Therapeutic Goods (Medical Devices) Amendment Regulations 2010 (No. 1)[1]

Select Legislative Instrument 2010 No. 25

I, QUENTIN BRYCE, 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 25 February 2010

QUENTIN BRYCE
Governor-General

By Her Excellency's Command

MARK BUTLER
Parliamentary Secretary for Health

Federal Register of Legislative Instruments F2010L00469

1 Name of Regulations

These Regulations are the *Therapeutic Goods (Medical Devices) Amendment Regulations 2010 (No. 1)*.

2 Commencement

These Regulations commence on 1 July 2010.

3 Amendment of *Therapeutic Goods (Medical Devices) Regulations 2002*

Schedule 1 amends the *Therapeutic Goods (Medical Devices) Regulations 2002*.

4 Definitions for transitional provisions

In regulations 5 to 7:

Act means the *Therapeutic Goods Act 1989*.

diagnostic goods for in vitro use has the same meaning as in the *Therapeutic Goods Regulations 1990* as in force on 30 June 2010.

in-house IVD medical device has the same meaning as in the *Therapeutic Goods (Medical Devices) Regulations 2002* as in force on 1 July 2010.

IVD medical device has the same meaning as in the *Therapeutic Goods (Medical Devices) Regulations 2002* as in force on 1 July 2010.

5 Transitional — certain devices

(1) This regulation applies to a diagnostic good for in vitro use that, immediately before 1 July 2010:

(a) was declared not to be a medical device under subsection 41BD (3) of the Act; and

(b) was:

(i) listed or registered under Part 3-2 of the Act; or

(ii) subject to an approval under paragraph 19 (1) (b) of the Act; or

(iii) exempt from listing or registration under Part 3-2 of the Act; or

(iv) a device for which an effective application for listing or registration under Part 3-2 of the Act had been made but not finally determined.

Note For circumstances in which an application under Part 3-2 of the Act is effective — see subsection 23 (2) of the Act.

(2) The amendments made by Schedule 1 apply to a device mentioned in subregulation (1):

(a) after 30 June 2010 — for purposes connected with:

(i) an application for including the device in the Register under Chapter 4 of the Act; or

(ii) including the device in the Register under Chapter 4 of the Act; and

(b) generally, after 30 June 2014.

(3) The listing or registration under Part 3-2 of the Act of a device mentioned in subparagraph (1) (b) (i) or (iv) is taken to be cancelled on:

(a) if no effective application for including the device in the Register under Chapter 4 of the Act has been made before 1 July 2014 — 1 July 2014; or

(b) the day on which inclusion of the device in the Register under Chapter 4 takes effect following an effective application of the kind mentioned in subparagraph (2) (a) (i).

(4) The amendments made by Schedule 1 apply after 30 June 2014 to a device mentioned in subparagraph (1) (b) (iii) if it was exempt before 1 July 2010.

(5) The amendments made by Schedule 1 apply to each of the following diagnostic goods for in vitro use that, immediately before 1 July 2010, was declared not to be a medical device under subsection 41BD (3) of the Act, until the exemption that applies to the device ceases to have effect:

(a) a device that was exempt from listing or registration under Part 3-2 of the Act because item 3 of Schedule 5A to the *Therapeutic Goods Regulations 1990* applied to it;

(b) a device mentioned in subparagraph (1) (b) (ii);

(c) a device for which an application under paragraph 19 (1) (b) of the Act had been made but not finally determined.

(6) For subparagraph (1) (b) (iv) and paragraph 5 (c), an application is ***finally determined*** at the first time that both the following conditions are met:

(a) a decision has been made whether to grant the application;

(b) there is no longer any possibility of a change in the outcome of the decision in terms of the granting of the approval for the import, export or supply, or the listing or registration of the device.

(7) For paragraph (6) (b), the exercise of a discretion, after the period has ended, to extend a period for seeking review by a court or tribunal of the decision or of starting other proceedings (including appeals) arising out of the application, decision or review is not to be considered.

6 Transitional — in-house IVD medical devices

The amendments made by Schedule 1 apply to an in-house IVD medical device after 30 June 2014.

7 Transitional — other devices

The amendments made by Schedule 1 apply, after 30 June 2010, to an IVD medical device that is not mentioned in regulation 5 or 6.

Schedule 1 Amendments

(regulation 3)

[1] Regulation 1.6

substitute

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 any of the following medical devices, a characteristic is the unique product identifier given to the device by its manufacturer to identify the device and any variants:

(a) a Class 4 IVD medical device, other than an immunohaematology reagent IVD medical device that is a Class 4 IVD medical device;

(b) a Class AIMD medical device;

(c) a Class III medical device.

[2] Paragraphs 1.7 (1) (a) to (c)

substitute

(a) for a Class 4 IVD medical device — the relevant preferred term; and

(b) for a Class 4 IVD medical device that is an immunohaematology reagent IVD medical device — the relevant Level 2 collective term; and

(c) for a Class 3 IVD medical device — the relevant Level 3 collective term, or if no Level 3 collective term exists, the relevant Level 2 collective term; and

(d) for a Class 2 IVD medical device — the relevant Level 2 collective term; and

(e) for a Class 1 IVD medical device or an export only IVD medical device — the relevant Level 1 collective term; and

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

(g) for any of the following — the relevant preferred term:

(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; and

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

[3] Subregulation 1.7 (2), before the definition of *ISO 15225:2000(E)*

insert

collective term means a term that:

(a) is used for those medical devices that share common features; and

(b) is identified in the Global Medical Device Nomenclature System Code; and

(c) is included in the document *Collective terms available as device nomenclature system codes for IVD medical devices for the purposes of section 41BE(3) of the Act*, published by the Therapeutic Goods Administration, as updated from time to time.

Examples

Examples of the use of a collective term include the following:

(a) to illustrate the scope of certificates issued by conformity assessment bodies when assessing which groups, families or types of medical devices are covered within a manufacturer's quality system;

(b) to identify the range of skills and general technological abilities for which a conformity assessment body has been approved and is so appointed by the relevant regulatory authority;

(c) for the exchange of information between regulatory authorities when general information on individual manufacturers' capabilities is notified.

[4] Regulations 3.1 and 3.2

substitute

3.1 Medical device classifications (Act s 41DB)

(1) For section 41DB of the Act, the following table specifies the medical device classifications.

Item	Medical device	Class	Class	Class	Class	Class
1	Medical devices other than IVD medical devices	I	IIa	IIb	III	AIMD
2	IVD medical devices and in-house IVD medical devices	1	2	3	4	

(2) In the table:

(a) the lowest level of medical device classification is specified in column 3; and

(b) successively higher levels of classification are specified in columns 4 to 6; and

(c) columns 6 and 7 are of equal classification; and

(d) a device specified in a column has the same level of classification as any other device specified in that column.

3.2 Classification of medical devices

(1) A medical device, other than an IVD medical device, has the medical device classification applying under the classification rules set out in Schedule 2.

(2) An IVD medical device has the medical device classification applying under the classification rules set out in Schedule 2A.

[5] Subregulation 3.3 (2)

substitute

(2) A medical device is classified as follows:

(a) if the medical device is a medical device other than an IVD medical device — having regard to the intended purpose of the device;

(b) if the medical device is an IVD medical device or an in-house IVD medical device — having regard to the intended purpose of the device in accordance with the following risk classes:

(i) Class 1 IVD medical device or Class 1 in-house IVD medical device — no public health risk or low personal risk;

(ii) Class 2 IVD medical device or Class 2 in-house IVD medical device — low public health risk or moderate personal risk;

(iii) Class 3 IVD medical device or Class 3 in-house IVD medical device —moderate public health risk or high personal risk;

(iv) Class 4 IVD medical device or Class 4 in-house IVD medical device — high public health risk.

[6] After subregulation 3.3 (7)

insert

(8) For classification of a medical device system or a medical device procedure pack, medicines are not considered to be integral to the system or the procedure pack.

(9) For a system or procedure pack that contains both the devices mentioned in subregulation (11), that have different levels of classification under the table in regulation 3.1, the classification level of the system or procedure pack is that of the highest class of device mentioned in subregulation (11).

(10) A system or procedure pack that contains both of the devices mentioned in subregulation (11), that have the same level of classification under the table in regulation 3.1, is classified according to its primary intended purpose.

(11) For subregulations (9) and (10), the devices are:

(a) an IVD medical device; and

(b) a medical device that is not an IVD medical device.

[7] Subregulation 3.4 (3)

substitute

(3) Subregulation (4) applies to the following devices:

(a) Class IIb medical devices;

(b) Class 3 IVD medical devices;

(c) Class IIa medical devices;

(d) Class 2 IVD medical devices;

(e) Class I medical devices;

(f) Class 1 IVD medical devices.

(4) The manufacturer of a device mentioned in subregulation (3) must apply to the device appropriate conformity assessment procedures, being:

(a) the minimum conformity assessment procedures that are 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.

[8] After regulation 3.6

insert

3.6A Class 4 IVD medical devices and Class 4 in-house IVD medical devices (other than devices used for special purpose)

The conformity assessment procedures that must be applied to a Class 4 IVD medical device or a Class 4 in-house IVD medical device, other than a device to be used for a special purpose, are, as the manufacturer prefers:

(a) the full quality assurance procedures; or

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

[9] After regulation 3.7

insert

3.7A Class 3 IVD medical devices (other than devices to be used for a special purpose)

The minimum conformity assessment procedures that must be applied to a Class 3 IVD medical device, other than a device to be used for a special purpose, are, as the manufacturer prefers:

(a) the full quality assurance procedures, other than clause 1.6 of Schedule 3; or

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

Note The manufacturer of a Class 3 IVD medical device may prefer to apply to the device the conformity assessment procedures that must be applied to an IVD medical device that is classified at a higher level — see subregulation 3.4 (3).

3.7B Class 3 in-house IVD medical devices

The conformity assessment procedures that must be applied to a Class 3 in-house IVD medical device are the procedures mentioned in Part 6A of Schedule 3.

[10] After regulation 3.8

insert

3.8A Class 2 IVD medical devices (other than devices to be used for a special purpose)

The minimum conformity assessment procedures that must be applied to a Class 2 IVD medical device, other than a device to be used for a special purpose, are, as the manufacturer prefers:

(a) the full quality assurance procedures, other than clause 1.6 of Schedule 3; or

(b) the declaration of conformity (not requiring assessment by Secretary) procedures and the production quality assurance procedures, other than clause 4.7 of Schedule 3.

Note The manufacturer of a Class 2 IVD medical device may prefer to apply to the device the conformity assessment procedures that must be applied to an IVD medical device that is classified at a higher level — see subregulation 3.4 (3).

3.8B Class 2 in-house IVD medical devices

The conformity assessment procedures that must be applied to a Class 2 in-house IVD medical device are the procedures mentioned in Part 6A of Schedule 3.

[11] After regulation 3.9

insert

3.9A Class 1 IVD medical devices (other than devices to be used for a special purpose)

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

Note The manufacturer of a Class 1 IVD medical device may prefer to apply to the device the conformity assessment procedures that must be applied to an IVD medical device that is classified at a higher level — see subregulation 3.4 (3).

3.9B Class 1 in-house IVD medical devices

The conformity assessment procedures that must be applied to a Class 1 in-house IVD medical device are the procedures mentioned in Part 6A of Schedule 3.

[12] Paragraph 3.10 (1) (d)

omit

applies.

insert

applies;

[13] After paragraph 3.10 (1) (d)

insert

(e) a system or procedure pack that contains at least 1 medical device, that is not an IVD medical device, and at least 1 IVD medical device.

[14] Subregulation 3.10 (1), note for paragraph (d)

substitute

Note for paragraph (d) A system or procedure pack is treated as a single medical device. If paragraph (1) (e) or 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 either Schedule 2 or Schedule 2A; 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.

Note for paragraph (e) A system or procedure pack that contains both a medical device (that is not an IVD medical device) and an IVD medical device is treated as a single medical device. For the system or procedure pack:

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

(b) the conformity assessment procedures that must be applied to the system or procedure pack are the procedures for medical devices used for a special purpose in clause 7.5 of Schedule 3.

[15] After subregulation 3.10 (1)

insert

(1A) Despite subregulation (1), this regulation does not apply to Class 1 in-house IVD medical devices, Class 2 in-house IVD medical devices or Class 3 in-house IVD medical devices.

Note The conformity assessment procedures that must be applied to Class 1 in-house IVD medical devices, Class 2 in-house IVD medical devices or Class 3 in-house IVD medical devices are the procedures mentioned in Part 6A of Schedule 3.

[16] Subregulation 3.10 (2), note

omit

[17] Paragraphs 4.1 (2) (a) to (d)

omit

medical devices

insert

medical devices, other than IVD medical devices,

[18] Paragraph 4.1 (2) (d)

omit

device.

insert

device;

[19] After paragraph 4.1 (2) (d)

insert

(e) Class 4 IVD medical devices and Class 4 in-house IVD medical devices.

[20] Subparagraph 4.1 (3) (a) (v)

omit

applies; or

insert

applies;

[21] After subparagraph 4.1 (3) (a) (v)

insert

(vi) a Class 1 IVD medical device, Class 1 in-house IVD medical device, Class 2 in-house IVD medical device or Class 3 in-house IVD medical device; or

[22] Paragraph 5.3 (1) (i)

omit

Agreement.

insert

Agreement;

[23] After paragraph 5.3 (1) (i)

insert

(j) any of the following IVD medical devices:

(i) non assay-specific quality control material that is intended for monitoring a Class 4 IVD medical device;

(ii) an IVD medical device that is intended for self-testing;

(iii) an IVD medical device that is intended for point of care testing;

(iv) a Class 3 IVD medical device that is intended for detecting the presence of, or exposure to, a sexually transmitted agent;

(v) an IVD medical device for managing or monitoring the treatment of infections diagnosed using a Class 4 IVD medical device (for example, quantitative nucleic acid test (NAT) and genotyping assays for HIV and HCV);

(vi) an IVD medical device that is intended to be supplied for use under the pharmaceutical benefits scheme;

(vii) an IVD medical device that is intended to be supplied for use in a national screening program;

(viii) if the Secretary is not satisfied that the body or authority mentioned in subregulation 3.5 (1) has the authority and expertise to exercise the power or function mentioned in that subregulation — an IVD medical device manufactured overseas.

[24] Schedule 1, after subclause 2 (2)

insert

(3) In paragraph 2 (d):

residual risk, for a medical device, means the risk remaining after the measures described in paragraphs (2) (a), (b) and (c) have been applied.

[25] Schedule 1, clause 6, heading

substitute

6 Benefits of medical devices to outweigh any undesirable effects

[26] Schedule 1, clause 6

omit

side

[27] Schedule 1, paragraph 7.1 (b)

omit

cells and body fluids;

insert

cells, body fluids and specimens;

[28] Schedule 1, paragraph 8.1 (2) (b)

substitute

(b) if appropriate, minimises contamination of the device or specimen by the patient, user or other person; and

(c) if appropriate, minimises contamination of the patient, user or other person by the device or specimen.

[29] Schedule 1, clause 8.2, heading

substitute

8.2 Control of animal, microbial or recombinant tissues, tissue derivatives, cells and other substances

[30] Schedule 1, paragraphs 8.2 (1) (a) and (b)

omit

tissues, cells

insert

tissues, tissue derivatives, cells

[31] Schedule 1, subclauses 8.2 (2) to (4)

omit each mention of

tissues, cells

insert

tissues, tissue derivatives, cells

[32] Schedule 1, clause 8.2, at the foot

insert

Note This may not apply to certain IVD medical devices if the characteristics mentioned in subclause 8.2 (5) are integral to the intended purpose of the IVD medical device.

[33] Schedule 1, paragraph 9.2 (g)

omit

combustion.

insert

combustion;

[34] Schedule 1, after paragraph 9.2 (g)

insert

(h) the risks associated with disposal of any waste substances.

[35] Schedule 1, subclause 12.13 (1)

omit

display a code that can be used

insert

incorporate, display, emit or exhibit a code or unique characteristic that can be used

[36] Schedule 1, subclause 12.13 (2)

after

code

insert

or unique characteristic

[37] Schedule 1, after subclause 13.1 (3)

insert

Note The information may also include diagrams or drawings.

[38] Schedule 1, clause 13.3, table, item 8

omit

particular individual and is intended for use only by that individual

insert

particular individual or health professional and is intended for use only by that individual or health professional

[39] Schedule 1, clause 13.3, table, item 9

substitute

9 If applicable, an indication that:

(a) if the device is a medical device other than an IVD medical device — the device is intended for pre-market clinical investigation; or

(b) if the device is an IVD medical device — the device is intended for performance evaluation only

[40] Schedule 1, paragraph 13.4 (2) (a)

substitute

(a) the device is a Class I medical device, a Class IIa medical device or a Class 1 IVD medical device; and

[41] Schedule 1, subclause 13.4 (3), table, item 9

omit

particular individual and is intended for use only by that individual

insert

particular individual or health professional and is intended for use only by that individual or health professional

[42] Schedule 1, subclause 13.4 (3), table, item 10

substitute

10	If applicable, an indication that: (a) if the device is a medical device other than an IVD medical device — the device is intended for pre-market clinical investigation; or (b) if the device is an IVD medical device — the device is intended for performance evaluation only

[43] Schedule 1, subclause 13.4 (3), table, after item 25

insert

25A	For a medical device, other than an IVD medical device, information about any tissues, tissue derivatives, cells or substances of animal origin that have been rendered non-viable, or tissues, cells or substances of microbial or recombinant origin that are included in the device

[44] Schedule 1, subclause 13.4 (3), table, after item 28

insert

29	For an IVD medical device, information (including, to the extent practicable, drawings and diagrams) about the following: (a) the scientific principle (the 'test principle') on which the performance of the IVD medical device relies; (b) specimen type, collection, handling and preparation; (c) reagent description and any limitations (for example, use with a dedicated instrument only); (d) assay procedure including calculations and interpretation of results; (e) interfering substances and their effect on the performance of the assay;

(f) analytical performance characteristics, such as sensitivity, specificity, accuracy and precision;

(g) clinical performance characteristics, such as sensitivity and specificity;

(h) reference intervals, if appropriate;

(i) any precautions to be taken in relation to substances or materials that present a risk of infection

[45] Schedule 1, after clause 14

insert

15 Principles applying to IVD medical devices only

(1) An IVD medical device must be designed and manufactured in a way in which the analytical and clinical characteristics support the intended use, based on appropriate scientific and technical methods.

(2) An IVD medical device must be designed in a way that addresses accuracy, precision, sensitivity, specificity, stability, control of known relevant interference and measurement of uncertainty, as appropriate.

(3) If performance of an IVD medical device depends in whole or part on the use of calibrators or control materials, the traceability of values assigned to the calibrators or control material must be assured through a quality management system.

(4) An IVD medical device must, to the extent reasonably practicable, include provision for the user to verify, at the time of use, that the device will perform as intended by the manufacturer.

(5) An IVD medical device for self-testing must be designed and manufactured so that it performs appropriately for its intended purpose, taking into account the skills and the means available to users and the influence resulting from variation that can reasonably be anticipated in the user's technique and environment.

(6) The information and instructions provided by the manufacturer of an IVD medical device for self-testing must be easy for the user to understand and apply.

(7) An IVD medical device for self-testing must be designed and manufactured in a way that reduces, to the extent practicable, the risk of error in the use of the device, the handling of the sample and the interpretation of results.

[46] Schedule 2, heading

substitute

Schedule 2 Classification rules for medical devices other than IVD medical devices

(regulation 3.2)

[47] Schedule 2, clause 5.8

omit

A medical device

insert

Despite any other classification in this Schedule, a medical device

[48] After Schedule 2

insert

Schedule 2A Classification rules for IVD medical devices

(regulation 3.2)

1.1 Detection of transmissible agents posing high public health risk

An IVD medical device intended to be used for any of the following purposes is classified as a Class 4 IVD medical device or a Class 4 in-house IVD medical device:

(a) to detect the presence of, or exposure to, transmissible agents in blood, blood components, blood products, cells, tissues or organs or any derivatives of these products of human or animal origin, in order to assess their suitability for transfusion or transplantation;

(b) to detect the presence of, or exposure to, a transmissible agent that causes a serious disease with a high risk of propagation in Australia.

1.2 Detection of red blood cell antigens and antibodies and non-red cell typing

(1) An IVD medical device is classified as a Class 3 IVD medical device or a Class 3 in-house IVD medical device if:

(a) the device is intended to be used for detection of biological markers in order to assess the immunological compatibility of blood, blood components, blood products, cells, tissues or organs that are intended for transfusion or transplantation; and

(b) the device is not a device mentioned in subclause (2).

(2) An IVD medical device intended to detect any of the following markers mentioned for the following blood group systems is classified as a Class 4 IVD medical device or a Class 4 in-house IVD medical device:

(a) ABO system — ABO1 (A), ABO2 (B), ABO3 (AB);

(b) Rhesus system — RH1 (D), RH2 (C), RH3 (E), RH4 (c), RH5 (e);

(c) Kell system — KEL1 (K);

(d) Kidd system — JK1 (Jka), JK2 (Jkb);

(e) Duffy system — FY1 (Fya), FY2 (Fyb).

1.3 Detection of transmissible agents or biological characteristics posing moderate public health risk or high personal risk

(1) An IVD medical device is classified as a Class 3 IVD medical device or a Class 3 in-house IVD medical device if it is intended for any of the following uses:

(a) detecting the presence of, or exposure to, a sexually transmitted agent;

(b) detecting the presence in cerebrospinal fluid or blood of an infectious agent with a risk of limited propagation;

(c) detecting the presence of an infectious agent, if there is a significant risk that an erroneous result would cause death or severe disability to the individual or foetus being tested;

(d) pre-natal screening of women in order to determine their immune status towards transmissible agents;

(e) determining infective disease status or immune status, if there is a risk that an erroneous result will lead to a patient management decision resulting in an imminent life-threatening situation for the patient;

(f) the selection of patients:

(i) for selective therapy and management; or

(ii) for disease staging; or

(iii) in the diagnosis of cancer;

(g) human genetic testing;

(h) to monitor levels of medicines, substances or biological components, when there is a risk that an erroneous result will lead to a patient management decision resulting in an immediate life-threatening situation for the patient;

(i) the management of patients suffering from a life-threatening infectious disease;

(j) screening for congenital disorders in a foetus.

Note for paragraph (f) An IVD medical device would fall into Class 2 under clause 1.7 if:

(a) a therapy decision would usually be made only after further investigation; or

(b) the device is used for monitoring.

(2) Despite subclause (1), an IVD medical device is classified as a Class 3 IVD medical device or a Class 3 in-house IVD medical device if it is used to test for transmissible agents included in the Australian National Notifiable Diseases Surveillance System (NNDSS) list as published from time to time by the Australian government.

1.4 IVD medical devices for self-testing

An IVD medical device for self-testing is classified as a Class 3 IVD medical device unless:

(a) the result of the examination is not determining a serious condition, ailment or defect; or

(b) the examination is preliminary and follow-up additional testing is required.

1.5 Non assay-specific quality control material

Despite clauses 1.1 to 1.4, an IVD medical device that is intended to be used as non assay-specific quality control material is classified as a Class 2 IVD medical device or a Class 2 in-house IVD medical device.

1.6 Reagents, instruments etc

(1) A reagent or other article that possesses specific characteristics, intended by the manufacturer, to make it suitable for in vitro diagnostic procedures related to a specific examination is classified as a Class 1 IVD medical device or a Class 1 in-house IVD medical device.

(2) Despite clauses 1.1 to 1.5, the following IVD medical devices are classified as Class 1 IVD medical devices or Class 1 in-house IVD medical devices:

(a) an instrument, intended by the manufacturer, to be specifically used for in vitro diagnostic procedures;

(b) a specimen receptacle, other than a specimen receptacle that is intended for use in self-testing;

(c) a microbiological culture medium.

(3) In this clause:

examination means a set of operations having the object of determining the value or characteristics of a property.

Note In some disciplines (for example, microbiology) an examination is the combination of a number of tests, observations or measurements.

specimen receptacle means a device, whether vacuum-type or not, specifically intended by its manufacturer for the primary containment and preservation of a specimen derived from the human body for the purpose of in vitro diagnostic examination.

Note 1 A specimen receptacle is considered to be an IVD medical device.

Note 2 A product for general laboratory use is not an IVD medical device unless the product is specifically intended by its manufacturer to be used for in vitro diagnostic examination.

1.7 Other IVD medical devices are Class 2 IVD medical devices

An IVD medical device not mentioned in this Schedule is classified as a Class 2 IVD medical device or a Class 2 in-house IVD medical device.

1.8 IVD medical devices intended for export only

Despite clauses 1.1 to 1.7, an IVD medical device is classified as a Class 1 IVD medical device if it is intended by the manufacturer for export only.

[49] Schedule 3, paragraph 1.1 (b)

after

for a

insert

Class 4 IVD medical device, Class 4 in-house IVD medical device,

[50] Schedule 3, subparagraph 1.4 (5) (c) (vi)

omit

the device

insert

the device, other than an IVD medical device,

[51] Schedule 3, after subparagraph 1.4 (5) (c) (vi)

insert

(via) for an IVD medical device — a statement indicating whether or not the device contains viable tissues, cells, or substances of human or animal origin;

[52] Schedule 3, clause 1.6, heading

substitute

1.6 Examination of design of Class 4 IVD medical device, Class 4 in-house IVD medical device, Class AIMD medical device or Class III medical device

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[53] Schedule 3, subclause 1.6 (1)

after

of a

insert

Class 4 IVD medical device, a Class 4 in-house IVD medical device, a

[54] Schedule 3, subclause 1.6 (5), note

substitute

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 3 IVD medical device — see Division 3.2, paragraph 3.7A (a); or

(c) a Class IIa medical device — see Division 3.2, paragraphs 3.8 (1) (a) and (2) (a); or

(d) a Class 2 IVD medical device — see Division 3.2, paragraph 3.8A (a).

[55] Schedule 3, paragraph 1.9 (1) (c)

after

is a

insert

Class 4 IVD medical device, Class 4 in-house IVD medical device,

[56] Schedule 3, paragraph 2.3 (3) (j)

omit

the device

insert

the device, other than an IVD medical device,

[57] Schedule 3, after paragraph 2.3 (3) (j)

insert

(ja) for an IVD medical device — a statement indicating whether or not the device contains viable tissues, cells, or substances of human or animal origin;

[58] Schedule 3, subclause 4.7 (1)

omit

Class III medical device or Class IIb medical device

insert

Class 4 IVD medical device, Class 4 in-house IVD medical device, Class 3 IVD medical device, Class III medical device or Class IIb medical device

[59] Schedule 3, subclause 4.7 (1), note

substitute

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 2 IVD medical device — see Division 3.2, paragraph 3.8A (b);

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

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

[60] Schedule 3, paragraph 4.8 (1) (c)

omit

Class III medical device or Class IIb medical device

insert

Class 4 IVD medical device, Class 4 in-house IVD medical device, Class 3 IVD medical device, Class III medical device or Class IIb medical device

[61] Schedule 3, after subparagraph 6.6 (2) (h) (i)

insert

(ia) a Class 2 IVD medical device;

[62] Schedule 3, after Part 6

insert

Part 6A Procedures applying only to certain classes of in-house IVD medical devices

1.1 Overview

The conformity assessment procedures set out in this Part apply to the manufacturer of a Class 3 in-house IVD medical device, Class 2 in-house IVD medical device or Class 1 in-house IVD medical device.

1.2 Procedures

(1) The manufacturer must, using a form approved by the Secretary, notify the Secretary, on a day (the ***notification day***) no later than 1 July 2014 and then annually on a day no later than the notification day, of the following matters:

(a) contact details of the laboratory;

(b) in-house IVD medical devices manufactured.

Penalty: 10 penalty units.

(2) A laboratory that manufactures an in-house IVD medical device must meet the National Pathology Accreditation Advisory Council performance standard *Requirements for the Development and Use of In-house In Vitro Diagnostic Devices (IVDs)* as amended from time to time.

(3) A laboratory that manufactures an in-house IVD medical device must be accredited as a medical testing laboratory by the National Association of Testing Authorities (NATA) or by a conformity assessment body determined by the Secretary.

(4) A laboratory that manufactures an in-house IVD medical device must meet the standard published by the International Organization for Standardization known as ISO 15189, *Medical laboratories — Particular requirements for quality and competence* as amended from time to time.

1.3 Information to be given to authorised person

(1) If asked to do so by an authorised person, the manufacturer of a 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 (2);

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

(iii) data for 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) The documentation must include the following information:

(a) the manufacturer's quality objectives;

(b) the organisation of the manufacturer's business, including 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, including 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 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 of it, 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 device contains viable tissues, cells or substances of human or animal origin;

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

(vii) a copy of the information to be provided with the kind of device, when relevant;

(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 information about the following:

(i) the processes and procedures to be used 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 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 for 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 to the design or production of such devices;

(g) whether:

(i) a conformity assessment standard, or part of a conformity assessment standard, has been applied to the system; or

(ii) the solutions adopted to ensure that the system is of a kind 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) 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.

1.4 Post-marketing system

(1) The manufacturer of an in-house IVD medical device must establish, and keep up-to-date, a post-marketing system that complies with subclause (2) for use for a device of that kind.

(2) A post-marketing system complies with this subclause in relation to an in-house IVD medical device if the system requires the manufacturer of the device to:

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

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

(c) 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 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.

[63] Schedule 3, paragraph 7.2 (2) (c)

omit

individual;

insert

individual or health professional;

[64] Schedule 4, item 1.1

after

importer's immediate family,

insert

or for use in the in vitro examination of a specimen obtained from the importer or a member of the importer's immediate family,

[65] Schedule 4, subparagraph 1.1 (b) (i)

substitute

(i) a device, other than an IVD medical device, that is manufactured using tissues, tissue derivatives, cells or substances of animal origin that have been rendered non-viable, or tissues, cells or substances of bacterial or recombinant origin; or

[66] Schedule 4, subparagraph 1.1 (b) (ii)

omit

device

insert

device, other than an IVD medical device,

[67] Schedule 4, paragraph 1.1 (c)

omit

in the case of a medical device classified as Class IIa or higher:

insert

in the case of a Class 4 IVD medical device, Class AIMD medical device, Class III medical device, Class 3 IVD medical device, Class IIb medical device, Class 2 IVD medical device or Class IIa medical device:

[68] Schedule 4, after item 2.9

insert

2.10	Medical device that is a Class 1, Class 2 or Class 3 in-house IVD medical device	(a) The device must comply with the essential principles. (b) The manufacturer of the device must apply the appropriate conformity procedures at all times. (c) The manufacturer of the device must, on request by the Secretary, provide samples of the device. (d) The manufacturer of the device must, on request by the Secretary, provide the following information: (i) whether the device complies with the essential principles; (ii) whether the conformity assessment procedures have been applied to the device; (iii) whether the device complies with every requirement (if any) relating to advertising applicable under Part 5-1 of the Act or the *Therapeutic Goods Regulations 1990*.

(e) The manufacturer of the device must, at all times, have available:

(i) sufficient information to substantiate that the conformity assessment procedures have been applied to the device; or

(ii) information relating to changes to the device, the product range, and quality management system.

(f) The manufacturer of the device must allow an authorised person to do any of the following:

(i) enter, at any reasonable time, any premises at which the manufacturer manufactures the device;

(ii) inspect the premises and medical devices of any kind on those premises and to examine, take measurements of, conduct tests on, require tests to be conducted on or take samples of medical devices of any kind on those premises or anything on those premises that relates to medical devices of any kind;

(iii) make any still or moving image or any recording of those premises or anything on those premises.

(g) If asked to do so by an authorised person, the manufacturer of the device must give to the person any documents relating to the device that the person requires and allow the person to copy the documents.

(h) The Secretary must not have directed that the supply of the device be stopped or should cease because the supply compromises public health and safety.

[69] Schedule 5, item 1.2

substitute

1.2	(a) 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	Subsection 41EJ (4) of the Act	6 760
	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.		
	(b) Review of conformity assessment certificate for an IVD medical device — surveillance assessment for conformity assessment certificate issued under conformity assessment procedures set out in Schedule 3, Part 1 or 4		6 970

[70] Schedule 5, item 1.3

after

Review of conformity assessment certificate

insert

for a medical device, other than an IVD medical device

[71] Schedule 5, after item 1.3

insert

1.3A	Review of conformity assessment certificate for an IVD medical device in relation to certification of compliance with the essential principles for conformity assessment certificate issued under conformity assessment procedures set out in:	Subsection 41EJ (4) of the Act	
	(a) Schedule 3, Part 1 — Full Quality Management System; or		23 900
	(b) Schedule 3, clause 1.6 — Design Examination; or		51 000
	(c) Schedule 3, clause 1.6 — Design Examination – Immunohaematology reagent medical devices; or		12 500
	(d) Schedule 3, clause 1.6 — Abridged Design Examination – previously registered IVDs; or		3 010
	(e) Schedule 3, Part 2 — Type Examination; or		33 000
	(f) Schedule 3, Part 4 — Production Quality Management System		21 000
	Note 1 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 2 For an assessment under paragraph (e), an additional fee to cover the costs of testing the relevant kind of medical device is also payable — see item 2.2 of this Schedule.		

[72] Schedule 5, item 1.4

substitute

1.4	Considering a submission to the Secretary in relation to a proposed suspension of a conformity assessment certificate, including a conformity assessment certificate for an IVD medical device	Subsection 41EN (2) and paragraph 63 (2) (h) of the Act	For a medical device, other than an IVD medical device — the fee applicable under item 1.14 to the kind of work to be undertaken For an IVD medical device — the fee applicable under item 1.14A to the kind of work to be undertaken

[73] Schedule 5, paragraph 1.5 (e)

omit

function

insert

function;

[74] Schedule 5, after paragraph 1.5 (e)

insert

(f)	IVD medical devices, including Class 4 in-house IVD medical devices	790

[75] Schedule 5, items 1.6 to 1.8

omit

medical device

insert

medical device, including an IVD medical device,

[76] Schedule 5, item 1.9

after

conformity assessment procedures

insert

for a medical device, other than an IVD medical device,

[77] Schedule 5, after item 1.9

insert

1.9A	Conformity assessment for an IVD medical device — initial assessment under conformity assessment procedures set out in:	Subsections 41LA (1) and (2) of the Act	
	(a) Schedule 3, Part 1 — Full Quality Management System; or		23 900
	(b) Schedule 3, clause 1.6 — Design Examination; or		51 000
	(c) Schedule 3, clause 1.6 — Design Examination – Immunohaemotology reagent medical devices; or		12 500

(d)	Schedule 3, clause 1.6 — Abridged Design Examination – previously registered IVDs; or	3 010
(e)	Schedule 3, Part 2 — Type Examination; or	33 000
(f)	Schedule 3, Part 4 — Production Quality Management System	21 000

Note 1 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 2 For an assessment under paragraph (e), 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 3 If the assessment is abridged, a reduced fee is payable — see regulation 9.4.

[78] Schedule 5, item 1.10

after each mention of

medical device,

insert

other than an IVD medical device,

[79] Schedule 5, after item 1.10

insert

1.10A	Conformity assessment — assessment because of changes or proposed changes to the IVD medical device or quality management system applying to that device *Note 1* 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 2* For an assessment under Schedule 3, Part 2, 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.	Subsections 41LA (1) and (2) of the Act	60% of initial fee under item 1.9A

[80] Schedule 5, item 1.12

omit

1.9 or 1.10

insert

1.9, 1.9A, 1.10 or 1.10A

[81] Schedule 5, after item 1.14

insert

1.14A	Application audit assessment for Class 1, Class 2 and Class 3 IVD medical devices	Subsections 41LA (3) and (4) of the Act	5 500

[82] Schedule 5, item 1.15

omit

medical device

insert

a medical device, including an IVD medical device,

[83] Schedule 5, after item 1.16

Insert

1.17	Initial and annual notification by a laboratory of its in-house IVD medical device	Subsection 63 (1) and paragraph 63 (2) (h) of the Act	810

[84] Schedule 5, clause 2.1

omit

1.9 or 1.10

insert

1.9, 1.9A, 1.10 or 1.10A

[85] Schedule 5, subclause 2.2 (1)

omit

paragraph 1.3 (b), 1.9 (c) or (d)

insert

paragraph 1.3 (b), 1.3A (e), 1.9 (c) or (d), 1.9A (e)

[86] Dictionary, definition of *Active implantable medical device*

substitute

active implantable medical device or ***AIMD*** 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.

[87] Dictionary, definition of *Authorised person*

substitute

authorised person — see regulation 10.1.

[88] Dictionary, definition of *central circulatory system*, paragraph (p)

substitute

(p) *arteriae ilica communis.*

[89] Dictionary, after definition of *classification rules*

insert

Class 1 in-house IVD medical device means an in-house IVD medical device that, under Division 3.1 of Part 3, is classified as Class 1.

Class 1 IVD medical device means an IVD medical device that, under Division 3.1 of Part 3, is classified as Class 1.

Class 2 in-house IVD medical device means an in-house IVD medical device that, under Division 3.1 of Part 3, is classified as Class 2.

Class 2 IVD medical device means an IVD medical device that, under Division 3.1 of Part 3, is classified as Class 2.

Class 3 in-house IVD medical device means an in-house IVD medical device that, under Division 3.1 of Part 3, is classified as Class 3.

Class 3 IVD medical device means an IVD medical device that, under Division 3.1 of Part 3, is classified as Class 3.

Class 4 in-house IVD medical device means an in-house IVD medical device that, under Division 3.1 of Part 3, is classified as Class 4.

Class 4 IVD medical device means an IVD medical device that, under Division 3.1 of Part 3, is classified as Class 4.

[90] Dictionary, definition of *Conformity assessment certificate*

substitute

conformity assessment certificate means a certificate issued under section 41EE of the Act.

[91] Dictionary, definitions of *Conformity assessment standard*, *current Poisons Standard* and *custom-made medical device*

substitute

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 made specifically in accordance with a request by a health professional specifying the design characteristics or construction of the medical device; and

(b) is intended:

(i) to be used only in relation to a particular individual; or

(ii) to be used by the health professional to meet special needs arising in the course of his or her practice.

[92] Dictionary, definition of *Device nomenclature system code*

substitute

device nomenclature system code, for a medical device, means the device nomenclature system code mentioned for the device in regulation 1.7.

[93] Dictionary, definition of *Ethics committee*

substitute

ethics committee — see subsection 3 (1) of the Act.

[94] Dictionary, definition of *Health professional*

substitute

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.

immunohaematology reagent IVD medical device means an IVD medical device that is a reagent, reagent product or related material that is intended by the manufacturer to be used to provide information about blood groups, red cell antigens or red cell antibodies, or to determine compatibility of blood or blood components for transfusion.

[95] Dictionary, after definition of *included in the Register*

insert

in-house IVD medical device means an IVD medical device that is:

(a) within the confines or scope of an Australian medical laboratory or Australian medical laboratory network:

(i) developed from first principles; or

(ii) developed or modified from a published source; or

(iii) developed or modified from any other source; or

(iv) used for a purpose, other than the intended purpose assigned by the manufacturer; and

(b) not supplied for use outside that medical laboratory or medical laboratory network.

[96] Dictionary, after definition of *invasive medical device*

insert

IVD medical device, or in vitro diagnostic medical device, means a medical device that is:

(a) a reagent, calibrator, control material, kit, specimen receptacle, software, instrument, apparatus, equipment or system, whether used alone or in combination with another diagnostic product for in vitro use; and

(b) intended by the manufacturer to be used in vitro for the examination of a specimen derived from the human body, solely or principally for:

(i) giving information about a physiological or pathological state or a congenital abnormality; or

(ii) determining safety and compatibility with a potential recipient; or

(iii) monitoring therapeutic measures; and

(c) not a product that is:

(i) intended for general laboratory use; and

(ii) not manufactured, sold or presented for use as an IVD medical device.

IVD medical device for self-testing means an IVD medical device intended to be used:

(a) in the home or similar environment by a lay person; or

(b) in the collection of a sample by a lay person and, if that sample is tested by another person, the results are returned directly to the person from whom the sample was taken without the direct supervision of a health professional who has formal training in a medical field or discipline to which the self-testing relates.

[97] Dictionary, after definition of *kind*

insert

lay person, for the use of an IVD medical device for self-testing, means an individual who does not have formal training in a medical field or discipline to which the self-testing relates.

[98] Dictionary, after definition of *medical device used for a special purpose*

insert

medical laboratory network means a network of laboratory organisations:

(a) that operate under a single approved pathology authority with a single quality management system; and

(b) for which:

(i) the activities of the network span more than 1 field of testing or program; or

(ii) the network operates at multiple sites within a field, or involves a combination of multiple sites and fields or programs.

[99] Dictionary, after definition of *medicine*

insert

point of care testing, for an IVD medical device, means testing performed outside the laboratory environment, near to or at the side of the patient, that is not done under the supervision of a trained laboratory professional.

[100] Dictionary, definitions of *Production quality assurance procedures*, *Product quality assurance procedures* and *Refurbishment*

substitute

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.

[101] Dictionary, after definition of *reusable surgical instrument*

insert

sample, for an IVD medical device for self-testing, means 1 or more specimens, taken from the human body, that:

(a) are intended to provide information on the human body; and

(b) may serve as a basis for a decision on the human body or its processes.

[102] Dictionary, definition of *serious*

substitute

serious, for a condition, ailment or defect, means a 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.

serious disease means a disease that:

(a) may result in death or long-term disability; and

(b) may be incurable or require major therapeutic interventions; and

(c) must be diagnosed accurately, to mitigate the public health impact of the disease.

[103] Dictionary, definition of *Sponsor*

substitute

sponsor — see subsection 3 (1) of the Act.

[104] Dictionary, definition of *Variant*

substitute

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 this definition, if the variation does not change the intended purpose of the device.

[105] Dictionary, definition of *Working day*

substitute

working day — see subsection 3 (1) of the Act.

Note

1. All legislative instruments and compilations are registered on the Federal Register of Legislative Instruments kept under the *Legislative Instruments Act 2003.* See http://www.frli.gov.au.