

MEDICAL DEVICES REGULATIONS

Interpretation

1. The definitions in this section apply in these Regulations.

"Act" means the *Food and Drugs Act. (Loi)*

"active device" means a medical device that depends for its operation on a source of energy other than energy generated by the human body or gravity. A medical device that transmits or withdraws energy or a substance to or from a patient without substantially altering the energy or the substance is not an active device. (*instrument actif*)

"active diagnostic device" means an active device that, whether used alone or in combination with another medical device, is intended to supply information for the purpose of detecting, monitoring or treating a physiological condition, state of health, illness or congenital deformity. (*instrument diagnostique actif*)

"active therapeutic device" means an active device that, whether used alone or in combination with another medical device, is intended to support, modify, replace or restore a biological function or structure for the purpose of treating or mitigating an illness or injury or a symptom of an illness or injury. (*instrument thérapeutique actif*)

"bar code" means a unique bar code in the symbology of the Universal Product Code (UPC), the Health Industry Business Communications Council (HIBCC) or the European Article Number (EAN), assigned to a medical device by the manufacturer. (*code à barres*)

"body orifice" means a natural opening or a permanent artificial opening in the body, such as a stoma. (*orifice du corps*)

"central cardiovascular system" means the heart, pericardium, pulmonary veins, pulmonary arteries, cardiac veins, coronary arteries, common carotid arteries, cerebral arteries, brachiocephalic artery, aorta, inferior and superior vena cava, renal arteries, iliac arteries and femoral arteries. (*système cardiovasculaire central*)

"central nervous system" means the brain, meninges, spinal cord and cerebrospinal fluid. (*système nerveux central*)

"closed-loop system", in respect of a medical device, means a system that enables the device to sense, interpret and treat a medical condition without human intervention. (*système à boucle fermée*)

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"Commissioner of Patents" means the Commissioner of Patents appointed under subsection 4(1) of the *Patent Act. (commissaire aux brevets)*

"control number" means a unique series of letters, numbers or symbols, or any combination of these, that is assigned to a medical device by the manufacturer and from which a history of the manufacture, packaging, labelling and distribution of a unit, lot or batch of the device can be determined. (*numéro de contrôle*)

"custom-made device" means a medical device, other than a mass-produced medical device, that

- (a) is manufactured in accordance with a health care professional's written direction giving its design characteristics;
 - (b) differs from medical devices generally available for sale or from a dispenser; and
 - (c) is
 - (i) for the sole use of a particular patient of that professional, or
 - (ii) for use by that professional to meet special needs arising in the course of his or her practice.
- (*instrument fait sur mesure*)

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"dental material" Repealed by P.C. 2002-792 of May 9, 2002.

"directions for use", in respect of a medical device, means full information as to the procedures recommended for achieving the optimum performance of the device, and includes cautions, warnings, contra-indications and possible adverse effects. (*mode d'emploi*)

"dispenser" means a person who is a member of a professional governing body and who is entitled, by virtue of their membership in that body, to manufacture or adapt a medical device in accordance with a health care professional's written directions in order to meet the specific requirements of a patient. (*préparateur*)

"General Council Decision" has the meaning assigned by subsection 30(6) of the Act. (*décision du Conseil général*)

"genetic testing" means the analysis of DNA, RNA or chromosomes for purposes such as the prediction of disease or vertical transmission risks, or monitoring, diagnosis or prognosis. (*test génétique*)

"health care facility" means a facility that provides diagnostic or therapeutic services to patients. It includes a group of such facilities that report to one common management that has responsibility for the activities carried out in those facilities. (*établissement de santé*)

"health care professional" means a person who is entitled under the laws of a province to provide health services in the province. (*professionnel de la santé*)

"identifier" means a unique series of letters or numbers or any combination of these or a bar code that is assigned to a medical device by the manufacturer and that identifies it and distinguishes it from similar devices. (*identificateur*)

"implant" means a medical device that is listed in Schedule 2. (*implant*)

"invasive device" means a medical device that is intended to come into contact with the surface of the eye or penetrate the body, either through a body orifice or through the body surface. (*instrument effractif*)

"*in vitro* diagnostic device" or "IVDD" means a medical device that is intended to be used *in vitro* for the examination of specimens taken from the body. (*instrument diagnostique in vitro ou IDIV*)

"manufacturer" means a person who sells a medical device under their own name, or under a trade-mark, design, trade name or other name or mark owned or controlled by the person, and who is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the device, or for assigning to it a purpose, whether those tasks are performed by that person or on their behalf. (*fabricant*)

"medical device" means a device within the meaning of the Act, but does not include any device that is intended for use in relation to animals. (*instrument médical*)

"medical device family" means a group of medical devices that are made by the same manufacturer, that differ only in shape, colour, flavour or size, that have the same design and manufacturing process and that have the same intended use. (*famille d'instruments*)

"medical device group" means a medical device comprising a collection of medical devices, such as a procedure pack or tray, that is sold under a single name. (*ensemble d'instruments*)

"medical device group family" means a collection of medical device groups that are made by the same manufacturer, that have the same generic name specifying their intended use, and that differ only in the number and combination of products that comprise each group. (*famille d'ensembles d'instruments*)

"name of the device", in respect of a medical device, includes any information necessary for the user to identify the device and to distinguish it from similar devices. (*nom de l'instrument*)

"near patient *in vitro* diagnostic device" or "near patient IVDD" means an *in vitro* diagnostic device that is intended for use outside a laboratory, for testing at home or at the point of care, such as a pharmacy, a health care professional's office or the bedside. (*instrument diagnostique clinique in vitro*)

"objective evidence" means information that can be proved true, based on facts obtained through observation, measurement, testing or other means, as set out in the definition "objective evidence" in section 2.19 of International Organization for Standardization standard ISO 8402:1994, *Quality management and quality assurance - Vocabulary*, as amended from time to time. (*preuve tangible*)

"person" includes a partnership and an association. (*personne*)

"qualified investigator" means a person who is a member in good standing of a professional association of persons entitled under the laws of a province to provide health care in the province and who is designated, by the ethics committee of the health care facility at which investigational testing is to be conducted, as the person to conduct the testing. (*chercheur compétent*)

"quality system certificate" means a valid quality system certificate described in paragraph 32(2)(f), (3)(j) or (4)(p), as applicable, that is issued by a registrar recognized by the Minister under section 32.1. (*certificat de système qualité*)

"recall", in respect of a medical device that has been sold, means any action taken by the manufacturer, importer or distributor of the device to recall or correct the device, or to notify its owners and users of its defectiveness or potential defectiveness, after becoming aware that the device

- (a) may be hazardous to health;
- (b) may fail to conform to any claim made by the manufacturer or importer relating to its effectiveness, benefits, performance characteristics or safety; or
- (c) may not meet the requirements of the Act or these Regulations. (*rappel*)

"safety and effectiveness requirements" means the safety and effectiveness requirements set out in sections 10 to 20. (*exigences en matière de sûreté et d'efficacité*)

"serious deterioration in the state of health" means a life-threatening disease, disorder or abnormal physical state, the permanent impairment of a body function or permanent damage to a body structure, or a condition that necessitates an unexpected medical or surgical intervention to prevent such a disease, disorder or abnormal physical state or permanent impairment or damage. (*détérioration grave de l'état de santé*)

"significant change" means a change that could reasonably be expected to affect the safety or effectiveness of a medical device. It includes a change to any of the following:

- (a) the manufacturing process, facility or equipment;
- (b) the manufacturing quality control procedures, including the methods, tests or procedures used to control the quality, purity and sterility of the device or of the materials used in its manufacture;
- (c) the design of the device, including its performance characteristics, principles of operation and specifications of materials, energy source, software or accessories; and
- (d) the intended use of the device, including any new or extended use, any addition or deletion of a contra-indication for the device and any change to the period used to establish its expiry data. (*modification importante*)

"surgical or dental instrument" means a reusable medical device that is intended for surgical or dental use, including cutting, drilling, sawing, scraping, clamping, hammering, puncturing, dilating, retracting or clipping, without connection to an active device. (*instrument chirurgical ou dentaire*)

"surgically invasive device" means an invasive device that is intended to enter the body through an artificially created opening that provides access to body structures and fluids. (*instrument effractif chirurgical*)

"system" means a medical device comprising a number of components or parts intended to be used together to fulfil some or all of the device's intended functions, and that is sold under a single name. (*système*)

"test kit" means an *in vitro* diagnostic device that consists of reagents or articles, or any combination of these, and that is intended to be used to conduct a specific test. (*trousse d'essai*)

"validation" means confirmation by examination and the provision of objective evidence that the requirements for a specific intended use have been fulfilled, as set out in the definition "validation" in section 2.18 of International Organization for Standardization standard ISO 8402:1994, *Quality management and quality assurance - Vocabulary*, as amended from time to time. (*validation*)

Application

2. These Regulations apply to

- (a) the sale and advertising for sale of a medical device; and
- (b) the importation of a medical device for sale or for use on individuals, other than importation for personal use.

3. (1) These Regulations also apply to an *in vitro* diagnostic product that is a drug or that contains a drug, as if the product were an *in vitro* diagnostic device.

(2) Subsection (1) does not apply to a drug listed in Schedule E or F to the Act, in the schedule to Part G or J of the *Food and Drug Regulations*, in the Schedules to the *Controlled Drugs and Substances Act* or in the schedule to the *Narcotic Control Regulations*.

4. Only sections 26 to 31, 37, 70, 75, 80, 86 and 87 apply to a dispenser.

5. These Regulations do not apply to a medical gas piping system that is assembled on site at a health care facility and permanently built into the structure of the facility, if
- (a) the system meets the requirements of National Standard of Canada CAN/CSA-Z305.1, *Nonflammable Medical Gas Piping Systems*, as amended from time to time; and
 - (b) a certificate of compliance with that standard has been issued by a testing agency that meets the requirements of National Standard of Canada CAN/CSA-Z305.4, *Qualification Requirements for Agencies Testing Nonflammable Medical Gas Piping Systems*, as amended from time to time.

Classification of Medical Devices

6. Medical devices are classified into one of Classes I to IV by means of the classification rules set out in Schedule 1, where Class I represents the lowest risk and Class IV represents the highest risk.
7. If a medical device can be classified into more than one class, the class representing the higher risk applies.

PART 1

GENERAL

Application

8. This part applies to medical devices that are not subject to Part 2 or 3.

Manufacturer's Obligations

9. (1) A manufacturer shall ensure that the medical device meets the safety and effectiveness requirements.
- (2) A manufacturer shall keep objective evidence to establish that the medical device meets those requirements.

Safety and Effectiveness Requirements

10. A medical device shall be designed and manufactured to be safe, and to this end the manufacturer shall, in particular, take reasonable measures to
- (a) identify the risks inherent in the device;
 - (b) if the risks can be eliminated, eliminate them;
 - (c) if the risks cannot be eliminated,
 - (i) reduce the risks to the extent possible,
 - (ii) provide for protection appropriate to those risks, including the provision of alarms, and
 - (iii) provide, with the device, information relative to the risks that remain; and
 - (d) minimize the hazard from potential failures during the projected useful life of the device.
11. A medical device shall not, when used for the medical conditions, purposes or uses for which it is manufactured, sold or represented, adversely affect the health or safety of a patient, user or other person, except to the extent that a possible adverse effect of the device constitutes an acceptable risk when weighed against the benefits to the patient and the risk is compatible with a high level of protection of health and safety.
12. A medical device shall perform as intended by the manufacturer and shall be effective for the medical conditions, purposes and uses for which it is manufactured, sold or represented.
13. During the projected useful life of a medical device, its characteristics and performance shall not deteriorate under normal use to such a degree that the health or safety of a patient, user or other person is adversely affected.

14. The characteristics and performance of a medical device shall not be adversely affected by transport or conditions of storage, taking into account the manufacturer's instructions and information for transport and storage.
15. Reasonable measures shall be taken to ensure that every material used in the manufacture of a medical device shall be compatible with every other material with which it interacts and with material that may come into contact with it in normal use, and shall not pose any undue risk to a patient, user or other person.
16. The design, manufacture and packaging of a medical device shall minimize any risk to a patient, user or other person from reasonably foreseeable hazards, including
- (a) flammability or explosion;
 - (b) presence of a contaminant or chemical or microbial residue;
 - (c) radiation;
 - (d) electrical, mechanical or thermal hazards; and
 - (e) fluid leaking from or entering into the device.
17. A medical device that is to be sold in a sterile condition shall be manufactured and sterilized under appropriately controlled conditions, and the sterilization method used shall be validated.
18. A medical device that is part of a system shall be compatible with every other component or part of the system with which it interacts and shall not adversely affect the performance of that system.
19. A medical device that performs a measuring function shall be designed to perform that function within tolerance limits that are appropriate for the medical conditions, purposes and uses for which the device is manufactured, sold or represented.
20. If a medical device consists of or contains software, the software shall be designed to perform as intended by the manufacturer, and the performance of the software shall be validated.

Labelling Requirements

21. (1) No person shall import or sell a medical device unless the device has a label that sets out the following information:
- (a) the name of the device;
 - (b) the name and address of the manufacturer;
 - (c) the identifier of the device, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family;
 - (d) in the case of a Class III or IV device, the control number;
 - (e) if the contents are not readily apparent, an indication of what the package contains, expressed in terms appropriate to the device, such as the size, net weight, length, volume or number of units;
 - (f) the word "Sterile", if the manufacturer intends the device to be sold in a sterile condition;
 - (g) the expiry date of the device, if the device has one, to be determined by the manufacturer on the basis of the component that has the shortest projected useful life;
 - (h) unless self-evident to the intended user, the medical conditions, purposes and uses for which the device is manufactured, sold or represented, including the performance specifications of the device if those specifications are necessary for proper use;
 - (i) the directions for use, unless directions are not required for the device to be used safely and effectively; and
 - (j) any special storage conditions applicable to the device.

(2) The information required pursuant to subsection (1) shall be expressed in a legible, permanent and prominent manner, in terms that are easily understood by the intended user.

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22. (1) Subject to subsection (2), if a medical device is intended to be sold to the general public, the information required by subsection 21(1) shall

- (a) be set out on the outside of the package that contains the device; and
- (b) be visible under normal conditions of sale.

(2) Where a package that contains a medical device is too small to display all the information in accordance with section 21, the directions for use shall accompany the device but need not be set out on the outside of the package or be visible under normal conditions of sale.

23. (1) Subject to subsection (3), the information required by subsection 21(1) shall, as a minimum, be in either English or French.

(2) Subject to subsection (3), where the directions for use are supplied in only one official language at the time of sale, directions for use in the other official language shall be made available by the manufacturer as soon as possible at the request of the purchaser.

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(3) In respect of a medical device to be sold to the general public, the information required by paragraphs 21(1)(a) and (e) to (j) shall, as a minimum, be in both English and French.

Contraceptive Devices - Advertising

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24. (1) For the purposes of subsections 3(1) and (2) of the Act and subject to section 27, a condom may be advertised and sold to the general public for the purpose of preventing the transmission of venereal disease if the advertisement and the label of the condom claim only that the condom reduces the risk of transmitting venereal disease.

(2) For the purpose of subsection 3(3) of the Act and subject to section 27, contraceptive devices, other than intrauterine devices, may be advertised to the general public by any means other than by the distribution of samples of the devices door-to-door or through the mail.

Class I Medical Devices

25. (1) If the Minister believes on reasonable grounds, after reviewing a report or information brought to the Minister's attention, that a Class I medical device may not meet the safety and effectiveness requirements, the Minister may request the manufacturer to submit, on or before a specified day, information to enable him or her to determine whether the device meets those requirements.

(2) The Minister may direct the manufacturer to stop the sale of a Class I medical device if

- (a) the manufacturer does not comply with a request made pursuant to subsection (1) by the day specified in the request; or
- (b) the Minister determines, on the basis of the information submitted pursuant to subsection (1), that the device does not meet the safety and effectiveness requirements.

(3) The Minister may lift the direction to stop the sale if

- (a) the manufacturer provides the information requested;
- (b) corrective action has been taken to ensure that the medical device satisfies the safety and effectiveness requirements; or
- (c) the Minister's determination was unfounded.

Class II, III and IV Medical Devices

Prohibition

26. Subject to section 37, no person shall import or sell a Class II, III or IV medical device unless the manufacturer of the device holds a licence in respect of that device or, if the medical device has been subjected to a change described in section 34, an amended medical device licence.

27. No person shall advertise a Class II, III or IV medical device for the purpose of sale unless
- (a) the manufacturer of the device holds a licence in respect of that device or, if the device has been subjected to a change described in section 34, an amended medical device licence; or
 - (b) the advertisement is placed only in a catalogue that includes a clear and visible warning that the devices advertised in the catalogue may not have been licensed in accordance with Canadian law.

Medical Devices Deemed Licensed

28. If a system is licensed, all of its components or parts that are manufactured by the manufacturer of the system are deemed, for the purposes of its importation, sale or advertisement, to have been licensed.
29. If a test kit is licensed, all of its reagents or articles that are manufactured by the manufacturer of the test kit are deemed, for the purposes of its importation, sale or advertisement, to have been licensed.
30. If a medical device or a medical device group is licensed and forms part of a medical device family or a medical device group family, as the case may be, all other medical devices or medical device groups in the family are deemed to have been licensed.
31. (1) If all the medical devices that form part of a medical device group are licensed, that medical device group is deemed to have been licensed.
- (2) If a medical device group is licensed, all the medical devices that form part of the medical device group are deemed, for the purposes of its importation, sale or advertisement, to have been licensed.

Application for a Medical Device Licence

32. (1) An application for a medical device licence shall be submitted to the Minister by the manufacturer of the medical device in a format established by the Minister and shall contain the following:
- (a) the name of the device;
 - (b) the class of the device;
 - (c) the identifier of the device, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family;
 - (d) the name and address of the manufacturer as it appears on the device label; and
 - (e) the name and address of the establishment where the device is being manufactured, if different from the one referred to in paragraph (d).
- (2) An application for a Class II medical device licence shall contain, in addition to the information and documents set out in subsection (1), the following:
- (a) a description of the medical conditions, purposes and uses for which the device is manufactured, sold or represented;
 - (b) a list of the standards complied with in the manufacture of the device to satisfy the safety and effectiveness requirements;
 - (c) an attestation by a senior official of the manufacturer that the manufacturer has objective evidence to establish that the device meets the safety and effectiveness requirements;
 - (d) an attestation by a senior official of the manufacturer that the device label meets the applicable labelling requirements of these Regulations;
 - (e) in the case of a near patient *in vitro* diagnostic device, an attestation by a senior official of the manufacturer that investigational testing has been conducted on the device using human subjects representative of the intended users and under conditions similar to the conditions of use; and
 - (f) a copy of a quality system certificate certifying that the quality system under which the device is manufactured satisfies National Standard of Canada CAN/CSA-ISO 13488-98, *Quality systems – Medical devices – Particular requirements for the application of ISO 9002*, as amended from time to time.

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(3) An application for a Class III medical device licence shall contain, in addition to the information and documents set out in subsection (1), the following:

- (a) a description of the device and of the materials used in its manufacture and packaging;
- (b) a description of the features of the device that permit it to be used for the medical conditions, purposes and uses for which it is manufactured, sold or represented;
- (c) a list of the countries other than Canada where the device has been sold, the total number of units sold in those countries, and a summary of any reported problems with the device and any recalls of the device in those countries;
- (d) a list of the standards complied with in the design and manufacture of the device to satisfy the safety and effectiveness requirements;
- (e) in the case of a device to be sold in a sterile condition, a description of the sterilization method used;
- (f) a summary of all studies on which the manufacturer relies to ensure that the device meets the safety and effectiveness requirements, and the conclusions drawn from those studies by the manufacturer;
- (g) a copy of the device label;
- (h) in the case of a near patient *in vitro* diagnostic device, a summary of investigational testing conducted on the device using human subjects representative of the intended users and under conditions similar to the conditions of use;
- (i) a bibliography of all published reports dealing with the use, safety and effectiveness of the device; and
- (j) a copy of a quality system certificate certifying that the quality system under which the device is designed and manufactured satisfies National Standard of Canada CAN/CSA-ISO 13485-98, *Quality systems – Medical devices – Particular requirements for the application of ISO 9001*, as amended from time to time.

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(4) An application for a Class IV medical device licence shall contain, in addition to the information and documents set out in subsection (1), the following:

- (a) a description of the device and of the materials used in its manufacture and packaging;
- (b) a description of the features of the device that permit it to be used for the medical conditions, purposes and uses for which it is manufactured, sold or represented;
- (c) a list of the countries other than Canada where the device has been sold, the total number of units sold in those countries, and a summary of any reported problems with the device and any recalls of the device in those countries;
- (d) a risk assessment comprising an analysis and evaluation of the risks, and the risk reduction measures adopted to satisfy the safety and effectiveness requirements;
- (e) a quality plan setting out the specific quality practices, resources and sequence of activities relevant to the device;
- (f) the specifications of the materials used in the manufacture and packaging of the device;
- (g) the manufacturing process of the device;
- (h) a list of the standards complied with in the design and manufacture of the device to satisfy the safety and effectiveness requirements;
- (i) detailed information on all studies on which the manufacturer relies to ensure that the device meets the safety and effectiveness requirements, including
 - (i) pre-clinical and clinical studies,
 - (ii) process validation studies,
 - (iii) if appropriate, software validation studies, and
 - (iv) literature studies;
- (j) in the case of a medical device other than an *in vitro* diagnostic device, manufactured from or incorporating animal or human tissue or their derivative, objective evidence of the biological safety of the device;
- (k) in the case of a near patient *in vitro* diagnostic device, detailed information on investigational testing conducted on the device using human subjects representative of the intended users and under conditions similar to the conditions of use;
- (l) a summary of the studies referred to in paragraph (i) and the conclusions drawn from those studies by the manufacturer;
- (m) a summary of the investigational testing referred to in paragraph (k) and the conclusions drawn from that testing by the manufacturer;
- (n) a bibliography of all published reports dealing with the use, safety and effectiveness of the device;
- (o) a copy of the device label; and
- (p) a copy of a quality system certificate certifying that the quality system under which the device is designed and manufactured satisfies National Standard of Canada CAN/CSA-ISO 13485-98, *Quality systems – Medical devices – Particular requirements for the application of ISO 9001*, as amended from time to time.

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Quality System Certificate

32.1 The Minister shall recognize a person as a registrar for the purpose of issuing quality system certificates if the person

- (a) has sufficient training, experience and technical knowledge in the design and manufacture of medical devices and in the effective implementation of quality systems to determine whether a quality system satisfies a standard referred to in paragraph 32(2)(f), (3)(j) or (4)(p); and
- (b) conducts quality system audits in accordance with the applicable guidelines and practices established by the International Organization for Standardization.

32.2 A quality system certificate is valid for the period, not exceeding three years, specified in it.

32.3 A registrar shall notify the Minister in writing within 15 days after suspending or cancelling a quality system certificate.

32.4 A registrar shall notify the Minister in writing within 15 days after the expiry of a quality system certificate if the certificate has not been renewed.

32.5 The Minister may cease to recognize a person as a registrar if the person no longer meets the requirements of section 32.1 or fails to comply with section 32.3 or 32.4.

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Foreign Manufacturers

- 33.** (1) If an application for a medical device licence is submitted by a manufacturer of a country other than Canada, the information and documents described in subsections 32(2) to (4) need not be submitted if
- (a) the applicant is governed, in that country, by a regulatory authority that is recognized by the Minister; and
 - (b) the application is accompanied by a certificate of compliance and a supporting summary report, issued by a conformity assessment body of that country that is recognized by the Minister, which certify that the medical device meets the safety and effectiveness requirements.
- (2) For the purposes of subsection (1), the Minister may recognize a regulatory authority and a conformity assessment body of a country other than Canada only if it has the ability to determine whether the device meets the safety and effectiveness requirements.
- (3) The Minister shall, on request, make available to any interested persons the list of recognized regulatory authorities and conformity assessment bodies of countries other than Canada.

Application for a Medical Device Licence Amendment

- 34.** If the manufacturer proposes to make one or more of the following changes, the manufacturer shall submit to the Minister, in a format established by the Minister, an application for a medical device licence amendment including the information and documents set out in section 32 that are relevant to the change:
- (a) in the case of a Class III or IV medical device, a significant change;
 - (b) a change that would affect the class of the device;
 - (c) a change in the name of the manufacturer;
 - (d) a change in the name of the device;
 - (e) a change in the identifier of the device, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family;
 - (f) in the case of a Class II medical device, a change in the medical conditions, purposes or uses for which the device is manufactured, sold or represented.

Additional Information and Samples

- 35.** (1) If the information and documents submitted in respect of an application for a medical device licence or a medical device licence amendment are insufficient to enable the Minister to determine whether a medical device meets the safety and effectiveness requirements, the Minister may request the manufacturer to submit, on or before a specified day, additional information necessary for making the determination.
- (2) In the course of examining the application, the Minister may require the applicant to provide samples of the medical device.

Issuance

- 36.** (1) If the Minister determines that a medical device in respect of which an application is submitted meets the safety and effectiveness requirements, the Minister shall
- (a) issue to the manufacturer of the device a medical device licence, in the case of an application for a medical device licence; or
 - (b) amend the medical device licence, in the case of an application for a medical device licence amendment.
- (2) The Minister may set out in a medical device licence terms and conditions respecting
- (a) the tests to be performed on a device to ensure that it continues to meet the safety and effectiveness requirements; and
 - (b) the requirement to submit the results and protocols of any tests performed.
- (3) The Minister may amend the terms and conditions of the medical device licence to take into account any new development with respect to the device.
- (4) The holder of the medical device licence shall comply with the terms and conditions of the licence.

Lot of *In Vitro* Diagnostic Devices

37. No person shall sell a medical device from a lot of licensed *in vitro* diagnostic devices in respect of which terms and conditions were set out in the licence pursuant to section 36, unless
- (a) the results and protocol of any test performed on the device in accordance with those terms and conditions have been provided to the Minister; and
 - (b) the Minister determines, on the basis of the information received under paragraph (a), that the device continues to meet the safety and effectiveness requirements.

Refusal to Issue

38. (1) The Minister may refuse to issue or amend a medical device licence if
- (a) the applicant does not comply with these Regulations or any provisions of the Act relating to medical devices;
 - (b) the applicant has made a false or misleading statement in the application;
 - (c) the medical device does not comply with the labelling requirements set out in sections 21 to 23; or
 - (d) the applicant has not complied with a request for additional information or samples made pursuant to section 35 by the day specified in the request.
- (2) The Minister shall refuse to issue or amend a medical device licence if the medical device does not meet the safety and effectiveness requirements or if the information or samples provided pursuant to section 35 are insufficient to enable the Minister to determine whether the medical device meets those requirements.
- (3) If the Minister refuses to issue or amend a medical device licence, the Minister shall
- (a) notify the applicant in writing of the reasons for the refusal; and
 - (b) give the applicant an opportunity to be heard.

Additional Information

39. If the Minister believes on reasonable grounds, after reviewing a report or information brought to the Minister's attention, that a licensed medical device may not meet the safety and effectiveness requirements, the Minister may request the manufacturer to submit, on or before a specified day, information or samples to enable the Minister to determine whether the device meets those requirements.

Suspension

40. (1) Subject to subsection (3), the Minister may suspend a medical device licence if the Minister has reasonable grounds to believe that
- (a) the licensee has contravened these Regulations or any provision of the Act relating to medical devices;
 - (b) the licensee has made a false or misleading statement in the application;
 - (c) the licensee has failed to comply with the terms and conditions of the licence;
 - (d) the licensee has not complied with a request for information or samples made pursuant to section 39 by the day specified in the request, or the information or samples provided are insufficient to enable the Minister to determine whether the medical device meets the safety and effectiveness requirements;
 - (e) the medical device no longer meets the safety and effectiveness requirements; or
 - (f) on the basis of information obtained after the device was licensed, the quality system under which the device has been designed, in the case of a Class III or IV device, or manufactured, assembled, processed, packaged, refurbished or modified, in the case of a Class II, III or IV device, is inadequate to ensure that the device meets its specifications.
- (2) Before suspending a medical device licence, the Minister shall consider
- (a) the licensee's history of compliance with these Regulations and with the provisions of the Act relating to medical devices; and
 - (b) the risk that allowing the licence to continue to be in force would constitute for the health or safety of patients, users or other persons.

(3) Subject to section 41, the Minister shall not suspend a medical device licence until

- (a) the Minister has sent the licensee a written notice that sets out the reason for the proposed suspension, any corrective action required to be taken and the time within which it must be taken;
- (b) if corrective action is required, the time set out in the notice has passed without the action having been taken; and
- (c) the licensee has been given an opportunity to be heard in respect of the suspension.

41. (1) The Minister may suspend a medical device licence without giving the licensee an opportunity to be heard if it is necessary to do so to prevent injury to the health or safety of patients, users or other persons, by giving the licensee a notice in writing that states the reason for the suspension.

(2) A licensee may ask the Minister, in writing, that the suspension be reconsidered.

(3) The Minister shall, within 45 days after the date of receiving the request, provide the licensee with an opportunity to be heard.

42. The Minister may reinstate a medical device licence if the situation giving rise to the suspension has been corrected or if the reason for the suspension was unfounded.

Obligation to Inform

43. (1) Every manufacturer of a licensed medical device shall, annually before November 1 and in a form authorized by the Minister, furnish the Minister with a statement signed by the manufacturer or by a person authorized to sign on the manufacturer's behalf

- (a) confirming that all the information and documents supplied by the manufacturer with respect to the device are still correct; or
- (b) describing any change to the information and documents supplied by the manufacturer with respect to the device, other than those to be submitted under section 34 or 43.1.

(2) If the manufacturer fails to comply with subsection (1), the Minister may cancel the medical device licence.

(3) If the holder of a medical device licence discontinues the sale of the medical device in Canada, the licensee shall inform the Minister within 30 days after the discontinuance, and the licence shall be cancelled at the time that the Minister is informed.

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Obligation to Submit Certificate

43.1 Subject to section 34, if a new or modified quality system certificate is issued in respect of a licensed medical device, the manufacturer of the device shall submit a copy of the certificate to the Minister within 30 days after it is issued.

Transitional Provision: The manufacturer of a medical device for which a medical device licence has been issued before the coming into force of these Regulations shall, before November 1, 2003, submit to the Minister, together with the statement required by subsection 43(1) of the *Medical Devices Regulations*, a copy of the quality system certificate referred to in paragraph 32(2)(f), (3)(j) or (4)(p) of those Regulations, as applicable.

**MEDICAL DEVICES TO BE SOLD FOR THE PURPOSES OF
IMPLEMENTING THE GENERAL COUNCIL DECISION**

Application

43.2 Sections 43.3 to 43.6 apply to a medical device in respect of which a manufacturer has applied to the Commissioner of Patents for an authorization under section 21.04 of the *Patent Act* for the purposes of implementing the General Council Decision.

Notices to Commissioner of Patents

43.3 The Minister shall notify the manufacturer and the Commissioner of Patents for the purposes of paragraph 21.04(3)(b) of the *Patent Act* that the manufacturer's medical device meets the requirements of the Act and these Regulations if

- (a) the manufacturer holds a medical device licence in respect of the device issued in accordance with section 36;
- (b) the Minister is satisfied that the manufacturer and the device comply with the Act and these Regulations;
- (c) the manufacturer has submitted to the Minister a copy of the application filed by the manufacturer with the Commissioner of Patents under section 21.04 of the *Patent Act*;
- (d) the manufacturer has submitted to the Minister information regarding the manner in which the mark referred to in paragraph 43.5(1)(a) is applied to all permanent components of the device; and
- (e) the manufacturer has submitted to the Minister a sample of the label for the device that includes the information required by paragraph 43.5(1)(b).

43.4 The Minister shall notify the manufacturer and the Commissioner of Patents for the purposes of paragraph 21.13(b) of the *Patent Act* in the event that the Minister is of the opinion that the manufacturer's medical device referred to in section 43.2 has ceased to meet the requirements of the Act and these Regulations.

Marking and Labelling

43.5 (1) No person shall sell a medical device referred to in section 43.2 unless

- (a) the mark "XCL" is displayed on all permanent components of the device; and
- (b) the label of the device displays the mark "XCL" followed by the control number referred to in paragraph 21(1)(d) and the words "FOR EXPORT UNDER THE GENERAL COUNCIL DECISION. NOT FOR SALE IN CANADA." or "POUR EXPORTATION AUX TERMES DE LA DÉCISION DU CONSEIL GÉNÉRAL. VENTE INTERDITE AU CANADA."

(2) The information required by subsection (1) shall be expressed in a legible, permanent and prominent manner.

Notice to Minister

43.6 The manufacturer of a medical device referred to in section 43.2 shall notify the Minister in writing not less than 15 days prior to commencing the manufacture of the device.

ESTABLISHMENT LICENCE

Prohibition

- 44.** (1) No person shall import or sell a medical device unless the person holds an establishment licence.
- (2) Subsection (1) does not apply to the importation or sale of a medical device by
- (a) a retailer;
 - (b) a health care facility;
 - (c) in the case of a Class II, III or IV medical device, the manufacturer of the medical device; or
 - (d) in the case of a Class I device, the manufacturer of the medical device, if the manufacturer imports or distributes solely through a person who holds an establishment licence.

Application

- 45.** An application for an establishment licence shall be submitted to the Minister in a format established by the Minister and shall contain the following:
- (a) the name and address of the establishment;
 - (b) the name, title and telephone number of the representative of the establishment to contact for any information concerning the application;
 - (c) a statement as to whether the activity of the establishment is importation or distribution, or both;

- (d) the names and addresses of the manufacturers of the devices that are being imported or distributed;
- (e) for each manufacturer, the medical specialities, selected from among the specialities established by the Minister, in respect of which the devices are imported or distributed;
- (f) for each manufacturer, the classes of the devices that are being imported or distributed;
- (g) an attestation by a senior official of the establishment that the establishment has documented procedures in place in respect of distribution records, complaint handling and recalls;
- (h) if the establishment imports devices, an attestation by a senior official of the establishment that the establishment has documented procedures in place in respect of mandatory problem reporting;
- (i) if the establishment imports or distributes Class II, III or IV devices, an attestation by a senior official of the establishment that the establishment has documented procedures in place, where applicable, for handling, storage, delivery, installation, corrective action and servicing in respect of those devices; and
- (j) the address of each building in Canada where the procedures described in paragraphs (g) to (i) are in place.

Issuance

- 46.** (1) If the Minister determines that the application for an establishment licence meets the requirements of section 45, the Minister shall issue to the applicant a licence in respect of the establishment.
- (2) An establishment licence shall expire on December 31 of each year.

Refusal

- 47.** (1) The Minister may refuse to issue an establishment licence if the applicant has made a false or misleading statement in the application.
- (2) The Minister shall refuse to issue an establishment licence if the Minister has reasonable grounds to believe that issuing such a licence would constitute a risk to the health or safety of patients, users or other persons.
- (3) If the Minister refuses to issue an establishment licence, the Minister shall
- (a) notify the applicant in writing of the reasons for the refusal; and
 - (b) give the applicant an opportunity to be heard.

Notification

- 48.** If, following the issuance of an establishment licence, there is a change to any of the information submitted in accordance with paragraph 45(a) or (b), the holder of the establishment licence shall submit the new information to the Minister within 15 days of the change.

Suspension

- 49.** (1) Subject to subsection (3), the Minister may suspend an establishment licence if the Minister has reasonable grounds to believe that
- (a) the licensee has contravened these Regulations or any provision of the Act relating to medical devices;
 - (b) the licensee has made a false or misleading statement in the application; or
 - (c) failure to suspend the establishment licence would constitute a risk to the health or safety of patients, users or other persons.
- (2) Before suspending an establishment licence, the Minister shall consider
- (a) the licensee's history of compliance with these Regulations and with the provisions of the Act relating to medical devices; and
 - (b) the risk that allowing the licence to continue to be in force would constitute for the health or safety of patients, users or other persons.

(3) Subject to section 50, the Minister shall not suspend an establishment licence until

- (a) the Minister has sent the licensee a written notice that sets out the reason for the proposed suspension, any corrective action required to be taken and the time within which it must be taken;
- (b) if corrective action is required, the time set out in the notice has passed without the action having been taken; and
- (c) the licensee has been given an opportunity to be heard in respect of the suspension.

50. (1) The Minister may suspend an establishment licence without giving the licensee an opportunity to be heard if it is necessary to do so to prevent injury to the health or safety of patients, users or other persons, by giving the licensee a notice in writing that states the reason for the suspension.

(2) A licensee may ask the Minister, in writing, that the suspension be reconsidered.

(3) The Minister shall, within 45 days after the date of receiving the request, provide the licensee with an opportunity to be heard.

51. The Minister may reinstate an establishment licence if the situation giving rise to the suspension has been corrected or if the reason for the suspension was unfounded.

Distribution Records

52. (1) The manufacturer, importer and distributor of a medical device shall each maintain a distribution record in respect of each device.

(2) Subsection (1) does not apply to

- (a) a retailer; or
- (b) a health care facility in respect of a medical device that is distributed for use within that facility.

53. The distribution record shall contain sufficient information to permit complete and rapid withdrawal of the medical device from the market.

54. (1) The distribution record maintained by a manufacturer of an implant shall also contain a record of the information received on the implant registration cards forwarded to the manufacturer from a health care facility pursuant to section 67.

(2) The manufacturer of an implant shall update the information referred to in subsection (1) in accordance with any information received from the health care facility or the patient.

55. The manufacturer, importer and distributor shall retain the distribution record maintained in respect of a medical device for the longer of

- (a) the projected useful life of the device, and
- (b) two years after the date the device is shipped.

56. Distribution records shall be maintained in a manner that will allow their timely retrieval.

Complaint Handling

57. (1) The manufacturer, importer and distributor of a medical device shall each maintain records of the following:

- (a) reported problems relating to the performance characteristics or safety of the device, including any consumer complaints, received by the manufacturer, importer or distributor after the device was first sold in Canada; and
- (b) all actions taken by the manufacturer, importer or distributor in response to the problems referred to in paragraph (a).

(2) Subsection (1) does not apply to

- (a) a retailer; or
- (b) a health care facility in respect of a medical device that is distributed for use within that facility.

58. The manufacturer, importer and distributor of a medical device shall each establish and implement documented procedures that will enable the manufacturer, importer or distributor to carry out

- (a) an effective and timely investigation of the problems referred to in paragraph 57(1)(a); and
- (b) an effective and timely recall of the device.

Mandatory Problem Reporting

59. (1) Subject to subsection (2), the manufacturer and the importer of a medical device shall each make a preliminary and a final report to the Minister concerning any incident that comes to their attention occurring inside or outside Canada and involving a device that is sold in Canada and that

- (a) is related to a failure of the device or a deterioration in its effectiveness, or any inadequacy in its labelling or in its the directions for use; and
- (b) has led to the death or a serious deterioration in the state of health of a patient, user or other person, or could do so were it to recur.

(2) The requirement to report an incident that occurs outside Canada does not apply unless the manufacturer has indicated, to a regulatory agency of the country in which the incident occurred, the manufacturer's intention to take corrective action, or unless the regulatory agency has required the manufacture to take corrective action.

60. (1) A preliminary report shall be submitted to the Minister

- (a) in respect of an incident that occurs in Canada
 - (i) within 10 days after the manufacturer or importer of a medical device becomes aware of an incident, if the incident has led to the death or a serious deterioration in the state of health of a patient, user or other person, or
 - (ii) within 30 days after the manufacturer or importer of a medical device becomes aware of an incident, if the incident has not led to the death or a serious deterioration in the state of health of a patient, user or other person, but could do so were it to recur; and
- (b) in respect of an incident that occurs outside Canada, as soon as possible after the manufacturer has indicated, to the regulatory agency referred to in paragraph 59(2), the manufacturer's intention to take corrective action, or after the regulatory agency has required the manufacturer to take corrective action.

(2) The preliminary report shall contain the following information:

- (a) the name of the device and its identifier, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family;
- (b) if the report is made by
 - (i) the manufacturer, the name and address of that manufacturer and of any known importer, and the name, title and telephone and facsimile numbers of a representative of the manufacturer to contact for any information concerning the incident, or
 - (ii) the importer of the device, the name and address of the importer and of the manufacturer, and the name, title and telephone and facsimile numbers of a representative of the importer to contact for any information concerning the incident;
- (c) the date on which the incident came to the attention of the manufacturer or importer;
- (d) the details known in respect of the incident, including the date on which the incident occurred and the consequences for the patient, user or other person;
- (e) the name, address and telephone number, if known, of the person who reported the incident to the manufacturer or importer;
- (f) the identity of any other medical devices or accessories involved in the incident, if known;
- (g) the manufacturer's or importer's preliminary comments with respect to the incident;
- (h) the course of action, including an investigation, that the manufacturer or importer proposes to follow in respect of the incident and a timetable for carrying out any proposed action and for submitting a final report, and
- (i) a statement indicating whether a previous report has been made to the Minister with respect to the device and, if so, the date of the report.

61. (1) After the preliminary report is made in accordance with section 60, a final report shall be submitted to the Minister in accordance with the timetable established under paragraph 60(2)(h).

(2) The final report shall contain the following information:

- (a) a description of the incident, including the number of persons who have experienced a serious deterioration in the state of their health or who have died;
- (b) a detailed explanation of the cause of the incident and a justification for the actions taken in respect of the incident; and
- (c) any actions taken as a result of the investigation, which may include
 - (i) increased post-market surveillance of the device,
 - (ii) corrective and preventive action respecting the design and manufacture of the device, and
 - (iii) recall of the device.

61.1 (1) Despite subsection 59(1), the manufacturer of a medical device may permit the importer of the device to prepare and submit the preliminary and final reports on the manufacturer's behalf if the information that the manufacturer and importer must include is identical.

(2) The manufacturer shall advise the Minister in writing if the manufacturer has permitted the importer to prepare and submit the reports on the manufacturer's behalf.

Recall

63. Sections 64 and 65 do not apply to

- (a) a retailer; or
- (b) a health care facility in respect of a medical device that is distributed for use within that facility.

64. The manufacturer and the importer of a medical device shall, on or before undertaking a recall of the device, each provide the Minister with the following:

- (a) the name of the device and its identifier, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family;
- (b) the name and address of the manufacturer and importer, and the name and address of the establishment where the device was manufactured, if different from that of the manufacturer;
- (c) the reason for the recall, the nature of the defectiveness or possible defectiveness and the date on and circumstances under which the defectiveness or possible defectiveness was discovered;
- (d) an evaluation of the risk associated with the defectiveness or possible defectiveness;
- (e) the number of affected units of the device that the manufacturer or importer
 - (i) manufactured in Canada,
 - (ii) imported into Canada, and
 - (iii) sold in Canada;
- (f) the period during which the affected units of the device were distributed in Canada by the manufacturer or importer;
- (g) the name of each person to whom the affected device was sold by the manufacturer or importer and the number of units of the device sold to each person;
- (h) a copy of any communication issued with respect to the recall;
- (i) the proposed strategy for conducting the recall, including the date for beginning the recall, information as to how and when the Minister will be informed of the progress of the recall and the proposed date for its completion;
- (j) the proposed action to prevent a recurrence of the problem; and
- (k) the name, title and telephone number of the representative of the manufacturer or importer to contact for any information concerning the recall.

65. The manufacturer and the importer of a medical device shall, as soon as possible after the completion of a recall, each report to the Minister

- (a) the results of the recall; and
- (b) the action taken to prevent a recurrence of the problem.

(1) Despite sections 64 and 65, the manufacturer of a medical device may permit the importer of the device to prepare and submit, on the manufacturer's behalf, the information and documents with respect to the recall if the information and documents that the manufacturer and importer must submit are identical.

(2) The manufacturer shall advise the Minister in writing if the manufacturer has permitted the importer to prepare and submit the information and documents with respect to the recall on the manufacturer's behalf.

Implant Registration

66. (1) Subject to section 68, the manufacturer of an implant shall provide, with the implant, two implant registration cards that contain

- (a) the name and address of the manufacturer;
- (b) the name and address of any person designated by the manufacturer for the collection of implant registration information;
- (c) a notice advising the patient that the purpose of the cards is to enable the manufacturer to notify the patient of new information concerning the safety, effectiveness or performance of the implant, and any required corrective action; and
- (d) a statement advising the patient to notify the manufacturer of any change of address.

(2) An implant registration card shall be designed for the recording of the following information:

- (a) the name of the device, its control number and its identifier, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family;
- (b) the name and address of the health care professional who carried out the implant procedure;
- (c) the date on which the device was implanted;
- (d) the name and address of the health care facility at which the implant procedure took place; and
- (e) the patient's name and address or the identification number used by the health care facility to identify the patient.

(3) The two implant registration cards referred to in subsection (1) shall be printed in both official languages; however, the manufacturer may choose to provide four cards, two in English and two in French.

67. (1) Subject to subsection (2), a member of the staff of the health care facility where an implant procedure takes place shall, as soon as possible after the completion of the procedure, enter the information required by subsection 66(2) on each implant registration card, give one card to the implant patient and forward one card to the manufacturer of the implant or the person designated pursuant to paragraph 66(1)(b).

(2) The patient's name and address shall not be entered on the implant registration card forwarded to the manufacturer or person designated pursuant to paragraph 66(1)(b) except with the patient's written consent.

(3) The health care facility, the manufacturer or the person designated pursuant to paragraph 66(1)(b) shall not disclose the patient's name or address, or any information that might identify the patient, unless the disclosure is required by law.

68. (1) The manufacturer of an implant may apply in writing to the Minister for authorization to use an implant registration method other than the implant registration cards described in section 66.

(2) The Minister shall authorize the use of the implant registration method proposed in the application referred to in subsection (1) if the Minister determines that the method will enable the manufacturer to achieve the purpose set out in paragraph 66(1)(c) as effectively as the use of implant registration cards.

(3) Where an authorization has been granted pursuant to subsection (2), the manufacturer shall implement the alternative implant registration method, and sections 66 and 67 shall apply with such modifications as are necessary.

PART 2

CUSTOM-MADE DEVICES AND MEDICAL DEVICES TO BE IMPORTED OR SOLD FOR SPECIAL ACCESS

Application

69. (1) This Part applies to custom-made devices and medical devices that are to be imported or sold for special access.

(2) In this Part, "special access" means access to a medical device for emergency use or if conventional therapies have failed, are unavailable or are unsuitable.

General

70. No person shall import or sell a Class III or IV custom-made device or a medical device for special access unless the Minister has issued an authorization for its sale or importation.

Authorization

71. (1) If a health care professional wishes to obtain a medical device referred to in section 70, the professional shall apply to the Minister for an authorization that would permit the manufacturer or importer of the device to sell, or to import and sell, the device to that professional.

(2) The application shall contain the following:

- (a) the name of the device, its class and its identifier, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family;
- (b) the number of units required;
- (c) the name and address of the manufacturer or importer;
- (d) the name, title and telephone number of the representative of the manufacturer or importer to contact for any information concerning the device;
- (e) the diagnosis, treatment or prevention for which the device is required;
- (f) a statement that sets out
 - (i) the reasons the device was chosen for the diagnosis, treatment or prevention,
 - (ii) the risks and benefits that are associated with its use, and
 - (iii) the reasons the diagnosis, treatment or prevention could not be accomplished using a licensed device that is available for sale in Canada;
- (g) the name and address of each health care facility at which the device is to be used by that professional;
- (h) the known safety and effectiveness information in respect of the device;
- (i) a written undertaking by the health care professional that the professional will inform the patient for whom the device is intended of the risks and benefits associated with its use;
- (j) the directions for use, unless directions are not required for the device to be used safely and effectively; and
- (k) in the case of a custom-made device, a copy of the health care professional's written direction to the manufacturer giving the design characteristics of the device.

72. (1) The Minister shall issue an authorization referred to in subsection 71(1) to a manufacturer or importer if the Minister determines that

- (a) the benefits that may be obtained by the patient through the use of the device outweigh the risks associated with its use;
- (b) the health or safety of patients, users or other persons will not be unduly affected;
- (c) a licensed device that would adequately meet the requirements of the patient is not available in Canada; and
- (d) the authorization is not being used by the manufacturer or importer to circumvent the requirements of Part 1.

(2) The authorization issued under subsection (1) shall specify

- (a) the number of units of the device authorized to be imported;
- (b) the number of units of the device authorized to be sold; and
- (c) the name of the health care professional to whom the manufacturer or importer may sell the device.

Additional Information

- 73.** If the information and documents submitted in respect of an application made pursuant to section 71 are insufficient to enable the Minister to determine whether the conditions set out in subsection 72(1) have been met, the manufacturer, importer or health care professional shall, at the request of the Minister, submit any further information relevant to the application that the Minister may request.
- 74.** The Minister may, in respect of an authorization that has been issued,
- (a) request the manufacturer, importer or health care professional to submit information in respect of the device if the Minister believes on reasonable grounds, after reviewing a report or information brought to the Minister's attention, that the device for which the authorization has been issued no longer meets the conditions set out in subsection 72(1); and
 - (b) issue a written cancellation of the authorization, giving reasons, if
 - (i) the Minister determines that the conditions set out in subsection 72(1) are no longer met, or
 - (ii) the information referred to in paragraph (a) has not been submitted.

Labelling

- 75.** No person shall import or sell a medical device in respect of which an authorization has been issued pursuant to section 72, or a Class I or II custom-made device, unless the device has a label that
- (a) sets out the name of the manufacturer;
 - (b) sets out the name of the device; and
 - (c) specifies whether the device is a custom-made device or is being imported or sold for special access.

Distribution Records

- 76.** The manufacturer or importer of a medical device in respect of which an authorization has been issued pursuant to section 72 shall maintain a distribution record in respect of the device in accordance with sections 52 to 56.

Reporting an Incident

- 77.** The health care professional referred to in subsection 71(1) shall, within 72 hours after the occurrence of an incident described in section 59 involving a medical device for which an authorization has been issued pursuant to section 72, report the incident to the Minister and to the manufacturer or importer of the device, and specify the nature of the incident and the circumstances surrounding it.

Implant Registration

- 9-05-02 | **78.** Sections 66 to 68 apply in respect of an implant that is imported or sold for special access.

PART 3

MEDICAL DEVICES FOR INVESTIGATIONAL TESTING INVOLVING HUMAN SUBJECTS

Application

- 79.** This Part applies to medical devices that are to be imported or sold for investigational testing involving human subjects.

General

- 80.** (1) Subject to subsections (2) and (3), no person shall import or sell a medical device for investigational testing.

(2) A manufacturer or importer of a Class II, III or IV medical device may sell the device to a qualified investigator for the purpose of conducting investigational testing if the manufacturer or importer holds an authorization issued under subsection 83(1) and possesses records that contain all the information and documents required by section 81.

(3) A manufacturer or importer of a Class I medical device may sell the device to a qualified investigator for the purpose of conducting investigational testing if the manufacturer or importer possesses records that contain all the information and documents required by section 81.

Records

81. The records referred to in section 80 shall contain the following:

- (a) the name, address and telephone number of the manufacturer and the importer of the device;
- (b) the name of the device, its class and its identifier, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family;
- (c) a description of the device and of the materials used in its manufacture and packaging;
- (d) a description of the features of the device that permit it to be used for the medical conditions, purposes and uses for which it is manufactured, sold or represented;
- (e) a list of the countries other than Canada where the device has been sold, the total number of units sold in those countries, and a summary of any reported problems with the device and any recalls of the device in those countries;
- (f) a risk assessment comprising an analysis and evaluation of the risks, and the risk reduction measures adopted for the purposes of conducting investigational testing of the device, including, as appropriate,
 - (i) the results of any previous research, testing and studies conducted with respect to the device,
 - (ii) a description of the methods currently used to diagnose or treat the medical condition in respect of which the investigational testing is being proposed, and
 - (iii) information respecting any cautions, warnings, contra-indications and possible adverse effects associated with the use of the device;
- (g) the names of all the qualified investigators to whom the device is proposed to be sold and their qualifications, including their training and experience;
- (h) the name and address of each institution at which the investigational testing is proposed to be conducted and, in the case of a Class III or IV device, written approval from the institution indicating that the investigational testing may be carried out there;
- (i) a protocol of the proposed investigational testing, including the number of units of the device proposed to be used for the testing, the hypothesis for and objective of the testing, the period of time during which the testing will be carried out and a copy of the patient consent form;
- (j) a copy of the device label; and
- (k) a written undertaking from each qualified investigator to
 - (i) conduct the investigational testing in accordance with the protocol provided by the manufacturer;
 - (ii) inform a patient who is to be diagnosed or treated using the device of any risks and benefits associated with its use, and obtain the patient's written consent for its use,
 - (iii) not use the device or permit it to be used for any purpose other than the investigational testing specified in the protocol,
 - (iv) not permit the device to be used by any other person except under the direction of the qualified investigator, and
 - (v) in the event of an incident described in section 59, report the incident and the circumstances surrounding it to the Minister and to the manufacturer or importer of the device within 72 hours after it comes to the attention of the qualified investigator.

Authorization

82. An application for an authorization referred to in subsection 80(2) shall be made in writing to the Minister and shall contain

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- (a) in the case of a Class II medical device or a Class III or IV *in vitro* diagnostic device that is not used for patient management, not including a near-patient *in vitro* diagnostic device, the information set out in paragraphs 81(a), (b) and (h) to (j); and
- (b) in the case of a Class III or IV medical device that is not covered by paragraph (a), the information and documents set out in section 81.

- 83.** (1) The Minister shall issue an authorization referred to in subsection 80(2) to a manufacturer or importer if the Minister determines that
- (a) the device can be used for investigational testing without seriously endangering the life, health or safety of patients, users or other persons;
 - (b) the investigational testing is not contrary to the best interests of patients on whom the testing will be conducted; and
 - (c) the objective of the testing will be achieved.
- (2) The authorization referred to subsection (1) shall specify
- (a) the name of any qualified investigator to whom the device may be sold;
 - (b) the type of diagnosis or treatment for which the device may be sold;
 - (c) the number of units of the device that are authorized to be sold; and
 - (d) the protocol according to which the investigational testing is to be conducted.

Additional Information

- 84.** If the information and documents submitted in respect of an application made pursuant to section 82 are insufficient to enable the Minister to determine whether the conditions set out in subsection 83(1) have been met, the manufacturer or importer shall, at the request of the Minister, submit any further information relevant to the application that the Minister may request.
- 85.** (1) The Minister may, in respect of a medical device in relation to which investigational testing is being conducted, request the manufacturer or importer of the device to submit information in respect of the testing if the Minister believes on reasonable grounds, after reviewing a report or information brought to the Minister's attention, that one of the following conditions may exist:
- (a) the testing seriously endangers the life, health or safety of patients, users or other persons;
 - (b) the testing is contrary to the best interests of patients on whom the testing is being conducted;
 - (c) the objective of the testing will not be achieved;
 - (d) the qualified investigator who is conducting the testing is not respecting the undertaking required by paragraph 81(k); or
 - (e) the information submitted in respect of the testing is false or misleading.
- (2) If the information requested pursuant to subsection (1) is not submitted, or if it is submitted and the Minister determines after reviewing it that a condition identified in that subsection exists, the Minister may, by written notice giving reasons,
- (a) in the case of a Class I device, direct the manufacturer or importer of the device to stop selling the device to any qualified investigator named in the notice; or
 - (b) in the case of a Class II, III or IV device, cancel the authorization referred to in subsection 83(1), in whole or in part.

Labelling

- 86.** No person shall import or sell a medical device for investigational testing unless the device has a label that sets out
- (a) the name of the manufacturer;
 - (b) the name of the device;
 - (c) the statements "Investigational Device" and "Instrument de recherche", or any other statement, in English and French, that conveys that meaning;
 - (d) the statements "To Be Used by Qualified Investigators Only" and "Réservé uniquement à l'usage de chercheurs compétents", or any other statement, in English and French, that conveys that meaning; and
 - (e) in the case of an IVDD, the statements "The performance specifications of this device have not been established" and "Les spécifications de rendement de l'instrument n'ont pas été établies", or any other statement, in English and French, that conveys that meaning.

Advertising

- 87.** No person shall advertise a medical device that is the subject of investigational testing unless
- (a) that person holds an authorization issued under subsection 83(1) to sell or import the device; and
 - (b) the advertisement clearly indicates that the device is the subject of investigational testing, and the purpose of the investigational testing.

Other Requirements

- 9-05-02 | **88.** The requirements set out in the following provisions apply to medical devices to which this Part applies:
- 9-05-02 |
- (a) sections 52 to 56 with respect to distribution records;
 - (b) sections 57 and 58 with respect to complaint handling;
 - (c) sections 59 to 61.1 with respect to mandatory problem reporting;
 - (d) sections 63 to 65.1 with respect to recalls; and
 - (e) sections 66 to 68 with respect to implant registration.

PART 4

EXPORT CERTIFICATES

- 89.** (1) For the purposes of section 37 of the Act, Schedule 3 sets out the form to be used for an export certificate for medical devices.
- (2) The export certificate shall be signed and dated by
- (a) where the exporter of the device is a corporation,
 - (i) the exporter's senior executive officer in Canada,
 - (ii) the exporter's senior regulatory officer in Canada, or
 - (iii) the authorized agent of the person referred to in subparagraph (i) or (ii); or
 - (b) where the exporter of the device is an individual,
 - (i) the exporter, or
 - (ii) the exporter's authorized agent.
- 90.** No person shall sign an export certificate that is false or misleading or that contains omissions that may affect its accuracy and completeness.
- 91.** The exporter of a device shall maintain, at their principal place of business in Canada, records that contain the completed export certificates and shall, when requested to do so by an inspector, submit the export certificates for examination.
- 92.** The exporter of a device shall retain the export certificate for a period of not less than five years after the date of export.

PART 5

TRANSITIONAL PROVISIONS, REPEAL AND COMING INTO FORCE

Transitional Provisions

- 93.** For the purposes of sections 94 and 95, "old regulations" means the *Medical Devices Regulations*, C.R.C., c. 871, and "Director" has the meaning assigned to it by those regulations.
- 94.** (1) Subject to subsection (2), if an application for a notice of compliance has been submitted with respect to a medical device pursuant to Part V of the old regulations but has not been processed by the Director as of June 30, 1998, an application for a medical device licence shall be made pursuant to these Regulations.
- (2) For the purposes of an application for a medical device licence, the information and documents required by paragraphs 32(2)(a) to (e), (3)(a) to (i) or (4)(a) to (o) are deemed to have been submitted if a notice of compliance with respect to the device has been issued under the old regulations.

95. (1) A medical device that, on June 30, 1998, is being sold in Canada pursuant to the old regulations is not required to be licensed until February 1, 1999, if,

- (a) in the case of a device that is subject to Part V of the old regulations, the manufacturer
 - (i) has a notice of compliance in respect of the device that is in effect on June 30, 1998, or
 - (ii) does not have a notice of compliance in respect of the device that is in effect on June 30, 1998, but has met, during the period beginning on October 8, 1982, and ending on March 31, 1983, the requirements for device notification pursuant to Part II of the old regulations in respect of the device; and
- (b) in the case of a device that is not subject to Part V of the old regulations, the manufacturer has, by June 30, 1998, furnished the Director with the notification required in subsection 24(1) of the old regulations in respect of the device.

(2) If an initial application for licensing of a medical device that is referred to in subsection (1) is submitted before February 1, 1999, the information and documents required by paragraphs 32(2)(a) to (e), (3)(a) to (i) or (4)(a) to (o) are deemed to have been submitted if

- (a) in the case of a device that is subject to Part V of the old regulations, the manufacturer
 - (i) has a notice of compliance in respect of the device that is in effect on June 30, 1998, or
 - (ii) does not have a notice of compliance that is in effect on June 30, 1998, in respect of the device, but has met, during the period beginning on October 8, 1982, and ending on March 31, 1983, the requirements for device notification pursuant to Part II of the old regulations in respect of the device;
- (b) in the case of a device that is not subject to Part V of the old regulations, the manufacturer has, by June 30, 1998, furnished the Director with the notification required in subsection 24(1) of the old regulations in respect of the device.

(3) Subsections (1) and (2) cease to apply in respect of a medical device if a change described in section 34 is made in respect of the device or if the notice of compliance is suspended or cancelled under section 40 of the old regulations.

(4) For the purposes of this section, a notice of compliance may be suspended or cancelled under section 40 of the old regulations as if that section were still in force.

Repeal

96. The *Medical Devices Regulations* are repealed.

Coming into Force

97. (1) Subject to subsections (2) to (5), these Regulations come into force on July 1, 1998.

(2) Section 32, except paragraphs (2)(f), (3)(j) and (4)(p), comes into force

- (a) in the case of a medical device referred to in section 94 or 95, on September 1, 1998;
- (b) in the case of any other medical device, on July 1, 1998.

14-6-01 |

(3) Paragraphs 32(2)(f), (3)(j) and (4)(p) come into force on January 1, 2003.

(4) Sections 43 and 44 come into force on January 1, 1999.

(5) Sections 45 to 51 come into force on November 1, 1998.

SCHEDULE 1
(Section 6)

CLASSIFICATION RULES FOR MEDICAL DEVICES

PART 1

MEDICAL DEVICES OTHER THAN *IN VITRO* DIAGNOSTIC DEVICES

Invasive Devices

Rule 1:

- (1) Subject to subrules (2) and (3), all surgically invasive devices are classified as Class II.
- (2) A surgically invasive device that is intended to diagnose, monitor, control or correct a defect of the central cardiovascular system or the central nervous system or of a fetus in utero is classified as Class IV.
- (3) A surgically invasive device that is intended to be absorbed by the body, or that is normally intended to remain in the body for at least 30 consecutive days, is classified as Class III.

Rule 2:

- (1) Subject to subrules (2) to (4), all invasive devices that penetrate the body through a body orifice or that come into contact with the surface of the eye are classified as Class II.
- (2) A device described in subrule (1) that is intended to be placed in the oral or nasal cavities as far as the pharynx or in the ear canal up to the ear drum is classified as Class I.
- (3) A device described in subrule (1) that is normally intended to remain in the body or in contact with the surface of the eye for at least 30 consecutive days is classified as Class III.
- (4) A device described in subrule (1) that is intended to be represented as preventing the transmission of infectious agents during sexual activities or reducing the risk thereof is classified as Class III.

Rule 3:

- Despite rules 1 and 2
- (a) all denture materials and orthodontic appliances, and their accessories, are classified as Class II;
 - (b) all surgical or dental instruments are classified as Class I; and
 - (c) all latex condoms are classified as Class II.

Non-invasive Devices

Rule 4:

- (1) Subject to subrule (2), all non-invasive devices that are intended to come into contact with injured skin are classified as Class II.
- (2) A device described in subrule (1) that is intended to be used as a mechanical barrier, for compression or for absorption of exudations, is classified as Class I.

Rule 5:

A non-invasive device intended for channelling or storing gases, liquids, tissues or body fluids for the purpose of introduction into the body by means of infusion or other means of administration is classified as Class II.

Rule 6:

(1) Subject to subrules (2) and (3), a non-invasive device intended for modifying the biological or chemical composition of blood or other body fluids, or liquids, for the purpose of introduction into the body by means of infusion or other means of administration is classified as Class III.

(2) A device described in subrule (1) whose characteristics are such that the modification process may introduce a foreign substance into the body that is potentially hazardous, taking into account the nature and quantity of the substance, is classified as Class IV.

(3) A device described in subrule (1) that accomplishes the modification by centrifugation, gravity filtration or the exchange of gas or heat is classified as Class II.

Rule 7:

(1) Subject to subrule (2), all other non-invasive devices are classified as Class I.

(2) A device described in subrule (1) is classified as Class II if it is intended

- (a) to act as a calibrator, tester or quality control support to another medical device; or
- (b) to be connected to an active device that is classified as Class II, III or IV.

Active Devices

Rule 8:

(1) Subject to subrules (2) and (3), an active device intended to emit ionizing radiation, including any device or software intended to control or monitor such a device or directly influence its performance, is classified as Class III.

(2) A device described in subrule (1) that is intended to be used in radiographic mode is classified as Class II.

(3) Despite subrule (2), an active device that is intended to be used for mammographies is classified as Class III.

Rule 9:

(1) Subject to subrules (2) and (3), an active therapeutic device, including any dedicated software, intended to be used to administer or withdraw energy to or from the body is classified as Class II.

(2) If the administration or withdrawal by a device described in subrule (1) is potentially hazardous, taking into account the nature of the administration or withdrawal, the intensity of the energy and the part of the body concerned, the device is classified as Class III.

(3) A device described in subrule (2) that is intended to control the treatment of a patient's condition through a closed loop system is classified as Class IV.

Rule 10:

(1) Subject to subrule (2), an active diagnostic device, including any dedicated software, that supplies energy for the purpose of imaging or monitoring physiological processes is classified as Class II.

(2) A device described in subrule (1) that is intended to be used to monitor, assess or diagnose a disease, a disorder, an abnormal physical state or a pregnancy, if erroneous readings could result in immediate danger, is classified as Class III.

Rule 11:

(1) Subject to subrules (2) and (3), an active device, including any dedicated software, intended to administer drugs, body fluids or other substances to the body or withdraw them from the body is classified as Class II.

(2) If the administration or withdrawal by a device described in subrule (1) is potentially hazardous, taking into account the nature of the administration or withdrawal, the nature of the substance involved and the part of the body concerned, the device is classified as Class III.

(3) A device described in subrule (2) that is intended to control the treatment of a patient's condition through a closed loop system is classified as Class IV.

Rule 12:

Any other active device is classified as Class I.

Special Rules

Rule 13:

A medical device that is intended to be used for

- (a) disinfecting or sterilizing blood, tissues or organs that are intended for transfusion or transplantation is classified as Class IV; and
- (b) disinfecting or sterilizing a medical device is classified as Class II.

Rule 14:

(1) Subject to subrule (2), any medical device manufactured from or incorporating non-viable or viable animal or human tissue or their derivatives, or a product produced through the use of recombinant DNA technology, is classified as Class IV.

(2) A device described in subrule (1) that is intended to come into contact with intact skin only is classified as Class I.

Rule 15:

Any medical device that is a material intended to be sold to a health care professional or dispenser for the specific purpose of configuration or arrangement into a mould or shape to meet the needs of an individual is classified in the class that applies to the finished medical device.

Rule 16:

Despite rules 1 to 15, a medical device set out in column 1 of an item of the table to this rule is classified as the class set out in column 2 of that item.

TABLE

Item	Column 1 Medical device	Column 2 Class
1.	Breast implants	IV
2.	Tissue expanders for breast reconstruction and augmentation	IV

PART 2

IN VITRO DIAGNOSTIC DEVICES

Use with respect to Transmissible Agents

Rule 1:

An IVDD that is intended to be used to detect the presence of, or exposure to, a transmissible agent in blood, blood components, blood derivatives, tissues or organs to assess their suitability for transfusion or transplantation is classified as Class IV.

Rule 2:

An IVDD that is intended to be used to detect the presence of, or exposure to, a transmissible agent is classified as Class II, unless

- (a) it is intended to be used to detect the presence of, or exposure to, a transmissible agent that causes a life-threatening disease if there is a risk of propagation in the Canadian population, in which case it is classified as Class IV; or
- (b) it falls into one of the following categories, in which case it is classified as Class III:
 - (i) it is intended to be used to detect the presence of, or exposure to, a transmissible agent that causes a serious disease where there is a risk of propagation in the Canadian population,
 - (ii) it is intended to be used to detect the presence of, or exposure to, a sexually transmitted agent,
 - (iii) it is intended to be used to detect the presence of an infectious agent in cerebrospinal fluid or blood, or
 - (iv) there is a risk that an erroneous result would cause death or severe disability to the individual being tested, or to the individual's offspring.

Rule 3:

An IVDD that is intended to be used for patient management is classified as Class II, unless it falls into one of the following categories, in which case it is classified as Class III:

- (a) it is intended to be used for the management of patients suffering from a life-threatening disease; or
- (b) 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.

Other Uses

Rule 4:

An IVDD that is not subject to rules 1 to 3 and that is intended to be used in diagnosis or patient management is classified as Class II, unless it falls into one of the following categories, in which case it is classified as Class III:

- (a) it is intended to be used in screening for or in the diagnosis of cancer;
- (b) it is intended to be used for genetic testing;
- (c) it is intended to be used in screening for congenital disorders in the fetus;
- (d) there is a risk that an erroneous diagnostic result would cause death or severe disability to the patient being tested or to that patient's offspring;
- (e) it is intended to be used for disease staging; or
- (f) it is intended to be used to monitor levels of drugs, substances or biological components, 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.

Rule 5:

An IVDD that is intended to be used for blood grouping or tissue typing to ensure the immunological compatibility of blood, blood components, tissue or organs that are intended for transfusion or transplantation is classified as Class III.

Special Rules

Rule 6:

A near patient IVDD is classified as Class III.

Rule 7:

In cases where an IVDD, including its analyzers, reagents and software, is intended to be used with another IVDD, the class of both IVDDs will be that of the IVDD in the class representing the higher risk.

Rule 8:

If rules 1 to 7 do not apply, all other IVDDs are classified as Class I.

Rule 9:

Despite rules 1 to 8, an IVDD set out in column 1 of an item of the table to this rule is classified as the class set out in column 2 of that item.

TABLE

Item	Column 1 IVDD	Column 2 Class
1.	Near patient <i>in vitro</i> diagnostic device for the detection of pregnancy or for fertility testing	II
2.	Near patient <i>in vitro</i> diagnostic device for determining cholesterol level	II
3.	Microbiological media used to identify or infer the identity of a microorganism	I
4.	IVDD used to identify or infer the identity of a cultured microorganism	I

SCHEDULE 2

(Section 1)

IMPLANTS

1. Heart valve
2. Annuloplasty ring
3. Active implantable device systems
 - (a) all models of implantable pacemakers and leads;
 - (b) all models of implantable defibrillators and leads;
 - (c) artificial heart;
 - (d) implantable ventricular support system; and
 - (e) implantable drug infusion system
4. Devices of human origin
 - (a) human dura mater; and
 - (b) wound covering containing human cells

SCHEDULE 3
(Section 89)

EXPORT CERTIFICATE FOR MEDICAL DEVICES

UNDER THE Medical Devices Regulations

I, _____, certify that I have knowledge of all matters contained in this certificate and that

1. I am (check applicable box)
 - (a) where the medical device described in this certificate is exported by a corporation
 - the exporter's senior executive officer;
 - the exporter's senior regulatory officer;
 - the authorized agent of the exporter's senior executive officer; or
 - the authorized agent of the exporter's senior regulatory officer; and
 - (b) where the medical device described in this certificate is exported by an individual
 - the exporter; or
 - the exporter's authorized agent.

(State name and address of exporter or, if a corporation,
name and address of principal place of business in Canada).

2. On the ____ day of _____, a package containing _____

(description of device, including serial number, model name, lot number and
quantity, as applicable; if additional space required, attach as Appendix "A")

is/will be consigned to _____
(name and address of consignee).

3. The package is marked in distinct overprinting with the word "Export" or "Exportation".
4. The medical device was not manufactured for consumption in Canada.
5. The medical device is not sold for consumption in Canada.
6. The package and its contents do not contravene any known requirement of the law of the country of _____
(state country of consignee).
7. All relevant information is contained in this certificate and no relevant information has been knowingly withheld.

Signature

Position title

Date

