essential Principle 4 – Comments................................................................................................11

Essential Principle 5 – Medical devices not to be adversely affected by transport or storage ....11
Essential Principle 5 – Comments................................................................................................11

Essential Principle 6 – Benefits of medical devices to outweigh any side effects .....................12
Essential Principle 6 – Comments................................................................................................12

Part 2 Principles about design and construction.................................................................................13

Essential Principle 7 – Chemical, physical and biological properties .........................................13
Essential Principle 7.1 – Choice of materials..................................................................................13
Essential Principle 7.1 - Comments ................................................................................................13

Essential Principle 7.2 - Minimisation of risks associated with contaminants and residues ..........13
Essential Principle 7.2 - Comments ................................................................................................13

Essential Principle 7.3 - Ability to be used safely with materials, etc ...........................................14
Essential Principle 7.3 - Comments ................................................................................................14

Essential Principle 7.4 - Verification of incorporated substance ...................................................15
Essential Principle 7.4 – Comments................................................................................................15

Essential Principle 7.5 - Minimisation of risks associated with leaching substances ...................15
Essential Principle 7.6 - Minimisation of risks associated with ingress or egress of substances .15
Essential Principle 7.6 - Comments ................................................................................................15

Essential Principle 8 - Infection and microbial contamination ......................................................16
Essential Principle 8.1 - Minimisation of risk of infection and contamination ..............................16
Essential Principle 8.1 - Comments ................................................................................................16

Essential Principle 8.2 - Control of animal, bacterial or recombinant tissues, cells and other substances ................................................................................................................................16
Essential Principle 8.2 - Comments ................................................................................................16

Essential Principle 8.3 - Medical devices to be supplied in a sterile state .....................................17
Essential Principle 8.3 - Comments ................................................................................................17

Essential Principle 8.4 - Medical devices to be supplied in a non-sterile state .............................17
Essential Principle 8.4 - Comments ................................................................................................17
Essential Principle 8.5 - Distinction between medical devices supplied in sterile and non-sterile state

Essential Principle 8.5 - Comments

Essential Principle 9 - Construction and environmental properties

Essential Principle 9.1 - Medical devices intended to be used in combination with other devices or equipment

Essential Principle 9.1 - Comments

Essential Principle 9.2 - Minimisation of risks associated with use of medical devices

Essential Principle 9.2 - Comments

Essential Principle 10 - Medical devices with a measuring function

Essential Principle 10 - Comments

Essential Principle 11 - Protection against radiation

Essential Principle 11.1 - Minimisation of exposure to radiation

Essential Principle 11.1 - Comments

Essential Principle 11.2 - Medical devices intended to emit radiation

Essential Principle 11.2 - Comments

Essential Principle 11.3 - Minimisation of exposure to unintended radiation

Essential Principle 11.3 - Comments

Essential Principle 11.4 - Operating instructions

Essential Principle 11.4 - Comments

Essential Principle 11.5 - Medical devices intended to emit ionising radiation – additional requirements

Essential Principle 11.5 - Comments

Essential Principle 12 - Medical devices connected to or equipped with an energy source

Essential Principle 12.1 - Medical devices incorporating electronic programmable systems

Essential Principle 12.1 - Comments

Essential Principle 12.2 - Safety dependent on internal power supply

Essential Principle 12.2 - Comments

Essential Principle 12.3 - Safety dependent on external power supply

Essential Principle 12.3 - Comments

Essential Principle 12.4 - Medical devices intended to monitor clinical parameters

Essential Principle 12.4 - Comments

Essential Principle 12.5 - Minimisation of risk of electromagnetic fields

Essential Principle 12.5 - Comments

Essential Principle 12.6 - Protection against electrical risks

Essential Principle 12.6 - Comments

Essential Principle 12.7 - Protection against mechanical risks

Essential Principle 12.7 - Comments

Essential Principle 12.8 - Protection against risks associated with vibration

Essential Principle 12.8 - Comments

Essential Principle 12.9 - Protection against risks associated with noise

Essential Principle 12.9 - Comments

Essential Principle 12.10 - Protection against risks associated with terminals and connectors

Essential Principle 12.10 - Comments

Essential Principle 12.11 - Protection against risks associated with heat

Essential Principle 12.11 - Comments

Essential Principle 12.12 - Protection against risks associated with administration of energy or substances

Essential Principle 12.12 - Comments

Essential Principle 12.13 - Active implantable medical devices

Essential Principle 12.13 - Comments
INTRODUCTION

This guidance document is one of a series that has been produced to help explain the new regulatory system for medical devices in Australia that commenced on 4 October 2002. The new system has been established by the Therapeutic Goods Act, 1989 (the Act) as amended by the Therapeutic Goods Amendment (Medical Devices) Bill, 2002 and the Therapeutic Goods (Medical Devices) Regulations, 2002.

Many other guidance documents are available in this series. The series was developed to assist a wide-ranging audience and additional documents can be included if there is enough demand. A separate guidance document is available describing the series.

Although each guidance document has been developed to provide information about particular aspects of the new medical devices regulatory system in Australia, it is expected that a certain amount of cross-referencing to other documents in the series will be inevitable.

“The essential principles set out the requirements relating to the safety and performance characteristics of medical devices. Compliance with applicable medical device standards is not mandatory, but it is one way to establish compliance with essential principles.” (section 41C of the Act)

The essential principles may define results to be achieved, performance levels, hazards to be addressed, or issues to be considered, for example, but do not necessarily specify how the principles can be satisfied or complied with. This provides flexibility for manufacturers and caters for technological advances and changes in the application of medical devices.

The essential principles can be divided into two main types:

- general principles - which always apply to all medical devices; and
- particular principles - which only apply to some medical devices.

It should be noted that both the general principles and the relevant particular principles have to be met in order to meet the requirements of the essential principles for all medical devices. Compliance with only the relevant particular principles does not ensure compliance with the general principles.

It is the manufacturer’s responsibility to demonstrate compliance with the essential principles for their medical devices.

Information provided by the manufacturer or the sponsor of a medical device is part of the essential principles. This requirement is also discussed in Guidance Document Number 20, Obligations of Sponsors and Manufacturers.
### PART 1 GENERAL PRINCIPLES

#### Essential Principle 1 - 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:

(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

(b) any risks associated with the use of the device are:

(i) acceptable risks when weighed against the intended benefit to the patient; and

(ii) compatible with a high level of protection of health and safety.

#### Essential Principle 1 - Comments

A fundamental concept in the design and production of a medical device is how the device is to be intended to be safely used, and by whom. A manufacturer is required to undertake a well-reasoned and documented analysis of the foreseeable risks which could occur by using the device and compare these with a well-reasoned and documented analysis of the benefits that would be provided for the patient or user of the medical device. These analyses have to recognise that a patient or user’s safety is paramount.

The analyses undertaken by the manufacturer could involve, but are not necessarily restricted to:

(i) Documenting a review of the design briefs or design solutions and compare these with the design specifications for the medical device. This would also include a well-reasoned risk assessment. It is also important to regularly update the risk analysis of the device to account for changes in knowledge or advances in the field to ensure that the medical device continues to function within an acceptably safe operating envelope.

(ii) Documenting a review of relevant published literature as well as including details of the manufacturer’s own experience with the medical device.

(iii) Assessing and documenting the compliance of the product and its packaging to specifications and standards.

(iv) Reviewing and documenting the labelling for the medical device as well as the instructions for use, if this is appropriate.

(v) Reviewing and documenting the final release procedures of the medical device prior to supply.

A manufacturer of a medical device that was designed, produced and supplied before the implementation of the revised regulatory system should undertake a well-reasoned and documented assessment of the points above and determine their relevance to the products in question when compared with the time the product has been supplied.
Essential Principle 2 - Design and construction of medical devices to conform with safety principles

(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.

(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:
   (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
   (b) second, eliminate, or reduce, these risks as far as possible by adopting a policy of inherently safe design and construction; and
   (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
   (d) fourth, inform users of any residual risks that may arise due to any shortcomings of the protection measures adopted.

Essential Principle 2 - Comments

The design and construction processes for a medical device need to take account of any foreseeable risks or hazards that may exist for, or could be created by, the device when used as intended. The ultimate design and construction of the device should, wherever possible and feasible, eliminate the identified risks or hazards or have methods established to alert and inform users of the medical device if risks or hazards could remain.

As for essential principle 1, a well-reasoned and documented risk analysis should be developed to demonstrate compliance with essential principle 2. It is also important to regularly update the risk analysis of the device to account for changes in knowledge or advances in the field to ensure that the design and construction of the medical device continue to conform with safety principles.

A manufacturer of a medical device that was designed, produced and supplied before the implementation of the revised regulatory system should undertake a well-reasoned and documented risk analysis and assess the outcomes of that analysis against their experiences gained from the supplied device.
Essential Principle 3 - Medical devices to be suitable for intended purpose

A medical device must:

(a) perform in the way intended by the manufacturer; and

(b) be designed, produced and packaged in a way that ensures that it is suitable for one or more of the purposes mentioned in the definition of medical device in subsection 41BD(1) of the Act.

Essential Principle 3 – Comments

The manufacturer of a medical device must have evidence, as demonstrated by appropriate test protocols, that the device performs as intended and is designed, produced, and packaged in a way that is consistent with the functions or purposes in the definition of a medical device below (section 41BD(1) of the Act) ie

“(a) any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following:

(i) diagnosis, prevention, monitoring, treatment or alleviation of disease;

(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;

(iii) investigation, replacement or modification of the anatomy or of a physiological process;

(iv) control of conception;

and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means; or

(b) an accessory to such an instrument, apparatus, appliance, material or other article.”

Where the manufacturer is operating an appropriate and certified quality system, this essential principle will be partly addressed by that certification.
Essential Principle 4 – Long term safety

A medical device must be designed and produced in a way that ensures that if:
(a) the device is used within the period, indicated by the manufacturer, in which the device can be safely used; and
(b) the device is not subjected to stresses that are outside the stresses that can occur during normal conditions of use; and
(c) the device is regularly maintained and calibrated in accordance with the manufacturer’s instructions;
the characteristics and performances mentioned in clauses 1, 2 and 3 are not adversely affected.

Essential Principle 4 – Comments

The manufacturer needs to have evidence that the design and production practices used for their medical device have taken into account:
- the expected lifetime of the device,
- identified stresses experienced by the medical device during normal use, and
- any regular maintenance and calibration requirements,
so that the device continues to comply with essential principles 1, 2 and 3.

Any adverse effects of these stresses must be considered and included in a well-reasoned and documented risk assessment.

The lifetime of a device is considered to include the period prior to first use, and the period (or number of uses) expected or recommended by the manufacturer. Assessment of this can be done by bench testing, simulated shelf life testing and clinical evaluation.

A documented review of complaint history would be used for products supplied before the introduction of the revised regulatory requirements.

Essential Principle 5 – Medical devices not to be adversely affected by transport or storage

A medical device must be designed, produced and packed in a way that ensures that the characteristics and performance of the device when it is being used for its intended purpose will not be adversely affected during transport and storage that is carried out taking account of the instructions and information provided by the manufacturer.

Essential Principle 5 – Comments

The manufacturer needs to have evidence that the design, production and packaging practices used for their medical device can ensure that the device maintains its characteristics and can still perform as intended when the device is transported or stored according to the manufacturer’s instructions or other information provided by them.

A documented review of complaint history would be used for products supplied before the introduction of the revised regulatory requirements.
<table>
<thead>
<tr>
<th>Essential Principle 6 – Benefits of medical devices to outweigh any side effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>The benefits to be gained from the use of a medical device for the performance intended by the manufacturer must outweigh any undesirable side effects from its use.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Essential Principle 6 – Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>To comply with this essential principle it is necessary, as part of a well-reasoned risk analysis, to identify and document any undesirable side effects and compare these with the benefits expected to be achieved through the use of the medical device. Manufacturers should also provide evidence that the outcomes or conclusions of the risk analysis have been acted on.</td>
</tr>
<tr>
<td>For devices that were being supplied prior to the implementation of the revised regulatory system, it is expected that the manufacturer would develop a reasoned and documented analysis comparing any undesirable side effects with the benefits gained from using the medical device which was based on their experience with the device in use.</td>
</tr>
</tbody>
</table>
Essential Principle 7 – Chemical, physical and biological properties

Essential Principle 7.1 – Choice of materials

In ensuring that the requirements of Part 1 are met in relation to a medical device, particular attention must be given to:
(a) the chemical and physical properties of the materials used and
(b) the compatibility between the materials used and biological tissues, cells and body fluids; having regard to the intended purpose of the device.

Essential Principle 7.1 - Comments

A manufacturer must be able to demonstrate that the materials used in the medical device are appropriate, given the intended purpose of the device. For example, a well-reasoned risk analysis should consider toxicity, flammability and biocompatibility risks, and examine if particular labelling or instructions could mitigate any residual risks.

Historical data on materials used in similar devices should be reviewed and included in the documented analysis.

A biological safety evaluation, based on relevant standards, should be made. It may be possible to limit any testing by considering the results of previous and relevant tests on the same or similar materials used in the same or similar applications.

Essential Principle 7.2 - Minimisation of risks associated with contaminants and residues

(1) A medical device must be designed, produced and packed in a way that ensures that any risks associated with contaminants and residues that may affect a person who is involved in transporting, storing or using the device, or a patient, are minimised, having regard to the intended purpose of the device.

(2) In minimising risks, particular consideration must be given to the likely duration and frequency of any tissue exposure associated with the transportation, storage or use of the device.

Essential Principle 7.2 - Comments

The design, production and packaging processes should take into account the outcomes or conclusions from a well-reasoned and documented risk analysis that has identified and analysed the significance of any foreseeable contaminants and residues that may affect anyone coming in contact with the device during transportation, storage or use. The contaminants and residues could include solvents, process and sterilisation residues, mould release agents, particulate contamination and fluid spillage. It may be necessary to use particular labelling or instructions supplied with the device to reduce or mitigate some risks if they cannot be eliminated.
### Essential Principle 7.3 - Ability to be used safely with materials, etc

1. A medical device must be designed and produced in a way that ensures that the device can be used safely with any material, substance or gas with which the device may come into contact during normal use or use in routine procedures.

2. If the device is intended to be used to administer medicine, it must be designed and produced in a way that ensures that the device:
   - (a) is compatible with the provisions and restrictions applying to the medicine to be administered;
   - (b) allows the medicine to perform as intended.

### Essential Principle 7.3 - Comments

The design, production and packaging processes should take into account the outcomes or conclusions from a well-reasoned and documented risk analysis that has identified and analysed the significance of any foreseeable interactions with materials, substances and gases arising from the intended use of the medical device. This analysis should also consider any specified materials that may be required to clean, disinfect or sterilise the medical device, as well as the effects of these materials during these procedures.

It may be necessary to use particular labelling or instructions supplied with the device to reduce or mitigate some risks associated with the interactions of these materials, substances or gases with the device.

Warnings are required if it is foreseeable that an interaction between the device and incompatible materials could occur. These warnings should be included in the labelling or instructions included with the device.

If the device is intended to administer medicine, the design, production and packaging processes should take into account any provisions or restrictions for the medicine as well as ensuring that the medicine can perform as intended.
**Essential Principle 7.4 - Verification of incorporated substance**

(1) If a medical device incorporates, as an integral part, a substance that, if used separately, might be considered to be a medicine that is intended to act on a patient in a way that is ancillary to the device:
   (a) the safety and quality of the substance must be verified in accordance with the requirements for medicines; and
   (b) the ancillary action of the substance must be verified having regard to the intended purpose of the device.

(2) For the purposes of this clause, any stable derivative of human blood or human plasma is considered to be a medicine.

**Essential Principle 7.4 – Comments**

A manufacturer of a medical device containing, as an integral part of the medical device, a medicine that acts on a patient in a subordinate or secondary way to the device’s intended purpose, must verify this relationship. In addition, the manufacturer will need to verify that the medicine meets all necessary regulatory requirements to be supplied as a medicine.

**Essential Principle 7.5 - Minimisation of risks associated with leaching substances**

A medical device must be designed and produced in a way that ensures that any risks associated with substances that may leach from the device are minimised.

**Essential Principle 7.5 - Comments**

The design and production processes should take into account the outcomes or conclusions from a well-reasoned and documented risk analysis that has identified and analysed the significance of any foreseeable effects of a substance which could leach from a medical device and the effects it could have on patients and other people.

**Essential Principle 7.6 - Minimisation of risks associated with ingress or egress of substances**

A medical device must be designed and produced in a way that ensures that any risks associated with unintentional ingress of substances into, or unintentional egress of substances out of, the device are minimised, having regard to the nature of the environment in which the device is intended to be used.

**Essential Principle 7.6 - Comments**

The design and production processes should take into account the outcomes or conclusions from a well-reasoned and documented risk analysis that has identified and analysed the significance of any foreseeable risks created by substances leaking from or into a medical device. Evidence of appropriate bench testing or clinical evaluation to confirm the design and production decisions resulting from the risk analysis should be provided.
Essential Principle 8 - Infection and microbial contamination

**Essential Principle 8.1 - Minimisation of risk of infection and contamination**

(1) A medical device must be designed and produced in a way that ensures the risk of infection to a patient, a user or any other person, is eliminated or minimised.

(2) The device must be designed in a way that:
   (a) allows it to be easily handled; and
   (b) if appropriate, minimises contamination of the device by the patient, or contamination of the patient by the device, during use.

**Essential Principle 8.1 - Comments**

The design and production processes should take account of the outcomes or conclusions from a well-reasoned and documented risk analysis that has identified and analysed the significance of any foreseeable risks of infections for patients and other people when the device is used. For example, sterilisation validation reports, bioburden data and the control of tissues of animal origin would be considered as acceptable supporting evidence of compliance with this essential principle.

**Essential Principle 8.2 - Control of animal, bacterial or recombinant tissues, cells and other substances**

(1) This clause applies in relation to a medical device that contains:
   (a) tissues, cells or substances of animal origin that have been rendered non-viable; and
   (b) tissues, cells or substances of microbial or recombinant origin.

(2) If the tissues, cells or substances originated from animals, the animals must have been subjected to appropriate veterinary controls and supervision, having regard to the intended use of the tissues, cells or substances.

(3) If the medical device contains tissues, cells or substances of animal origin, a record must be kept of the country of origin of each animal from which the tissues, cells or substances originated.

(4) The processing, preservation, testing and handling of tissues, cells or substances of animal, microbial or recombinant origin must be carried out in a way that ensures the highest standards of safety for a patient, the user of the device, and any other person.

(5) In particular, the production process must implement validated methods of elimination, or inactivation, in relation to viruses and other transmissible agents.

**Essential Principle 8.2 - Comments**

This essential principle establishes the need for various controls, supervisory procedures, records and processing requirements for medical devices that contain tissues, cells or substances of animal origin that have been rendered non-viable, and tissues, cells or substances of microbial or recombinant origin.
Essential Principle 8.3 - Medical devices to be supplied in a sterile state

(1) This clause applies in relation to a medical device that is intended by the manufacturer to be supplied in a sterile state.
(2) The device must be designed, produced and packed in a way that ensures that the device is sterile when it is supplied, and will remain sterile, if stored and transported in accordance with the directions of the manufacturer, until the protective packaging is opened or damaged.
(3) The device must be produced and sterilised using an appropriate validated method.
(4) The device must be produced in appropriately controlled conditions.

Essential Principle 8.3 - Comments

This essential principle establishes particular design, production and packaging requirements for medical devices intended to be supplied in a sterile condition.

Essential Principle 8.4 - Medical devices to be supplied in a non-sterile state

(1) A medical device that is intended by the manufacturer to be supplied in a non-sterile state must be packed in a way that ensures that the device maintains the level of cleanliness stipulated by the manufacturer.
(2) If the device is intended to be sterilised before it is used, the device must be packed in a way that:
   (a) ensures that the risk of microbial contamination is minimised; and
   (b) is suitable, having regard to the method of sterilisation that the manufacturer indicates is to be used for the device.
(3) The device must be produced in appropriately controlled conditions.

Essential Principle 8.4 - Comments

This essential principle establishes particular production and packaging requirements for medical devices intended to be supplied in a non-sterile condition. In addition, for medical devices intended to be sterilised before use, it also requires that a well-reasoned and documented risk analysis has analysed any foreseeable risks of microbial contamination and taken account of these risks through the use of adequate and appropriate packaging procedures.

Essential Principle 8.5 - Distinction between medical devices supplied in sterile and non-sterile state

If a medical device is supplied in both a sterile state and a non-sterile state, the information provided with the device must clearly indicate whether the device is in a sterile state or a non-sterile state.

Essential Principle 8.5 - Comments

This essential principle requires that a manufacturer clearly labels their medical devices as “STERILE” or “NON-STERILE” if they produce the device in both sterility conditions.
### Essential Principle 9 - Construction and environmental properties

<table>
<thead>
<tr>
<th>Essential Principle 9.1 - Medical devices intended to be used in combination with other devices or equipment</th>
</tr>
</thead>
<tbody>
<tr>
<td>A medical device that is intended by the manufacturer to be used in combination with another medical device or other equipment (including a connection system) must be designed and produced in a way that ensures that:</td>
</tr>
<tr>
<td>(a) the medical device, and any other device or equipment with which it is used, operate in a safe way; and</td>
</tr>
<tr>
<td>(b) the intended performance of the device, and any other device or equipment with which it is used, is not impaired.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Essential Principle 9.1 - Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>This essential principle requires that if medical devices are intended to be used with other medical devices, evidence needs to be provided that the combination of the devices still allows all the medical devices to be operated safely and without any impairment to the intended performance of any of the medical devices. This can be demonstrated through appropriate testing procedures.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Essential Principle 9.2 - Minimisation of risks associated with use of medical devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>A medical device must be designed and produced in a way that ensures that, as far as practicable, the following risks are removed or minimised:</td>
</tr>
<tr>
<td>(a) the risk of injury arising from the physical features of the device;</td>
</tr>
<tr>
<td>(b) any risks associated with reasonably foreseeable environmental conditions;</td>
</tr>
<tr>
<td>(c) the risk of reciprocal interference involving other devices that are normally used in an investigation or treatment of the kind for which the device is intended to be used;</td>
</tr>
<tr>
<td>(d) any risks arising if maintenance or calibration of the device is not possible;</td>
</tr>
<tr>
<td>(e) any risks associated with the ageing of materials used in the device;</td>
</tr>
<tr>
<td>(f) any risks associated with the loss of accuracy of any measuring or control mechanism of the device;</td>
</tr>
<tr>
<td>(g) the risk of fire or explosion occurring during normal use of the device, and in the event of a single fault condition, especially if the device is intended to be exposed to flammable substances or substances that can cause combustion.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Essential Principle 9.2 – Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>The design and production processes should take account of the outcomes or conclusions from a well-reasoned and documented risk analysis that has identified and analysed the significance of any of the listed foreseeable risks when the device is used.</td>
</tr>
</tbody>
</table>
### Essential Principle 10 - Medical devices with a measuring function

1. A medical device that has a measuring function must be designed and produced in a way that ensures that the device provides accurate, precise and stable measurements within the limits indicated by the manufacturer and having regard to the intended purpose of the device.

2. The measurement, monitoring and display scale of the device must be designed and produced in accordance with ergonomic principles, having regard to the intended purpose of the device.

3. The measurements made by the device must be expressed:
   
   a. in Australian legal units of measurement; or
   
   b. if the device measures a physical quantity for which no Australian legal unit of measurement has been prescribed under the *National Measurement Act 1960*, in units approved by the Secretary for the particular device.

### Essential Principle 10 - Comments

This essential principle requires that the medical device must be designed and produced in a way that ensures that the manufacturer’s specifications for accuracy, precision and stability are met. It also requires that the specifications for accuracy and stability be justified in the technical documentation for the medical device.

Ergonomic principles concerned with how a user of the device interprets the outputs from the device and uses the device must be incorporated in the design and production processes for the device.

The measurement outputs have to be in legal or, if not legal in Australia, in approved units.
**Essential Principle 11 - Protection against radiation**

<table>
<thead>
<tr>
<th>Essential Principle 11.1 - Minimisation of exposure to radiation</th>
</tr>
</thead>
<tbody>
<tr>
<td>A medical device must be designed and produced in a way that ensures that the exposure of a patient, the user, or any other person, to radiation is minimised, having regard to the levels of radiation required to enable the device to perform its therapeutic and diagnostic functions and the intended purpose of the device.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Essential Principle 11.1 - Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>This essential principle is intended to cover all forms of radiation.</td>
</tr>
</tbody>
</table>

The design and production processes should take account of the outcomes or conclusions from a well-reasoned and documented risk analysis that has identified and analysed the significance of any foreseeable risks of exposure to any form of radiation for patients and other people when the device is used. Evidence of appropriate testing to confirm the design and production decisions resulting from the risk analysis should be provided.

<table>
<thead>
<tr>
<th>Essential Principle 11.2 - Medical devices intended to emit radiation</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) This clause applies in relation to a medical device that is intended by a manufacturer to emit hazardous levels of visible or invisible radiation because the emission is necessary for a specific medical purpose, the benefit of which is considered to outweigh the risks inherent in the emission.</td>
</tr>
<tr>
<td>(2) The device must be designed and produced in a way that ensures that the user can control the level of the emission.</td>
</tr>
<tr>
<td>(3) The device must be designed and produced in a way that ensures the reproducibility and tolerance of relevant variable parameters.</td>
</tr>
<tr>
<td>(4) If practicable, the device must be fitted with a visual indicator or an audible warning, or both, that operates if potentially hazardous levels of radiation are emitted.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Essential Principle 11.2 - Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>The design and production processes should take account of the outcomes or conclusions from a well-reasoned and documented risk analysis that has identified and analysed the significance of any foreseeable risks of exposure to radiation intentionally emitted from a medical device. This includes ensuring that appropriate control and indicator mechanisms have been incorporated in the device as well as ensuring the operational consistency of variable parameters relevant to the emission of the radiation and the operation of the device.</td>
</tr>
</tbody>
</table>

Evidence of appropriate testing to confirm the design and production decisions resulting from the risk analysis should be provided.
## Essential Principle 11.3 - Minimisation of exposure to unintended radiation

A medical device must be designed and produced in a way that ensures that the exposure of a patient, the user, or any other person, to the emission of unintended, stray or scattered radiation is minimised.

### Essential Principle 11.3 – Comments

The design and production processes should take account of the outcomes or conclusions from a well-reasoned and documented risk analysis that has identified and analysed the significance of any foreseeable risks of exposure to any unintended emissions of radiation for patients and other people when the device is used. Evidence of appropriate testing to confirm the design and production decisions resulting from the risk analysis should be provided.

## Essential Principle 11.4 - Operating instructions

The operating instructions for a medical device that emits radiation must include detailed information about the following matters:

(a) the nature of the radiation emitted;
(b) the means by which patients and users can be protected from the radiation;
(c) ways to avoid misusing the device;
(d) ways to eliminate any risks inherent in the installation of the device.

### Essential Principle 11.4 – Comments

A well-reasoned and documented risk analysis is expected to identify and analyse the significance of any foreseeable risks associated with the use of a medical device designed to emit radiation. As a result of the risk analysis, the operating instructions for the device must include particular information about the emitted radiation, appropriate protection measures, foreseeable misuse of the device and eliminating foreseeable risks arising from the installation of the device.
Essential Principle 11.5 - Medical devices intended to emit ionising radiation – additional requirements

(1) This clause applies, in addition to clauses 11.1 to 11.4, in relation to a medical device that is intended by the manufacturer to emit ionising radiation.

(2) The device must be designed and produced in a way that ensures that, if practicable, the quantity, geometry and energy distribution (or quality) of radiation emitted can be controlled and varied, having regard to the intended purpose of the device.

(3) If the device is intended to be used for diagnostic radiology, the device must be designed and produced in a way that ensures that, when used in relation to a patient for a purpose intended by the manufacturer;
   (a) the device achieves an appropriate image or output quality for that purpose; and
   (b) the exposure of the patient, or the user, to radiation is minimised.

(4) If the device is intended to be used for therapeutic radiology, the device must be designed and produced in a way that ensures that the delivered dose of radiation, the type and energy of the radiation beam, and, if appropriate, the energy distribution of the radiation beam, can be reliably controlled and monitored.

Essential Principle 11.5 – Comments

In addition to complying with other essential principles, the design and production processes should also take account of the outcomes or conclusions from a well-reasoned and documented risk analysis that has identified and analysed the significance of particular foreseeable issues and risks relating to the emission of ionising radiation by medical devices. Evidence of appropriate testing to confirm the design and production decisions resulting from the risk analysis should be provided.
Essential Principle 12 - Medical devices connected to or equipped with an energy source

Essential Principle 12.1 - Medical devices incorporating electronic programmable systems

A medical device that incorporates an electronic programmable system must be designed and produced in a way that ensures that:
(a) the performance, reliability, and repeatability of the system are appropriate for the intended purpose of the device; and
(b) any consequent risks associated with a single fault condition in the system are minimised.

Essential Principle 12.1 – Comments

The design and production processes for a medical device incorporating electronic programmable systems should take account of the outcomes or conclusions from a well-reasoned and documented risk analysis that has identified and analysed the significance of any foreseeable risks relating to the consistent operation of the device and particular risks. Evidence of appropriate testing to confirm the design and production decisions resulting from the risk analysis should be provided.

Essential Principle 12.2 - Safety dependent on internal power supply

(1) This clause applies in relation to a medical device if the safety of a patient on whom the device is to be used will depend on an internal power supply for the device.
(2) The device must be fitted with a means of determining the state of the power supply.

Essential Principle 12.2 - Comments

This essential principle requires a device to be fitted with means of determining the state of internal power supplies.

Essential Principle 12.3 - Safety dependent on external power supply

(1) This clause applies in relation to a medical device if the safety of a patient on whom the device is to be used will depend on an external power supply for the device.
(2) The device must be fitted with an alarm system that indicates whether a power failure has occurred.

Essential Principle 12.3 - Comments

This essential principle requires a device to be fitted with a power failure alarm if an external power supply is required.
**Essential Principle 12.4 - Medical devices intended to monitor clinical parameters**

A medical device that is intended by the manufacturer to be used to monitor one or more clinical parameters of a patient must be fitted with an appropriate alarm system to warn the user if a situation has developed that could lead to the death of the patient or a severe deterioration in the state of the patient’s health.

**Essential Principle 12.4 - Comments**

This essential principle requires that particular medical devices be fitted with appropriate critical alarm systems.

---

**Essential Principle 12.5 - Minimisation of risk of electromagnetic fields**

A medical device must be designed and produced in a way that ensures that the risk of an electromagnetic field being created that could impair the operation of other devices or equipment being used in the vicinity of the medical device is minimised.

**Essential Principle 12.5 - Comments**

The design and production processes for a medical device should take account of the outcomes or conclusions from a well-reasoned and documented risk analysis that has identified and analysed the significance of any foreseeable risks relating to the effects of electromagnetic fields on other equipment or devices. Evidence of appropriate testing to confirm the design and production decisions resulting from the risk analysis should be provided.

---

**Essential Principle 12.6 - Protection against electrical risks**

A medical device must be designed and produced in a way that ensures that, as far as possible, when the device is installed correctly, and the device is being used for an intended purpose under normal conditions of use and in the event of a single fault condition, patients, users, and any other persons, are protected against the risk of accidental electric shock.

**Essential Principle 12.6 - Comments**

The design and production processes for a medical device should take account of the outcomes or conclusions from a well-reasoned and documented risk analysis that has identified and analysed the significance of any foreseeable risks to patients, users and other people from accidental electric shocks resulting from single fault conditions occurring during normal use. Evidence of appropriate testing to confirm the design and production decisions resulting from the risk analysis should be provided.
**Essential Principle 12.7 Protection against mechanical risks**

A medical device must be designed and produced in a way that ensures that a patient, the user and any other person, is protected against any mechanical risks associated with the use of the device.

**Essential Principle 12.7 - Comments**

The design and production processes for a medical device should take account of the outcomes or conclusions from a well-reasoned and documented risk analysis that has identified and analysed the significance of any foreseeable mechanical risks to patients, users and other people when the device is used as intended. Evidence of appropriate testing to confirm the design and production decisions resulting from the risk analysis should be provided.

**Essential Principle 12.8 - Protection against risks associated with vibration**

1. A medical device must be designed and produced in a way that ensures that any risks associated with vibrations generated by the device are minimised.
2. If vibrations are not part of the intended performance of the device, particular attention must be given to relevant technical progress, and the available means, for limiting vibrations, particularly at source.

**Essential Principle 12.8 - Comments**

The design and production processes for a medical device should take account of the outcomes or conclusions from a well-reasoned and documented risk analysis that has identified and analysed the significance of any foreseeable vibrations, either intentional or unintentional. Evidence of appropriate testing to confirm the design and production decisions resulting from the risk analysis should be provided.

**Essential Principle 12.9 - Protection against risks associated with noise**

1. A medical device must be designed and produced in a way that ensures that any risks associated with noise emitted by the device are minimised.
2. If noise is not part of the intended performance of the device, particular attention must be given to relevant technical progress, and the available means, for reducing the emission of noise, particularly at source.

**Essential Principle 12.9 - Comments**

The design and production processes for a medical device should take account of the outcomes or conclusions from a well-reasoned and documented risk analysis that has identified and analysed the significance of any foreseeable noise emitted by the device, either intentional or unintentional. Evidence of appropriate testing to confirm the design and production decisions resulting from the risk analysis should be provided.
**Essential Principle 12.10 - Protection against risks associated with terminals and connectors**

A medical device that is intended by the manufacturer to be connected to an electric, gas, hydraulic, pneumatic or other energy supply must be designed and produced in a way that ensures that any risks to the user associated with the handling of a terminal or connector on the device, in relation to the energy supply, are minimised.

**Essential Principle 12.10 - Comments**

For particular medical devices, the design and production processes should take account of the outcomes or conclusions from a well-reasoned and documented risk analysis that has identified and analysed the significance of any foreseeable risks associated with the connection to energy supplies. Evidence of appropriate testing to confirm the design and production decisions resulting from the risk analysis should be provided.

**Essential Principle 12.11 - Protection against risks associated with heat**

A medical device must be designed and produced in a way that ensures that, during normal use, any accessible part of the device (other than any part intended by the manufacturer to supply heat or reach a given temperature), and any area surrounding an accessible part of the device, does not reach a potentially dangerous temperature.

**Essential Principle 12.11 - Comments**

The design and production processes for certain medical devices should take account of the outcomes or conclusions from a well-reasoned and documented risk analysis that has identified and analysed the significance of any foreseeable risks associated with heat produced by the device. Evidence of appropriate testing to confirm the design and production decisions resulting from the risk analysis should be provided.
Essential Principle 12.12 - Protection against risks associated with administration of energy or substances

(1) This clause applies in relation to a medical device that is intended by the manufacturer to be used to administer energy or a substance to a patient.

(2) The device must be designed and produced in a way that ensures that:
   (a) the delivered rate and amount of energy, or of the substance, can be set and maintained accurately to ensure the safety of the patient and the user; and
   (b) as far as possible, the accidental release of dangerous levels of energy or of the substance is prevented.

(3) The device must be fitted with a means of indicating or, if appropriate, preventing inadequacies in the rate and amount of energy, or of the substance, administered that might cause danger to the patient, the user or any other person.

(4) The functions of each control and indicator on the device must be clearly specified on the device.

(5) If the instructions for the operation of the device, or the operating or adjustment parameters for the device, are displayed by means of a visual system incorporated into the device, the instructions or parameters must be able to be understood by the user and, if appropriate, the patient.

Essential Principle 12.12 - Comments

The design and production processes for certain medical devices should take account of the outcomes or conclusions from a well-reasoned and documented risk analysis that has identified and analysed the significance of any foreseeable risks associated with the control and delivery of energy or substances to patients or users. This also includes the requirement to ensure that operational information displayed by the device is clearly understandable. Evidence of appropriate testing to confirm the design and production decisions resulting from the risk analysis should be provided.

Essential Principle 12.13 - Active implantable medical devices

(1) An active implantable medical device must display a code that can be used to identify:
   (a) the type of device; and
   (b) the manufacturer of the device; and
   (c) the year of manufacture of the device.

(2) the code must be able to be read without the need for surgery to the person in whom the device is implanted.

Essential Principle 12.13 - Comments

This essential principle requires that certain information can be ascertained about an active implantable medical device.
## Essential Principle 13 - Information to be provided with medical devices

### Essential Principle 13.1 - Information to be provided with medical devices – general

1. The following information must be provided with a medical device:
   - (a) information identifying the device;
   - (b) information identifying the manufacturer of the device;
   - (c) information explaining how to use the device safely, having regard to the training and knowledge of potential users of the device.

2. In particular:
   - (a) the information required by clause 13.3 must be provided with a medical device; and
   - (b) if instructions for use of the device are required under subclause 13.4, the information mentioned in subclause 13.4(3) must be provided in those instructions.

3. The information:
   - (a) must be provided in English; and
   - (b) may also be provided in any other language.

4. The format, content and location of the information must be appropriate for the device and its intended purpose.

5. Any number, letter, symbol, or letter or number in a symbol, used in the information must be legible and at least 1 millimetre high.

6. If a symbol or identification colour that is not included in a medical device standard is used in the information provided with the device, or in the instructions for use of the device, the meaning of the symbol or identification colour must be explained in the information provided with the device or the instructions for use of the device.

### Essential Principle 13.1 – Comments

This essential principle establishes the general requirements for information to be provided with a medical device.
## Essential Principle 13.2 - Information to be provided with medical devices – location

1. Unless it is impracticable and inappropriate to do so, the information required to be provided with a medical device must be provided on the device itself.

2. If it is not practicable to comply with subclause (1) in relation to the provision of the information, the information must be provided:
   (a) on the packaging used for the device; or
   (b) in the case of devices that are packaged together because individual packaging of the devices is not practicable – on the outer packaging used for the devices.

3. If it is not practicable to comply with subclause (1) or (2) in relation to the provision of the information under clause 13.3, the information must be provided on a leaflet supplied with the device.

4. If it is not practicable to comply with subclause (1) or (2) in relation to the provision of the information under clause 13.4, the information must be provided in a printed document or using other appropriate media.

## Essential Principle 13.2 – Comments

This essential principle establishes where information provided with a medical device must be provided.
**Essential Principle 13.3 - Information to be provided with medical devices – requirements**

The information mentioned below must be provided with a medical device.

1. The manufacturer’s name, or trade name, and address
2. The intended purpose of the device, the intended user of the device, and the kind of patient on whom the device is intended to be used (if this information is not obvious)
3. Sufficient information to enable a user to identify the device, or if relevant, the contents of packaging
4. Any particular handling or storage requirements applying to the device
5. Any warnings, restrictions, or precautions that should be taken, in relation to the use of the device
6. Any special operating instructions for the use of the device
7. If applicable, an indication that the device is intended for a single use only
8. If applicable, an indication that the device has been custom-made for a particular individual and is intended for use only by that individual
9. If applicable, an indication that the device is intended to be used only for clinical or performance investigations before being supplied
10. For a sterile device, the word “STERILE” and information about the method that was used to sterilise the device
11. The batch code, lot number or serial number of the device.
12. If applicable, a statement of the date (expressed in a way that clearly identifies the month and year) up to when the device can be safely used
13. If the information provided with the device does not include the information mentioned in item 12 – a statement of the date of manufacture of the device (this may be included in the batch code, lot number or serial number of the device provided the date is clearly identifiable)
14. If applicable, the words “for export only”

**Essential Principle 13.3 - Comments**

This essential principle establishes what information must be provided with a medical device.
Essential Principle 13.4 - Instructions for use

(1) Instructions for the use of a medical device must be provided with the device.

(2) However, instructions for use of a medical device need not be provided with the device, or may be abbreviated, if:
   (a) the device is a Class I medical device or a Class IIa medical device; and
   (b) the device can be used safely for its intended purpose without instructions.

(3) Instructions for the use of a medical device must include information mentioned below that is applicable to the device.
   (1) The manufacturer’s name, or trade name, and address
   (2) The intended purpose of the device, the intended user of the device, and the kind of patient on whom the device is intended to be used
   (3) Information about any risk arising because of other equipment likely to be present when the device is being used for its intended purpose (for example, electrical interference from electro-surgical devices or magnetic field interference from magnetic resonance imaging devices)
   (4) Information about the intended performance of the device and any undesirable side effects caused by use of the device
   (5) Any contra-indications, warnings, restrictions, or precautions that may apply in relation to the use of the device
   (6) Sufficient information to enable a user to identify the device, or if relevant, the contents of the packaging
   (7) Any particular handling or storage requirements applying to the device
   (8) If applicable, an indication that the device is intended for a single use only
   (9) If applicable, an indication that the device has been custom-made for a particular individual and is intended for use only by that individual
   (10) If applicable, an indication that the device is intended to be used only for clinical or performance investigations before being supplied
   (11) For a sterile device, the word “STERILE” and information about the method that was used to sterilise the device
   (12) For a device that is intended by the manufacturer to be supplied in a sterile state:
       (a) an indication that the device is sterile; and
       (b) information about what to do if sterile packaging is damaged and;
       (c) if appropriate, instructions for re-sterilisation of the device
   (13) For a medical device that is intended by the manufacturer to be sterilised before use – instructions for cleaning and sterilising the device which, if followed, will ensure that the device continues to comply with the applicable provisions of the essential principles
   (14) Any special operating instructions for the use of the device
   (15) Information to enable the user to verify whether the device is properly installed and whether it can be operated safely and correctly, including details of calibration (if any) needed to ensure that the device operates properly and safely during its intended life
   (16) Information about the nature and frequency of regular and preventative maintenance of the device, including information about the replacement of consumable components of the device during its intended life
   (17) Information about any treatment or handling needed before the device can be used
(18) 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

(19) For an implantable device – information about any risks associated with its implantation

(20) For a reusable device:
(a) information about the appropriate processes to allow reuse of the device (including information about cleaning, disinfection, packaging, and, if appropriate, resterilisation of the device); and
(b) an indication of the number of times the device may be safely reused

(21) For a medical device that is intended by the manufacturer to emit radiation for medical purposes – details of the nature, type, intensity and distribution of the radiation emitted

(22) Information about precautions that should be taken by a patient and the user if the performance of the device changes

(23) Information about precautions that should be taken by a patient and the user if it is reasonably foreseeable that use of the device will result in the patient or user being exposed to adverse environmental conditions

(24) Adequate information about any medicinal product that the device is designed to administer, including any limitations on the substances that may be administered using the device

(25) 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

(26) Information about precautions that should be taken by a patient and the user if there are special or unusual risks associated with the disposal of the device

(27) Information about the degree of accuracy claimed if the device has a measuring function

(28) Information about any particular facilities required for use of the device or any particular training or qualifications required by the user of the device.

**Essential Principle 13.4 - Comments**

This essential principle establishes what information must be provided in the instructions for use of the medical device.
<table>
<thead>
<tr>
<th><strong>Essential Principle 14 - Clinical Evidence</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Every medical device requires clinical evidence, appropriate for the use and classification of the device, demonstrating that the device complies with the applicable provisions of the essential principles.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Essential Principle 14 – Comments</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>For more information on the clinical evidence requirements please refer to Guidance Document Number 4, Clinical Evidence Requirements for the Inclusion of Medical Devices in the Australian Register of Therapeutic Goods.</td>
</tr>
</tbody>
</table>