DRAFT FOR REVIEW

Statutory Instrument 2011.

[CAP. 15:03

Medicines and Allied Substances Control (Medical Devices) Regulations, 2011

ARRANGEMENT OF SECTIONS

PRELIMINARY

Section

IT is hereby notified that the Minister of Health and Child Welfare has, in terms of section 74 and after consultation with the Authority in terms of section 38, of the Medicines and Allied Substances Control Act [*Chapter 15:03*], made the following regulations:—

Title

1. These regulations may be cited as the Medicines and Allied Substances Control (Medical Devices) Regulations, 2011.

Interpretation

2. In these regulations—

"appropriate fee" means the fee prescribed in the First Schedule;

"authorised person" means—

(a) a person who is authorised by a principal or that principal's agent to import or export that principal's medical devices; or

(b) any person or organisation approved as such by the Authority;

"form" means the appropriate form set out in the Second Schedule;

"medical device" means any instrument, apparatus, implement, machine, appliance, implant, in-vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose of -

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

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

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

(d) supporting or sustaining life;

(e) control of conception;

(f) disinfection of medical devices;

(g) providing information for medical purposes by means of *in vitro* examination of specimens derived from the human body;

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

"port of entry" means any place designated as such in terms of section 21;

"principal" means the person who owns the medical device;

"principal's agent" means a person designated as such by the principal to represent the principal's interests in Zimbabwe.

Application

3. These regulations shall apply to all medical devices except those exempted in the Third Schedule.

Classification of Medical Devices

4**.** The classification of medical devices shall be as provided in the Fourth Schedule.

PART I

DATABASE OF INFORMATION

Database to be established and maintained

5(1) The Director-General shall ensure that a database containing information required to be entered in that database under these regulations, is established and maintained.

(2) 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 subsection (4).

(3) The database may be maintained in any form as 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.

Information required to be entered in the database

6 (1) The following information shall 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 principal or principal's agent of that device, together with—

(i) the address of the registered office of business in Zimbabwe of the principal or principal's agent; and

(ii) the address of the registered office of business of the manufacturer, whether in Zimbabwe or a foreign country; and

(iii) a contact telephone number or email address for the manufacturer and the principal or principal's agent;

(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 shall be entered into the database.

(3) Notwithstanding subsection (1), if a particular principal or principal's agent is the principal or principal's agent of two 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 principal or principal's agent 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 subsection (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 subsection (3), two (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.

Information and declaration to be supplied by principal or principal's agent

7. A principal or principal's agent of a medical device shall, within thirty working days of becoming the principal or principal's agent of the device—

(a) ensure that the information required to be entered in the database under these

regulations is received by the Director-General; and

(b) provide to the Director-General a declaration by the principal or principal's agent or an employee of the principal or principal's agent that complies with section 8.

Declaration

8. The declaration required in terms of section 7(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 principal or principal's agent for use for its intended purpose; and

(c) the information supplied by, or on behalf of the principal or principal's agent under section 7(1)(a) is accurate and complete.

Updated information to be supplied by principal or principal's agent

9. (1) 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 principal or principal's agent, or a lapse in any certification relating to the device or kind of device, or otherwise.

(2) If this subsection applies, the principal or principal's agent shall, within ten working days of the information ceasing to be accurate or complete, ensure that the Director-General is notified of the correct details, or the complete information, as the case requires.

Principal or principal's agent shall ensure compliance with sections 6, 7 and 9

10. The principal or principal's agent of a medical device or a kind of medical device shall put in place any procedures necessary to ensure that the principal or principal's agent is able to comply with sections 6, 7 and 9.

Prohibited statements

11. No manufacturer or principal or principal's agent 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 Authority.

PART II

IMPORT AND EXPORT

Control of imports and exports

12. (1) No person shall import into or export from Zimbabwe any medical device otherwise than in accordance with the terms and conditions of a permit issued by the Authority.

(2) No person shall import into or export from Zimbabwe any medical device, for the purpose of wholesale dealing, unless he is duly appointed as an authorised person by the principal or the principal's agent, in respect of that medical device.

(3) Notification of appointment of any person as an authorised person in terms of subsection (2) shall be made to the Director-General in Form D.I.E.1.

(4) Any pharmacist, veterinary surgeon, dental practitioner or medical practitioner may import into Zimbabwe any listed medical devices for use on his or her customers, patients, or clientele, as the case may be.

Application for the issue of import or export permit

13. (1) An application for the issue of a permit shall be made to the Director-General—

(a) in the case of an application for an import permit, in Form D.I.E.2 and shall be accompanied by the fee prescribed in the First Schedule;

(b) in the case of an application for an export permit, in Form D.I.E.3 and shall be accompanied by the fee prescribed in the First Schedule.

(2) An application for the issue of an import permit shall state, for each medical device to be imported—

(a) the name and address of the importer; and

(b) the trade name or proprietary name of the medical device, if any; and

(c) the GMDNS of the medical device; and

(d) the total quantity of the medical device; and

(e) name and address of the supplier; and

(f) the name and address of the manufacturer, if not the same as the supplier; and

(g) the Zimbabwean authorisation number; and

(h) the cost, insurance, freight (CIF) value of the consignment; and

(i) the port of entry.

(3) Every application for an import permit shall be accompanied by a copy of the proforma invoice and proof of consent by the principal or his or duly authorised importer to import the medical device to which the application relates.

(4) An application for the issue of an export permit shall state, for each medical device to be exported—

(a) the name and address of the exporter; and

(b) the trade name or proprietary name of the medicine, if any; and

(c) the GMDNS of the medical device; and

(d) the total quantity of the medical device; and

(e) the name and address of the manufacturer; and

(f) the Zimbabwean authorisation number; and

(g) the cost, insurance, freight (CIF) value of the consignment; and

(h) the port of entry.

(5) The fees specified in the First Schedule shall not be payable by any person or organisation that has been exempted, in writing, by the Authority.

Issue of permit

14. The Director-General may issue an import or export permit to any authorised person who makes an application in terms of section 13 and in issuing such permit the Director-General may impose such conditions as he or she may consider necessary or desirable.

Refusal of permit by Director-General

15.(1) The Director-General may refuse to grant a permit to any person who makes an application in terms of section 13.

(2) Where the Director-General intends to refuse to issue a permit in accordance with subsection (1), he or she shall inform the principal or principal's agent in writing of his or her intention and the reasons thereof and request the principal or principal's agent to submit to him or her, within seven days, any representations he or she may wish to make on the matter.

(3) If—

(a) no representations are submitted in terms of subsection (2); or

(b) after considering any representations submitted in terms of subsection (2),

the Director-General is of the opinion that a permit should not be issued, he or she shall notify the principal or the principal's agent of his or her refusal to issue the permit.

Form of permit

16. A permit issued in respect of—

(a) an application to import a Class I or IIa medical device shall be in Form D.I.E. 4;

(b) an application to export a Class I or IIa medical device shall be in Form D.I.E. 5;

(c) an application to import a Class IIb and above medical device shall be in Form D.I.E. 6;

(d) an application to export a Class IIb and above medical device shall be in Form D.I.E. 7.

Duration of permit

17 (1) Any permit, which is issued for the import or export of Class 1 or Class IIa medical devices, shall be valid for a period of twelve months from the date of issue:

Provided that such permit may be extended for a further period of not more than six months.

(2) Any permit, which is issued for the import or export of Class IIb or above medical devices, shall be valid for a period of six months from the date of issue:

Provided that such permit may be extended for a further period of not more than six months.

Consignment verification

18. Every person who is issued with an import permit in terms of section 14 shall, on the importation of such medical device pay a consignment verification fee prescribed in the First Schedule.

Variation, amendment and cancellation of permits

19 (1) The Director-General may at any time—

(a) amend or vary the conditions of; or

(b) revoke;

any permit issued in terms of section 14 as he or she deems fit:

Provided that the Director-General, before taking any action in terms of subsection (1), shall notify the permit holder, in writing.

(2) The provisions of section 15 shall, *mutatis mutandis* apply.

Provisions applicable to import and export of medical devices

20. In addition to such terms and conditions as may be fixed in a permit to import or export any medical device, the importer or the exporter of any medical device shall comply with the following conditions—

(a) no import or export of any medical device shall be done through ordinary or registered post; and

(b) the importer or exporter of any medical device shall notify the Authority, within 30 days of the import or export of any medical device by him or her and the notification shall be made in Form D.I.E. 8 and 9 respectively.

Ports of entry

21 (1) For the purposes of these regulations, the following places are designated as ports of entry—

(a) Bulawayo Airport;

(b) Harare Airport;

(c) Beitbridge;

(d) Bulawayo;

(e) Forbes Border Post;

(f) Harare; and

(g) Plumtree.

(2) No person shall import any medical device except through the port of entry listed in terms of subsection (1).

PART III

GENERAL CONDITIONS OF SALE OF MEDICAL DEVICES

Sale of medical devices

22. No person shall sell any medical device from any premises by wholesale unless such premises are licensed for wholesale by the appropriate Local Authority.

Purchase of medical devices

23. No person shall purchase or receive any medical devices from an unauthorised person or source.

Preservation of records

24. Every person who sells medical devices shall keep or cause to be kept a record of such sale for a period of five years and shall preserve such record on the premises in which the selling takes place:

Provided that where the premises cease to be used or licensed, such person shall make arrangements, acceptable to the Authority, for the preservation or destruction of such records.

Restriction on advertising medical devices

25. (1) No person shall advertise any medical device without the approval of the Authority in writing.

(2) No person shall publish any statement that directly or by implication indicates or suggests that the approval of a medical device for distribution is an endorsement of the safety or suitability for use of that product by the Authority.

Withdrawal of medical devices

26. Where the Authority is of the opinion that the withdrawal of any batch of medical devices is necessary for the protection of the public, the Authority may require any person to withdraw such batch of medical devices in accordance with the procedure as determined by the Authority.

Destruction of medical devices

27. Where medical devices are withdrawn in terms of section 26 above, the Authority may order the destruction of the withdrawn medical devices, at the expense of the importer, if it is necessary for the protection of the public.

Offences and penalties

28. Any person who—

(a) imports or exports any medical device without a permit issued in terms of section 6; or

(b) fails to comply with the conditions of a permit issued to him or her;

shall be guilty of an offence and liable to a fine not exceeding level seven or to imprisonment for a period not exceeding six months or to both such fine and such imprisonment.

FIRST SCHEDULE (*Sections 2 and 13*)

FEES

		US$
1.	Application for an import permit for each product	50.00
2.	Application for an export permit for each product	50.00
3.	Consignment verification	0,5% of CIF value

SECOND SCHEDULE (*SECTION 2*)[8]

FORMS

FORM D.I.E. 1

MEDICINES AND ALLIED SUBSTANCES CONTROL ACT [*CHAPTER 15:03*]

NOTIFICATION OF APPOINTMENT OF AUTHORIZED IMPORTER/EXPORTER

(To be submitted in duplicate)

Notification of the appointment of an authorized importer/ exporter in terms of section 12(3).

It is requested that this form be completed legibly, preferably printed.

1. Name and address of Principal

……

……

……

Telephone no…… Fax:…… E-mail ……..

2. Name and address of Authorized Importer/Exporter *(* Delete the inapplicable)*

……

……

……

Telephone no……..Fax……..E-mail……

3. Date of Appointment……..

4. Duration of Appointment……

[8]The proposed forms are highlighted for discussion.

5. Products authorized to be imported/ exported

……
……
……
……

6. Signed ……
Name ……
Date ……

7. If on behalf of a company, state position in company

…….

Note:

This form must be accompanied by a letter from the principal on its letterhead confirming the appointment of the importer/exporter.

FOR OFFICIAL USE ONLY

APPLICATION APPROVED/REJECTED

IF REJECTED, STATE REASONS

……
……
……
RECOMMENDED…….
APPROVED……
PERMIT NO. …… ...ISSUED ON …… (DATE)
SIGNED …… DIRECTOR GENERAL
MEDICINES CONTROL AUTHORITY OF ZIMBABWE

FORM D.I.E. 2

MEDICINES AND ALLIED SUBSTANCES CONTROL ACT *[CHAPTER 15:03]*

APPLICATION FOR AN IMPORT PERMIT

(To be submitted in duplicate)

An application in terms of section 13(1)(a).

It is requested that this form be completed legibly, preferably printed. Delay will be caused if this form is not completed properly, or if any of the questions below are not answered or if the declaration is not signed.

NOTE: COPY OF PROFORMA INVOICE AND PROOF OF CONSENT TO IMPORTATION BY PRINCIPAL MUST BE ATTACHED TO THIS APPLICATION

1. Full name and address of importer
   .....
   .....
   .....

   Telephone no…… Fax:…… E-mail …….

2. Full name and address of importer of supplier in exporting country
   .....
   .....
   .....

   Telephone no…… Fax:…… E-mail ……...

3. The medical devices are to be imported:
   * by sea and/or rail via

   …….....

   *by road via

   …….....

   *by air-freight via

   …….....

   (Delete the inapplicable words)*

and will be imported through ……. Customs Office.

(State port of entry)

4. Approximate date of arrival ……

5. State the purpose for which the medical devices are required (e.g. clinical trial, general medical use, etc.)
   ……
   ……

6. Particulars of medical devices to be imported *(If insufficient space provided add additional sheets)*

Item No.	Trade Name of medical device	International Non-Proprietary Name (INN) of medical device	GMDNS of medical device	Total Quantity	Name and Address of Supplier	Name and Address of Manufacturer	Zimbabwean Authorisation Number	Cost Insurance and Freight (CIF) Value

7. I, the undersigned, hereby declare that, to the best of my knowledge, all the information provided herein and in the appendices is correct and true.

Signed ……..

Name ……..

Date ……..

8. If on behalf of a company, state position in company

……..……

……..…….

FOR OFFICIAL USE ONLY

APPLICATION APPROVED/REJECTED

IF REJECTED, STATE REASONS

……..……

……

……

RECOMMENDED……

APPROVED……

PERMIT NO. …… ..ISSUED ON ……(DATE)

SIGNED …… DIRECTOR GENERAL
MEDICINES CONTROL AUTHORITY OF ZIMBABWE

FORM D.I.E. 3

MEDICINES AND ALLIED SUBSTANCES CONTROL ACT *[CHAPTER 15:03]*
APPLICATION FOR AN EXPORT PERMIT

An application in terms of section 13(1)(b).

It is requested that this form be completed legibly, preferably printed. Delay will be caused if this form is not completed properly, or if any of the questions below are not answered, or if the declaration is not signed.

1. Full name and address of exporter
   .....
   .....
   .....

   Telephone no …… Fax …… E-mail.…….

2. Medical devices are to be exported:
   *by rail via ……
   *by road via……
   *by air-freight via ……
   (Delete the inapplicable words)*
   and will be exported through ……. Customs Office.
   (State port of entry)

3. Full name and address of person to whom the medical devices are to be exported

……

……

……

……

Telephone no……. Fax ……. E-mail..……

4. Country of importer of the medical devices

……

5. Particulars of medical devices to be exported *(If insufficient space provided add additional sheets)*

Item No.	Trade Name of medical device	International Non-Proprietary Name (INN) of medical device	GMDNS	Total Quantity	Name and Address of Supplier	Name and Address of Manufacturer	Zimbabwean Authorisation Number	Cost Insurance and Freight (CIF) Value

6. Expected date of dispatch …….....

7. I, the undersigned, hereby declare that, to the best of my belief, all the information provided herein and in the appendices is correct and true.

Signed ……..

Name ……...

Date ……...

8. If on behalf of a company, state position in company

……..…….....

FOR OFFICIAL USE ONLY

APPLICATION APPROVED/REJECTED

IF REJECTED, STATE REASONS

……

……

……

RECOMMENDED……

APPROVED…….

PERMIT NO. ……. ISSUED ON ……(DATE)

SIGNED …… DIRECTOR GENERAL
MEDICINES CONTROL AUTHORITY OF ZIMBABWE

FORM D.I.E. 4

PERMIT NO……..

MEDICINES AND ALLIED SUBSTANCES CONTROL ACT *[CHAPTER 15:03]*

PERMIT TO IMPORT MEDICAL DEVICES (Class I or IIa)
(Issued in terms of section 16(a))

1. Name of Importer ……
2. Address …….....
3. Telephone no.……Fax …….E-mail ……...
4. Particulars of medical devices to be imported.

Item	Trade Name	International	GMDN	Total	Name and	Name and	Zimbabwea

No.	of medical device	Non-Proprietary Name (INN) of medical device	S	Quantity	Address of Supplier	Address of Manufacturer	n Authorisation Number

5. Port of Entry ……

6. Period of validity of permit ……

7. Expected date of arrival of medical devices…….…….

8. Date of issue of permit ……....

……

DIRECTOR-GENERAL

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

FORM D.I.E. 5

PERMIT NO……..

MEDICINES AND ALLIED SUBSTANCES CONTROL ACT *[CHAPTER 15:03]*

PERMIT TO EXPORT MEDICAL DEVICES (Class I or IIa)

(Issued in terms of section 16(b))

1. Name of Exporter ……..**.....**
2. Address …….....
3. Telephone no……Fax. ……E-mail …….
4. Particulars of medical devices to be exported.

Item No.	Trade Name of medical devices	International Non-Proprietary Name (INN) of medical device	GMDNS	Total Quantity	Name and Address of Importer	Name and Address of Manufacturer	Zimbabwean Authorisation Number

5. Port of Entry ……
6. Period of validity of permit ……
7. Name and address of the importer …….
   ……
8. Country of importer ……**....**
9. The medical device will be exported through the Customs Office at ……...
10. Port of Entry in importing country…….**.....**
11. Expected date of arrival in importing country …….
12. Date of issue of permit ……**...**

……
DIRECTOR-GENERAL
MEDICINES CONTROL AUTHORITY OF ZIMBABWE

FORM D.I.E. 6

PERMIT NO……..

MEDICINES AND ALLIED SUBSTANCES CONTROL ACT *[CHAPTER 15:03]*

PERMIT TO IMPORT MEDICAL DEVICES (Class IIb and above)
(Issued in terms of section 16(c))

1. Name of Importer ……
2. Address …….....
3. Telephone no……Fax …….E-mail ……
4. Particulars of medical devices to be imported.

Item No.	Trade Name of medical device	International Non-Proprietary Name (INN) of medical device	GMDNS	Total Quantity	Name and Address of Supplier	Name and Address of Manufacturer	Zimbabwean Authorisation Number

5. Port of Entry …….

6. Period of validity of permit …….

7. Expected date of arrival of medical devices…….

8. Date of issue of permit ……..

……
DIRECTOR-GENERAL
MEDICINES CONTROL AUTHORITY OF ZIMBABWE

FORM D.I.E. 7

PERMIT NO……..

MEDICINES AND ALLIED SUBSTANCES CONTROL ACT *[CHAPTER 15:03]*
PERMIT TO EXPORT MEDICAL DEVICES (Class IIb and above)
(Issued in terms of section 16(d))

1. Name of Exporter …….....
2. Address ……...
3. Telephone no……Fax. ……E-mail …….
4. Particulars of medical devices to be exported.

Item No.	Trade Name of medical devices	International Non-Proprietary Name (INN) of medical device	GMDNS	Total Quantity	Name and Address of Importer	Name and Address of Manufacturer	Zimbabwean Authorisation Number

5. Port of Entry ……
6. Period of validity of permit ……
7. Name and address of the importer …….
   ……
8. Country of importer ……....
9. The medical device will be exported through the Customs Office at ……...
10. Port of Entry in importing country…….....
11. Expected date of arrival in importing country …….
12. Date of issue of permit ……...

……
DIRECTOR-GENERAL
MEDICINES CONTROL AUTHORITY OF ZIMBABWE

FORM D.I.E. 8

MEDICINES AND ALLIED SUBSTANCES CONTROL ACT [*CHAPTER 15:03*]
NOTIFICATION OF IMPORT

(To be submitted in duplicate)

Notification of the receipt of imported consignment of medical devices in terms of section 20(b).

It is requested that this form be completed legibly, preferably printed.

NOTIFICATION OF IMPORTATION

Medicines Control Authority of Zimbabwe
P O Box 10559
Harare

It is hereby certified that the following medical devices:

.....

.....

.....

.....

(Add additional sheets of paper if necessary)

have been imported on Import Licence Number: …… dated ……

Date of importation: ….....

Full name: .....

Signature: …….....

Date :.....

State position in company ……..

On behalf of: .....

(*Name of company*)

FORM D.I.E. 9

MEDICINES AND ALLIED SUBSTANCES CONTROL ACT [*CHAPTER 15:03*]

NOTIFICATION OF EXPORT

(To be submitted in duplicate)

Notification of the dispatch of exported consignment of medical devices in terms of section 20(b).

It is requested that this form be completed legibly, preferably printed.

NOTIFICATION OF EXPORTATION

Medicines Control Authority of Zimbabwe

P O Box 10559

Harare

It is hereby certified that the following medical devices:

.....

.....

.....

.....

(Add additional sheets of paper if necessary)

have been exported on Export Licence Number: …… dated ……

Date of exportation: .....

Full name: ..... Signature: .....

Date: .....

State position in company ……

On behalf of: .....

(*Name of company*)

THIRD SCHEDULE (*Section 3*)

EXEMPT MEDICAL DEVICES

1. Exempt devices

1.1 Any medical device that is imported into Zimbabwe for use by the importer, or a member of the importer's immediate family.

1.2 Any medical device that is exported from Zimbabwe and is not intended for commercial supply.

1.3 Samples of a medical device that is imported, exported, manufactured or supplied for any of the following purposes:

a) submission to a regulatory authority;
b) subjection to developmental or quality control procedures;
c) examination, demonstration or display, with notice included to the effect that the device is not available for general supply unless it is included in the register;
d) subjection to analysis or laboratory testing procedures.

1.4 Any medical device that is imported into Zimbabwe solely for the purpose of being exported from Zimbabwe.

1.5 Any medical device that the Authority may in writing, exempt, from the operation of any or all of the provisions of these regulations.

FOURTH SCHEDULE (*Section 4*)

CLASSIFICATION OF DEVICES

Classification rules

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

Part 1 Interpretation

1.1 Transient, short-term and long-term use

For this Schedule:

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

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

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

Part 2 Rules for non-invasive medical devices

2.1 Non-invasive medical devices — general

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

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

(1) This section applies to:

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

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

(c) a non-invasive medical device that:

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

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

(2)The device is classified as Class IIa.

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

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

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

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

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

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

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

(a) as a mechanical barrier; or

(b) for compression; or

(c) for the absorption of exudates;

the device is classified as Class I.

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

Part 3 Rules for invasive medical devices and implantable medical devices

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

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

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

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

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

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

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

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

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

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

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

3.2 Surgically invasive medical devices intended for transient use

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

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

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

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

(5) If:

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

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

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

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

the device is classified as Class IIb.

3.3 Surgically invasive medical devices intended for short-term use

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

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

(3) If:

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

(b) the device is intended by the manufacturer to undergo a chemical change in a patient's body (other than a device that is intended by the manufacturer to be placed in the teeth); or
(c) the device is intended by the manufacturer to administer medicine;
the device is classified as Class IIb.
Note for paragraph (b)
A device that is intended by the manufacturer to be placed in the teeth, and to undergo a chemical change in the body, is classified as Class IIa — see subsection (2).

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

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

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

(c) to have a biological effect; or

(d) to be wholly, or mostly, absorbed by a patient's body;
the device is classified as Class III.
(5) For this section, a medical device that is intended by the manufacturer to be placed in the teeth includes a medical device that is intended by the manufacturer to penetrate a tooth, but does not include a medical device that is intended by the manufacturer to penetrate a tooth and enter the gum or bone beyond the tooth.

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

(1) This section applies to:
(a) a surgically invasive medical device that is intended for long-term use; and
(b) an implantable medical device.
(2) Subject to subsections (3) and (4), the device is classified as Class IIb.
(3) If the device is intended by the manufacturer to be placed in the teeth of a patient, the device is classified as Class IIa.
(4) If the device is intended by the manufacturer:

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

(b) to have a biological effect; or

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

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

(e) to be used to administer medicine;

the device is classified as Class III.

Note for paragraph (d)

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

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

Part 4 Special rules for active medical devices

4.1 Active medical devices — general

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

4.2 Active medical devices for therapy

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

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

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

4.3 Active medical devices for diagnosis

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

(2) If:

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

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

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

the device is classified as Class IIa.

Note for paragraph (a)

A device that is intended only to illuminate the patient's body in the visible spectrum is classified as Class I — see section 4.1 of this Schedule.

(3) If:

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

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

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

the device is classified as Class IIb.

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

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

(2) If the device is of a kind such that the administration or removal of the medicine, body liquids or other substances is potentially hazardous to the patient, having regard to the nature

of the substances involved, the part of the patient's body concerned, and the characteristics of the device, the device is classified as Class IIb.

Part 5 Special rules for particular kinds of medical devices

5.1 Medical devices incorporating a medicine

(1) This section applies to a medical device of any kind that incorporates, or is intended to incorporate, as an integral part, a substance that:
(a) if used separately, would be a medicine; and
(b) is liable to act on a patient's body with action ancillary to that of the device.
(2) The device is classified as Class III.
(3) For the purposes of this section, any stable derivative of human blood or human plasma is considered to be a medicine.

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

(1) Subject to subsection (2), a medical device that is intended by the manufacturer to be used for contraception, or the prevention of sexually transmitted diseases, is classified as Class IIb.
(2) If the device is an implantable medical device or an invasive medical device that is intended for long-term use, the device is classified as Class III.

5.3 Medical devices intended for disinfecting, cleaning, etc.

(1) A medical device that is intended by the manufacturer specifically to be used for disinfecting, cleaning, rinsing or hydrating contact lenses is classified as Class IIb.
(2) A medical device that is intended by the manufacturer specifically to be used for disinfecting another medical device is classified as Class IIb.
(3) This section does not apply to a medical device that is intended by the manufacturer to be used only to clean another medical device (other than contact lenses) by means of physical action.
Note
A medical device of the kind described in subsection (3) is classified as Class I — see section 2.1 of this Schedule.

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

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

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

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

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

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

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

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

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

Note

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

5.6 Medical devices that are blood bags

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

5.7 Active implantable medical devices

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

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

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

5.8 Medical devices that are mammary implants

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