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>
</tbody>
</table>
Disclaimer ..............................................................................................................................................2

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

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

Introduction ............................................................................................................................................5

What must be done before an application for inclusion of a medical device is made? .......................5

What does the Act consider to be an application for the inclusion of a medical device on the Australian register of therapeutic goods? ..................................................................................................................5

Which products will be selected for an application audit? .................................................................6

What does an application audit entail? ........................................................................................................7

What additional information will be requested? ....................................................................................8

Level 1 Application Audit .................................................................................................................8

Level 2 Application Audit .................................................................................................................9

General Requirements For The Information to Be Supplied ..............................................................9

Language ..........................................................................................................................................10

Units .................................................................................................................................................10

Text and Drawings ...........................................................................................................................10

Written Information ..........................................................................................................................10

Number of Copies ..............................................................................................................................10

Presentation ......................................................................................................................................10

Pagination .........................................................................................................................................10

Indexing, Cross-referencing and Labelling .....................................................................................10

Timeframe for the provision of information ......................................................................................11

When will an application selected for an application audit lapse? ..................................................11

What happens after the TGA decides to issue a certificate of inclusion? .........................................11

Attachment 1. Applications for inclusion to be selected for audit by the TGA .................................12

Attachment 2. Essential principles checklist ..................................................................................13
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* as amended by the *Therapeutic Goods Amendment (Medical Devices) Bill 2002* (the Act) and the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations).

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.

WHAT MUST BE DONE BEFORE AN APPLICATION FOR INCLUSION OF A MEDICAL DEVICE IS MADE?

A medical device manufacturer has to demonstrate conformity with the Australian essential principles before a sponsor can make an application for inclusion in the ARTG of that device. The manufacturer must follow a conformity assessment procedure appropriate to the class of the medical device.

WHAT DOES THE ACT CONSIDER TO BE AN APPLICATION FOR THE INCLUSION OF A MEDICAL DEVICE ON THE AUSTRALIAN REGISTER OF THERAPEUTIC GOODS?

The Internet based Device Electronic Application and Lodgement system (DEAL) should be used to make an application to include medical devices in the Australian Register of Therapeutic Goods (ARTG). This is required before a medical device can be supplied in Australia. The DEAL system is the approved form and format of an application for the inclusion of a medical device. If Internet access is not available, arrangements can be made by contacting the Application Entry and Coordination Section of the Office of Devices, Blood and Tissues to lodge a paper application. However, when this application is received it will then have to be entered into the DEAL system by TGA staff. This is likely to cause delays in processing the application.

The applicant will also need to:

- pay the prescribed fee,
- certify that certain information is available; and
- certify an undertaking to provide the information to the TGA on request.

Using the DEAL process for most successful applications for the inclusion of a medical device in the ARTG will result in an ‘automatic’ inclusion. This means that there will not be any further assessment of the application by the TGA prior to the devices being included in the ARTG.
The TGA requires the applicant to officially declare that:

- the intended purpose assigned to the device by the manufacturer makes the device a medical device by definition;
- the supply of the device in Australia will only be for the purpose assigned to the device by the manufacturer, as claimed in the information accompanying the device (labelling and instructions for use) or in any advertising material concerning the device, however made;
- the manufacturer has applied the Australian classification rules to determine the class of the device for Australia;
- the manufacturer has demonstrated that the device complies with the essential principles;
- the manufacturer has selected and applied an appropriate conformity assessment procedure;
- the applicant is either holding information to substantiate:
  - conformity with the essential principles or has procedures in place with the manufacturer, to obtain the relevant information within 20 working days. (This is typically the technical documentation for the medical device. A manufacturer’s declaration of conformity or, quality management system or product certifications would not be considered sufficient information.)
  - the application of an appropriate conformity assessment procedure or has procedures in place with the manufacturer, to obtain the relevant information within 20 working days. (This is typically the manufacturer’s quality manual and the results of third party quality management system audits. A manufacturer’s declaration of conformity or, quality management system or product certifications would not be considered sufficient information.)
- the applicant has confirmed that the advertising materials, however made, comply with the any advertising requirements that may apply to it;
- the device does not contain any substances that are prohibited imports under the Customs Act 1901, such as substances of abuse; and
- the applicant has fully disclosed all relevant information required by the application.

Note:
The definition of the intended purpose, the classification of a device, the selection and application of a conformity assessment procedure and the compliance with the essential principles are obligations on the manufacturer under Section 41DA of the Act and not the applicant or sponsor. The purpose of the certification made by the applicant under Section 41FD of the Act, among other things, is to officially state that the manufacturer has carried out their obligations. This certification is necessary to ensure that the Australian legal entity, responsible for the supply of the medical device in Australia, the sponsor, knows that the requirements for supply are being met.

WHICH PRODUCTS WILL BE SELECTED FOR AN APPLICATION AUDIT?
The Act and Regulations specify that applications to include certain medical devices in the ARTG must be selected for an application audit. An application audit assessment fee will be charged for these cases. The TGA may also select any other application for inclusion for an application audit. An audit assessment fee will not be charged for these audits. In addition, two levels of audit have
been established by the Regulations. Attachment 1 indicates which products must or may be selected for an application audit as well as the type of audit.

If the outcome of an application audit is satisfactory a certificate of inclusion in the ARTG will be issued to the applicant. If the application audit is unsuccessful the application will be rejected and applicant will be advised in writing. Reapplication should not be attempted until it can be verified that the manufacturer has completed the appropriate conformity assessment procedures.

WHAT DOES AN APPLICATION AUDIT ENTAIL?

An application audit will confirm that manufacturer of a medical device has carried out the conformity assessment procedures appropriate to the class of the medical device. The TGA may consider any of the following in an application audit:

- Is the application an ‘effective’ application?
  - Has an application been made using the approved form?
  - Has an application been made in the correct format, including the provision of any particular information required by the form? This may include information such as the signed sponsor’s declaration, the manufacturer’s declaration of conformity or quality system or product certifications.
  - Has the prescribed application fee been paid?
  - If the Regulations require a TGA issued Conformity Assessment Certificate for the purpose of making an application for inclusion in the ARTG, is such a certificate held by the applicant and is it in force?
  - Does the application contain information that is false or misleading?
- Are the matters that the applicant has certified under Section 41FD correct?
  - Is the device a medical device?
  - Is it clear that the device is intended for the purpose stated by the manufacturer on the label, instructions for use or advertising material? Where ambiguity may exist has the manufacturer clarified the intended use?
  - Has the device been correctly classified?
  - Is there evidence that the manufacturer has demonstrated that a device conforms to the essential principles? Satisfactory evidence for the purpose of an application audit will include the manufacturer’s declaration of conformity and, where relevant, product certifications from acceptable conformity assessment bodies. The TGA will not be reassessing a product as part of an application audit.
  - Does the applicant hold sufficient information or have procedures in place to obtain sufficient information to substantiate conformity with the essential principles? Is the technical documentation present and complete?
  - Is there evidence that the manufacturer has applied a Conformity Assessment Procedure, appropriate to the class of the device? Satisfactory evidence for the purpose of an application audit will include the manufacturer’s declaration of conformity and, where relevant, quality management system certifications from acceptable conformity assessment bodies. TGA will not be reassessing a quality management system as part of an application audit.
  - Does the applicant hold sufficient information or have procedures in place to obtain sufficient information to substantiate that the manufacturer has applied an appropriate conformity assessment procedure?
  - Does the advertising material, however made, conform to any advertising requirement for the device?
Does the device contain a substance that would be a prohibited import under the
*Customs Act 1901*?

Is the application form complete and has all the information required by the
application been provided? Are there any inconsistencies in the application form or
the information provided with the application form.

On occasion the TGA may request additional evidence that the pre-conditions for an application
have been met.

During an application audit the TGA will not undertake any assessment or activity that would
normally be performed by the manufacturer or the TGA as part of a conformity assessment
procedure.

If all aspects of the audit are satisfactory, the applicant will be notified, and the medical device will
be included in the ARTG.

If the decision is not to include the kind of medical device in the ARTG the TGA will state the
reasons for the decision when the applicant is notified.

**WHAT ADDITIONAL INFORMATION WILL BE REQUESTED?**

**Level 1 Application Audit**

For a Level 1 application audit, the following are required:

- an original or notarised copy of the manufacturer's Declaration of Conformity,
  
  **Note:** A declaration of conformity to Australian requirements is required. A declaration of conformity to the Medical Devices Directive (MDD) or Active Implantable Medical Devices Directive (AIMDD) in Europe is not acceptable.

- evidence of third party certification of an assessment of the medical device and/or
  manufacturer,
  
  **Note:** This may include quality systems certificates, and design examination or type examination certificates, from an EU MDD or AIMDD Notified Body - as relevant to the medical device class. This is not required for Class I medical devices. The evidence supplied must be original or notarised copies.

- clear, legible copies of representative information accompanying the kind of medical
device:
  - labelling;
  - instructions for use; and
  - any advertising material (eg. brochures, web-pages, published advertisements, etc.)

  **Note:** Labelling and instructions for use are not necessarily required for every model or variant unless there are significant differences in content. However the copies provided are required to be representative.
Level 2 Application Audit

For a Level 2 Application Audit, the following are required in addition to those outlined for a Level 1 Audit:

- the risk analysis performed by the manufacturer for the device and referred to during the Conformity Assessment Procedures;

- a summary of the clinical evidence used to establish conformity with Australian Essential Principle number 14, and as described in Guidance Document Number 4: Clinical Evidence Requirements for Inclusion of Medical Devices in the Australian Register of Therapeutic Goods;

Note: The clinical evidence provided should include:

- an expert report and;

- evidence to support the expertise of its author (eg a curriculum vitae).

- an essential principles checklist that summarises the conformity to each applicable essential principle by reference to appropriately applied standards, or other means. Standards referenced in a Medical Device Standards Order or Conformity Assessment Standards Order, if appropriately applied, may be used to demonstrate conformity without further justification. Other standards or methods may require additional justification. An essential principles checklist is available as Attachment 2.

- the following documentary evidence, issued by the assessment body, related to the certification of an assessment of the medical device and/or manufacturer:
  - quality system certification or re-certification audit report;
  - the most recent quality system surveillance audit report; and
  - documentary evidence (eg correspondence from the Notified Body) of appropriate close-out of all non-conformities identified in the quality system audit reports.

- the design examination or type examination report, issued by the assessment body, related to the certification of an assessment of the medical device and/or manufacturer;

- the manufacturer's validation reports for any "Special Processes", as identified by the manufacturer during conformity assessment. For example, as described in clause 4.9 of the standards AS ISO 13485-2002 and AS ISO 13488-2002 (by reference to ISO 9001:1994 clause 4.9) or international equivalents. For a sterile medical device this should always include validation of the sterilisation process.

GENERAL REQUIREMENTS FOR THE INFORMATION TO BE SUPPLIED

Each dossier submitted in support of an application audit must contain the information specified in the preceding sections. In addition, the following should be included:
- a copy of the DEAL application form
- the appropriate fee for the level of application audit specified by the TGA.

**Language**

All information must be submitted in English. Where material is not originally in English, an authenticated translation should be submitted. The TGA reserves the right to request the original material at any time.

**Units**

Metric units shall be used. Units generally accepted in clinical practice may also be used (e.g. mmHg).

**Text and Drawings**

All text and drawings must be legible and drawings clearly labelled. Drawings must be full size copies but not facsimile reproductions.

**Written Information**

All written material, apart from drawings, brochures and manuals, should be submitted on A4 size paper. The written material should be bound in loose-leaf binders. The spines of the binders should be such that the folder will open flat.

**Number of Copies**

The original and one complete copy of written material must be submitted. Other copies may be requested if required.

The second, and any additional copies supplied may be on CD-ROM. If electronic copies are submitted, they must be in unprotected portable file document (pdf) format.

**Presentation**

Each volume and CD-ROM should be clearly labelled on the spine and the front cover with:

- DEAL application reference number
- device name;
- sponsor name and;
- volume and copy number.

**Pagination**

All pages must be serially numbered throughout the submission. In correspondence, all references should specify not only the page numbers but also the volume of the submission.

**Indexing, Cross-referencing and Labelling**

A table of contents should be included at the front of the first volume and sub-tables at the front of each subsequent volume.
TIMEFRAME FOR THE PROVISION OF INFORMATION

The Act and Regulations require that the sponsor either hold documentation to substantiate compliance with the essential principles, or have in place procedures to obtain that documentation from the manufacturer within 20 days. The sponsor is required to certify that he/she has procedures in place to address these requirements. Therefore, during the application audit process, only 1 further request for information will be sent by the TGA. If the quality if the information sent in response to this request, is not acceptable, then rejection proceedings will commence.

WHEN WILL AN APPLICATION SELECTED FOR AN APPLICATION AUDIT LAPSE?

An application that has been selected for an application audit will lapse if:

- the applicant does not provide the information requested by the TGA;
- the applicant does not provide a reasonable number of samples of the device that have been requested;
- the information provided by an applicant in support of an application is false or misleading; or
- the applicant fails to pay the application audit assessment fee

WHAT HAPPENS AFTER THE TGA DECIDES TO ISSUE A CERTIFICATE OF INCLUSION?

If the application audit does not find any inconsistencies in an application and all the appropriate fees have been paid, the medical device in question will be included in the ARTG and a certificate of inclusion will be issued by the TGA.

A unique number will be assigned to the entry. The entry is valid from the day specified in the certificate and remains valid until it is either suspended or cancelled from the ARTG.
## ATTACHMENT 1. APPLICATIONS FOR INCLUSION TO BE SELECTED FOR AUDIT BY THE TGA

<table>
<thead>
<tr>
<th>Kinds of Medical Devices</th>
<th>Applications to be Audited</th>
<th>Level of Audit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any kind of medical device not specified below</td>
<td>May be selected</td>
<td>To be determined on a case by case basis</td>
</tr>
<tr>
<td>Medical devices manufactured in Australia</td>
<td>No</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Medical devices previously registered on the ARTG after 4 October 2000, that underwent “full” evaluation by the TGA</td>
<td>Yes</td>
<td>1</td>
</tr>
<tr>
<td>Posterior Chamber PMMA monofocal intra-ocular lens</td>
<td>Yes</td>
<td>1</td>
</tr>
<tr>
<td>Barrier contraceptives or devices intended to prevent transmission of disease in the course of penile penetration during sexual intercourse, other than condoms</td>
<td>Yes</td>
<td>2</td>
</tr>
<tr>
<td>Class AIMD medical devices</td>
<td>Yes</td>
<td>2</td>
</tr>
<tr>
<td>Class III medical devices not assessed under the EC MRA of the EFTA MRA</td>
<td>Yes</td>
<td>2</td>
</tr>
<tr>
<td>Implantable breast prostheses containing material of fluid consistency other than water only or a saline solution only</td>
<td>Yes</td>
<td>2</td>
</tr>
<tr>
<td>Implantable contraceptive devices</td>
<td>Yes</td>
<td>2</td>
</tr>
<tr>
<td>Implantable intra-ocular lens</td>
<td>Yes</td>
<td>2</td>
</tr>
<tr>
<td>Intra-ocular visco-elastic fluids</td>
<td>Yes</td>
<td>2</td>
</tr>
<tr>
<td>Medical devices intended by the manufacturer specifically to be used for disinfecting another medical device</td>
<td>Yes</td>
<td>2</td>
</tr>
<tr>
<td>Prosthetic heart valves</td>
<td>Yes</td>
<td>2</td>
</tr>
</tbody>
</table>
### ATTACHMENT 2. ESSENTIAL PRINCIPLES CHECKLIST

#### 1. GENERAL PRINCIPLES

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 of 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.

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.
<table>
<thead>
<tr>
<th>Manufacturer:</th>
<th>Product:</th>
<th>ID:</th>
</tr>
</thead>
<tbody>
<tr>
<td>A/NA*</td>
<td>Medical Device Standards applied by manufacturer</td>
<td>Other standards or procedures applied by manufacturer</td>
</tr>
</tbody>
</table>

### 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.

### 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.

### 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.

### 6. Benefits of medical devices to outweigh any side effects
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 arising from its use.
2. PRINCIPLES ABOUT DESIGN AND CONSTRUCTION

7. Chemical, physical and biological properties

<table>
<thead>
<tr>
<th>7.1 Choice of materials</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>In ensuring that the requirements of Part 1 are met in relation to a medical device, particular attention must be given to:</td>
<td></td>
</tr>
<tr>
<td>(a) the chemical and physical properties of the materials used in the device; and</td>
<td></td>
</tr>
<tr>
<td>(b) the compatibility between the materials used and biological tissues, cells and body fluids; having regard to the intended purpose of the device.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>7.2 Minimisation of risks associated with contaminants and residues</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>(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.</td>
<td></td>
</tr>
<tr>
<td>(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.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>7.3 Ability to be used safely with materials, etc</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>(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.</td>
<td></td>
</tr>
<tr>
<td>(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:</td>
<td></td>
</tr>
<tr>
<td>(a) is compatible with the provisions and restrictions applying to the medicine to be administered; and</td>
<td></td>
</tr>
<tr>
<td>(b) allows the medicine to perform as intended.</td>
<td></td>
</tr>
</tbody>
</table>
7.4 **Verification of incorporated substance**

(1) If a medical device incorporates, or is intended to incorporate, 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:
   - the safety and quality of the substance must be verified in accordance with the requirements for medicines; and
   - 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.

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.

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.

8. **Infection and microbial contamination**

8.1 **Minimisation of risk of infection and contamination**

(1) A medical device must be designed and produced in a way that ensures that 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:
   - allows it to be easily handled; and
   - if appropriate, minimises contamination of the device by the patient, or contamination of the patient by the device, during use.
Medical Devices Essential Principles Checklist

<table>
<thead>
<tr>
<th>Manufacturer:</th>
<th>A/NA*</th>
<th>Medical Device Standards applied by manufacturer</th>
<th>Other standards or procedures applied by manufacturer</th>
<th>Evidence of compliance or reason for non-applicability</th>
</tr>
</thead>
</table>

* - APPLICABLE/NOT APPLICABLE

8.2 Control of animal, microbial 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.

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.
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.

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.

9. Construction and environmental properties

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

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:
   (a) the medical device, and any other device or equipment with which it is used, operate in a safe way; and
   (b) the intended performance of the device, and any other device or equipment with which it is used, is not impaired.
9.2 Minimisation of risks associated with use of medical devices

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:
(a) the risk of injury arising from the physical features of the device;
(b) any risks associated with reasonably foreseeable environmental conditions;
(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;
(d) any risks arising if maintenance or calibration of the device is not possible;
(e) any risks associated with the ageing of materials used in the device;
(f) any risks associated with the loss of accuracy of any measuring or control mechanism of the device;
(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.

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.

11. Protection against radiation

11.1 Minimisation of exposure to 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 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.
### 11.2 Medical devices intended to emit radiation

1. **Medical devices intended to emit radiation**
   - 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.
   - The device must be designed and produced in a way that ensures that the user can control the level of the emission.
   - The device must be designed and produced in a way that ensures the reproducibility and tolerance of relevant variable parameters.
   - 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.

### 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.

### 11.4 Operating instructions

- The operating instructions for a medical device that emits radiation must include detailed information about the following matters:
  - the nature of the radiation emitted;
  - the means by which patients and users can be protected from the radiation;
  - ways to avoid misusing the device;
  - ways to eliminate any risks inherent in the installation of the device.
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.

12. Medical devices connected to or equipped with an energy source

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.

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.
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.

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.

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.

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.

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

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.
<table>
<thead>
<tr>
<th>12.9</th>
<th>Protection against risks associated with noise</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1)</td>
<td>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.</td>
</tr>
<tr>
<td>(2)</td>
<td>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.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>12.10</th>
<th>Protection against risks associated with terminals and connectors</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>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.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>12.11</th>
<th>Protection against risks associated with heat</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>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.</td>
</tr>
</tbody>
</table>
### 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.

### 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.
### 13. Information supplied by the manufacturer

**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.
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 printed documents or other appropriate media.
13.3 Information to be provided with medical devices – particular 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 where these are 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 on use, 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”

Note: In addition to the information mentioned above, regulation 10.2 requires certain information to be provided with a medical device.
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:
   - the device is a Class I medical device or a Class IIa medical device; and
   - 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 images)
   4. Information about the intended performance of the device and any undesirable side effects caused by use of the device
   5. Any contraindications, warnings, restrictions on use, or precautions that may apply in relation to 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:
      - an indication that the device is sterile; and
      - information about what to do if sterile packaging is damaged and;
      - if appropriate, instructions for resterilisation of the device.
<table>
<thead>
<tr>
<th>Medical Devices Essential Principles Checklist</th>
</tr>
</thead>
<tbody>
<tr>
<td>* - APPLICABLE/NOT APPLICABLE *</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Manufacturer:</th>
<th>Product:</th>
<th>ID:</th>
</tr>
</thead>
<tbody>
<tr>
<td>A/NA*</td>
<td>Medical Device Standards applied by manufacturer</td>
<td>Other standards or procedures applied by manufacturer</td>
</tr>
</tbody>
</table>

(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 use 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
### Medical Devices Essential Principles Checklist

<table>
<thead>
<tr>
<th>A/NA*</th>
<th>Medical Device Standards applied by manufacturer</th>
<th>Other standards or procedures applied by manufacturer</th>
<th>Evidence of compliance or reason for non-applicability</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* - APPLICABLE/NOT APPLICABLE

14. **Clinical evidence**

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.

**Note:** See regulation 3.11 and the clinical evaluation procedures.

- (24) Adequate information about any medicinal product that the device is designed to administer, including and 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 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.