Reprint
as at 21 November 2003

Medicines (Database of Medical Devices) Regulations 2003

(SR 2003/325)

Silvia Cartwright, Governor-General

Order in Council

At Wellington this 17th day of November 2003

Present:
Her Excellency the Governor-General in Council

Pursuant to section 105 of the Medicines Act 1981, Her Excellency the Governor-General, acting on the advice of the Minister of Health tendered after consultation with the organisations and bodies appearing to the Minister to be representative of persons likely to be substantially affected by them, and acting on the advice and with the consent of the Executive Council, makes the following regulations.

Note
Changes authorised by section 17C of the Acts and Regulations Publication Act 1989 have been made in this reprint.

A general outline of these changes is set out in the notes at the end of this reprint, together with other explanatory material about this reprint.

These regulations are administered by the Ministry of Health.

Contents

Regulations

1 Title

These regulations are the Medicines (Database of Medical Devices) Regulations 2003.

2 Commencement

These regulations come into force on 1 January 2004.

3 Interpretation

In these regulations, unless the context otherwise requires,—

accessory means an article that is intended by the manufacturer to be used together with a medical device to enable the device to be used as the manufacturer of the device intended

Act means the Medicines Act 1981

active implantable medical device or **AIMD** means an active medical device that is intended by the manufacturer—

(a) either—

(i) to be introduced wholly, or partially, into the human body by surgical or medical intervention; or

(ii) to be introduced into a natural orifice in the human body by medical intervention; 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 that 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 a medical device to which paragraph (a) applies 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 person, 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 person, 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

body orifice—

(a) means a natural opening, or a permanent artificial opening, in a person's body; and

(b) includes the external surface of a person's eyeball

Class I medical device means a medical device required by regulation 13 and Schedule 2 to be classified as a Class I medical device

Class IIa medical device means a medical device required by regulation 13 and Schedule 2 to be classified as a Class IIa medical device

Class IIb medical device means a medical device required by regulation 13 and Schedule 2 to be classified as a Class IIb medical device

Class III medical device means a medical device required by regulation 13 and Schedule 2 to be classified as a Class III medical device

Class AIMD (Active Implantable Medical Device) means a medical device required by regulation 13 and Schedule 2 to be classified as a Class AIMD medical device

database means the database of medical devices established and maintained under regulation 4

Director-General has the same meaning as it has in section 2(1) of the Act

exempt medical device means a medical device of the kind described in Schedule 1

implantable medical device means a medical device (other than an active implantable medical device) that is intended by the manufacturer—

(a) to be wholly introduced into the human body by surgical intervention, and to remain in place after the procedure; or

(b) to be partially introduced into the human body by surgical intervention, and to remain in place for at least 30 days after the procedure; or

(c) to replace an epithelial surface or the surface of a person's eye by surgical intervention, and to remain in place after the procedure

intended purpose, in relation to a 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 relating 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 human body through a body orifice or through the surface of the body

medical device has the same meaning as it has in section 2(1) of the Act

Ministry of Health means the department of the Public Service referred to by that name

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

sponsor, in relation to a medical device,—

(a) means—

(i) a person in New Zealand who exports, or arranges the exportation of, the device from New Zealand:

(ii) a person in New Zealand who imports, or arranges the importation of, the device into New Zealand:

(iii) a person in New Zealand who manufactures the device in New Zealand, or arranges for another person to manufacture the device in New Zealand, for supply (whether in New Zealand or elsewhere); but

(b) does not include a person who—

(i) exports, imports, or manufactures a device; or

(ii) arranges for the exportation, importation, or manufacture of a device,—

on behalf of another person who, at the time of the exportation, importation, manufacture, or making of the arrangements, is a resident of, or is carrying on business in, New Zealand

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:

(b) a medical device that is intended by the manufacturer to be used to penetrate the human body in any way other than through a body orifice.

Database of information

4 Database to be established and maintained

(1) The Director-General must ensure that a database containing information required to be entered in that database under these regulations, is established and maintained.

(2) The Director-General and any person authorised by the Director-General may, at any time,—

(a) correct any inaccurate information contained in the database; and

(b) add other information about any medical device, any similar product that may in future be treated as a medical device, or any matter relating to the use of medical devices or any particular medical device that is allowed to be included in the database under subclause (4).

(3) The database may be maintained in any form the Director-General considers appropriate (including wholly or partly in electronic form).

(4) The database may include any information (other than advertising or promotional material, or any information that the Director-General considers unsuitable for inclusion) about—

(a) any medical device:

(b) any similar product that may in future be treated as a medical device:

(c) any matter relating to the use of medical devices or any particular medical device.

5 Information required to be entered in database

(1) The following information must be entered into the database in respect of each medical device that is not an exempt medical device:

(a) the risk classification of that device:

(b) the name of the manufacturer and the sponsor of that device, together with—

(i) the address of the registered office or principal place of business in New Zealand of the sponsor; and

(ii) the address of the registered office or principal place of business of the manufacturer (whether in New Zealand or overseas); and

(iii) a contact telephone number or email address for the manufacturer and the sponsor:

(c) the product description attributed to the device by the Global Medical Device Nomenclature System (**GMDNS**).

(2) A unique product identifier for each Class III and Class AIMD medical device that is not an exempt medical device must be entered into the database.

(3) Despite subclause (1), if a particular sponsor is the sponsor of 2 or more medical devices, it is only necessary to enter information in respect of each kind of device (instead of in respect of each device) for which the sponsor is responsible, if each of the devices of the same kind—

(a) was made by the same manufacturer; and

(b) has the same GMDNS code; and

(c) has the same risk classification; and

(d) is a Class I, Class IIa, or Class IIb medical device.

(4) For the purposes of subclause (2), a **unique product identifier** for a medical device is a trade name or brand name, combined if the Director-General so requires, with a form of product identification.

(5) For the purposes of subclause (3), 2 or more medical devices are of the same kind if those devices are—

(a) substantially similar to one another; and
(b) designed to be used in the same way and for the same purpose.

6 Information and declaration to be supplied by sponsor

A sponsor of a medical device must, within 30 working days of becoming the sponsor of the device,—

(a) ensure that the information required to be entered in the database under these regulations is received by the Director-General or other person who maintains the database on behalf of the Director-General; and
(b) provide to the Director-General or other person who maintains the database on behalf of the Director-General a declaration by the sponsor or an employee of the sponsor that complies with regulation 7.

7 Declaration

The declaration required by regulation 6(b) is a declaration that—

(a) the medical device or kind of medical device, as the case requires, in respect of which information is supplied, is a medical device or kind of medical device (within the meaning of these regulations) and is correctly classified in accordance with these regulations:
(b) the medical device or kind of medical device, as the case requires, will only be recommended by the sponsor for use for its intended purpose:
(c) the information supplied by, or on behalf of, the sponsor under regulation 6(a) is accurate and complete.

8 Updated information to be supplied by sponsor

(1) Subclause (2) applies if any information recorded on the database in respect of a medical device or kind of medical device ceases to be accurate or complete (whether because of a change of circumstances, for example, a change in the name of a manufacturer or sponsor, or a lapse in any certification relating to the device or kind of device, or otherwise).

(2) If this subclause applies, the sponsor must, within 10 working days of the information ceasing to be accurate or complete,

ensure that the Director-General or any person who maintains the database on behalf of the Director-General is notified of the correct details, or the complete information, as the case requires.

9 Sponsor must make arrangements to ensure compliance with regulations 5, 6, and 8

The sponsor of a medical device or a kind of medical device must put in place any procedures necessary to ensure that the sponsor is able to comply with regulations 5, 6, and 8.

10 Prohibited statements

No manufacturer or sponsor of a medical device or kind of medical device may publish any statement that directly or by implication indicates or suggests that inclusion of the medical device or kind of medical device in the database is an endorsement of the safety or suitability for use of that product by the Director-General or the Ministry of Health.

Medical device risk classifications

11 Medical device risk classifications in general

(1) Medical devices have the following risk classifications:

(a) Class I:

(b) Class IIa:

(c) Class IIb:

(d) Class III:

(e) Class AIMD (Active Implantable Medical Device).

(2) Class I is the lowest level of risk classification; Class IIa and Class IIb are successively higher levels of risk classification; and Class III and Class AIMD (Active Implantable Medical Device) are the highest levels of risk classification.

12 Risk classification of particular medical devices

A medical device has the risk classification given by the risk classification rules set out in Schedule 2, as applied by regulation 13.

13 Principles for applying the risk classification rules

(1) The principles set out in this regulation must be applied when determining the correct risk classification for a medical device under the risk classification rules set out in Schedule 2.

(2) A medical device must be 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 must be classified separately.

(4) An accessory to a medical device must be classified separately from a medical device.

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

(6) If a medical device is not designed to be used solely or principally in a particular part of a patient's body, the medical device must be 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 risk classification rules apply to the medical device, the medical device has the highest level of risk classification applying under the applicable risk classification rules.

14 Offences

A sponsor who contravenes any of regulations 6, 8, 9, or 10 commits an offence and is punishable on summary conviction by a fine not exceeding $500.

Transitional provisions

15 Transitional provisions

(1) The sponsor of any specified medical device is not required to comply with regulations 6 to 9 in respect of that medical device until the later of the following dates (the **applicable date**):

(a) 1 January 2005:

(b) a date after 1 January 2005 specified by the Director-General (by notice in the *Gazette*) as the compliance date for the purposes of this regulation.

(2) For the purpose of subclause (1), regulation 6 applies as if for the words "within 30 days of becoming the sponsor of the device" there were substituted the words "within 30 days of the date referred to in regulation 15(1) (the **applicable date**)".

(3) In this regulation, **specified medical device** means a medical device or kind of medical device, as the case requires, that—

(a) was manufactured in New Zealand, exported from New Zealand, imported into New Zealand, or sold in New Zealand, before the commencement of these regulations; and

(b) continues, on or after the applicable date, to be manufactured in New Zealand, exported from New Zealand, imported into New Zealand, or sold in New Zealand.

(4) The sponsor of a medical device or kind of medical device, as the case requires, is not required to comply with regulations 6 to 9 in respect of that medical device or kind of medical device if—

(a) the medical device or kind of medical device—

(i) ceased, before the commencement of these regulations to be manufactured in New Zealand, exported from New Zealand, imported into New Zealand, or sold in New Zealand; or

(ii) continued to be manufactured in New Zealand, exported from New Zealand, imported into New Zealand, or sold in New Zealand on or after the commencement of these regulations but ceased before the applicable date to be manufactured in New Zealand, exported from New Zealand, imported into New Zealand, or sold in New Zealand; and

(b) the medical device or kind of medical device is not subsequently manufactured in New Zealand, exported from New Zealand, imported into New Zealand, or sold in New Zealand on or after the applicable date.

Schedule 1
r 3

Exempt medical devices

The following are exempt medical devices:

(a) any medical device (other than a medical device to which clause 13(2) of Schedule 2 applies) that is also a medicine (within the meaning of section 3(1) of the Act):

(b) any medical device that is—

(i) manufactured in response to a request by a registered health professional (within the meaning of section 2(1) of the Act) that specifies the design characteristics of the device; and

(ii) intended to be used only in relation to a particular patient:

(c) a medical device supplied to a practitioner (within the meaning of section 2(1) of the Act) for use in relation to a particular patient of the practitioner:

(d) any medical device that—

(i) has been imported into New Zealand; and

(ii) is being held by the New Zealand Customs Service pending export from New Zealand to another country:

(e) any diagnostic device that is—

(i) commonly known as an *in vitro* diagnostic device; and

(ii) intended for use only within a particular laboratory:

(f) any diagnostic device made in a laboratory that is intended for use in another laboratory (whether or not as a consequence of the purchase of the device by the owner of the other laboratory or otherwise):

(g) any medical device imported by a person solely for that person's own use:

(h) any medical device imported for use in a clinical trial:

(i) any medical device that is included in any class of medical device declared to be an exempt class of medical device by notice issued by the Director-General in the *Gazette*.

Schedule 2

rr 3, 12, 13

Medical devices risk classification rules

1 Interpretation

For the purposes of 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:

(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:

(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.

Rules for classifying non-invasive medical devices

2 Medical devices in general

A non-invasive medical device is classified as Class I, unless the device is classified at a higher level under another clause of this schedule.

3 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 person; 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 person; 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) A medical device to which this clause applies is classified as Class IIa.

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

(1) 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) Despite subclause (1), if the treatment for which the medical device to which this clause applies is designed consists of filtration, centrifugation, or exchanges of gas or heat, the device is classified as Class IIa.

5 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) A medical device to which this clause applies is classified as Class IIa.

(3) Despite subclause (2), a medical device to which this clause applies is classified as Class I if it is intended to be used—

(a) as a mechanical barrier; or

(b) for compression; or

(c) for the absorption of exudates.

(4) Despite subclause (2), if a device to which this clause applies 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.

Rules for classifying invasive medical devices and implantable medical devices

6 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 a medical device to which this clause applies 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, the device is classified as Class IIa unless 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, in which case the device is classified as Class I:

(c) if the device is intended for long-term use, the device is classified as Class IIb unless 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, in which case the device is classified as Class IIa.

(3) Despite subclause (2), if a medical device to which this clause applies 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.

7 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) A medical device to which this clause applies is classified as Class IIa.

(3) Despite subclause (2), if a medical device to which this clause applies 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) Despite subclause (2), if a medical device to which this clause applies is a reusable surgical instrument, the device is classified as Class I.

(5) Despite subclause (2), a medical device to which this clause applies is classified as Class IIb 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.

8 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) A medical device to which this clause applies is classified as Class IIa.

(3) Despite subclause (2), a medical device to which this clause applies is classified as Class IIb 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; which is classified as Class IIa); or

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

(4) Despite subclause (2), a medical device to which this clause applies is classified as Class III 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 person's body.

(5) For the purposes of this clause and clause 9, a **medical device** that is intended by the manufacturer to be placed in the teeth—

(a) includes a medical device that is intended by the manufacturer to penetrate a tooth; but

(b) 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.

9 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) A medical device to which this clause applies is classified as Class IIb.

(3) Despite subclause (2), if a medical device to which this clause applies is intended by the manufacturer to be placed in the teeth, the device is classified as Class IIa.

(4) Despite subclause (2), a medical device to which this clause applies is classified as Class III 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 person'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; which is classified as Class IIa); or

(e) to be used to administer medicine.

Special rules for classifying active medical devices

10 Active medical devices in general

An active medical device is classified as Class I, unless the device is classified at a higher level under another clause in this schedule.

11 Active medical devices for therapy

(1) 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) Despite subclause (1), if a device referred to in subclause (1) 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) Despite subclause (1), 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 referred to in subclause (2) is classified as Class IIb.

12 Active medical devices for diagnosis

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

(2) A medical device to which this clause applies is classified as Class IIa 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; which is classified as Class I); 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 subclause (3)(a)).

(3) A medical device to which this clause applies is classified as Class IIb 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).

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

(1) 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) However, if a device referred to in subclause (1) 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.

Special rules for classifying particular kinds of medical devices

14 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) A medical device to which this clause applies is classified as Class III.

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

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

(1) 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) Despite subclause (1), if a medical device referred to in that subclause is an implantable medical device or an invasive medical device that is intended for long-term use, the device is classified as Class III.

16 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; which is classified as Class I.

17 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.

18 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) A medical device to which this clause applies 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.

(3) A medical device to which subclause (2)(a) or (b) applies is classified as Class I.

19 Medical devices that are blood bags

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

20 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.

21 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.

22 Medical devices that are mammary implants

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

Diane Morcom,
Clerk of the Executive Council.

Explanatory note

This note is not part of the regulations, but is intended to indicate their general effect.

These regulations, which come into force on 1 January 2004, establish a requirement for the Director-General of Health to establish a database of information about medical devices. The regulations impose obligations on certain people (sponsors of medical devices) to supply information necessary for the Director-General to establish and maintain the database, and to make declarations concerning the information that is supplied. Failure to comply with certain obligations under the regulations is an offence punishable on summary conviction by a fine not exceeding $500. The regulations also set out rules to be applied in determining the risk classifications that apply to medical devices.

Issued under the authority of the Acts and Regulations Publication Act 1989.
Date of notification in *Gazette*: 20 November 2003.

Contents

Notes

1 General

This is a reprint of the Medicines (Database of Medical Devices) Regulations 2003. The reprint incorporates all the amendments to the regulations as at 21 November 2003, as specified in the list of amendments at the end of these notes.

Relevant provisions of any amending enactments that have yet to come into force or that contain relevant transitional or savings provisions are also included, after the principal enactment, in chronological order.

2 Status of reprints

Under section 16D of the Acts and Regulations Publication Act 1989, reprints are presumed to correctly state, as at the date of the reprint, the law enacted by the principal enactment and by the amendments to that enactment. This presumption applies even though editorial changes authorised by section 17C of the Acts and Regulations Publication Act 1989 have been made in the reprint.

This presumption may be rebutted by producing the official volumes of statutes or statutory regulations in which the principal enactment and its amendments are contained.

3 How reprints are prepared

A number of editorial conventions are followed in the preparation of reprints. For example, the enacting words are not included in Acts, and provisions that are repealed or revoked are omitted. For a detailed list of the editorial conventions, *see*

http://www.pco.parliament.govt.nz/legislation/reprints.shtml or Part 8 of the *Tables of Acts and Ordinances and Statutory Regulations and Deemed Regulations in Force*.

4 Changes made under section 17C of the Acts and Regulations Publication Act 1989

Section 17C of the Acts and Regulations Publication Act 1989 authorises the making of editorial changes in a reprint as set out in sections 17D and 17E of that Act so that, to the extent permitted, the format and style of the reprinted enactment is consistent with current legislative drafting practice. Changes that would alter the effect of the legislation are not permitted.

A new format of legislation was introduced on 1 January 2000. Changes to legislative drafting style have also been made since 1997, and are ongoing. To the extent permitted by section 17C of the Acts and Regulations Publication Act 1989, all legislation reprinted after 1 January 2000 is in the new format for legislation and reflects current drafting practice at the time of the reprint.

In outline, the editorial changes made in reprints under the authority of section 17C of the Acts and Regulations Publication Act 1989 are set out below, and they have been applied, where relevant, in the preparation of this reprint:

- omission of unnecessary referential words (such as "of this section" and "of this Act")
- typeface and type size (Times Roman, generally in 11.5 point)
- layout of provisions, including:
  - indentation
  - position of section headings (eg, the number and heading now appear above the section)
- format of definitions (eg, the defined term now appears in bold type, without quotation marks)
- format of dates (eg, a date formerly expressed as "the 1st day of January 1999" is now expressed as "1 January 1999")
- position of the date of assent (it now appears on the front page of each Act)

- punctuation (eg, colons are not used after definitions)
- Parts numbered with roman numerals are replaced with arabic numerals, and all cross-references are changed accordingly
- case and appearance of letters and words, including:
  - format of headings (eg, headings where each word formerly appeared with an initial capital letter followed by small capital letters are amended so that the heading appears in bold, with only the first word (and any proper nouns) appearing with an initial capital letter)
  - small capital letters in section and subsection references are now capital letters
- schedules are renumbered (eg, Schedule 1 replaces First Schedule), and all cross-references are changed accordingly
- running heads (the information that appears at the top of each page)
- format of two-column schedules of consequential amendments, and schedules of repeals (eg, they are rearranged into alphabetical order, rather than chronological).

5 List of amendments incorporated in this reprint (most recent first)

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