Therapeutic Goods (Medical Devices) Regulations 2002

Statutory Rules 2002 No. 1 236

I, PETER JOHN HOLLINGWORTH, Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following Regulations under the *Therapeutic Goods Act 1989*.

Dated - 3 OCT 2002 2002

PETER HOLLINGWORTH
Governor-General

By His Excellency's Command

TRISH WORTH
Parliamentary Secretary to the Minister for Health and Ageing

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Part 1 Preliminary

1.1 Name of Regulations

These Regulations are the *Therapeutic Goods (Medical Devices) Regulations 2002*.

1.2 Commencement

These Regulations commence on the commencement of Schedule 1 to the *Therapeutic Goods Amendment (Medical Devices) Act 2002*.

1.3 Definitions — the dictionary etc

(1) The dictionary at the end of these Regulations defines certain words and expressions, and includes, for that purpose, references to certain words and expressions that are defined in the Act or elsewhere in these Regulations (***signpost definitions***).

Example

The signpost definition '***medical device*** — see section 41BD of the Act' means that the expression ***medical device*** is defined in section 41BD of the *Therapeutic Goods Act 1989*.

Note The dictionary only includes a signpost definition for a word or expression that is defined elsewhere in these Regulations if the word or expression is used in more than one regulation.

(2) The dictionary is part of these Regulations.

(3) A definition in these Regulations applies to each use of the word or expression in these Regulations, unless the contrary intention appears.

1.4 Medical devices with a measuring function

(1) For these Regulations, a medical device has a ***measuring function*** if the device is intended by the manufacturer to measure:

(a) quantitatively a physiological or anatomical parameter; or

(b) a quantity, or a qualifiable characteristic, of energy or substances delivered to or removed from the human body.

(2) The measurements given by a medical device that has a measuring function:

(a) must:

(i) be displayed in Australian legal units of measurement or other units of measurement approved by the Secretary for the particular device; or

(ii) be compared to at least one point of reference indicated in Australian legal units of measurement or other units of measurement approved by the Secretary for the particular device; and

(b) must be accurate to enable the device to achieve its intended purpose.

1.5 Refurbishment (Act s 3 (1))

(1) A ***refurbishment*** of a medical device is taken to have occurred if the medical device, or a part of the device, is substantially rebuilt from one or more used medical devices of that kind so as to create a medical device that is able to be used for the purpose originally intended by the manufacturer of the original device.

(2) Without limiting subregulation (1), a ***refurbishment*** of a medical device may involve the following actions:

(a) stripping the device into component parts or sub-assemblies;

(b) checking parts of the device for suitability for reuse;

(c) replacing component parts or sub-assemblies of the device that are not suitable for reuse;

(d) assembling reclaimed or replacement component parts or sub-assemblies of the device or another used device;

(e) testing a reassembled device against the specifications of the original device or, if the manufacturer has revised those specifications, the revised specifications;

(f) identifying an assembled device as a refurbished device.

1.6 Kinds of medical devices — other common characteristics (Act s 41BE (1) (e))

For paragraph 41BE (1) (e) of the Act, in relation to a Class III medical device, or Class AIMD medical device, a characteristic is the unique product identifier given to the device by its manufacturer to identify the device and any variants.

1.7 Device nomenclature system codes (Act s 41BE (3))

(1) In accordance with the Global Medical Device Nomenclature System Code, as set out in ISO 15225:2000(E), the device nomenclature system code specified for a medical device is:

(a) for a Class AIMD medical device, Class III medical device, Class IIb medical device or Class IIa medical device — the relevant preferred term; and

(b) for any of the following:

(i) a Class I medical device that the manufacturer intends to be supplied in a sterile state;

(ii) a Class I medical device that has a measuring function;

(iii) a Class I medical device for which there is no relevant template term —

the relevant preferred term; and

(c) for any other Class I medical device — the relevant template term.

(2) In this regulation:

ISO 15225:2000(E) means International Standard ISO 15225:2000(E) (Nomenclature — Specification for a nomenclature system for medical devices for the purposes of regulatory data exchange).

relevant preferred term, for a medical device, means the preferred term for that device under ISO 15225:2000(E).

relevant template term, for a medical device, means the template term for that device under ISO 15225:2000(E).

Part 2 Essential principles

2.1 Essential principles (Act s 41CA)

For section 41CA of the Act, the essential principles for medical devices are set out in Schedule 1.

Part 3 Conformity assessment procedures

Division 3.1 Medical device classifications

3.1 Medical device classifications (Act s 41DB)

(1) For section 41DB of the Act, the following medical device classifications are specified:

(a) Class I;

(b) Class IIa;

(c) Class IIb;

(d) Class III;

(e) Class AIMD (active implantable medical devices).

(2) For these Regulations:

(a) the lowest level of medical device classification is specified by paragraph (1) (a); and

(b) successively higher levels of classification are specified by paragraphs (1) (b) and (c); and

(c) the highest level of classification is specified by paragraphs (1) (d) and (e).

3.2 Classification of medical devices

A medical device has the medical device classification applying under the classification rules set out in Schedule 2.

3.3 Principles for applying the classification rules

(1) For the purpose of classifying a medical device, the principles set out in this regulation apply.

(2) A medical device is classified having regard to the intended purpose of the device.

(3) If a medical device is designed to be used in combination with another medical device, each of the devices is classified separately.

(4) An accessory to a medical device is classified separately from the medical device.

(5) If a medical device is driven, or influenced, by an item of software, the software has the same classification as the medical device.

(6) If a medical device is not designed to be used solely or principally in a specific part of a patient's body, the medical device is classified having regard to the most critical specified use of the medical device.

(7) If, based on the intended purpose of the device, 2 or more classification rules apply to the medical device, the device has the highest level of classification applying under the applicable classification rules.

Division 3.2 Conformity assessment procedures

3.4 Conformity assessment procedures (Act s 41DA)

(1) For section 41DA of the Act, the requirements relating to the obligations of manufacturers of medical devices (the ***conformity assessment procedures***) are set out in Schedule 3.

(2) The application of the conformity assessment procedures to a medical device, or a kind of medical device, is set out in this Division.

(3) The manufacturer of a Class IIb medical device, Class IIa medical device or Class I medical device must apply to the device appropriate conformity assessment procedures, being:

(a) the minimum conformity assessment procedures applicable, under this Division, to the device; or

(b) if the manufacturer prefers, conformity assessment procedures that are applicable, under this Division, to a medical device that is classified at a higher level than the device concerned.

3.5 Medical devices manufactured outside Australia

(1) For the purpose of applying conformity assessment procedures to a kind of medical device that is manufactured outside Australia, a power or function of the Secretary, in relation to an assessment to be conducted under the procedures, may be exercised or performed at the place where the manufacturer is located, and at the manufacturing site, by a body or authority that the Secretary is satisfied has the authority and expertise to exercise that power or perform that function.

(2) If, under the conformity assessment procedures, the manufacturer of the kind of medical device is required to give information of a kind mentioned in paragraph 41MP (2) (a) or (b) of the Act to the Secretary, the information must be given to the Secretary in addition to any such information that is given to the body or authority mentioned in subregulation (1).

3.6 Class III medical devices and Class AIMD medical devices (other than medical devices used for a special purpose)

(1) Subject to subregulation (2), the conformity assessment procedures that must be applied to a Class III medical device, or a Class AIMD medical device, (other than a medical device used for a special purpose) are, as the manufacturer prefers:

(a) the full quality assurance procedures; or

(b) the type examination procedures and:

(i) the verification procedures; or

(ii) the production quality assurance procedures.

(2) If the device is intended by the manufacturer to be supplied in a sterile state, the conformity assessment procedures that must be applied to the device are, as the manufacturer prefers:

(a) the full quality assurance procedures; or

(b) the type examination procedures and the production quality assurance procedures.

3.7 Class IIb medical devices (other than medical devices used for a special purpose)

(1) Subject to subregulation (2), the minimum conformity assessment procedures that must be applied to a Class IIb medical device (other than a medical device used for a special purpose) are, as the manufacturer prefers:

(a) the full quality assurance procedures (other than clause 1.6); or

(b) the type examination procedures and:

(i) the verification procedures; or

(ii) the production quality assurance procedures; or

(iii) the product quality assurance procedures.

(2) If the device is intended by the manufacturer to be supplied in a sterile state, the minimum conformity assessment procedures that must be applied to the device are, as the manufacturer prefers:

(a) the full quality assurance procedures (other than clause 1.6); or

(b) the type examination procedures and the production quality assurance procedures.

Note The manufacturer of a Class IIb medical device (other than a medical device used for a special purpose) may prefer to apply to the device the conformity assessment procedures that must be applied to a medical device that is classified at a higher level — see subregulation 3.4 (3).

3.8 Class IIa medical devices (other than medical devices used for a special purpose)

(1) Subject to subregulation (2), the minimum conformity assessment procedures that must be applied to a Class IIa medical device (other than a medical device used for a special purpose) are, as the manufacturer prefers:

(a) the full quality assurance procedures (other than clause 1.6); or

(b) the declaration of conformity (not requiring assessment by Secretary) procedures and:

(i) the verification procedures (other than clause 3.5); or

(ii) the production quality assurance procedures (other than clause 4.7); or

(iii) the product quality assurance procedures (other than clause 5.7).

(2) If the device is intended by the manufacturer to be supplied in a sterile state, the minimum conformity assessment procedures that must be applied to the device are, as the manufacturer prefers:

(a) the full quality assurance procedures (other than clause 1.6); or

(b) the production quality assurance procedures (other than clause 4.7) and the declaration of conformity (not requiring assessment by Secretary) procedures.

Note The manufacturer of a Class IIa medical device (other than a medical device used for a special purpose) may prefer to apply to the device the conformity assessment procedures that must or may be applied to a medical device that is classified at a higher level — see subregulation 3.4 (3).

3.9 Class I medical devices (other than medical devices used for a special purpose)

(1) Subject to subregulations (2) and (3), the minimum conformity assessment procedures that must be applied to a Class I medical device (other than a medical device used for a special purpose) are the declaration of conformity (not requiring assessment by Secretary) procedures.

(2) If the device is intended by the manufacturer to be supplied in a sterile state, and the manufacturer applies the declaration of conformity (not requiring assessment by Secretary) procedures to the device, the production quality assurance procedures (other than clause 4.7) must also be applied to the device.

(3) If the device has a measuring function, and the manufacturer applies the declaration of conformity (not requiring assessment by Secretary) procedures, one of the following sets of procedures, as the manufacturer prefers, must also be applied to the device:

(a) the verification procedures (other than clause 3.5);

(b) the production quality assurance procedures (other than clause 4.7);

(c) the product quality assurance procedures (other than clause 5.7).

Note The manufacturer of a Class I medical device (other than a medical device used for a special purpose) may prefer to apply to the device the conformity assessment procedures that must be applied to a medical device that is classified at a higher level — see subregulation 3.4 (3).

3.10 Medical devices used for a special purpose

(1) This regulation applies to the following kinds of medical devices (***medical devices used for a special purpose***):

(a) an exempt device;

(b) a medical device that is the subject of an approval under section 41HB of the Act;

(c) a medical device that is the subject of an authority under section 41HC of the Act;

(d) a system or procedure pack to which subregulation (3) applies.

Note for paragraph (a) An ***exempt device*** is a medical device of a kind that is exempted from the operation of Division 3 of Part 4-11 of the Act by the regulations (see subsection 3 (1) of the Act). Division 7.1 and Schedule 4 of these Regulations deal with exempt devices.

Note for paragraph (d) A system or procedure pack is treated as a single medical device. If subregulation (3) does not apply to a system or procedure pack:

(a) the system or procedure pack is classified in accordance with Division 3.1 and Schedule 2; and

(b) the conformity assessment procedures that must be applied to the system or procedure pack are the procedures that apply to the relevant classification.

(2) The conformity assessment procedures that must be applied to a medical device used for a special purpose are the procedures for medical devices used for a special purpose.

Note For 2 years after the commencement of these Regulations, Chapter 3 of the Act continues to apply to custom-made medical devices, and the procedures for medical devices used for a special purpose do not need to be applied to them in that period. This is because, for that 2 year period, custom-made medical devices continue to be exempt goods or are declared, by order published in the *Gazette* under subsection 41BD (3) of the Act, not to be, for the purposes of the Act, medical devices.

(3) This subregulation applies to a system or procedure pack:

(a) that contains only one or more of the following:

(i) a medical device, or devices, to which the relevant conformity assessment procedures have been applied;

(ii) a medicine or medicines, or other therapeutic goods, that are entered on the Register;

(iii) any other item or items that are not therapeutic goods when in the package; and

(b) that has been put together in accordance with the intended purpose of each medical device and the approved indications for use of each medicine and other therapeutic goods; and

(c) the contents of which are compatible, having regard to the intended purpose of each medical device, the approved indications for use of each medicine or other therapeutic goods, and the intended purpose of the system or procedure pack.

(4) If a system or procedure pack is intended by the manufacturer to be supplied in a sterile state, the production quality assurance procedures (other than clause 4.7) must also be applied to the system or procedure pack in relation to the aspects of the manufacturing process that relate to ensuring that the system or procedure pack is supplied and maintained in a sterile state.

Note If the package contains a medicine, the manufacturer of the system or procedure pack must ensure that the method to be used for sterilisation or resterilisation is appropriate or is in accordance with the approved indications for use of the medicine.

3.11 Medical devices to which the clinical evaluation procedures must be applied

(1) Subject to subregulation (2), in addition to the conformity assessment procedures that are applied to a medical device in accordance with another regulation in this Division, the clinical evaluation procedures must also be applied to the device, for the purpose of demonstrating that the device complies with the applicable provisions of the essential principles, in particular:

(a) clause 1 of Schedule 1 (identification of the benefits and risks associated with the use of the device); and

(b) clause 3 of Schedule 1 (use of the device for its intended purpose); and

(c) clause 6 of Schedule 1 (acceptability of any side effects associated with the use of the device).

(2) This regulation does not apply to any of the following:

(a) an exempt device (other than an exempt device of a kind described in item 1.3 or 1.5 of Schedule 4);

(b) a medical device that is the subject of an approval under section 41HB of the Act;

(c) a medical device that is the subject of an authority under section 41HC of the Act.

3.12 Records to be provided in English

All records (including correspondence) provided by the manufacturer of a medical device in relation to the application of the conformity assessment procedures to the device must be in English.

3.13 Assessment or verification at intermediate stage of manufacture

(1) At the request of a person, and on payment of the prescribed fee, the Secretary may arrange for assessment or verification procedures to be carried out in relation to the application of the conformity assessment procedures to an article that is intended to be used in the manufacture of a medical device.

(2) A request may be made:

(a) at any stage of the manufacturing process; and

(b) whether or not an application has been made in relation to the article:

(i) for a conformity assessment certificate in respect of a medical device; or

(ii) for inclusion of a kind of medical device in the Register.

Part 4 Conformity assessment certificates

Division 4.1 Issuing conformity assessment certificates

4.1 When conformity assessment certificates are required (Act s 41EA)

(1) For paragraph 41EA (a) of the Act and subject to subregulation (3), the kind of manufacturer in respect of whom a conformity assessment certificate must be issued before a valid application can be made for kinds of medical devices manufactured by that manufacturer to be included in the Register, is a manufacturer who manufactures medical devices in Australia.

(2) For paragraph 41EA (b) of the Act and subject to subregulation (3), the kinds of medical devices in respect of which a conformity assessment certificate must be issued before a valid application can be made for those kinds of medical devices to be included in the Register, are medical devices manufactured outside Australia that are of the following kinds:

(a) medical devices that contain tissues of animal origin that have been rendered non-viable (other than those that are intended to come into contact with intact skin only);

(b) medical devices that contain tissues, cells or substances of microbial or recombinant origin and are intended for use in or on the human body;

(c) medical devices incorporating stable derivatives of human blood or human plasma that are liable to act on the human body in a way that is ancillary to the device;

(d) medical devices that incorporate, or are 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.

(3) This regulation does not apply to:

(a) any of the following:

(i) a Class I medical device that is not intended to be supplied in a sterile state or that does not have a measuring function;

(ii) an exempt device;

(iii) a medical device that is the subject of an approval under section 41HB of the Act;

(iv) a medical device that is the subject of an authority under section 41HC of the Act;

(v) a system or procedure pack to which subregulation 3.10 (3) applies; or

(b) a manufacturer of a medical device of a kind mentioned in paragraph (a).

4.2 Considering applications for conformity assessment certificates (Act s 41EC)

For subsection 41EC (2) of the Act, the following other requirements of the conformity assessment procedures are specified:

(a) the applicable requirements in relation to the establishment and maintenance of a post-market monitoring, reporting and corrective action system;

(b) the applicable requirements in relation to the keeping of records.

4.3 Time for making decision on applications (Act s 41ED, s 63 (2) (dc))

(1) This regulation applies to an application for the issue of a conformity assessment certificate in respect of a kind of medical device if, in considering the application, the Secretary is required to examine the design of the device.

(2) The Secretary must make a decision on the application within 255 working days after the application is received at an office of the Department specified by the Secretary.

(3) For subregulation (2), a working day that occurs in any of the following periods is to be disregarded:

(a) if the Secretary sends a query, or a request for information, to the applicant or sponsor — the period beginning on the day when the query or request is sent and ending at the end of the day when the Secretary receives from the applicant or sponsor a response that enables the Secretary to proceed with the assessment;

(b) if an appeal is lodged in relation to the application — the period beginning on the day when the appeal is lodged and ending at the end of the day when the appeal is finally determined;

(c) any other period in relation to which the applicant or sponsor agrees in writing for the purposes of this subregulation.

Division 4.2 Suspension of conformity assessment certificates

4.4 Period for revocation of suspension (Act s 41EP, s 63 (2) (db))

(1) This regulation applies to an application to the Secretary under paragraph 41EP (2) (a) of the Act to revoke the suspension of a conformity assessment certificate.

(2) The Secretary must make a decision on the application within 40 working days after the application is received at an office of the Department specified by the Secretary.

Division 4.3 Transfer of conformity assessment certificates

4.5 Application of Division 4.3

This Division applies in relation to a manufacturer of a medical device in respect of whom a conformity assessment certificate is issued.

4.6 Death, bankruptcy or winding up of manufacturer

(1) If the manufacturer dies, the manufacturer's legal personal representative:

(a) is taken to be the person in respect of whom the conformity assessment certificate is issued; and

(b) must notify the Secretary, in writing, of the death not later than 3 months after it occurred.

(2) If the manufacturer becomes bankrupt, the trustee in bankruptcy of the manufacturer's estate:

(a) is taken to be the person in respect of whom the conformity assessment certificate is issued; and

(b) must notify the Secretary, in writing, of the manufacturer's bankruptcy not later than 3 months after it occurred.

(3) If the manufacturer is a body corporate that is wound up, the liquidator of the body corporate:

(a) is taken to be the person in respect of whom the conformity assessment certificate is issued; and

(b) must notify the Secretary, in writing, of the winding up of the body corporate not later than 3 months after it occurred.

Note See also regulations 4.10 and 4.11.

4.7 Disposal of business or amalgamation with another manufacturer

(1) This regulation applies if the name of the manufacturer is changed in any of the following circumstances:

(a) the manufacturer agrees to dispose of a business concerned with the manufacture of the medical device, and it is agreed that the disposal is to include a transfer of the conformity assessment certificate issued in respect of the manufacturer and the medical device;

(b) in the case of a manufacturer that is a body corporate — the manufacturer amalgamates with another body corporate under a name that is different from the name of the manufacturer on the conformity assessment certificate.

(2) The person to whom the business is disposed of, or the body corporate with whom the manufacturer amalgamates:

(a) is taken to be the person in respect of whom the conformity assessment certificate is issued; and

(b) must, not later than 3 months after the disposal or amalgamation, apply to the Secretary, in writing, for the name of the manufacturer to be changed on the conformity assessment certificate.

4.8 Change of name of manufacturer

If the name of the manufacturer is changed:

(a) the manufacturer, as renamed, is taken to be the person in respect of whom the conformity assessment certificate is issued; and

(b) the manufacturer must, not later than 3 months after the name is changed, notify the Secretary, in writing, of the new name and the circumstances in which the change occurred.

Note See also regulations 4.10 and 4.11.

4.9 Effect of conformity assessment certificate after transfer, etc

If a conformity assessment certificate is taken to be issued in respect of a person because of the operation of regulation 4.6, 4.7 or 4.8:

(a) the certificate has effect as if it had actually been issued in respect of that person; and

(b) the medical devices to which the certificate relates may continue to be manufactured while the certificate is in effect.

4.10 Notification to Secretary of events

(1) If a person is required to notify the Secretary of an event under this Division, the person must send to the Secretary sufficient documentary evidence to establish the matter asserted in the notification.

(2) If, at any time, the Secretary becomes aware that he or she has not been notified of an event as required by this Division, the Secretary may suspend or revoke the conformity assessment certificate to which the event relates.

4.11 Notification of change of name or suspension or revocation of conformity assessment certificate

(1) If, under this Division, the Secretary:

(a) changes the name of a manufacturer on a conformity assessment certificate; or

(b) suspends or revokes a conformity assessment certificate issued in respect of a manufacturer;

the Secretary must, as soon as practicable after changing the name or suspending or revoking the conformity assessment certificate:

(c) notify the manufacturer that the name has been changed or the conformity assessment certificate has been suspended or revoked; and

(d) ask the manufacturer to return to the Secretary the conformity assessment certificate that was given before the change of name or suspension or revocation.

(2) If a manufacturer receives a notice under subregulation (1), the manufacturer must return to the Secretary, as soon as practicable after receiving the notice, the conformity assessment certificate that was given before the change of name or suspension or revocation.

Penalty: 5 penalty units.

(3) An offence against subregulation (2) is an offence of strict liability.

Note For ***strict liability***, see section 6.1 of the *Criminal Code*.

Part 5 Including medical devices in the Register

Division 5.1 Including medical devices in the Register

Note Regulation 5.1 is intentionally not used.

5.2 Matters to be certified — period for obtaining information from manufacturer (Act s 41FD)

For subparagraphs 41FD (e) (ii) and (g) (ii) of the Act, the period is 20 working days.

5.3 Applications to be selected for auditing (Act s 41FH)

(1) For paragraph 41FH (1) (a) of the Act and subject to subregulation (2), an application for any of the following kinds of medical devices to be included in the Register is prescribed:

(a) a medical device (other than a condom) that is a barrier indicated for contraception or prevention of the transmission of disease in the course of penile penetration during sexual intercourse;

(b) a medical device that is an implantable contraceptive device;

(c) a medical device that is an implantable breast prosthesis containing material of fluid consistency (other than water only or a saline solution only);

(d) a medical device of a kind described in subclause 5.3 (2) of Schedule 2;

Note Subclause 5.3 (2) of Schedule 2 applies to a medical device that is specifically intended by the manufacturer to be used for disinfecting another medical device.

(e) a Class AIMD medical device;

(f) a medical device that is a prosthetic heart valve;

(g) a medical device that is an implantable intra-ocular lens;

(h) a medical device that is an intra-ocular visco-elastic fluid;

(i) a Class III medical device that has not been assessed under the EC Mutual Recognition Agreement or the EFTA Mutual Recognition Agreement.

(2) Subregulation (1) does not apply to an application for a kind of medical device to be included in the Register if a conformity assessment certificate has been issued, and has not been suspended or revoked, in respect of the kind of medical device.

(3) For this regulation:

(a) a medical device is ***assessed under the EC Mutual Recognition Agreement*** if the device is assessed by a conformity assessment body designated by the European Community; and

(b) a medical device is ***assessed under the EFTA Mutual Recognition Agreement*** if the device is assessed by a conformity assessment body designated by the European Free Trade Association.

5.4 Lapsing of applications — failure to pay assessment fee — specified period (Act s 41FK)

For paragraph 41FK (e) of the Act, the period is 40 working days.

Division 5.2 Conditions

Note Regulation 5.5 is intentionally not used.

5.6 Conditions applying automatically — period for obtaining information from manufacturer (Act s 41FN)

For subparagraphs 41FN (3) (a) (ii) and (b) (iii) of the Act, the period is 20 working days.

5.7 Conditions applying automatically — period for giving information about adverse events etc (Act s 41FN)

(1) For paragraph 41FN (3) (d) of the Act, the period in which a person in relation to whom a kind of medical device is included in the Register must give information of a kind mentioned in subsection 41MP (2) of the Act to the Secretary is:

(a) if the information relates to an event or other occurrence that represents a serious threat to public health — 48 hours after the person becomes aware of the event or occurrence; and

(b) if the information relates to an event or other occurrence that led to the death, or a serious deterioration in the state of health, of a patient, a user of the device, or another person — 10 days after the person becomes aware of the event or occurrence; and

(c) if the information relates to an event or other occurrence a recurrence of which might lead to the death, or a serious deterioration in the state of health, of a patient, a user of the device, or another person — 30 days after the person becomes aware of the event or occurrence.

(2) For paragraph (1) (a), an event or other occurrence, in relation to a kind of medical device, ***represents a serious threat to public health*** if:

(a) the event or other occurrence is a hazard arising from a systematic failure of the device that becomes known to the person in relation to whom the device is included in the Register; and

(b) the event or other occurrence may lead to the death of, or a serious injury to, a patient, a user of the device or another person; and

(c) the existence of, probable rate of occurrence of, or degree of severity of harm caused by, the hazard was not previously known or anticipated by the manufacturer of the device; and

(d) the manufacturer will be required to take prompt action to eliminate, or reduce the risk of, the hazard.

(3) For paragraphs (1) (b) and (c), an event or other occurrence leads to a ***serious deterioration*** in the state of health of a person if the event or other occurrence causes, or contributes to:

(a) a life-threatening illness or injury suffered by the person; or

(b) a permanent impairment of a bodily function of the person; or

(c) permanent damage to a body structure of the person; or

(d) a condition requiring medical or surgical intervention to prevent such permanent impairment or damage.

5.8 Conditions applying automatically — requirements in relation to information about kind of medical device (Act s 41FN)

For subsection 41FN (4) of the Act, the information required for the purposes of paragraph 41FN (3) (e) of the Act in relation to a kind of medical device that is included in the Register in relation to a person is:

(a) any information that the person is aware of relating to:

(i) any malfunction or deterioration in the characteristics or performance of the kind of device; or

(ii) any inadequacy in the design, manufacture, labelling, instructions for use or advertising materials of the kind of device; or

(iii) any use in accordance with, or contrary to, the use intended by the manufacturer of the kind of device;

that has led to any complaint or problem in relation to the kind of device, no matter how minor; and

(b) any information of the kind mentioned in subsection 41MP (2) of the Act that the person is aware of in relation to the kind of device.

Part 6 Suspension and cancellation from the Register

6.1 Period for revocation of suspension (Act s 41GD, s 63 (2) (dd))

(1) This regulation applies to an application to the Secretary under paragraph 41GD (2) (a) of the Act to revoke the suspension of a kind of medical device from the Register.

(2) The Secretary must make a decision on the application within 40 working days after the application is received at an office of the Department specified by the Secretary.

Part 7 Exempting medical devices from inclusion in the Register

Division 7.1 Exempt devices

7.1 Exempt devices — general (Act s 41HA)

(1) For paragraph 41HA (1) (b) of the Act, a kind of medical device mentioned in Part 1 of Schedule 4 is exempt from the operation of Division 3 of Part 4-11 of the Act.

(2) For paragraph 41HA (1) (b) and subsection 41HA (2) of the Act, a kind of medical device mentioned in column 2 of an item in Part 2 of Schedule 4 is exempt from the operation of Division 3 of Part 4-11 of the Act, subject to compliance with the conditions mentioned in column 3 of that item.

(3) If:

(a) a kind of medical device that is exempt from the operation of Division 3 of Part 4-11 of the Act ceases to be so exempt; and

(b) an application was made for the kind of device to be included in the Register before the device ceased to be exempt;

the kind of device is taken to be exempt from the operation of Division 3 of Part 4-11 of the Act until the application is determined.

7.2 Exempt devices — use in life-threatening cases (Act s 41HA)

(1) For paragraph 41HA (1) (b) of the Act, and without limiting regulation 7.1, a kind of medical device is exempt from the operation of Division 3 of Part 4-11 of the Act if:

(a) the kind of device is to be used in or on a person who is a Category A patient; and

(b) the following conditions are satisfied in relation to the use of the device:

(i) the person in or on whom the kind of device is to be used, or the person's guardian, has given informed consent to the use of the device in or on the person;

(ii) the medical practitioner by whom, or at whose direction, the device is to be used has signed a statement in accordance with regulation 8.2;

(iii) the device is used in accordance with the direction of the medical practitioner who requested its use.

(2) In this regulation:

Category A patient means a person who is seriously ill with a condition that is reasonably likely to lead to the person's death within less than a year or, without early treatment, to the person's premature death.

informed consent, in relation to treatment or proposed treatment of a person, means consent to the treatment of the person that is freely given on the basis of information concerning the potential risks and benefits of the treatment that is sufficient to allow the person, or the person's guardian, to make an informed decision about whether to consent to the treatment.

Division 7.2 Exemptions for experimental uses

7.3 Conditions of approval — use of device by person to whom approval is given (Act s 41HB)

(1) For subsection 41HB (3) of the Act, the conditions mentioned in this regulation apply to an approval granted to a person to use a kind of medical device solely for experimental purposes in humans.

(2) Before the commencement of any clinical trial proposed to be undertaken in relation to the device, the person to whom the approval is granted and the principal investigator of the clinical trial must give to the National Manager of the Therapeutic Goods Administration:

(a) a written assurance that each clinical trial will be conducted in accordance with the 'National Statement on Ethical Conduct in Research Involving Humans', published by the National Health and Medical Research Council, as in force from time to time; and

(b) a written undertaking:

(i) that the person will comply with any request by an authorised person, whether made before or after the commencement of a clinical trial, to give to the authorised person information about the conduct of the trial; and

(ii) that the person will allow an authorised person to do any of the things mentioned in regulation 7.4 in relation to a clinical trial.

7.4 Powers of authorised persons in relation to medical devices being used in clinical trials

(1) For subparagraph 7.3 (2) (b) (ii) and subject to subregulation (2), an authorised person may do any of the following things in relation to a clinical trial of a kind of medical device that has been approved for use solely for experimental purposes in humans:

(a) enter the site of the trial;

(b) search the site and anything on the site;

(c) inspect, examine, take measurements of, or conduct tests on (including by the taking of samples), anything on the site that relates to the trial;

(d) take photographs, make video recordings or make sketches of the site or anything on the site;

(e) inspect any book, record or other document on the site that relates to the trial;

(f) request the principal investigator of the trial to:

(i) answer any question asked by the authorised person; or

(ii) produce any book, record or other document requested by the authorised person.

(2) An authorised person is not entitled to do a thing mentioned in subregulation (1) if:

(a) the principal investigator, or any other person present at the site concerned and in apparent control, requests the authorised person to produce his or her identity card for inspection; and

(b) the authorised person fails to comply with the request.

Note See section 52 of the Act in relation to identity cards.

(3) The principal investigator, or any other person present at the site and in apparent control, is entitled to observe a search conducted under paragraph (1) (b), but must not obstruct the search.

(4) Subregulation (3) does not prevent 2 or more areas of the site being searched at the same time.

7.5 Conditions of approval — use of device by another person (Act s 41HB)

(1) For subsection 41HB (7) of the Act, the conditions mentioned in this regulation apply to the use by a person, for experimental purposes in humans, of a kind of medical device that is the subject of an approval granted to someone else under paragraph 41HB (1) (e) of the Act.

(2) The use of the device must comply with a procedural protocol approved by the ethics committee that is to be responsible for monitoring the conduct of the trial at each trial site (the ***responsible ethics committee***).

(3) The use of the device must be in accordance with the ethical standards set out in the 'National Statement on Ethical Conduct in Research Involving Humans', published by the National Health and Medical Research Council, as in force from time to time.

(4) The person must cease using the device if the responsible ethics committee informs the principal investigator of the clinical trial that the use is inconsistent with:

(a) the protocol mentioned in subregulation (2); or

(b) any condition subject to which approval for the use was given.

Division 7.3 Exemptions for medical practitioners

7.6 Classes of medical practitioners and recipients (Act s 41HC)

(1) A class of medical practitioners prescribed for the purposes of paragraph 41HC (4) (a) of the Act is the class of medical practitioners each of whom is:

(a) a specialist medical practitioner who is engaged in clinical practice in a hospital and is endorsed by the ethics committee of the hospital; or

(b) a specialist medical practitioner who is engaged in treating patients outside a hospital and is endorsed by an ethics committee that:

(i) has expertise relating to the principal activities of the practitioner; or

(ii) conducts its activities within the geographic area where the medical practitioner is engaged in treating patients.

(2) A class of recipients prescribed for the purposes of paragraph 41HC (4) (c) of the Act is the class of recipients each of whom is a person who is suffering from a life-threatening or otherwise serious illness or condition.

(3) For subsection 41HC (4) of the Act, each of the following is an exceptional circumstance in which paragraph 41HC (4) (b) of the Act does not apply:

(a) the Secretary is satisfied that the medical practitioner has no access to an ethics committee;

(b) the medical practitioner has an endorsement from a specialist college that does not have an ethics committee, but has expertise relevant to the treatment of the condition for which the authority is sought.

7.7 Circumstances for supply of device under authority (Act s 41HC)

For subsection 41HC (5) of the Act, a kind of medical device may be supplied under an authority under section 41HC of the Act if the supplier of the device complies with the directions relating to the therapeutic intervention, or class of therapeutic intervention, mentioned in the authority.

Part 8 Obtaining information

8.1 Notice period (Act s 41JA)

For paragraph 41JA (2) (a) of the Act, the notice period for a kind of medical device in relation to which a person is required, by written notice given by the Secretary under subsection 41JA (1) of the Act, to give information to the Secretary is:

(a) if the information relates to manufacturing records — 5 years; and

(b) if the information relates to distribution records:

(i) in the case of records relating to a Class AIMD medical device, Class III medical device, or Class IIb medical device that is an implantable medical device — 10 years; and

(ii) in the case of records relating to any other device — 5 years.

8.2 Exempt devices — statement by medical practitioner (Act s 41JD)

(1) For subsection 41JD (2) of the Act, a statement by a medical practitioner in relation to the use of an exempt device in or on a person who is a Category A patient must include the following:

(a) the initial letters of the person's given name and surname, and the person's date of birth and sex;

(b) the diagnosis of the person's condition;

(c) the expected duration of the treatment;

(d) a description of the exempt device;

(e) the supplier of the exempt device;

(f) the number of units of the exempt device to be supplied;

(g) the treating medical practitioner's name, practising address and other contact details;

(h) a statement to the effect that:

(i) the person in or on whom the exempt device is to be used is a Category A patient; and

(ii) the person, or the person's guardian, has given informed consent to the use of the device in or on the person.

(2) The medical practitioner who signs the statement must send a copy of the statement to the Secretary within 20 working days after signing it.

Penalty: 10 penalty units.

(3) An offence against subregulation (2) is an offence of strict liability.

Note For ***strict liability***, see section 6.1 of the *Criminal Code*.

(4) In this regulation:

Category A patient has the same meaning as in regulation 7.2.

informed consent has the same meaning as in regulation 7.2.

Part 9 Fees

9.1 Fees

The following fees are prescribed:

(a) the fee mentioned in column 4 of an item in Part 1 of Schedule 5 in relation to the matter mentioned in column 2 of that item;

(b) the additional fees mentioned in Part 2 of Schedule 5.

9.2 Application audit assessment fee (Act ss 41LA, 41LB)

For section 41LB of the Act, an application audit assessment fee is due and payable on the day when the application that is to be audited is delivered to an office of the Department specified by the Secretary.

9.3 Conformity assessment fee (Act ss 41LA, 41LB)

(1) For section 41LB of the Act, and subject to subregulation (2), a conformity assessment fee for consideration of an application for a conformity assessment certificate is due and payable in full:

(a) on the day specified in a notice given to the applicant by the Secretary; or

(b) if the application is withdrawn before a decision is made in relation to the application and within the period mentioned in subregulation 4.3 (2) — on the day when the application is withdrawn.

Note See section 41LE of the Act in relation to the requirement to pay three-quarters only of the conformity assessment fee in relation to certain kinds of applications.

(2) If:

(a) in accordance with section 41LE of the Act, an applicant has paid three-quarters of the conformity assessment fee in relation to an application for a conformity assessment certificate; and

(b) the application is withdrawn before a decision is made in relation to the application and within the period mentioned in subregulation 4.3 (2);

the part of the fee that is unpaid is due and payable on the day when the application is withdrawn.

(3) If the Secretary considers that additional assessment work is required in relation to an application for a conformity assessment certificate, the additional amount is due and payable on the day specified in a notice given to the applicant by the Secretary.

Note The fee for any additional work is prescribed in item 1.12 of Schedule 5.

9.4 Conformity assessment fee — abridged assessment

(1) This regulation applies in relation to an application for a conformity assessment certificate in respect of a kind of medical device if, before the commencement of these Regulations, the Secretary has undertaken a full assessment of the device under the EC Mutual Recognition Agreement or the EFTA Mutual Recognition Agreement.

(2) If the Secretary considers that he or she has sufficient information relating to the device to allow assessment of the device under these Regulations to be abridged:

(a) the Secretary may decide to conduct an abridged assessment of the device; and

(b) if the Secretary so decides, the conformity assessment fee for consideration of the application is $2 500.

9.5 Payment of assessment fee by instalments (Act s 41LC)

(1) For section 41LC of the Act, the Secretary may, subject to subregulation (7), approve, in relation to a kind of medical device, the payment of an assessment fee by instalments if:

(a) the person who is liable to pay the fee (the ***applicant***) has applied in writing to pay the amount by instalments; and

(b) the amount payable exceeds $10 000; and

(c) the Secretary is reasonably satisfied that the applicant will experience financial hardship if the amount is paid before the commencement of the consideration or audit of the application to which the fee relates (the ***relevant application***); and

(d) any information or material required under subregulation (3) has been given to the Secretary.

(2) An application under subregulation (1) must:

(a) state the reasons why paying the full amount of the fee before the consideration or audit of the relevant application commences would cause financial hardship to the applicant; and

(b) have with it documents or other material in support of the application.

(3) The Secretary may reasonably require information or material in addition to the documents or material mentioned in paragraph (2) (b).

(4) If the Secretary approves an application for payment by instalments:

(a) half of the fee is due for payment before the commencement of the consideration or audit of the relevant application; and

(b) one-quarter of the fee is due for payment at the end of one month after the last day when the amount referred to in paragraph (a) may be paid; and

(c) the remaining one-quarter of the fee is due for payment:

(i) if the relevant application is withdrawn — when the application is withdrawn; and

(ii) in any other case — when the applicant is notified of the Secretary's decision in respect of the relevant application under section 41EE or 41FJ of the Act.

(5) If the Secretary receives an application for payment by instalments, the Secretary must:

(a) within 30 days of receiving the application and any information or material required under subregulation (3), give notice, in writing, to the applicant stating whether the application has been approved; and

(b) if the application is approved, include with the notice information about the amount of each instalment and when it is due for payment.

(6) If:

(a) the Secretary approves an application for payment by instalments; and

(b) any amount of the instalment payable by the applicant is not paid when it becomes due for payment;

the balance of the fee becomes due for payment.

(7) This regulation does not apply if another assessment fee, or an evaluation fee under section 24 of the Act, (or part of either of those kinds of fee) that is due for payment by the applicant is unpaid.

Part 10 Miscellaneous

10.1 Authorised persons

An authorised person under paragraph (a) of the definition of ***authorised person*** in subsection 3 (1) of the Act is authorised to exercise powers given to an authorised person under a provision of these Regulations.

10.2 Imported medical devices — information about sponsor

(1) The sponsor of a medical device imported into Australia must ensure that information about the sponsor is provided in such a way as to allow the sponsor to be identified.

(2) If the sponsor of a medical device arranges for a label to be attached or affixed to the device for the purpose of complying with subregulation (1) or for any other purpose (for example, to comply with a labelling requirement under the law of a State or Territory), the label must not in any way adulterate the device or obscure the information provided with the device by the manufacturer.

Penalty: 10 penalty units.

10.3 Custom-made medical devices — information about manufacturer

(1) The manufacturer of a custom-made medical device that is manufactured in Australia must give the following information about the device to the Secretary:

(a) the manufacturer's name and business address;

(b) a description of the kinds of medical devices being custom-made by the manufacturer (including the device nomenclature system code for any such devices).

Penalty: 10 penalty units.

(2) The sponsor of a custom-made medical device that is imported into Australia must give the following information about the device to the Secretary:

(a) the sponsor's name and address;

(b) the manufacturer's name and business address;

(c) a description of the kinds of medical devices being custom-made by the manufacturer (including the device nomenclature system code for any such devices).

Penalty: 10 penalty units.

10.4 Offences — period for notifying adverse events (Act s 41MP)

For paragraph 41MP (1) (c) of the Act, the period for giving information of a kind mentioned in subsection 41MP (2) of the Act is the relevant period specified in regulation 5.7.

10.5 Delegation — powers and functions under these Regulations

The Secretary may, by signed instrument, delegate a power or function of the Secretary under these Regulations to:

(a) an officer of the Department; or

(b) the National Manager, Therapeutic Goods Administration.

10.6 Delegation — powers under paragraph 41HB (1) (d) of the Act

(1) In this regulation:

delegation means a delegation, under subsection 57 (3) of the Act, of powers of the Secretary, under paragraph 41HB (1) (d) of the Act, to approve the use of a specified medical device or kind of medical device in the treatment of a person.

(2) A delegate may only be a person who:

(a) is a medical practitioner registered in a State or internal Territory and employed by an institution that has an ethics committee; and

(b) is proposed by the medical superintendent or, if there is no medical superintendent, the person occupying a position comparable to that of medical superintendent, of the institution, as a person to be a delegate under subsection 57 (3) of the Act.

(3) If:

(a) a person proposes another person under paragraph (2) (b) as a person to be a delegate; and

(b) that other person becomes a delegate;

the first-mentioned person must supervise each approval that the delegate grants under the delegation.

(4) An instrument of delegation must describe the person or class of persons to be treated with the medical device or kind of medical device to which the delegation relates.

(5) A delegation may be made for the purpose of allowing the delegate to grant an approval in relation to:

(a) a particular medical device or kind of medical device; or

(b) a particular class of medical devices;

for treating a specific illness or condition.

(6) A delegate may grant an approval under a delegation only if:

(a) a medical practitioner, other than the delegate, has stated in writing that the person who is to be treated with the medical device of a kind to which the approval relates has an illness or condition that requires treatment with that kind of medical device; and

(b) an ethics committee has agreed to the granting of an approval under paragraph 41HB (1) (d) of the Act for the use, in the circumstances in which the delegate grants the approval, of the kind of medical device to which the delegation relates.

10.7 Review of decisions

(1) In this regulation:

decision has the same meaning as in the *Administrative Appeals Tribunal Act 1975*.

initial decision means a decision of the Secretary under any of the following provisions:

(a) subregulation 4.10 (2);

(b) paragraph 9.4 (2) (a);

(c) subregulation 9.5 (1).

reviewable decision means a decision of the Minister under subregulation (4).

(2) The Minister may, by signed instrument, delegate a power or function of the Minister under this regulation to:

(a) an officer of the Department; or

(b) the National Manager, Therapeutic Goods Administration.

(3) A person whose interests are affected by an initial decision may request the Minister to reconsider the decision by notice in writing given to the Minister within 90 days after the decision first comes to the person's notice.

(4) The Minister must reconsider the initial decision as soon as practicable after receiving a request under subregulation (3), and may:

(a) confirm the initial decision; or

(b) revoke the initial decision; or

(c) revoke the initial decision and make a decision in substitution for the initial decision.

(5) After reconsidering an initial decision, the Minister must give to the applicant a notice in writing stating:

(a) the result of the reconsideration; and

(b) that the applicant may, unless subsection 28 (4) of the *Administrative Appeals Tribunal Act 1975* applies:

(i) apply for a statement setting out the reasons for the decision on reconsideration; and

(ii) subject to that Act, make an application to the Administrative Appeals Tribunal for review of that decision.

(6) If a person who makes a request under subregulation (3) does not receive notice of the decision of the Minister on reconsideration within 60 days after making the request, the Minister is taken to have confirmed the initial decision.

(7) If written notice of the making of an initial decision is given to a person whose interests are affected by the decision, the notice must include a statement to the effect that a person whose interests are affected by the decision may:

(a) seek a reconsideration of the decision under this regulation; and

(b) subject to the *Administrative Appeals Tribunal Act 1975*, if the person is dissatisfied with the decision upon reconsideration, make an application to the Administrative Appeals Tribunal for review of that decision.

(8) Any failure to comply with the requirements of subregulation (6) or (7) in relation to a decision does not affect the validity of the decision.

(9) Application may be made to the Administrative Appeals Tribunal for review of a reviewable decision.

Note Under section 27A of the *Administrative Appeals Tribunal Act 1975*, the decision-maker must give to any person whose interests are affected by the decision notice, in writing or otherwise, of the making of the decision and of the person's right to have the decision reviewed. In giving that notice, the decision-maker must have regard to the Code of Practice determined under section 27B of that Act (*Gazette* No. S 342, 7 December 1994), accessible on the Internet at:

http://scaleplus.law.gov.au/html/instruments/0/14/0/IN000020.htm

Schedule 1 Essential principles

(regulation 2.1)

Part 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 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.

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.

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.

Part 2 Principles about design and construction

7 Chemical, physical and biological properties

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 in the device; and

(b) the compatibility between the materials used and biological tissues, cells and body fluids;

having regard to the intended purpose of the device.

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.

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; and

(b) allows the medicine to perform as intended.

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:

(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.

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:

(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.

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.

(3) The device must be produced in appropriately controlled conditions.

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 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) This clause applies in relation to a medical device that is intended by the 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.

(2) The device must be designed and produced in a way that ensures that the user can control the level of the emission.

(3) The device must be designed and produced in a way that ensures the reproducibility and tolerance of relevant variable parameters.

(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.

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:

(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.

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 user, 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.

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.

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.

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.

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 to be provided with medical devices

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 or 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 required 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 required under clause 13.4, the information must be provided in a printed document or using other appropriate media.

13.3 Information to be provided with medical devices — particular requirements

The information mentioned in the following table must be provided with a medical device.

Item	Information to be provided
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 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

Item	Information to be provided
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 in the above table, 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 the 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 in the following table that is applicable to the device.

Item	Information to be provided
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

Item	Information to be provided
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 use of the device
6	Sufficient information to enable a user to identify the device, or if relevant, the contents of 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 resterilisation 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

Item	Information to be provided
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 medical 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

Item	Information to be provided
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

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.

Schedule 2 Classification rules

(regulation 3.2)

Part 1 Interpretation

1.1 Transient, short-term and long-term use

For this Schedule:

(a) a medical device is intended for transient use if the manufacturer intends the device to be used continuously for less than 60 minutes; and

(b) a medical device is intended for short-term use if the manufacturer intends the device to be used continuously for at least 60 minutes but not more than 30 days; and

(c) a medical device is intended for long-term use if the manufacturer intends the device to be used continuously for more than 30 days.

Part 2 Rules for non-invasive medical devices

2.1 Non-invasive medical devices — general

A non-invasive medical device is classified as Class I, unless the device is classified at a higher level under another clause in this Part or in Part 4 or 5 of this Schedule.

2.2 Non-invasive medical devices intended to channel or store blood, etc

(1) This clause applies to:

(a) a non-invasive medical device that is intended by the manufacturer to be used to channel or store blood or body liquids that are to be infused, administered or introduced into a patient; and

(b) a non-invasive medical device that is intended by the manufacturer to be used to store an organ, part of an organ or body tissue that is to be later introduced into a patient; and

(c) a non-invasive medical device that:

(i) is intended by the manufacturer to be used to channel or store a liquid or gas that is to be infused, administered or introduced into a patient; and

(ii) may be connected to an active medical device classified as Class IIa or higher.

(2) The device is classified as Class IIa.

2.3 Non-invasive medical devices intended to modify the biological or chemical composition of blood, etc

(1) Subject to subclause (2), a non-invasive medical device that is intended by the manufacturer to be used to modify the biological or chemical composition of blood, other body liquids, or other liquids intended to be infused into a patient, is classified as Class IIb.

(2) If the treatment for which the device is designed consists of filtration, centrifugation or exchanges of gas or heat, the device is classified as Class IIa.

2.4 Non-invasive medical devices intended to have contact with injured skin

(1) This clause applies to a non-invasive medical device that is intended by the manufacturer to be used in contact with injured skin (including a device the principal intention of which is to manage the micro-environment of a wound).

(2) Subject to subclauses (3) and (4), the device is classified as Class IIa.

(3) If the device is intended to be used:

(a) as a mechanical barrier; or

(b) for compression; or

(c) for the absorption of exudates;

the device is classified as Class I.

(4) If the device is intended to be used principally for wounds that have breached the dermis and the wounds can only heal by secondary intent, the device is classified as Class IIb.

Part 3 Rules for invasive medical devices and implantable medical devices

3.1 Invasive medical devices intended to be used by penetration of body orifices

(1) This clause applies to an invasive medical device (other than a surgically invasive medical device) that is intended by the manufacturer to be used to penetrate a body orifice of a patient.

(2) If the device is not intended to be connected to an active medical device, the following rules apply:

(a) if the device is intended for transient use, the device is classified as Class I;

(b) if the device is intended for short-term use:

(i) the device is classified as Class IIa; or

(ii) if the device is intended to be used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum, or in a nasal cavity — the device is classified as Class I;

(c) if the device is intended for long-term use:

(i) the device is classified as Class IIb; or

(ii) if the device is intended to be used in the oral cavity as far as the pharynx or in an ear canal up to the ear drum, or the device is intended to be used in a nasal cavity and the device is not liable to be absorbed by the mucous membrane — the device is classified as Class IIa.

(3) If the device is intended to be connected to an active medical device that is classified as Class IIa or higher, the device is classified as Class IIa.

3.2 Surgically invasive medical devices intended for transient use

(1) This clause applies to a surgically invasive medical device that is intended for transient use.

(2) Subject to subclauses (3) to (5), the device is classified as Class IIa.

(3) If the device is intended by the manufacturer specifically to be used to diagnose, monitor, control or correct a defect of the heart, or the central circulatory system, of a patient through direct contact with these parts of the body, the device is classified as Class III.

(4) If the device is a reusable surgical instrument, the device is classified as Class I.

(5) If:

(a) the device is intended by the manufacturer to be used to supply energy in the form of ionising radiation; or

(b) the device is intended by the manufacturer to have a biological effect; or

(c) the device is intended by the manufacturer to be wholly, or mostly, absorbed by the patient's body; or

(d) the device is intended by the manufacturer to be used to administer medicine to a patient by means of a delivery system, and the administration is potentially hazardous to the patient having regard to the characteristics of the device;

the device is classified as Class IIb.

3.3 Surgically invasive medical devices intended for short-term use

(1) This clause applies to a surgically invasive medical device that is intended for short-term use.

(2) Subject to subclauses (3) and (4), the device is classified as Class IIa.

(3) If:

(a) the device is intended by the manufacturer to be used to supply energy in the form of ionising radiation; or

(b) the device is intended by the manufacturer to undergo a chemical change in a patient's body (other than a device that is intended by the manufacturer to be placed in the teeth); or

(c) the device is intended by the manufacturer to administer medicine;

the device is classified as Class IIb.

Note for paragraph (b) A device that is intended by the manufacturer to be placed in the teeth, and to undergo a chemical change in the body, is classified as Class IIa — see subclause (2).

(4) If the device is intended by the manufacturer:

(a) specifically to be used to diagnose, monitor, control or correct a defect of the heart, or the central circulatory system, of a patient through direct contact with these parts of the body; or

(b) specifically to be used in direct contact with the central nervous system of a patient; or

(c) to have a biological effect; or

(d) to be wholly, or mostly, absorbed by a patient's body;

the device is classified as Class III.

(5) For this clause, a medical device that is intended by the manufacturer to be placed in the teeth includes a medical device that is intended by the manufacturer to penetrate a tooth, but does not include a medical device that is intended by the manufacturer to penetrate a tooth and enter the gum or bone beyond the tooth.

3.4 Surgically invasive medical devices intended for long-term use and implantable medical devices

(1) This clause applies to:

(a) a surgically invasive medical device that is intended for long-term use; and

(b) an implantable medical device.

(2) Subject to subclauses (3) and (4), the device is classified as Class IIb.

(3) If the device is intended by the manufacturer to be placed in the teeth of a patient, the device is classified as Class IIa.

(4) If the device is intended by the manufacturer:

(a) to be used in direct contact with the heart, the central circulatory system or the central nervous system of a patient; or

(b) to have a biological effect; or

(c) to be wholly, or mostly, absorbed by a patient's body; or

(d) to undergo a chemical change in a patient's body (other than a device that is intended by the manufacturer to be placed in the teeth); or

(e) to be used to administer medicine;

the device is classified as Class III.

Note for paragraph (d) A device that is intended by the manufacturer to be placed in the teeth, and to undergo a chemical change in the body, is classified as Class IIa — see subclause (3).

(5) For this clause, a medical device that is intended by the manufacturer to be placed in the teeth includes a medical device that is intended by the manufacturer to penetrate a tooth, but does not include a medical device that is intended by the manufacturer to penetrate a tooth and enter the gum or bone beyond the tooth.

Part 4 Special rules for active medical devices

4.1 Active medical devices — general

An active medical device is classified as Class I, unless the device is classified at a higher level under another clause in this Part or in Part 2, 3 or 5.

4.2 Active medical devices for therapy

(1) Subject to subclause (2), an active medical device for therapy that is intended by the manufacturer to be used to administer energy to a patient, or exchange energy to or from a patient, is classified as Class IIa.

(2) If the device is of a kind such that the administration or exchange of energy occurs in a potentially hazardous way, having regard to the nature, density and site of application of the energy, the device is classified as Class IIb.

(3) An active medical device that is intended by the manufacturer to be used to control or monitor, or directly influence, the performance of an active medical device for therapy of the kind mentioned in subclause (2) is classified as Class IIb.

4.3 Active medical devices for diagnosis

(1) This clause applies to an active medical device for diagnosis.

(2) If:

(a) the device is intended by the manufacturer to be used to supply energy that will be absorbed by a patient's body (other than a device that is intended only to illuminate the patient's body in the visible spectrum); or

(b) the device is intended by the manufacturer to be used to image *in vivo* distribution of radiopharmaceuticals in a patient; or

(c) the device is intended by the manufacturer to be used to allow direct diagnosis or monitoring of vital physiological processes of a patient (other than a device of a kind mentioned in paragraph (3) (a));

the device is classified as Class IIa.

Note for paragraph (a) A device that is intended only to illuminate the patient's body in the visible spectrum is classified as Class I — see clause 4.1 of this Schedule.

(3) If:

(a) the device is intended by the manufacturer specifically to be used to monitor vital physiological parameters of a patient, and the nature of the variations monitored is of a kind that could result in immediate danger to the patient (for example, variations in cardiac performance, respiration, activity of the central nervous system); or

(b) the device is intended by the manufacturer to emit ionising radiation and to be used for diagnostic or therapeutic interventional radiology; or

(c) the device is intended by the manufacturer to be used to control or monitor, or directly influence, the performance of a device of the kind mentioned in paragraph (b);

the device is classified as Class IIb.

4.4 Active medical devices intended to administer or remove medicines, etc from a patient's body

(1) Subject to subclause (2), an active medical device that is intended by the manufacturer to be used to administer medicine, body liquids or other substances to a patient, or to remove medicine, body liquids or other substances from a patient, is classified as Class IIa.

(2) If the device is of a kind such that the administration or removal of the medicine, body liquids or other substances is potentially hazardous to the patient, having regard to the nature of the substances involved, the part of the patient's body concerned, and the characteristics of the device, the device is classified as Class IIb.

Part 5 Special rules for particular kinds of medical devices

5.1 Medical devices incorporating a medicine

(1) This clause applies to a medical device of any kind that incorporates, or is intended to incorporate, as an integral part, a substance that:

(a) if used separately, would be a medicine; and

(b) is liable to act on a patient's body with action ancillary to that of the device.

(2) The device is classified as Class III.

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

5.2 Medical devices intended for contraception or prevention of sexually transmitted diseases

(1) Subject to subclause (2), a medical device that is intended by the manufacturer to be used for contraception, or the prevention of sexually transmitted diseases, is classified as Class IIb.

(2) If the device is an implantable medical device or an invasive medical device that is intended for long-term use, the device is classified as Class III.

5.3 Medical devices intended for disinfecting, cleaning, etc

(1) A medical device that is intended by the manufacturer specifically to be used for disinfecting, cleaning, rinsing or hydrating contact lenses is classified as Class IIb.

(2) A medical device that is intended by the manufacturer specifically to be used for disinfecting another medical device is classified as Class IIb.

(3) This clause does not apply to a medical device that is intended by the manufacturer to be used only to clean another medical device (other than contact lenses) by means of physical action.

Note A medical device of the kind described in subclause (3) is classified as Class I — see clause 2.1 of this Schedule.

5.4 Non-active medical devices intended to record X-ray diagnostic images

A non-active medical device that is intended by the manufacturer to be used to record X-ray diagnostic images is classified as Class IIa.

5.5 Medical devices containing non-viable animal tissues, cells or other substances, or microbial or recombinant tissues, cells or other substances

(1) This clause applies to a medical device if the device contains:

(a) tissues, cells or substances of animal origin that have been rendered non-viable, or tissues, cells or substances of microbial or recombinant origin; or

(b) a combination of tissues, cells or substances of the kind described in paragraph (a).

(2) The device is classified as Class III, unless:

(a) the device contains only tissues, cells or substances of animal origin that have been rendered non-viable; and

(b) the device is intended by the manufacturer to come into contact with intact skin only.

Note A medical device that conforms with the description in paragraphs (2) (a) and (b) is classified as Class I under clause 2.1 of this Schedule.

5.6 Medical devices that are blood bags

A medical device that is a blood bag is classified as Class IIb.

5.7 Active implantable medical devices

(1) An active implantable medical device is classified as Class AIMD.

(2) An implantable accessory to an active implantable medical device is classified as Class III.

(3) An active medical device that is intended by the manufacturer to be used to control or monitor, or directly influence, the performance of an active implantable medical device is classified as Class III.

5.8 Medical devices intended for export only

A medical device that is intended by the manufacturer to be for export only is classified as Class I.

5.9 Medical devices that are mammary implants

A medical device that is a mammary implant is classified as Class III.

Schedule 3 Conformity assessment procedures

(regulation 3.4)

Part 1 Full quality assurance procedures

1.1 Overview

The conformity assessment procedures set out in this Part provide for the manufacturer of a kind of medical device:

(a) to:

(i) implement a quality management system for the design, production, packaging, labelling and final inspection of the kind of device; and

(ii) arrange for assessment of the system by the Secretary; and

(b) for a Class AIMD medical device or Class III medical device — to arrange for examination of the design of the kind of device by the Secretary; and

(c) to allow the Secretary to monitor the operation of, and carry out inspections of, the system; and

(d) to make a declaration of conformity in relation to the kind of device; and

(e) to:

(i) notify the Secretary of any change to the system, or to the kinds of devices to which the system is to be applied; and

(ii) arrange for assessment of any such change by the Secretary; and

(f) to establish and keep up-to-date a post-market monitoring, reporting and corrective action system.

Note See Division 3.2 in relation to the kinds of medical devices to which these conformity assessment procedures may be applied.

1.2 References to kinds of medical devices

A reference in this Part to a kind of medical device includes a reference to an individual medical device.

1.3 Implementation and assessment of quality management system

(1) The manufacturer of a kind of medical device must:

(a) implement a quality management system for the design, production, packaging, labelling and final inspection of the kind of device; and

(b) arrange for assessment of the system by the Secretary.

(2) For the purpose of enabling the assessment to be carried out, the manufacturer must have available, in writing, the following information and undertakings:

(a) the name and business address of the manufacturer;

(b) details of each manufacturing site where the system is to be applied;

(c) all relevant information about the kind of medical devices to which the system is to be applied;

(d) the documentation in relation to the system;

(e) an undertaking by the manufacturer to continue to comply with the requirements of the system after assessment;

(f) an undertaking by the manufacturer to ensure that the system is at all times adequate and efficacious;

(g) an undertaking by the manufacturer to notify the Secretary, or the person in relation to whom the kind of device is included in the Register, of any information of the kind mentioned in subparagraph 1.4 (3) (c) (i) or (ii) that the manufacturer becomes aware of in relation to the kind of medical device.

1.4 Requirements of quality management system

(1) A quality management system that is to be assessed under clause 1.3 must meet the requirements of this clause.

(2) The system must be of a kind such that its application will ensure that each medical device to which the system is applied complies with the applicable provisions of the essential principles, the classification rules, and these conformity assessment procedures, at each stage, from the design of the device until its final inspection before being supplied.

(3) The system must include post-marketing requirements under which the manufacturer of a medical device to which the system is applied is required:

(a) to systematically review experience gained, post-production, in relation to medical devices of that kind; and

(b) to implement appropriate means to apply any necessary corrective action in relation to the design or production of such devices; and

(c) to notify the Secretary, or the person in relation to whom the kind of device is included in the Register, as soon as practicable after becoming aware of:

(i) information relating to:

(A) any malfunction or deterioration in the characteristics or performance of the kind of device; or

(B) any inadequacy in the design, production, labelling or instructions for use of the kind of device, or in the advertising material for the kind of device; or

(C) any use in accordance with, or contrary to, the use intended by the manufacturer of the kind of device;

that might lead, or might have led, to the death of a patient or a user of the device, or to a serious deterioration in his or her state of health; or

(ii) information relating to any technical or medical reason for a malfunction or deterioration of a kind mentioned in subparagraph (i) that has led the manufacturer to take steps to recover devices of that kind that have been distributed.

Note See also paragraph 41FN (3) (d) and section 41MP of the Act in relation to the requirement to give certain information about a medical device to the Secretary.

(4) Each requirement of the system must be documented in a systematic and orderly way in the form of written policies and procedures (for example, as quality programs, quality plans, quality manuals or quality records).

(5) The documentation of the system must include adequate information in relation to the following matters:

(a) the manufacturer's quality objectives;

(b) the organisation of the manufacturer's business, including, in particular, a description of the following:

(i) the organisational structure of the business;

(ii) the responsibilities of managerial staff and their authority in relation to the quality of the design and production of medical devices manufactured by the manufacturer;

(iii) the methods of monitoring whether the system is operating effectively, in particular, whether the desired quality of design and product is being achieved and how products that fail to meet the desired quality are controlled;

(c) the design of the kind of medical device to which the system is to be applied, including, in particular, the following:

(i) details of the processes, systems and measures used for controlling, monitoring and verifying that at each stage of the design process, the device complies with the applicable provisions of the essential principles;

(ii) a general description of the kind of device, and of any variants of the kind of device, that the manufacturer plans to manufacture;

(iii) details of the design specifications for the kind of device, including:

(A) any medical device standard or conformity assessment standard that has been applied to the device; and

(B) the results of the risk analysis carried out; and

(C) if no medical device standard or conformity assessment standard, or part only of such a standard, has been applied to the device — the solutions adopted to ensure that each device complies with the applicable provisions of the essential principles;

(iv) for a kind of device that is intended by the manufacturer to be connected to another device — evidence demonstrating that the device will comply with the applicable provisions of the essential principles when it is connected to the other device and both devices are being used for their intended purposes;

(v) a statement indicating whether or not the kind of device incorporates, or is intended to incorporate, as an integral part, a substance mentioned in clause 7.4 of the essential principles, and, for a device that will do so, data derived from tests conducted in relation to the device and the substance, and their interaction;

(vi) a statement indicating whether or not the device contains tissues, cells or substances of animal origin that have been rendered non-viable, or tissues, cells or substances of microbial or recombinant origin;

(vii) a copy of the clinical evidence, in relation to the kind of device, required by the clinical evaluation procedures;

(viii) a copy of the information to be provided with the kind of device;

(d) the inspection and quality assurance techniques to be applied in the production of the kind of medical device to which the system is to be applied, including, in particular, information about the following:

(i) the processes and procedures to be used (particularly in relation to sterilisation) and the documents relating to those processes and procedures;

(ii) the procedures to be used for purchasing goods or services in relation to the production of the kind of device and the documents relating to those procedures;

(iii) product identification procedures to be prepared and kept up-to-date from drawings, specifications or other documents at each stage of production;

(e) the tests or trials to be carried out before, during and after production of the kind of medical device to which the system is to be applied, including, in particular, information about:

(i) the frequency with which the tests or trials are to be carried out; and

(ii) the equipment (including the traceability of the calibration of the equipment) used, or to be used, to carry out the tests or trials;

(f) the system for reviewing experience gained in the post-production phase in relation to the kind of medical device to which the quality management system has been applied, and the means by which any necessary corrective action will be applied in relation to the design or production of such devices;

(g) whether a conformity assessment standard has been applied to the system and, if no conformity assessment standard, or part only of a conformity assessment standard, has been applied to the system — the solutions adopted to ensure that the system complies with subclause (2).

1.5 Changes to quality management system or kinds of medical device to which system is to be applied

(1) This clause applies to the manufacturer of a kind of medical device if:

(a) the manufacturer has implemented, and had assessed under clause 1.3 of this Schedule, a quality management system that is to be applied to the kind of device; and

(b) after assessment, the manufacturer plans to make:

(i) a substantial change to the system; or

(ii) a change to the kinds of medical devices to which the system is to be applied.

(2) The manufacturer must:

(a) notify the Secretary, in writing, of the proposed change; and

(b) arrange for assessment of the change by the Secretary to verify whether the system, as changed, meets the requirements of clause 1.4 of this Schedule.

(3) For the purpose of enabling the assessment to be carried out, the manufacturer must have available, in writing, details of any consequential changes to the information and documentation required under subclause 1.3 (2) of this Schedule in relation to the system or kinds of devices.

(4) After any change to the quality management system, the manufacturer must ensure that the changed system continues to meet the requirements of clause 1.4 of this Schedule.

1.6 Examination of design of Class AIMD medical device or Class III medical device

(1) This clause applies to the manufacturer of a Class AIMD medical device, or a Class III medical device, to which the quality management system that is to be assessed under clause 1.3 is to be applied.

(2) For the purpose of assessing whether the kind of medical device complies with the applicable provisions of the essential principles, the manufacturer of the device must arrange for examination by the Secretary of the design of the kind of device.

(3) For the purpose of enabling the examination to be carried out, the manufacturer must have available:

(a) information, in writing, in relation to the following matters in relation to the kind of medical device:

(i) the design;

(ii) the production process;

(iii) the intended performance; and

(b) a copy of the documentation mentioned in paragraph 1.4 (5) (c) of this Schedule necessary to assess whether the kind of medical device complies with the applicable provisions of the essential principles.

(4) If, after examination by the Secretary of the design of a kind of medical device, the manufacturer makes a substantial change to the design, or the intended performance, of the kind of device, the manufacturer must:

(a) notify the Secretary, in writing, of the change; and

(b) arrange for examination of the change by the Secretary to assess whether the design, or the intended performance, of the medical device, as changed, complies with the applicable provisions of the essential principles.

(5) For the purpose of enabling an examination to be carried out under subclause (4), the manufacturer must have available, in writing, details of any consequential changes to the documentation in relation to the design of the device mentioned in paragraph 1.4 (5) (c) of this Schedule.

Note This clause need not be applied to:

(a) a Class IIb medical device (see Division 3.2, paragraphs 3.7 (1) (a) and (2) (a)); or

(b) a Class IIa medical device (see Division 3.2, paragraphs 3.8 (1) (a) and (2) (a)).

1.7 Information to be given to authorised person

(1) If requested to do so by an authorised person, the manufacturer of a kind of medical device must:

(a) give to the Secretary the following information in relation to the quality management system or the kinds of medical device to which the system is applied:

(i) a copy of the documentation mentioned in subclause 1.4 (5) of this Schedule;

(ii) data in relation to the design of the kinds of medical device (for example, the results of any analysis of the device, calculations, tests);

(iii) data in relation to the manufacture of the kinds of medical device (for example, inspection reports, test data, calibration data, information about the qualifications of staff); and

(b) arrange for tests specified by the authorised person to be carried out for the purpose of checking whether the quality management system is operating effectively.

(2) If any inspections or tests are carried out by an authorised person in relation to the manufacturer's premises, or medical devices produced by the manufacturer, the manufacturer may ask the authorised person to give to the manufacturer a report stating the findings of the inspections or tests.

1.8 Declaration of conformity

(1) The manufacturer of a kind of medical device to which a quality management system that has been assessed under clause 1.3 of this Schedule has been applied must make a declaration of conformity in relation to the kind of device.

(2) The declaration must:

(a) state that the declaration is a declaration of conformity made under clause 1.8 of Schedule 3 to the *Therapeutic Goods (Medical Devices) Regulations 2002*; and

(b) state the name and business address of the manufacturer of the device; and

(c) state the following information in relation to each kind of medical device to which the system has been applied:

(i) the unique product identifier (for example, the product name or model number);

(ii) the medical device classification;

(iii) the device nomenclature system code; and

(d) if the system has not been applied to all medical devices of that kind manufactured by the manufacturer — give details of the medical devices to which the system has been applied (for example, by reference to lot numbers, batches or serial numbers, or by specifying the kinds of medical devices or the times of manufacture); and

(e) state that each kind of medical device to which the system has been applied complies with the applicable provisions of the essential principles, the classification rules, and the full quality assurance procedures, at each stage, from the design of the device until its final inspection before being supplied; and

(f) state:

(i) the conformity assessment certificate number issued in relation to the system or the kind of medical devices to which the system has been applied; and

(ii) if applicable, the number of, or other identifying reference to, any equivalent approval or certificate (however described) issued outside Australia in relation to the system or the kind of medical devices to which the system has been applied; and

(g) give details of any conformity assessment standard or medical device standard that has been applied to a kind of device to which the system has been applied; and

(h) be signed by a person authorised by the manufacturer; and

(i) set out the name and position of the person signing the declaration; and

(j) state the date when the declaration is signed.

1.9 Records

(1) The manufacturer of a kind of medical device to which a quality management system that has been assessed under clause 1.3 of this Schedule has been applied must keep the following records in relation to the system and the kind of device:

(a) the documentation mentioned in subclause 1.4 (5) of this Schedule;

(b) details of any changes made to the system and to the information and documentation required under subclause 1.3 (2) of this Schedule;

(c) if the device is a Class AIMD medical device or Class III medical device, the information and documentation required under subclause 1.6 (3) of this Schedule;

(d) details of any changes made to the kind of medical device and to the documentation in relation to the design of the device mentioned in paragraph 1.4 (5) (c) of this Schedule;

(e) the declaration of conformity under clause 1.8 of this Schedule;

(f) details of the systematic review carried out, post-production, in relation to medical devices of that kind;

(g) any notice, report, certificate or other document in relation to the system issued to the manufacturer by the Secretary.

(2) The manufacturer must keep the records for at least 5 years after the manufacture of the last medical device to which the quality management system was applied.

(3) On request from the Secretary, the manufacturer must make the records available to the Secretary.

Part 2 Type examination procedures

2.1 Overview

The conformity assessment procedures set out in this Part provide for the manufacturer to arrange for examination by the Secretary of a representative sample of a kind of medical device (the ***type***).

Note See Division 3.2 in relation to the kinds of medical devices to which these conformity assessment procedures may be applied.

2.2 References to kinds of medical devices

A reference in this Part to a kind of medical device includes a reference to an individual medical device.

2.3 Examination of type

(1) The manufacturer of a medical device must arrange for examination of the type by the Secretary.

(2) For the purpose of enabling the examination to be carried out, the manufacturer must have available, in writing, the following information:

(a) the name and business address of the manufacturer;

(b) the documentation mentioned in subclause (3) in relation to the type.

(3) For paragraph (2) (b), the documentation must include adequate information about the design, production process and intended performance of the type, and must include, in particular, the following:

(a) a general description of the type, and of any variants of the type that the manufacturer plans to manufacture;

(b) diagrams or drawings of the design of the type, including diagrams or drawings of any components, sub-assemblies or circuits of the type;

(c) any descriptions or explanations that are necessary to enable the diagrams or drawings mentioned in paragraph (b), or the intended operation of the type, to be properly understood;

(d) the proposed method or methods of manufacture of the type;

(e) if the type is intended by the manufacturer to be supplied in a sterile state — a description of the method used to sterilise the type;

(f) details of each medical device standard or conformity assessment standard that has been applied, wholly or in part, to the type;

(g) if no medical device standard or conformity assessment standard has been applied, or such a standard has been only partly applied, to the type — descriptions of the solutions adopted to ensure that the type complies with the applicable provisions of the essential principles;

(h) the results of any design calculations, risk analyses, investigations, technical tests, or any other tests, carried out in relation to the type;

(i) a statement indicating whether or not the type incorporates, or is intended to incorporate, as an integral part, a substance mentioned in clause 7.4 of the essential principles, and, for a type that does so, data derived from tests conducted in relation to the type and the substance, and their interaction;

(j) a statement indicating whether or not the device contains tissues, cells or substances of animal origin that have been rendered non-viable, or tissues, cells or substances of microbial or recombinant origin;

(k) a copy of the clinical evidence, in relation to the kind of device, required by the clinical evaluation procedures;

(l) a copy of the information to be provided with the type.

(4) The manufacturer must make available to the Secretary for examination:

(a) a sample of the type; and

(b) on request from the Secretary, additional samples of the type.

(5) If the type is intended by the manufacturer to be connected to another medical device, the manufacturer must, on request from the Secretary, make available to the Secretary, or arrange for the Secretary to have access to, a sample of the device.

2.4 Changes to design of medical device after examination

(1) This clause applies if, after examination by the Secretary of a type, the manufacturer of the type plans to make a substantial change to the design, or intended performance, of the kind of medical device to which the type relates.

(2) The manufacturer must:

(a) notify the Secretary, in writing, of the proposed change; and

(b) arrange for examination of the change by the Secretary to verify whether the type, as changed, meets the requirements of clause 2.3 of this Schedule.

(3) For the purpose of enabling the examination to be carried out, the manufacturer must have available, in writing, details of any consequential changes to the documentation required under subclause 2.3 (3) of this Schedule in relation to the type.

2.5 Records

(1) The manufacturer of the type that has been examined under this Part must keep the following records:

(a) the documentation required under subclause 2.3 (3) of this Schedule in relation to the type;

(b) details of any changes made to the type and to the documentation required under subclause 2.3 (3) of this Schedule;

(c) any notice, report, certificate or other document in relation to the type issued to the manufacturer by the Secretary.

(2) The manufacturer must keep the records for at least 5 years after the manufacture of the last medical device of that type.

(3) On request from the Secretary, the manufacturer must make the records available to the Secretary.

Part 3 Verification procedures

3.1 Overview

The conformity assessment procedures set out in this Part provide for the manufacturer of a kind of medical device:

(a) to arrange for examination and testing of the kind of device by the Secretary; and

(b) to make a declaration of conformity in relation to the kind of device; and

(c) to establish and keep up-to-date a post-market monitoring, reporting and corrective action system.

Note See Division 3.2 in relation to the kinds of medical devices to which these conformity assessment procedures may be applied.

3.2 References to kinds of medical devices

A reference in this Part to a kind of medical device includes a reference to an individual medical device.

3.3 Verification of conformity

(1) The manufacturer of a medical device must arrange for examination and testing by the Secretary of each device of that kind, or a representative sample from a batch of medical devices of that kind, to verify that:

(a) for a kind of device in relation to which the type examination procedures have been applied — each device, or representative sample, conforms to the approved type; and

(b) for a kind of device to which the declaration of conformity (not requiring assessment by Secretary) procedures have been applied — each device, or representative sample, is in accordance with the technical documentation prepared under clause 6.4 of those procedures for that kind of device; and

(c) each device, or representative sample, complies with the applicable provisions of the essential principles, the classification rules and these conformity assessment procedures.

(2) For the purpose of enabling the examination and testing to be carried out, the manufacturer must have available, in writing, the following information and undertakings:

(a) the name and business address of the manufacturer;

(b) the documentation describing the manufacturing process to be used to manufacture the kind of device;

(c) a description of the procedures that have been, or will be, implemented to ensure that all devices of that kind manufactured by the manufacturer will be uniform;

(d) an undertaking to implement those procedures to ensure that all devices of that kind manufactured by the manufacturer will be uniform;

(e) an undertaking by the manufacturer to notify the Secretary, or the person in relation to whom the kind of device is included in the Register, of any information of the kind mentioned in subparagraph 3.4 (2) (c) (i) or (ii) that the manufacturer becomes aware of in relation to the kind of medical device;

(f) for a kind of device in relation to which the type examination procedures have been applied — evidence that the device conforms to the approved type and a copy of the technical documentation required under subclause 2.3 (3) of the type examination procedures for the approved type;

(g) for a kind of device to which the declaration of conformity (not requiring assessment by Secretary) procedures have been applied — a copy of the technical documentation prepared under clause 6.4 of those procedures for that kind of device.

(3) The manufacturer must make available to the Secretary for examination and testing:

(a) for a kind of device in relation to which the type examination procedures have been applied:

(i) each medical device that is to be verified in relation to the approved type; or

(ii) each medical device selected by the Secretary on a statistical basis from a uniform batch of devices that are to be verified in relation to the approved type; and

(b) for a kind of device to which the declaration of conformity (not requiring assessment by Secretary) procedures have been applied:

(i) each medical device of that kind to which those procedures have been applied; or

(ii) each medical device selected by the Secretary on a statistical basis from a uniform batch of devices of that kind to which those procedures have been applied.

3.4 Requirements of manufacturing system

(1) The manufacturer of a medical device must ensure that:

(a) for a kind of device in relation to which the type examination procedures have been applied — the process used to manufacture the device results in the device conforming to the approved type; and

(b) for a kind of device to which the declaration of conformity (not requiring assessment by Secretary) procedures have been applied — the process used to manufacture the device results in the device being in accordance with the technical documentation prepared under clause 6.4 of those procedures for that kind of device.

(2) The manufacturer of a medical device of a kind mentioned in subclause (1) must ensure that the process used to manufacture the device includes post-marketing requirements under which the manufacturer is required:

(a) to systematically review experience gained in the post-production phase in relation to medical devices of that kind; and

(b) to implement appropriate means to apply any necessary corrective action in relation to the design or production of such devices; and

(c) to notify the Secretary, or the person in relation to whom the kind of device is included in the Register, as soon as practicable after becoming aware of:

(i) information relating to:

(A) any malfunction or deterioration in the characteristics or performance of the kind of device; or

(B) any inadequacy in the design, production, labelling, instructions for use or advertising materials of the kind of device; or

(C) any use in accordance with, or contrary to, the use intended by the manufacturer of the kind of device;

that might lead, or might have led, to the death of a patient or a user of the device, or to a serious deterioration in his or her state of health; or

(ii) information relating to any technical or medical reason for a malfunction or deterioration of a kind mentioned in subparagraph (i) that has led the manufacturer to take steps to recover devices of that kind that have been distributed.

Note See also paragraph 41FN (3) (d) and section 41MP of the Act in relation to the requirement to give certain information about a medical device to the Secretary.

(3) Before manufacturing a medical device of a kind mentioned in subclause (1), the manufacturer must prepare documentation describing the manufacturing process to be used to produce the device.

(4) Without limiting subclause (3), the documentation must include a description of the procedures that have been, or will be, implemented to ensure that all devices of that kind manufactured by the manufacturer will be uniform.

3.5 Declaration of conformity

(1) The manufacturer of a Class AIMD medical device, Class III medical device or Class IIb medical device that has been verified under this Part must make a declaration of conformity in relation to the kind of device.

Note This clause need not be applied to the following kinds of medical devices if the declaration of conformity (not requiring assessment by Secretary) procedures have been applied to the device:

(a) a Class IIa medical device (see Division 3.2, subparagraph 3.8 (1) (b) (i));

(b) a Class I medical device that has a measuring function (see Division 3.2, paragraph 3.9 (3) (a)).

(2) The declaration must:

(a) state that the declaration is a declaration of conformity made under clause 3.5 of Schedule 3 to the *Therapeutic Goods (Medical Devices) Regulations 2002*; and

(b) state the name and business address of the manufacturer of the device; and

(c) state the following information in relation to each device that has been verified:

(i) the unique product identifier (for example, the product name or model number);

(ii) the medical device classification;

(iii) the device nomenclature system code; and

(d) if the verification does not relate to all medical devices of that kind manufactured by the manufacturer — give details of the medical devices to which the verification relates (for example, by reference to lot numbers, batches or serial numbers, or by specifying the kinds of medical devices or the times of manufacture); and

(e) for a kind of device in relation to which the type examination procedures have been applied:

(i) state the conformity assessment certificate number issued in relation to the approved type, and, if applicable, the number of, or other identifying reference to, any equivalent approval or certificate (however described) issued outside Australia in relation to the approved type; and

(ii) state that the kind of device conforms to the approved type; and

(f) state that each kind of medical device or batch of devices complies with the applicable provisions of the essential principles and the classification rules;

(g) state the basis on which the declaration is made; and

(h) give details of any conformity assessment standard or medical device standard that has been applied to the kind of device or the processes used to manufacture the device; and

(i) be signed by a person authorised by the manufacturer; and

(j) set out the name and position of the person signing the declaration; and

(k) state the date when the declaration is signed.

3.6 Records

(1) The manufacturer of a kind of medical device that has been verified under this Part must keep the following records:

(a) the documentation mentioned in subclause 3.4 (3) of this Schedule;

(b) for a Class AIMD medical device, Class III medical device or Class IIb medical device — the declaration of conformity under clause 3.5 of this Schedule;

(c) any notice, report, certificate or other document in relation to the device, or a batch of devices that includes the device, issued to the manufacturer by the Secretary.

(2) The manufacturer must keep the records for at least 5 years after the manufacture of the last medical device to which the verification relates.

(3) On request from the Secretary, the manufacturer must make the records available to the Secretary.

Part 4 Production quality assurance procedures

4.1 Overview

The conformity assessment procedures set out in this Part provide for the manufacturer of a kind of medical device:

(a) to:

(i) implement a quality management system for the production and final inspection of the kind of device; and

(ii) arrange for assessment of the system by the Secretary; and

(b) to allow the Secretary to monitor the operation of, and carry out inspections of, the system; and

(c) to make a declaration of conformity in relation to the kind of device; and

(d) to:

(i) notify the Secretary of any change to the system; and

(ii) arrange for assessment of any such change by the Secretary; and

(e) to establish and keep up-to-date a post-market monitoring, reporting and corrective action system.

Note See Division 3.2 in relation to the kinds of medical devices to which these conformity assessment procedures may be applied.

4.2 References to kinds of medical devices

A reference in this Part to a kind of medical device includes a reference to an individual medical device.

4.3 Implementation and assessment of production quality management system

(1) The manufacturer of a medical device must:

(a) implement a quality management system for the production and final inspection of the kind of device; and

(b) arrange for assessment of the system by the Secretary.

(2) For the purpose of enabling the assessment to be carried out, the manufacturer must have available, in writing, the following information and undertakings:

(a) the name and business address of the manufacturer;

(b) details of each manufacturing site where the system is to be applied;

(c) all relevant information about the kinds of medical devices to which the system is to be applied;

(d) the documentation in relation to the system;

(e) an undertaking by the manufacturer to continue to comply with the requirements of the system after assessment;

(f) an undertaking by the manufacturer to ensure that the system is at all times adequate and efficacious;

(g) for a kind of device in relation to which the type examination procedures have been applied — evidence that the device conforms to the approved type and a copy of the technical documentation required under subclause 2.3 (3) of the type examination procedures for the approved type;

(h) for a kind of device to which the declaration of conformity (not requiring assessment by Secretary) procedures have been applied — a copy of the technical documentation prepared under clause 6.4 of those procedures for that kind of device;

(i) an undertaking by the manufacturer to notify the Secretary, or the person in relation to whom the kind of device is included in the Register, of any information of the kind mentioned in subparagraph 4.4 (3) (c) (i) or (ii) that the manufacturer becomes aware of in relation to the kind of medical device.

4.4 Requirements of production quality management system

(1) A quality management system that is to be assessed under clause 4.3 must meet the requirements of this clause.

(2) The system must be of a kind such that its application will ensure that:

(a) each medical device to which the system is applied that is of a kind in relation to which the type examination procedures have been applied conforms to the approved type; and

(b) each medical device to which the system is applied that is of a kind to which the declaration of conformity (not requiring assessment by Secretary) procedures are applied is in accordance with the technical documentation prepared under clause 6.4 of those procedures for the device.

(3) The system must include post-marketing requirements under which the manufacturer of a medical device to which the system is applied is required:

(a) to systematically review experience gained in the post-production phase in relation to medical devices of that kind; and

(b) to implement appropriate means to apply any necessary corrective action in relation to the design or production of such devices; and

(c) to notify the Secretary, or the person in relation to whom the kind of device is included in the Register, as soon as practicable after becoming aware of:

(i) information relating to:

(A) any malfunction or deterioration in the characteristics or performance of the kind of device; or

(B) any inadequacy in the design, production, labelling, instructions for use or advertising materials of the kind of device; or

(C) any use in accordance with, or contrary to, the use intended by the manufacturer of the kind of device;

that might lead, or might have led, to the death of a patient or a user of the device, or to a serious deterioration in his or her state of health; or

(ii) information relating to any technical or medical reason for a malfunction or deterioration of a kind mentioned in subparagraph (i) that has led the manufacturer to take steps to recover devices of that kind that have been distributed.

Note See also paragraph 41FN (3) (d) and section 41MP of the Act in relation to the requirement to give certain information about a medical device to the Secretary.

(4) Each requirement of the system must be documented in a systematic and orderly way in the form of written policies and procedures (for example, as quality programs, quality plans, quality manuals or quality records).

(5) The documentation of the system must include adequate information in relation to the following matters:

(a) the manufacturer's quality objectives;

(b) the organisation of the manufacturer's business, including, in particular, a description of the following:

(i) the organisational structure of the business;

(ii) the responsibilities of managerial staff and their authority in relation to the production of the medical devices produced by the manufacturer;

(iii) the methods of monitoring whether the system is operating effectively, in particular, whether the desired quality of product is being achieved and how products that fail to meet the desired quality are controlled;

(c) the inspection and quality assurance techniques applied in the manufacturing process, including, in particular, information about the following:

(i) the processes and procedures to be used (particularly in relation to sterilisation) and the documents relating to those procedures;

(ii) the procedures to be used for purchasing goods or services in relation to the production of the kind of device produced and the documents relating to those procedures;

(iii) product identification procedures to be prepared and kept up-to-date from drawings, specifications or other documents at each stage of manufacture;

(d) the tests or trials to be carried out before, during and after production of the kind of medical device to which the system is to be applied, including, in particular, information about:

(i) the frequency with which the tests or trials are to be carried out; and

(ii) the equipment (including the traceability of the calibration of the equipment) used, or to be used, to carry out the tests or trials;

(e) the system for reviewing experience gained in the post-production phase in relation to the kind of medical device to which the quality management system has been applied, and the means by which any necessary corrective action will be applied in relation to the design or production of such devices;

(f) whether a conformity assessment standard has been applied to the system and, if no conformity assessment standard, or part only of a conformity assessment standard, has been applied to the system — the solutions adopted to ensure that the system complies with subclause (2).

4.5 Changes to production quality management system

(1) This clause applies to the manufacturer of a medical device if:

(a) the manufacturer has implemented, and had assessed under clause 4.3 of this Schedule, a quality management system that is to be applied to the device; and

(b) after assessment, the manufacturer plans to make a substantial change to the system.

(2) The manufacturer must:

(a) notify the Secretary, in writing, of the proposed change; and

(b) arrange for assessment of the change by the Secretary to verify whether the system, as changed, meets the requirements of clause 4.4 of this Schedule.

(3) For the purpose of enabling the assessment to be carried out, the manufacturer must have available, in writing, details of any consequential changes to the information and documentation required under subclause 4.3 (2) of this Schedule in relation to the system.

(4) After any change to the quality management system, the manufacturer must ensure that the changed system continues to meet the requirements of clause 4.4 of this Schedule.

4.6 Information to be given to authorised person

(1) If requested to do so by an authorised person, the manufacturer of a medical device must:

(a) give to the Secretary the following information in relation to the quality management system or the kinds of medical device to which the system is applied:

(i) a copy of the documentation mentioned in subclause 4.4 (5) of this Schedule;

(ii) data in relation to the production of the kinds of medical device (for example, inspection reports, test data, calibration data, information about the qualifications of staff); and

(b) arrange for tests specified by the authorised person to be carried out for the purpose of checking whether the quality management system is operating effectively.

(2) If any inspections or tests are carried out by an authorised person under this clause, the manufacturer may ask the authorised person to give to the manufacturer a report stating the findings of the inspections or tests.

4.7 Declaration of conformity

(1) The manufacturer of a Class AIMD medical device, Class III medical device or Class IIb medical device to which a quality management system that has been assessed under clause 4.3 of this Schedule has been applied must make a declaration of conformity in relation to the kind of device.

Note This clause need not be applied to the following kinds of medical devices if the declaration of conformity (not requiring assessment by Secretary) procedures have been applied to the device:

(a) a Class IIa medical device (see Division 3.2, subparagraph 3.8 (1) (b) (ii));

(b) a Class I medical device that the manufacturer intends to be supplied in a sterile state (see Division 3.2, subclause 3.9 (2));

(c) a Class I medical device that has a measuring function (see Division 3.2, paragraph 3.9 (3) (b)).

(2) The declaration must:

(a) state that the declaration is a declaration of conformity made under clause 4.7 of Schedule 3 to the *Therapeutic Goods (Medical Devices) Regulations 2002*; and

(b) state the name and business address of the manufacturer of the device; and

(c) state the following information in relation to each kind of medical device to which the system has been applied:

(i) the medical device classification;

(ii) the device nomenclature system code; and

(d) if the system has not been applied to all medical devices of that kind manufactured by the manufacturer — give details of the medical devices to which the system has been applied (for example, by reference to lot numbers,

batches or serial numbers, or by specifying the kinds of medical devices or the times of manufacture); and

(e) for a kind of device in relation to which the type examination procedures have been applied — state that:

(i) the type examination procedures have been applied to the kind of device; and

(ii) the kind of device conforms to the approved type; and

(f) state:

(i) the conformity assessment certificate number issued in relation to the system or the kind of medical devices to which the system has been applied; and

(ii) if applicable, the number of, or other identifying reference to, any equivalent approval or certificate (however described) issued outside Australia in relation to the system or the kind of medical devices to which the system has been applied; and

(g) state that each kind of medical device to which the system has been applied complies with the applicable provisions of the essential principles, the classification rules and the production quality assurance procedures before being supplied; and

(h) give details of any conformity assessment standard that has been applied to the system; and

(i) be signed by a person authorised by the manufacturer; and

(j) set out the name and position of the person signing the declaration; and

(k) state the date when the declaration is signed.

4.8 Records

(1) The manufacturer of a kind of medical device to which a quality management system that has been assessed under clause 4.3 of this Schedule has been applied must keep the following records in relation to the system and the kind of device:

(a) the documentation mentioned in subclause 4.4 (5) of this Schedule;

(b) details of any changes made to the system and to the information and documentation required under subclause 4.5 (3) of this Schedule;

(c) for a Class AIMD medical device, Class III medical device or Class IIb medical device — the declaration of conformity under clause 4.7 of this Schedule;

(d) any notice, report, certificate or other document in relation to the system issued to the manufacturer by the Secretary.

(2) The manufacturer must keep the records for at least 5 years after the manufacture of the last medical device to which the quality management system was applied.

(3) On request from the Secretary, the manufacturer must make the records available to the Secretary.

Part 5 Product quality assurance procedures

5.1 Overview

The conformity assessment procedures set out in this Part provide for the manufacturer of a kind of medical device:

(a) to:

(i) implement a product quality management system for the final inspection and testing of the kind of device; and

(ii) arrange for assessment of the system by the Secretary; and

(b) to allow the Secretary to monitor the operation of, and carry out inspections of, the system; and

(c) to make a declaration of conformity in relation to the kind of device; and

(d) to:

(i) notify the Secretary of any change to the system, or to the kinds of devices to which the system is to be applied; and

(ii) arrange for assessment of any such change by the Secretary; and

(e) to establish and keep up-to-date a post-market monitoring, reporting and corrective action system.

Note See Division 3.2 in relation to the kinds of medical devices to which these conformity assessment procedures may be applied.

5.2 References to kinds of medical devices

A reference in this Part to a kind of medical device includes a reference to an individual medical device.

5.3 Implementation and assessment of product quality management system

(1) The manufacturer of a medical device must:

(a) implement a product quality management system for the final inspection and testing of the kind of device; and

(b) arrange for assessment of the system by the Secretary.

(2) For the purpose of enabling the assessment to be carried out, the manufacturer must have available, in writing, the following information and undertakings:

(a) the name and business address of the manufacturer;

(b) details of each manufacturing site where the system is to be applied;

(c) all relevant information about the kinds of medical devices to which the system is to be applied;

(d) the documentation in relation to the system;

(e) an undertaking by the manufacturer to continue to comply with the requirements of the system after assessment;

(f) an undertaking by the manufacturer to ensure that the system is at all times adequate and efficacious;

(g) for a kind of device in relation to which the type examination procedures have been applied — evidence that the device conforms to the approved type and the technical documentation required under subclause 2.3 (3) of the type examination procedures for the device;

(h) for a kind of device to which the declaration of conformity (not requiring assessment by Secretary) procedures have been applied — a copy of the technical documentation prepared under clause 6.4 of those procedures for that kind of device;

(i) an undertaking by the manufacturer to notify the Secretary, or the person in relation to whom the kind of device is included in the Register, of any information of the kind mentioned in subparagraph 5.4 (3) (c) (i) or (ii) that the manufacturer becomes aware of in relation to the kind of medical device.

5.4 Requirements of product quality management system

(1) A quality management system that is to be assessed under clause 5.3 must meet the requirements of this clause.

(2) The system must be of a kind such that its application will ensure that each medical device, or representative sample of each batch of medical devices, is examined and tested to ensure that the device, or representative sample:

(a) for a kind of device in relation to which the type examination procedures have been applied — conforms to the approved type; or

(b) for a kind of device to which the declaration of conformity (not requiring assessment by Secretary) procedures have been applied — is in accordance with the technical documentation prepared under clause 6.4 of those procedures for the device.

(3) The system must include post-marketing requirements under which the manufacturer of a medical device to which the system is applied is required:

(a) to systematically review experience gained in the post-production phase in relation to medical devices of that kind; and

(b) to implement appropriate means to apply any necessary corrective action in relation to the design or production of such devices; and

(c) to notify the Secretary, or the person in relation to whom the kind of device is included in the Register, as soon as practicable after becoming aware of:

(i) information relating to:

(A) any malfunction or deterioration in the characteristics or performance of the kind of device; or

(B) any inadequacy in the design, production, labelling, instructions for use or advertising materials of the kind of device; or

(C) any use in accordance with, or contrary to, the use intended by the manufacturer of the kind of device;

that might lead, or might have led, to the death of a patient or a user of the device, or to a serious deterioration in his or her state of health; or

(ii) information relating to any technical or medical reason for a malfunction or deterioration of a kind mentioned in subparagraph (i) that has led the manufacturer to take steps to recover devices of that kind that have been distributed.

Note See also paragraph 41FN (3) (d) and section 41MP of the Act in relation to the requirement to give certain information about a medical device to the Secretary.

(4) Each requirement of the system must be documented in a systematic and orderly way in the form of written policies and procedures (for example, as quality programs, quality plans, quality manuals or quality records).

(5) The documentation of the system must include adequate information in relation to the following matters:

(a) the manufacturer's quality objectives;

(b) the organisation of the manufacturer's business, including, in particular, a description of the following:

(i) the organisational structure of the business;

(ii) the responsibilities of managerial staff and their authority in relation to the quality of the medical devices manufactured by the manufacturer;

(iii) the methods of monitoring whether the system is operating effectively, in particular, whether the desired quality of product is being achieved and how products that fail to meet the desired quality are controlled;

(c) the examinations and tests to be carried out after manufacture, including, in particular, information about:

(i) the frequency with which the examinations and tests are to be carried out; and

(ii) the equipment (including the traceability of the calibration of the equipment) to be used to carry out the examinations and tests;

(d) the quality records to be kept, including, for example, records in relation to inspections, tests, calibration of equipment and qualifications of staff.

5.5 Changes to product quality management system or kinds of medical device

(1) This clause applies to the manufacturer of a medical device if:

(a) the manufacturer has implemented, and had assessed under clause 5.3 of this Schedule, a quality management system that is to be applied to the device; and

(b) after assessment, the manufacturer plans to make:

(i) a substantial change to the system; or

(ii) a change to the kinds of medical devices to which the system is to be applied.

(2) The manufacturer must:

(a) notify the Secretary, in writing, of the proposed change; and

(b) arrange for assessment of the change by the Secretary to verify whether the system, as changed, meets the requirements of clause 5.4 of this Schedule.

(3) For the purpose of enabling the assessment to be carried out, the manufacturer must have available, in writing, details of any consequential changes to the information and documentation required under subclause 5.3 (2) of this Schedule in relation to the system or kinds of devices.

(4) After any change to the quality management system, the manufacturer must ensure that the changed system continues to meet the requirements of clause 5.4 of this Schedule.

5.6 Information to be given to authorised person

(1) If requested to do so by an authorised person, the manufacturer of a medical device must:

(a) give to the Secretary any of the following information in relation to the quality management system or the kinds of medical device to which the system is applied:

(i) a copy of the documentation mentioned in subclause 5.4 (5) of this Schedule;

(ii) the quality records in relation to the final inspection and testing of the kinds of medical device to which the system is applied (for example, inspection reports, test data, calibration data, information about the qualifications of staff); and

(b) arrange for tests specified by the authorised person to be carried out for the purpose of checking whether the quality management system is operating effectively.

(2) If any inspections or tests are carried out by an authorised person in relation to the manufacturer's premises, or medical devices manufactured by the manufacturer, the manufacturer may ask the authorised person to give to the manufacturer a report stating the findings of the inspections or tests.

5.7 Declaration of conformity

(1) The manufacturer of a Class IIb medical device to which a quality management system that has been assessed under clause 5.3 of this Schedule has been applied must make a declaration of conformity in relation to the kind of device.

Note This clause need not be applied to the following kinds of medical devices if the declaration of conformity (not requiring assessment by Secretary) procedures have been applied to the device:

(a) a Class IIa medical device (see Division 3.2, subparagraph 3.8 (1) (b) (iii));

(b) a Class I medical device that has a measuring function (see Division 3.2, paragraph 3.9 (3) (c)).

(2) The declaration must:

(a) state that the declaration is a declaration of conformity made under clause 5.7 of Schedule 3 to the *Therapeutic Goods (Medical Devices) Regulations 2002*; and

(b) state the name and business address of the manufacturer of the device; and

(c) state the following information in relation to each kind of medical device to which the system has been applied:

(i) the unique product identifier (for example, the product name or model number);

(ii) the medical device classification;

(iii) the device nomenclature system code; and

(d) if the system has not been applied to all medical devices of that kind manufactured by the manufacturer — give details of the medical devices to which the system has been applied (for example, by reference to lot numbers, batches or serial numbers, or by specifying the kinds of medical devices or the times of manufacture); and

(e) for a kind of device in relation to which the type examination procedures have been applied — state that:

(i) the type examination procedures have been applied to the kind of device; and

(ii) the kind of device conforms to the approved type; and

(f) for a kind of device to which the declaration of conformity (not requiring assessment by Secretary) procedures have been applied — state that the kind of device is in accordance with the technical documentation prepared under clause 6.4 of those procedures for the kind of device; and

(g) state:

(i) the conformity assessment certificate number issued in relation to the system or the kind of medical devices to which the system has been applied; and

(ii) if applicable, the number of, or other identifying reference to, any equivalent approval or certificate (however described) issued outside Australia in relation to the system or the kind of medical devices to which the system has been applied; and

(h) give details of any conformity assessment standard that has been applied to the system; and

(i) be signed by a person authorised by the manufacturer; and

(j) set out the name and position of the person signing the declaration; and

(k) state the date when the declaration is signed.

5.8 Records

(1) The manufacturer of a kind of medical device to which a quality management system that has been assessed under clause 5.3 of this Schedule has been applied must keep the following records in relation to the system and the kind of device:

(a) the documentation mentioned in subclause 5.4 (5) of this Schedule;

(b) details of any changes made to the system and to the information and documentation required under subclause 5.5 (3) of this Schedule;

(c) details of any changes made to the kinds of medical devices to which the system was applied;

(d) for a Class IIb medical device — the declaration of conformity under clause 5.7 of this Schedule;

(e) any notice, report, certificate or other document in relation to the system issued to the manufacturer by the Secretary.

(2) The manufacturer must keep the records for at least 5 years after the manufacture of the last medical device to which the quality management system was applied.

(3) On request from the Secretary, the manufacturer must make the records available to the Secretary.

Part 6 Declaration of conformity (not requiring assessment by Secretary) procedures

6.1 Overview

The conformity assessment procedures set out in this Part provide for the manufacturer of a kind of medical device:

(a) to prepare technical documentation in relation to the kind of device to enable assessment of the device; and

(b) to make a declaration of conformity in relation to the kind of device; and

(c) to establish and keep up-to-date a post-market monitoring, reporting and corrective action system.

Note See Division 3.2 in relation to the kinds of medical devices to which these conformity assessment procedures may be applied.

6.2 References to kinds of medical devices

A reference in this Part to a kind of medical device includes a reference to an individual medical device.

6.3 Implementation

(1) The manufacturer of a medical device must prepare technical documentation in relation to the kind of device in a form that, if the Secretary decides to do so, would allow the Secretary to assess whether the device complies with the applicable provisions of the essential principles, the classification rules and these conformity assessment procedures.

(2) For the purpose of enabling an assessment to be carried out, the manufacturer must have available, in writing, the following information and undertakings:

(a) the name and business address of the manufacturer;

(b) details of each manufacturing site where these conformity assessment procedures are to be applied;

(c) all relevant information required to identify the kinds of medical devices to which these conformity assessment procedures are to be applied;

(d) an undertaking by the manufacturer to notify the Secretary, or the person in relation to whom the kind of device is included in the Register, of any information of the kind mentioned in subparagraph 6.5 (2) (c) (i) or (ii) that the manufacturer becomes aware of in relation to a kind of medical device.

6.4 Required technical documentation

(1) The technical documentation must include adequate information in relation to the kind of device, and must include, in particular, the following:

(a) a general description of the kind of device, and of any variants of the kind of device that the manufacturer plans to manufacture;

(b) diagrams or drawings of the design of the kind of device, including diagrams or drawings of any components, sub-assemblies or circuits of the kind of device;

(c) any descriptions or explanations that are necessary to enable the diagrams or drawings mentioned in paragraph (b), or the intended operation of the kind of device, to be properly understood;

(d) if the kind of device is intended by the manufacturer to be supplied in a sterile state — a description of the method used to sterilise the kind of device;

(e) details of each medical device standard or conformity assessment standard that has been applied, wholly or in part, to the kind of device;

(f) if no medical device standard or conformity assessment standard has been applied, or a medical device standard or conformity assessment standard has been only partly applied, to the kind of device — the solutions adopted to ensure that each device complies with the applicable provisions of the essential principles;

(g) the results of any design calculations, risk analyses, investigations, technical tests, or any other tests, carried out in relation to the kind of device;

(h) if the kind of device is intended by the manufacturer to be connected to another device — evidence demonstrating that the device will comply with the applicable provisions of the essential principles when it is connected to the other device and both devices are being used for their intended purposes;

(i) a copy of the clinical evidence, in relation to the kind of device, required by the clinical evaluation procedures;

(j) a copy of the information to be provided with the kind of device.

(2) If the manufacturer makes a change to the design or the production of the kind of medical device after the technical documentation has been prepared (for example, because it was necessary to apply corrective action in relation to the kind of device), the manufacturer must revise the technical documentation to take account of the change.

6.5 Post-marketing system

(1) The manufacturer of a medical device to which technical documentation prepared under clause 6.4 of this Schedule applies must establish, and keep up-to-date, a post-marketing system that complies with subclause (2) for use in relation to devices of that kind.

(2) A post-marketing system complies with this subclause in relation to a medical device if the system requires the manufacturer of the device:

(a) to systematically review experience gained in the post-production phase in relation to medical devices of that kind; and

(b) to implement appropriate means to apply any necessary corrective action in relation to the design or production of such devices; and

(c) to notify the Secretary, or the person in relation to whom the kind of device is included in the Register, as soon as practicable after becoming aware of:

(i) information relating to:

(A) any malfunction or deterioration in the characteristics or performance of the kind of device; or

(B) any inadequacy in the design, production, labelling, instructions for use or advertising materials of the kind of device; or

(C) any use in accordance with, or contrary to, the use intended by the manufacturer of the kind of device;

that might lead, or might have led, to the death of a patient or a user of the device, or to a serious deterioration in his or her state of health; or

(ii) information relating to any technical or medical reason for a malfunction or deterioration of a kind mentioned in subparagraph (i) that has led the manufacturer to take steps to recover devices of that kind that have been distributed.

Note See also paragraph 41FN (3) (d) and section 41MP of the Act in relation to the requirement to give certain information about a medical device to the Secretary.

6.6 Declaration of conformity

(1) The manufacturer of a kind of medical device to which technical documentation prepared under clause 6.4 of this Schedule applies must make a declaration of conformity in relation to the kind of device.

(2) The declaration must:

(a) state that the declaration is a declaration of conformity made under clause 6.6 of Schedule 3 to the *Therapeutic Goods (Medical Devices) Regulations 2002*; and

(b) state the name and business address of the manufacturer of the device; and

(c) state the following information in relation to each kind of medical device to which the technical documentation applies:

(i) the unique product identifier (for example, the product name or model number);

(ii) the medical device classification;

(iii) the device nomenclature system code; and

(d) if the technical documentation applies to a Class IIa medical device that the manufacturer intends to be supplied in a sterile state or a Class I medical device that the manufacturer intends to be supplied in a sterile state — state that the production quality assurance procedures have also been applied to the device; and

(e) if the technical documentation applies to a Class IIa medical device that the manufacturer intends to be supplied in a non-sterile state, or a Class I medical device that has a measuring function and that the manufacturer intends to be supplied in a non-sterile state — state which of the following conformity assessment procedures have also been applied to the device:

(i) the verification procedures;

(ii) the production quality assurance procedures;

(iii) the product quality management system procedures; and

(f) if the technical documentation does not apply to all medical devices of that kind manufactured by the manufacturer — give details of the medical devices to which the technical documentation applies (for example, by reference to lot numbers, batches or serial numbers, or by specifying the kinds of medical devices or the times of manufacture); and

(g) state that each kind of medical device to which the technical documentation applies complies with the applicable provisions of the essential principles, the classification rules, and these procedures; and

(h) if the technical documentation applies to any of the following kinds of medical devices:

(i) a Class IIa medical device;

(ii) a Class I medical device that the manufacturer intends to be supplied in a sterile state;

(iii) a Class I medical device that has a measuring function;

state:

(iv) the conformity assessment certificate number issued in relation to the kind of medical device, or the quality management system that has been applied to the kind of device, as a result of the application to the device of the conformity assessment procedures set out in Part 3, 4 or 5 of this Schedule; and

(v) if applicable, the number of, or other identifying reference to, any equivalent approval or certificate (however described) issued outside Australia in relation to the kind of medical device, or the quality management system that has been applied to the kind of device; and

(i) give details of any medical device standard or conformity assessment standard that has been applied to the device; and

(j) be signed by a person authorised by the manufacturer; and

(k) set out the name and position of the person signing the declaration; and

(l) state the date when the declaration is signed.

6.7 Records

(1) The manufacturer of a medical device to which technical documentation prepared under clause 6.4 of this Schedule applies must keep the following records:

(a) the technical documentation prepared under clause 6.4 of this Schedule, including any revisions of the documentation prepared as a result of changes to the design or production of the kind of device;

(b) details of any changes made to the design or production of the kind of medical device and to the documentation required under clause 6.4 of this Schedule;

(c) the declaration of conformity under clause 6.6 of this Schedule.

(2) The manufacturer must keep the records for at least 5 years after the manufacture of the last medical device to which the technical documentation prepared clause 6.4 of this Schedule applies.

(3) On request from the Secretary, the manufacturer must make the records available to the Secretary.

Part 7 Procedures for medical devices used for a special purpose

7.1 Overview

The conformity assessment procedures set out in this Part provide for the manufacturer of a medical device used for a special purpose:

(a) to prepare a written statement containing certain information in relation to the device; and

(b) to prepare and keep up-to-date particular documentation in relation to the device.

7.2 Custom-made medical devices

(1) This clause applies to a custom-made medical device.

Note For 2 years after the commencement of these Regulations, Chapter 3 of the Act continues to apply to custom-made medical devices, and the procedures for medical devices used for a special purpose do not need to be applied to them in that period. This is because, for that 2 year period, custom-made medical devices continue to be exempt goods or are declared, by order published in the *Gazette* under subsection 41BD (3) of the Act, not to be, for the purposes of the Act, medical devices.

(2) The manufacturer of the device must prepare a written statement in relation to the device including the following:

(a) the name and business address of the manufacturer;

(b) sufficient information to enable the user to identify the device or, if relevant, the contents of packaging;

(c) a statement to the effect that the device is intended by the manufacturer to be used only in relation to a particular individual;

(d) the name of the individual in relation to whom the device is intended to be used;

(e) the name and business address of the health professional who provided the specification for the device;

(f) the particular design characteristics or construction of the device as specified by the health professional who provided the specification for the device;

(g) a statement to the effect that the device complies with the applicable provisions of the essential principles or, if the device does not comply with all applicable provisions of the essential principles, a statement explaining which provisions of the essential principles the device does not comply with and the reasons for the non-compliance.

(3) The statement must:

(a) be signed by a person authorised by the manufacturer of the device; and

(b) set out the name and position of the person signing the statement; and

(c) state the date when the statement is signed.

(4) The manufacturer must prepare, and keep up-to-date, documentation in relation to the device, including information in relation to the design, production and intended performance of the device.

(5) The manufacturer must take all measures necessary to ensure that the process used to manufacture the device results in the device complying with the documentation mentioned in subclause (4).

(6) The manufacturer must notify the Secretary as soon as practicable after becoming aware of:

(a) information relating to:

(i) any malfunction or deterioration in the characteristics or performance of the device; or

(ii) any inadequacy in the design, production, labelling or instructions for use of the device; or

(iii) any use in accordance with, or contrary to, the use intended by the manufacturer of the device;

that might lead, or might have led, to the death of a patient or a user of the device, or to a serious deterioration in his or her state of health; or

(b) information relating to any technical or medical reason for a malfunction or deterioration of a kind mentioned in paragraph (a) that has led the manufacturer to take steps to recover a device that has been distributed.

Note Clauses 7.3 and 7.4 are intentionally not used.

7.5 System or procedure packs

(1) The manufacturer of a system or procedure pack must make a declaration of conformity in relation to the system or procedure pack.

(2) The declaration must:

(a) state that the declaration is a declaration of conformity made under clause 7.5 of Schedule 3 to the *Therapeutic Goods (Medical Devices) Regulations 2002*; and

(b) state the name and business address of the manufacturer of the system or procedure pack; and

(c) state sufficient information to enable the user to identify the system or procedure pack or, if relevant, the contents of packaging; and

(d) identify each item in the package; and

(e) state that the manufacturer has evidence:

(i) that the relevant conformity assessment procedures have been applied to each medical device in the package; and

(ii) that each medical device in the package complies with the applicable provisions of the essential principles; and

(f) state the registration or listing number for each medicine or other therapeutic goods in the package; and

(g) state that each medical device in the package is intended to be used for its original intended purpose, and each medicine or other therapeutic goods in the package is intended to be used within the approved indications for use specified by the manufacturers of those items; and

(h) state:

(i) that the mutual compatibility of each medical device, medicine or other therapeutic goods, and any other goods, in the package has been verified in accordance with any instructions for use provided by the manufacturer of each item or the approved indications for use of each item; and

(ii) that the manufacturer has manufactured the system or procedure pack in accordance with those instructions (if any) or indications; and

(i) state that the information supplied with the system or procedure pack for the use of the system or procedure pack includes instructions for use provided by the manufacturer of each item in the package; and

(j) state that the process of manufacturing the system or procedure pack, and the verification and packaging of the system or procedure pack, has been subjected to a documented method of internal control and inspection that ensures the safety, quality, performance and effectiveness of each item in the package; and

(k) if the system or procedure pack is intended by the manufacturer to be supplied in a sterile state — state that the production quality assurance procedures (other than clause 4.7) have been applied to the system or procedure pack in accordance with the manufacturer's instructions for use, or the approved indications for use, of each item in the package; and

(l) be signed by a person authorised by the manufacturer; and

(m) set out the name and position of the person signing the declaration; and

(n) state the date when the declaration is signed.

(3) The manufacturer of a system or procedure pack must establish, and keep up-to-date, a post-marketing system that complies with subclause (4) for use in relation to the system or procedure pack.

(4) A post-marketing system complies with this subclause in relation to a system or procedure pack if the post-marketing system requires the manufacturer of the system or procedure pack:

(a) to systematically review experience gained in the post-production phase in relation to the system or procedure pack; and

(b) to implement appropriate means to apply any necessary corrective action in relation to the production of the system or procedure pack; and

(c) to notify the Secretary as soon as practicable after becoming aware of:

(i) information relating to:

(A) any malfunction or deterioration in the characteristics or performance of the system or procedure pack; or

(B) any inadequacy in the production, labelling, instructions for use or advertising materials of the system or procedure pack; or

(C) any use in accordance with, or contrary to, the use intended by the manufacturer of the system or procedure pack;

that might lead, or might have led, to the death of a patient or a user of the system or procedure pack, or to a serious deterioration in his or her state of health; or

(ii) information relating to any technical or medical reason for a malfunction or deterioration of a kind mentioned in subparagraph (i) that has led the manufacturer to take steps to recover system or procedure packs of that kind that have been distributed.

Note See also paragraph 41FN (3) (d) and section 41MP of the Act in relation to the requirement to give certain information about a medical device to the Secretary.

7.6 Records

(1) The manufacturer must keep the statement and documentation required under the relevant clause of this Schedule in relation to a medical device to which the conformity assessment procedures in this Part have been applied.

(2) The manufacturer must keep the statement and documentation for at least 5 years after the manufacture of the last medical device to which the statement and documentation relates.

(3) On request from the Secretary, the manufacturer must make the statement and documentation available to the Secretary.

Part 8 Clinical evaluation procedures

8.1 Overview

The conformity assessment procedures set out in this Part provide for the manufacturer of a kind of medical device to obtain and evaluate clinical data in relation to the kind of device.

Note See regulation 3.11 in relation to the kinds of medical devices to which these conformity assessment procedures must be applied.

8.2 References to kinds of medical devices

A reference in this Part to a kind of medical device includes a reference to an individual medical device.

8.3 Obtaining clinical data

(1) The manufacturer of a kind of medical device must obtain clinical data in relation to the device in the form of either or both of the following:

(a) clinical investigation data in accordance with clause 8.4;

(b) a literature review in accordance with clause 8.5.

(2) The manufacturer must ensure that the clinical data obtained takes account of any medical device standard or conformity assessment standard that may apply to the device.

8.4 Clinical investigation data

(1) For clause 8.3, ***clinical investigation data***, in relation to a kind of medical device, includes:

(a) documentation in relation to the design, approval, conduct and results of each investigation carried out by the manufacturer of the device in relation to the use of the device in or on a human body; and

(b) a record of qualitative or quantitative information obtained through observation, measurement, tests or any other means used to assess the operation of the device; and

(c) a written report by an expert in the relevant field, being a report that contains a critical evaluation of all the clinical investigation data held in relation to the device.

(2) The documentation mentioned in paragraph (1) (a) must be in a form that allows the manufacturer to evaluate whether the device complies with the applicable provisions of the essential principles.

(3) The record mentioned in paragraph (1) (b) must be in a form that allows the information in it to be independently assessed and verified.

(4) If clinical investigation data is collected in Australia, the investigation must have been conducted in accordance with the ethical standards set out in the 'National Statement on Ethical Conduct in Research Involving Humans', published by the National Health and Medical Research Council, as in force from time to time.

(5) If clinical investigation data is collected outside Australia, the investigation must have been conducted in accordance with the principles of the Declaration of Helsinki, as in force at the time and place where the investigation was conducted.

8.5 Literature review

For clause 8.3, a ***literature review***, in relation to a kind of medical device, includes:

(a) a compilation, prepared using a documented methodology, of published literature and unpublished scientific literature, both favourable and unfavourable, relating to medical devices of that kind, including the following:

(i) expert opinion;

(ii) information about the hazards and associated risks arising from the use of the device for its intended purpose, and the foreseeable misuse of the device;

(iii) information about the performance of devices of that kind, including a description of the techniques used to examine whether devices of that kind achieve their intended purpose; and

(b) a written report by an expert in the relevant field, being a report that contains a critical evaluation of the compilation of literature mentioned in paragraph (a).

8.6 Evaluation of clinical data

(1) The manufacturer of a kind of medical device must ensure that the clinical data is evaluated by competent clinical experts.

(2) The manufacturer must ensure that clinical evidence demonstrating that the device complies with the applicable provisions of the essential principles is documented in writing.

Schedule 4 Exempt devices

(regulation 7.1)

Part 1 Exempt devices — general

Item	Kinds of medical devices
1.1	Medical device that is imported into Australia for use in the treatment of the importer, or a member of the importer's immediate family, if: (a) the device does not contain a substance the importation of which is prohibited under the *Customs Act 1901*; and (b) in the case of: (i) a device that is manufactured using tissues, cells or substances of animal origin that have been rendered non-viable, or tissues, cells or substances of bacterial or recombinant origin; or (ii) a device that incorporates, or is intended to incorporate, as an integral part, a stable derivative of human blood or blood plasma — the device is the subject of an approval under section 41HB of the Act; and (c) in the case of a medical device classified as Class IIa or higher: (i) the quantity imported in one importation is not more than the amount required to give 3 months treatment using the device according to the treating medical practitioner's directions; and (ii) the total quantity imported in a 12 month period is not more than the amount required to give 15 months treatment using the device according to the treating medical practitioner's directions; and (d) in the case of a device that is subject to Schedule 4 or Schedule 8 to the current Poisons Standard, or a device that incorporates, or is intended to incorporate, as an integral part, a substance that is subject to either of those Schedules — the device, or substance, is acknowledged in writing by a medical practitioner registered under a law of a State or Territory to be appropriate treatment for the importer or family member (unless the device is carried by the importer as a passenger on a ship or an aeroplane)

Item	Kinds of medical devices
1.2	Medical device that is exported from Australia and: (a) is not intended for commercial supply; and (b) does not contain a substance the export of which is prohibited under the *Customs Act 1901*; and (c) is not intended for use for experimental purposes on humans
1.3	Samples of a medical device that is imported into Australia, exported from Australia, or manufactured or supplied in Australia for any of the following purposes (other than for supply for use in or on a human being): (a) submission to a regulatory authority; (b) subjection to developmental or quality control procedures; (c) examination, demonstration or display, with notice included to the effect that the device is not available for general supply unless it is included in the Register; (d) subjection to analysis or laboratory testing procedures
1.4	Medical device that: (a) is imported into Australia solely for the purpose of being exported from Australia; and (b) while in Australia, remains subject to the control of the Australian Customs Service; and (c) is not subject to any of the activities mentioned in section 41BG of the Act by a manufacturer in Australia
1.5	Custom-made medical device

Part 2 Exempt devices — exemption subject to conditions

Item	Kinds of medical devices	Conditions
2.1	Medical device that is imported into Australia and is held under the direct control of the sponsor, until the device is: (a) the subject of a notification under item 2.3; or (b) approved for importation into Australia under section 41HB of the Act; or (c) authorised for supply under section 41HC of the Act; or (d) used for a Category A patient, within the meaning of regulation 7.2	(a) The supply of the device must be in accordance with the relevant notification, approval, authorisation or medical practitioner's direction. (b) The device must be kept in a warehouse or properly secured area under the control of the sponsor. (c) If the device is not used within 12 months of importation, the device must be destroyed or returned to the consignor of the device within 1 month after the end of that period. (d) The sponsor must: (i) keep records relating to the source and supply of the device; and (ii) if the device is destroyed under paragraph (c), keep records relating to the destruction; and (iii) if requested by the Secretary, give the records to the Secretary.
2.2	Medical device affected by section 41FH of the Act that is imported into Australia and is held under the direct control of the sponsor until a decision is made under section 41FI of the Act in relation to the device	(a) The sponsor must: (i) keep records relating to the source of the device; and (ii) if requested by the Secretary, give the records to the Secretary; and (iii) before importing the device, have lodged an application under section 41FC of the Act for the device to be included in the Register.

Item	Kinds of medical devices	Conditions
		(b) If the application is not successful, the goods must be destroyed or returned to the consignor of the device within 1 month of the decision not to include the device in the Register.
2.3	Medical device to be used solely for experimental purposes in humans	(a) Before starting to use the device, the sponsor must notify the Secretary: (i) in a form approved by the Secretary; and (ii) in accordance with any requirements determined by the Secretary for the form of notification; that the sponsor intends to sponsor a clinical trial using the device. (b) The notification must be accompanied by the notification fee specified in item 1.8 of Schedule 5. (c) The approval of the device for this purpose must be given by the sponsor (if the sponsor is conducting the trial), or by the body or organisation conducting the trial for the sponsor, having regard to the advice of the ethics committee that has, or will assume, responsibility for monitoring the conduct of the trial. (d) The terms of the approval by the sponsor, body or organisation mentioned in paragraph (c) must be no less restrictive than the terms advised by the responsible ethics committee.

Item	Kinds of medical devices	Conditions
		(e) The trial must not be the subject of a direction by the Secretary that the trial not be conducted, or that it be stopped, because the Secretary has become aware that to conduct or continue the trial would be contrary to the public interest. (f) The sponsor (if the sponsor is conducting the trial), or the body or organisation conducting the trial for the sponsor, must not receive, or have received, advice from the responsible ethics committee that is inconsistent with the continuation of the trial. (g) The conditions stated in regulation 7.5 must be complied with, as if that regulation applied to a person using a medical device under this item.
2.4	Medical device that is imported into Australia by a member of a group of persons who are visiting Australia to participate in a national or international sporting event	(a) The device must be for use in the treatment of a member or members of the visiting group. (b) The importation of the device must not be prohibited under the *Customs (Prohibited Imports) Regulations 1956*. (c) The device must not be supplied to, or used in the treatment of, a person who is not a member of the visiting group. (d) The device must be destroyed or removed from Australia at the end of the visit. (e) A member of the group must be responsible for the control and custody of the device while the group is in Australia.

Item	Kinds of medical devices	Conditions
		(f) The person mentioned in paragraph (e) must: (i) carry a list, in English, of the quantity and nature of the device imported; and (ii) keep a record of the use of the device while the group is in Australia; and (iii) produce the list or record for inspection at the request of a customs officer or a person who is an authorised person for the purposes of section 41FN of the Act.
2.5	Medical device that is imported into Australia by a member of a group of persons, being members of the military forces of another country who are visiting Australia for military training	(a) The device must be for use in the treatment of a member or members of the visiting group. (b) The device must not be supplied to, or used in the treatment of, a person other than a member of: (i) the visiting group; or (ii) the Australian Defence Force. (c) The device must be destroyed or removed from Australia at the end of the visit. (d) A member of the group to whom the device has been issued must be responsible for the control and custody of the device while the group is in Australia. (e) The person mentioned in paragraph (d) must: (i) carry a list, in English, of the quantity and nature of the device imported; and

Item	Kinds of medical devices	Conditions
		(ii) keep a record of the use of the device while the group is in Australia; and (iii) produce the list or record for inspection at the request of a customs officer or a person who is an authorised person for the purposes of section 41FN of the Act.

Schedule 5 Fees

(regulation 9.1)

Part 1 General

Item	Matter	Provision of Act or these Regulations	Amount ($)
1.1	Application for conformity assessment certificate	paragraph 41EB (2) (a) of the Act	620
1.2	Review of conformity assessment certificate — surveillance assessment for conformity assessment certificate issued under conformity assessment procedures set out in Schedule 3, Part 1, 4 or 5 *Note 1* If the assessment involves an assessment of a medicinal component, an additional fee is payable — see item 1.11. *Note 2* If a supplementary assessment, or an assessment outside Australia, is required, an additional fee is payable — see item 1.12 and clause 2.1 of this Schedule.	subsection 41EJ (4) of the Act	5 370
1.3	Review of conformity assessment certificate — in relation to certification of compliance with the essential principles for conformity assessment certificate issued under conformity assessment procedures set out in: (a) Schedule 3, clause 1.6; or	subsection 41EJ (4) of the Act	32 930

Item	Matter	Provision of Act or these Regulations	Amount ($)
	(b) Schedule 3, Part 2 (including management of testing, analysis, and reporting on examination of the type)		25 320
	Note 1 If the assessment involves an assessment of a medicinal component, an additional fee is payable — see item 1.11.		
	Note 2 If a supplementary assessment, or an assessment outside Australia, is required, an additional fee is payable — see item 1.12 and clause 2.1 of this Schedule.		
	Note 3 For an assessment under paragraph (b), an additional fee to cover the costs of testing the relevant kind of medical device is also payable — see clause 2.2 of this Schedule.		
1.4	Considering a submission to the Secretary in relation to a proposed suspension of a conformity assessment certificate	subsection 41EN (2) and paragraph 63 (2) (h) of the Act	The fee applicable under item 1.14 to the kind of work to be undertaken
1.5	Application for the following kinds of medical devices to be included in the Register:	paragraph 41FC (2) (b) of the Act	
	(a) a Class AIMD medical device;		820
	(b) a Class III medical device		820
	(c) a Class IIb medical device;		620
	(d) a Class IIa medical device;		620

Item	Matter	Provision of Act or these Regulations	Amount ($)
	(e) a Class I medical device that the manufacturer intends to be supplied in a sterile state or that has a measuring function		620
	Note for paragraph (e) At present, there is no fee for an application to include any other Class I medical device in the Register.		
1.6	Considering submissions to the Secretary in relation to a proposed suspension of a kind of medical device from the Register	subsection 41GB (2) and paragraph 63 (2) (h) of the Act	The fee applicable under item 1.14 to the kind of work to be undertaken
1.7	Application for approval to use a specified kind of medical device solely for experimental purposes in humans	paragraph 41HB (5) (c) of the Act	11 330
1.8	Notification of intention to sponsor a clinical trial of a medical device to be used solely for experimental purposes in humans	Schedule 4, item 2.3, paragraph (b) of these Regulations	220
1.9	Conformity assessment — initial assessment under conformity assessment procedures set out in:	subsections 41LA (1) and (2) of the Act	
	(a) Schedule 3, Part 1; or		18 380
	(b) Schedule 3, clause 1.6; or		36 390
	(c) Schedule 3, Part 2 (including management of testing, analysis, and reporting on examination of the type); or		25 320
	(d) Schedule 3, Part 3 (including management of testing, analysis, and reporting on verification of the type); or		17 690

Item	Matter	Provision of Act or these Regulations	Amount ($)
	(e) Schedule 3, Part 4; or		16 130
	(f) Schedule 3, Part 5		13 900
	Note 1 If the assessment involves an assessment of a medicinal component, an additional fee is payable — see item 1.11.		
	Note 2 If a supplementary assessment, or an assessment outside Australia, is required, an additional fee is payable — see item 1.12 and clause 2.1 of this Schedule.		
	Note 3 For an assessment under paragraph (c) or (d), an additional fee to cover the costs of testing the relevant kind of medical device is also payable — see clause 2.2 of this Schedule.		
	Note 4 If the assessment is abridged, a reduced fee is payable — see regulation 9.4.		
1.10	Conformity assessment — assessment consequent on change to medical device, or quality management system applying to medical device, under conformity assessment procedures set out in:	subsections 41LA (1) and (2) of the Act	
	(a) Schedule 3, Part 1; or		11 030
	(b) Schedule 3, clause 1.6; or		21 830
	(c) Schedule 3, Part 2 (including management of testing, analysis, and reporting on examination of the type); or		15 190
	(d) Schedule 3, Part 4; or		9 680

Item	Matter	Provision of Act or these Regulations	Amount ($)
	(e) Schedule 3, Part 5		8 340
	Note 1 If the assessment involves an assessment of a medicinal component, an additional fee is payable — see item 1.11.		
	Note 2 If a supplementary assessment, or an assessment outside Australia, is required, an additional fee is payable — see item 1.12 and clause 2.1 of this Schedule.		
	Note 3 For an assessment under paragraph (c), an additional fee to cover the costs of testing the relevant kind of medical device, or quality management system, is also payable — see clause 2.2 of this Schedule.		
1.11	If an assessment of a medical device involves an assessment of the medicinal component of the device — for an assessment of the data relating to the medicinal component (and in addition to the fee required under item 1.2, 1.3, 1.9 or 1.10)	subsections 41EJ (4) and 41LA (1) and (2) of the Act	The fee applicable under paragraph 4 (b) or (c) or 5 (b) or (d) of Schedule 9 to the *Therapeutic Goods Regulations 1990*
1.12	If a supplementary assessment of a medical device is required, in addition to the assessment mentioned in item 1.2, 1.3, 1.9 or 1.10	subsections 41EJ (4) and 41LA (1) and (2) of the Act	255 for each hour for each assessor involved
	Note For an assessment conducted outside Australia, an additional fee is payable — see clause 2.1 of this Schedule.		

Item	Matter	Provision of Act or these Regulations	Amount ($)
1.13	Application audit assessment, Level 1 — verification of sponsor's application and evidence of conformity	subsections 41LA (3) and (4) of the Act	2 390
1.14	Application audit assessment, Level 2 — for Level 1 activities and review of evidence of conformity	subsections 41LA (3) and (4) of the Act	4 380
1.15	Application for consent of Secretary to importation into Australia, supply for use in Australia, or exportation from Australia of medical device	section 41MA and paragraph 63 (2) (h) of the Act	280
1.16	Intermediate stage assessment or verification procedures to be carried out in relation to the application of the conformity assessment procedures to an article	Subregulation 3.13 (1) of these Regulations	The fee applicable under item 1.9, 1.10 or 1.12 to the kind of work to be undertaken

Part 2 Additional fees

2.1 Supplementary assessment

In addition to the assessment fee mentioned in item 1.2, 1.3, 1.9 or 1.10 of this Schedule, the following fees apply:

(a) for each assessment that is required to be conducted — an amount that reimburses the costs and reasonable expenses of travel by each assessor involved, including travel both in and outside Australia;

(b) for an assessment that is required to be conducted outside Australia — an amount calculated at the rate of $255 for each hour of preparation by each assessor involved.

2.2 Costs of testing

(1) In addition to the assessment fee mentioned in paragraph 1.3 (b), 1.9 (c) or (d) or paragraph 1.10 (c) of this Schedule, a fee for the costs of testing the relevant kind of medical device, or quality management system, applies.

(2) The fee is the amount that reimburses the Department for:

(a) the costs incurred in purchasing, establishing and setting-up the equipment to be used to conduct the tests; and

(b) the direct costs of conducting the tests (including the cost of any consumables used in conducting the tests).

Dictionary

(regulation 1.3)

accessory — see subsection 3 (1) of the Act.

Act means the *Therapeutic Goods Act 1989*.

active implantable medical device means an active medical device (other than an implantable medical device) that is intended by the manufacturer:

(a) either:

(i) to be, by surgical or medical intervention, introduced wholly, or partially, into the body of a human being; or

(ii) to be, by medical intervention, introduced into a natural orifice in the body of a human being; and

(b) to remain in place after the procedure.

active medical device:

(a) means a medical device that is intended by the manufacturer:

(i) to depend for its operation on a source of electrical energy or other source of energy (other than a source of energy generated directly by a human being or gravity); and

(ii) to act by converting this energy; but

(b) does not include a medical device that is intended by the manufacturer to transmit energy, a substance, or any other element, between an active medical device and a human being without any significant change in the energy, substance or other element being transmitted.

active medical device for diagnosis means an active medical device that is intended by the manufacturer to be used on a human being, either alone or in combination with another medical device, to supply information for the purpose of detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities.

active medical device for therapy means an active medical device that is intended by the manufacturer to be used on a human being, either alone or in combination with another medical device, to support, modify, replace or restore biological functions or structures for the purpose of treating or alleviating an illness, injury or handicap.

animal means an invertebrate or vertebrate member of the animal kingdom.

application audit assessment fee — see subsection 3 (1) of the Act.

approved type means a type that has been examined and approved by the Secretary under the type examination procedures.

assessment fee — see subsection 3 (1) of the Act.

Australian legal unit of measurement has the meaning given by the *National Measurement Act 1960*.

authorised person — see regulation 10.1.

body orifice:

(a) means a natural opening, or a permanent artificial opening, in a human being's body; and

(b) includes the external surface of a human being's eyeball.

British Pharmacopoeia — see subsection 3 (1) of the Act.

central circulatory system means the system in a human being comprising the following vessels:

(a) *arteriae pulmonales*;

(b) *aorta ascendens*;

(c) *arteriae coronariae*;

(d) *arteria carotis communis*;

(e) *arteria carotis externa*;

(f) *arteria carotis interna*;

(g) *arteriae cerebrales*;

(h) *trucus brachicephalicus*;

(i) *venae cordis*;

(j) *venae pulmonales*;

(k) *venae cava superior*;

(l) *venae cava inferior*;

(m) *arcus aorta*;

(n) *thoracica aorta*;

(o) *abdominalis aorta*;

(p) *ilica communis*.

central nervous system means the system in a human being comprising the brain, meninges and spinal cord.

classification means a medical device classification.

classification rules, in relation to a medical device, means the rules for classifying the device set out in Schedule 2.

Class I medical device means a medical device that, under Division 3.1 of Part 3, is classified as Class I.

Class IIa medical device means a medical device that, under Division 3.1 of Part 3, is classified as Class IIa.

Class IIb medical device means a medical device that, under Division 3.1 of Part 3, is classified as Class IIb.

Class III medical device means a medical device that, under Division 3.1 of Part 3, is classified as Class III.

Class AIMD medical device means an active implantable medical device that, under Division 3.1 of Part 3, is classified as Class AIMD.

clinical evaluation procedures means the conformity assessment procedures set out in Part 8 of Schedule 3.

conformity assessment certificate means a certificate issued under section 41EE of the Act.

conformity assessment fee — see subsection 3 (1) of the Act.

conformity assessment procedures means the conformity assessment procedures set out in Schedule 3.

conformity assessment standard — see subsection 3 (1) of the Act.

current Poisons Standard — see subsection 3 (1) of the Act.

custom-made medical device means a medical device that:

(a) is specifically made in accordance with a request by a health professional specifying the design characteristics or construction of the medical device; and

(b) is intended to be used only in relation to a particular individual.

declaration of conformity (not requiring assessment by Secretary) procedures means the conformity assessment procedures set out in Part 6 of Schedule 3.

device nomenclature system code, in relation to a medical device, means the device nomenclature system code specified for the device in regulation 1.7.

EC Mutual Recognition Agreement — see subsection 3 (1) of the Act.

EFTA Mutual Recognition Agreement — see subsection 3 (1) of the Act.

essential principles means the essential principles set out in Schedule 1.

ethics committee — see subsection 3 (1) of the Act.

exempt device — see subsection 3 (1) of the Act.

Note See also Division 7.1 of these Regulations.

full quality assurance procedures means the conformity assessment procedures set out in Part 1 of Schedule 3.

health professional includes a person who is:

(a) a medical practitioner, a dentist or any other kind of health care worker registered under a law of a State or Territory; or

(b) a biomedical engineer, chiropractor, optometrist, orthodontist, osteopath, pharmacist, physiotherapist, podiatrist, prosthetist or rehabilitation engineer.

implantable medical device means a medical device (other than an active implantable medical device) that is intended by the manufacturer:

(a) to be, by surgical intervention, wholly introduced into the body of a human being, and to remain in place after the procedure; or

(b) to replace, by surgical intervention, an epithelial surface, or the surface of an eye, of a human being, and to remain in place after the procedure; or

(c) to be, by surgical intervention, partially introduced into the body of a human being, and to remain in place for at least 30 days after the procedure.

included in the Register — see subsection 3 (1) of the Act.

intended purpose, of a kind of medical device, means the purpose for which the manufacturer of the device intends it to be used, as stated in:

(a) the information provided with the device; or

(b) the instructions for use of the device; or

(c) any advertising material applying to the device.

invasive medical device means a medical device that is intended by the manufacturer to be used, in whole or in part, to penetrate the body of a human being through a body orifice or through the surface of the body.

kind, in relation to a medical device — see section 41BE of the Act.

manufacturer — see section 41BG of the Act.

measuring function, in relation to a medical device — see regulation 1.4.

medical device — see section 41BD of the Act.

medical device classification means a medical device classification specified in subregulation 3.1 (1).

Note See also the definition in subsection 3 (1) of the Act.

medical device standard — see subsection 3 (1) of the Act.

medical device used for a special purpose means a medical device to which regulation 3.10 applies.

medical practitioner means a person registered as a medical practitioner under a law of a State or Territory that provides for the registration of medical practitioners.

medicine — see subsection 3 (1) of the Act.

post-production phase, in relation to a medical device, means the period during which the device is stored, transported, supplied for use and used (whether in Australia or not).

principal investigator, in relation to a clinical trial of a kind of medical device, means the person who is in charge of the conduct of the trial.

procedures for medical devices used for a special purpose means the conformity assessment procedures set out in Part 7 of Schedule 3.

production quality assurance procedures means the conformity assessment procedures set out in Part 4 of Schedule 3.

product quality assurance procedures means the conformity assessment procedures set out in Part 5 of Schedule 3.

refurbishment, of a medical device — see regulation 1.5.

Register — see subsection 3 (1) of the Act.

reusable surgical instrument means a medical device that is intended by the manufacturer:

(a) to be used surgically, without being connected to an active medical device, for cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or any other similar procedure; and

(b) to be reused after the appropriate procedures specified by the manufacturer in the instructions for use have been carried out.

serious, in relation to a form of a disease, condition, ailment or defect, means a form of the disease, condition, ailment or defect that is:

(a) generally accepted as not being appropriate to be diagnosed or treated without consulting a medical practitioner, dentist or other kind of health care worker registered under a law of a State or Territory; or

(b) generally accepted to be beyond the ability of the average person to evaluate accurately, or treat safely, without supervision by a medical practitioner, dentist or other kind of health care worker registered under a law of a State or Territory.

specialist has the same meaning as in the *Health Insurance Act 1973*.

sponsor — see subsection 3 (1) of the Act.

surgically invasive medical device means:

(a) an invasive medical device that is intended by the manufacturer to be used with the aid, or in the context, of a surgical operation; and

(b) a medical device that is intended by the manufacturer to be used to penetrate the body of a human being in any way other than through a body orifice.

system or procedure pack — see section 41BF of the Act.

therapeutic goods — see subsection 3 (1) of the Act.

type means a representative sample of a kind of medical device.

type examination procedures means the conformity assessment procedures set out in Part 2 of Schedule 3.

variant means a medical device the design of which has been varied to accommodate different patient anatomical requirements (for example, relating to the shape, size, length, diameter or gauge of the device), or any other variation approved by the Secretary for the purposes of this definition, provided the variation does not change the intended purpose of the device.

verification procedures means the conformity assessment procedures set out in Part 3 of Schedule 3.

working day — see subsection 3 (1) of the Act.

Note

1. Notified in the *Commonwealth of Australia Gazette* on 4 2002. 4 October