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HEALTH PRODUCTS ACT (CHAPTER 122D)

HEALTH PRODUCTS (MEDICAL DEVICES) REGULATIONS 2010

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In exercise of the powers conferred by sections 45, 71 and 72 of the Health Products Act, the Health Sciences Authority, with the approval of the Minister for Health, hereby makes the following Regulations:

PART I

PRELIMINARY

Citation and commencement

1. These Regulations may be cited as the Health Products (Medical Devices) Regulations 2010 and shall come into operation on 10th August 2010.

Definitions

2. In these Regulations, unless the context otherwise requires —

"active implantable medical device" means any active medical device that is intended by its product owner —

(*a*) to be introduced, either —

(i) by surgical or medical intervention, wholly or partially into the body of a human being; or

(ii) by medical intervention, into a body orifice; and

(*b*) to remain in place after the procedure;

"active medical device" means any medical device —

(*a*) the operation of which depends on a source of electrical energy or any source of power other than that directly generated by a human body or gravity; and

(*b*) which acts by converting that energy,

but does not include any medical device intended to transmit any energy, substance or other element between that medical device and a patient without any significant change to that energy, substance or element;

"Authority's website" means the Authority's Internet website at http://www.hsa.gov.sg as may be updated from time to time;

"body orifice" means any natural opening in a human body, the external surface of any eyeball, or any permanent artificial opening, such as a stoma or permanent tracheotomy;

"custom-made medical device" means a medical device that —

(*a*) is made at the request of a qualified practitioner and in accordance with the specifications of the qualified practitioner regarding the design characteristics or construction of the medical device;

(*b*) is intended to be used only in relation to a particular individual; and

(*c*) is not adapted from a mass-produced medical device;

"field safety corrective action" means any action taken to reduce the risk of death or serious deterioration in the state of health of a person associated with the use of a medical device, including —

(*a*) the return of the medical device to its product owner;

(*b*) the replacement or destruction of the medical device;

(*c*) any action regarding the use of the medical device that is taken in accordance with the advice of its product owner;

(*d*) the clinical management of any patient who has used the medical device;

(*e*) the modification of the medical device;

(*f*) the retrofitting of the medical device in accordance with any modification to it or any change to its design by its product owner;

(*g*) the making of any permanent or temporary change to the labelling or instructions for use of the medical device; or

(*h*) any upgrade to any software used with the medical device, including any such upgrade carried out by remote access;

"harm" means any physical injury or damage to the health of a person, or any damage to property or the environment;

"hazard" means any potential source of harm;

"implantable medical device" means any medical device which is intended by its product owner —

(*a*) to be wholly introduced into a human body, or to replace a human epithelial surface or the surface of a human eye, by surgical intervention, and to remain in place after the surgical intervention; or

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

and includes any such medical device that is wholly or partially absorbed by the human body, epithelial surface or eye;

"in vitro diagnostic product" —

(*a*) means any reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination with any other reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, that is intended by its product owner to be used *in vitro* for the examination of any specimen, including any blood or tissue donation, derived from the human body, solely or principally for the purpose of providing information —

(i) concerning a physiological or pathological state or a congenital abnormality;

(ii) to determine the safety and compatibility of any blood or tissue donation with a potential recipient thereof; or

(iii) to monitor therapeutic measures; and

(*b*) includes a specimen receptacle;

"intended use" or "intended purpose" , in relation to a medical device or its process or service, means the objective intended use or purpose, as the case may be, of the medical device, process or service, as reflected in the specifications, instructions and information provided by the product owner of the medical device;

"licensee" means a holder of any licence issued by the Authority under the Act;

"medical device" means a medical device referred to in the First Schedule to the Act;

"medicinal product" has the same meaning as in section 3 of the Medicines Act (Cap. 176);

"non-viable", in relation to a biological entity, means that the entity is incapable of growth, development and reproduction;

"objective evidence" means information that can be proved to be true, based on facts obtained through observation, measurement, testing or any other means;

"product owner", in relation to a health product, means a person who —

(*a*) supplies the health product under his own name, or under any trade mark, design, trade name or other name or mark owned or controlled by him; and

(*b*) is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the health product, or for assigning to it a purpose, whether those tasks are performed by him or on his behalf;

""professional use only" medical device" means a medical device that is to be used on an individual solely by, or under the supervision of, a qualified practitioner;

"qualified practitioner" means —

(*a*) a registered medical practitioner under the Medical Registration Act (Cap. 174), when acting in the course

of providing medical treatment to a patient under his care; or

(*b*) a registered dentist under the Dental Registration Act (Cap. 76) whose name appears in the first division of the Register of Dentists maintained and kept under section 13(1)(*a*) of that Act, when acting in the course of providing dental treatment to a patient under his care;

"refurbished medical device" means a medical device the whole or any part of which has been substantially rebuilt, re-equipped or restored, whether or not using parts from one or more used medical devices of that same kind, so as to create a medical device that can be used for the purpose originally intended by the product owner of the original medical device, and without prejudice to the generality of the foregoing, a refurbishment of a medical device may involve any or all of the following actions:

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

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

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

(*d*) assembling reclaimed or replacement component parts of the medical device or another medical device;

(*e*) testing the reassembled medical device against the specifications of the original medical device or, if the product owner of the original medical device has revised those specifications, the revised specifications;

(*f*) identifying the reassembled medical device as a refurbished medical device;

"registered midwife" has the same meaning as in section 2 of the Nurses and Midwives Act (Cap. 209);

"registered nurse" has the same meaning as in section 2 of the Nurses and Midwives Act;

"registered pharmacist" has the same meaning as in section 2 of the Pharmacists Registration Act (Cap. 230);

"risk" means a combination of the probability of occurrence of harm and the severity of that harm;

"serious deterioration in the state of health", in relation to a person, means —

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

(*b*) a permanent impairment of a bodily function of that person;

(*c*) any permanent damage to any part of that person's body; or

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

"specimen" means a discrete portion of a body fluid or tissue, or of any other sample associated with a human body, which is taken for —

(*a*) examination;

(*b*) study; or

(*c*) analysis of one or more quantities or characteristics, in order to determine the character of the whole;

"specimen receptacle" means any receptacle, whether vacuum-type or not, intended by its product owner to be used for the primary containment of any specimen derived from a human body;

"trade description" means any description, statement or indication which, directly or indirectly and by whatever means given, relates to any of the following matters in respect of a medical device:

(*a*) the quantity, length, width, height, area, volume, capacity or weight of the medical device;

(*b*) the method of manufacture, production, processing, modification, refurbishment or reconditioning of the medical device;

(*c*) the components or composition of the medical device;

(*d*) the fitness for purpose (including expiry date), strength, performance, behaviour or accuracy of the medical device;

(*e*) any physical or other characteristics of the medical device not referred to in paragraphs (*a*) to (*d*);

(*f*) the testing of the medical device by any person and the results thereof;

(*g*) the approval of the medical device by any person or its conformity with a description or class of medical devices approved by any person;

(*h*) the place or date of the manufacture, production, processing, modification, refurbishment or reconditioning of the medical device;

(i) the name of the person who manufactured, produced, processed, modified, refurbished or reconditioned the medical device;

(*j*) any other history, including any history of previous ownership or use, of the medical device.

PART II

MANUFACTURE AND IMPORT OF MEDICAL DEVICES WITHOUT LICENCE

Custom-made medical devices

3.—(1) A private hospital, medical clinic or healthcare establishment licensed under the Private Hospitals and Medical Clinics Act (Cap. 248) may manufacture a medical device without holding a manufacturer's licence under section 12(1) of the Act, if the

medical device is manufactured at the request of any qualified practitioner practising at the private hospital, medical clinic or healthcare establishment, for the use of any patient thereat.

(2) A private hospital, medical clinic or healthcare establishment referred to in paragraph (1) shall be subject to the duties and obligations of a manufacturer of a medical device under regulations 33(*a*), 38, 39, 41, 42 and 44 to 47.

Manufacture of medical devices by way of secondary assembly

4.—(1) A person may manufacture a medical device without holding a manufacturer's licence under section 12(1) of the Act, if the medical device is manufactured before 1st August 2011 solely by way of secondary assembly.

(2) A person referred to in paragraph (1) shall be subject to the duties and obligations of a manufacturer of a medical device under regulations 33(*a*), 38, 39, 41, 42 and 44 to 47.

(3) In this regulation —

"primary packaging", in relation to a medical device, means packaging that maintains the sterility or integrity of the medical device;

"secondary assembly" means the process of repackaging a medical device from its original packaging into another packaging, without any breach of the primary packaging, before the medical device is sold or supplied.

PART III

SUPPLY OF MEDICAL DEVICES

Division 1 — Wholesale supply

Wholesaling of self-manufactured medical devices

5. A licensed manufacturer who manufactures a medical device may supply that medical device by wholesale without holding a wholesaler's licence under section 14(1) of the Act.

Division 2 — Unregistered medical devices

Exception for custom-made medical devices

6. Without prejudice to any other provision in this Division, the prohibition in section 15(1) of the Act against the supply of an unregistered health product shall not apply to the supply of a custom-made medical device that is unregistered.

Exception for refurbished medical devices

7. Without prejudice to any other provision in this Division, the prohibition in section 15(1) of the Act against the supply of an unregistered health product shall not apply to the return, after refurbishment of a medical device, of the unregistered refurbished medical device to the private hospital, medical clinic, clinical laboratory or healthcare establishment licensed under the Private Hospitals and Medical Clinics Act (Cap. 248) which owns the medical device.

Exception for medical devices for patients' use

8. Without prejudice to any other provision in this Division, the prohibition in section 15(1) of the Act against the supply of an unregistered health product shall not apply to the supply of an unregistered medical device by or on behalf of, or procured by or on behalf of —

(*a*) a qualified practitioner for the use of a patient of that qualified practitioner; or

(*b*) a private hospital, medical clinic or clinical laboratory licensed under the Private Hospitals and Medical Clinics Act (Cap. 248) for the use of a patient of that private hospital, medical clinic or clinical laboratory,

if the Authority has granted an importer's licence or a wholesaler's licence in respect of the medical device for such use.

Exception for export or re-export

9. Without prejudice to any other provision in this Division, the prohibition in section 15(1) of the Act against the supply of an

unregistered health product shall not apply to the supply of a medical device that is manufactured solely for export or that is imported solely for re-export, if the Authority has granted an importer's licence or a wholesaler's licence in respect of the medical device for the purpose of export or re-export only.

Exception for non-clinical use

10.—(1) Without prejudice to any other provision in this Division, the prohibition in section 15(1) of the Act against the supply of an unregistered health product shall not apply to the supply of a medical device that is imported, supplied or used for a non-clinical purpose, if the Authority has granted an importer's licence or a wholesaler's licence in respect of the medical device for such purpose.

(2) In paragraph (1), "non-clinical purpose" means any purpose other than a purpose described in the second column of item 1 of the First Schedule to the Act.

Exception for certain Class A medical devices

10A. Without prejudice to any other provision in this Division, the prohibition in section 15(1) of the Act against the supply of an unregistered health product shall not apply to the supply of a Class A medical device —

(*a*) which is listed in the first column of the Sixth Schedule;

(*b*) which is not of or does not bear a description or an intended purpose which is substantially different from the description or intended purpose described in the second column of that Schedule; and

(*c*) which is not intended to be supplied in a sterile state.

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Exceptions for phased implementation of prohibition

11.—(1) Without prejudice to any other provision in this Division, the prohibition in section 15(1) of the Act against the supply of an unregistered health product shall not apply to —

(*a*) the supply no later than 31st December 2011 of an unregistered Class A or B medical device —

(i) which is not an implantable medical device;

(ii) which is not, or cannot be, licensed as a medicinal product under the Medicines Act (Cap. 176) before 10th August 2010; and

(iii) in respect of which the Authority does not at any time receive any information concerning, and does not at any time become aware of, any defect or adverse effect under section 42(2) of the Act;

(*b*) the supply on or after 1st January 2012 of an unregistered Class A or B medical device —

(i) which is listed on the Class A or B Medical Device Transition List as published on the Authority's website on or before 1st January 2012;

(ii) which qualifies for evaluation under an abridged evaluation process referred to in regulation 26;

(iii) which is not, or cannot be, licensed as a medicinal product under the Medicines Act (Cap. 176) before 10th August 2010;

(iv) which complies with the First Schedule;

(v) in respect of which the Authority does not at any time receive any information concerning, and does not at any time become aware of, any defect or adverse effect under section 42(2) of the Act; and

(vi) in respect of which the Authority receives, before 1st December 2011, and does not at any time reject, an application for registration as a Class A or B medical device;

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(*c*) the supply no later than 31st July 2011 of an unregistered Class C or D medical device —

(i) which is not an implantable medical device; and

(ii) in respect of which a licence to deal with the medical device has been granted under section 5 or 6 of the Radiation Protection Act (Cap. 262) and has not expired;

(*d*) the supply at any time of an unregistered Class C or D medical device —

(i) which is listed on the Class C or D Medical Device Transition List as published on the Authority's website on or before 10th August 2010;

(ii) which qualifies for evaluation under an abridged evaluation process referred to in regulation 26;

(iii) which, if it is an implantable medical device, has been approved, before 1st January 2011, by at least 2 competent regulatory agencies referred to in regulation 26;

(iv) which complies with the First Schedule;

(v) in respect of which the Authority does not at any time receive any information concerning, and does not at any time become aware of, any defect or adverse effect under section 42(2) of the Act; and

(vi) in respect of which the Authority receives, and does not at any time reject, an application for registration as a Class C or D medical device;

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(*e*) the retail supply, at any time, by a retail supplier of an unregistered medical device that the retail supplier has taken possession of before 10th August 2010; and

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(*f*) the retail supply, at any time, by a retail supplier of an unregistered Class A or B medical device that the retail supplier has taken possession of on or after 10th August 2010 but before 5th April 2012.

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(2) For the purposes of paragraph (1), a medical device shall be treated as assigned to a particular class of medical devices, if it would

have been assigned to that class according to regulation 24 had the medical device been registered.

Division 3 — Requirements for supply

Testing of registered medical devices before supply

12.—(1) For the purposes of section 17(1) of the Act, the supply of any registered medical device taken from a lot or consignment of such registered medical devices shall be carried out only after the following requirements are complied with:

(*a*) 2 samples (or more if required by the Authority) of the registered medical devices taken from that lot or consignment at each periodic taking of samples therefrom have been tested or analysed in accordance with the requirements specified by the Authority for registering that medical device;

(*b*) the results and protocol of any test or analysis have been provided to the Authority; and

(*c*) the Authority is satisfied from the results and protocol that a registered medical device from that lot or consignment meets or continues to meet the requisite standards of quality, safety and efficacy.

(2) For the purposes of paragraph (1)(*c*), a registered medical device found in the same lot or consignment from which the samples are taken under paragraph (1)(*a*) shall be presumed to possess the same properties as the samples.

Supply of "professional use only" medical devices

13. For the purposes of section 17(1) of the Act —

(*a*) no licensed wholesaler of medical devices shall supply any registered "professional use only" medical device to any person who intends to supply that medical device to others unless that person is —

(i) also a licensed wholesaler of medical devices; or

(ii) a qualified practitioner; and

(*b*) no person shall supply, by way of administration or application to any other person, any registered "professional use only" medical device, unless the person administering or applying the medical device is, or acts under the supervision of, a qualified practitioner.

PART IV

PRESENTATION OF MEDICAL DEVICES

Trade descriptions

14.—(1) For the purposes of section 18(1) of the Act, the presentation of a medical device shall comply with the following requirements:

(*a*) no trade description which is false or misleading, or which explicitly or implicitly suggests that the supply or use of the medical device is promoted or endorsed by the Authority, shall be applied to the medical device; and

(*b*) no change or modification made, or caused to be made, to the presentation of the medical device, for the purpose of promoting or demonstrating the use of the medical device, shall cause the medical device to depart from its product owner's specifications in relation to its intended purpose, design, components and method of installation or operation.

(2) For the purposes of paragraph (1)(*a*) —

(*a*) a trade description is false or misleading, if it —

(i) contains any false statement or information concerning the medical device; or

(ii) is likely to create an erroneous impression regarding the formulation, composition, design specification, quality, safety, efficacy or uses of the medical device; and

(*b*) a person applies a trade description to a medical device, if he —

(i) affixes or annexes the trade description to, or in any manner marks it on or incorporates it in —

(A) the medical device; or

(B) any thing in or on the medical device or with which the medical device is supplied;

(ii) places the medical device in, on or with any thing which the trade description has been affixed or annexed to, marked on or incorporated in; or

(iii) makes any oral or written statement of the trade description, or uses the trade description in any other manner, which is likely to be understood as referring to the medical device.

(3) Where a medical device is supplied pursuant to a request in which a trade description is used, and it is reasonable in the circumstances to infer that any medical device so supplied will correspond to that trade description, the person supplying the medical device shall be deemed to have applied that trade description to the medical device.

Information to be provided with medical devices

15.—(1) For the purposes of section 18(1) of the Act, no person shall supply any medical device unless the following information accompanies the medical device when it is supplied:

(*a*) the trade or brand name of the medical device;

(*b*) if the medical device is not manufactured in Singapore, the name, address and contact particulars of the importer of the medical device;

(*c*) where the medical device is supplied for use in any investigational testing —

(i) the statement "Investigational Device", or any other statement in English that conveys that meaning;

(ii) the statement "To Be Used by Qualified Investigators Only", or any other statement in English that conveys that meaning; and

(iii) in the case of an *in vitro* diagnostic product, the statement "The performance specifications of this device have not been established", or any other statement in English that conveys that meaning;

(*d*) where the medical device is contained in a package and the contents of the package are not readily apparent, an indication of what the package contains, expressed in terms appropriate to the medical device, such as the size, net weight, length, volume or number of units;

(*e*) the expiry date of the medical device, if the medical device has one, as determined by the product owner of the medical device on the basis of the component of the medical device that has the shortest projected useful life; and

(*f*) the information referred to in paragraphs 42, 44 and 45 of the First Schedule.

(2) The information referred to in paragraph (1) shall be provided in the manner specified in paragraph 43 of the First Schedule.

General provisions as to labelling

16.—(1) The Authority may stipulate —

(*a*) under section 24(5) of the Act, in the conditions attached to a licence in respect of a medical device; or

(*b*) under section 32 of the Act, in the conditions attached to the registration of a medical device,

a requirement to use a label, sticker or packaging insert or any other means for presenting any information accompanying the medical device.

(2) All information on the label of a medical device shall be provided in English, and may, in addition, be provided in any other language.

(3) All numbers, letters and symbols used to provide any information on the label of a medical device shall be legible, permanent and prominent in colour, size and positioning.

(4) If a symbol or code (whether in the form of a colour or otherwise) is used to provide any information on the label of a medical device, an explanation of the symbol or code shall be provided.

Substantiation of assertions of uniqueness and prominence in presentations

17.—(1) For the purposes of section 18(1) of the Act, where the presentation of a medical device includes any trade description containing any statement, assertion, certification, award or feature of uniqueness or prominence differentiating the medical device from any other competing or similar medical device, the statement, assertion, certification, award or feature must be substantiated by facts or evidence.

(2) For the purposes of paragraph (1), the facts or evidence required for substantiation include —

(*a*) in relation to a certification or an award, the identity of the certifying or awarding body and the date the certification or award was granted; and

(*b*) in relation to any claim of historical precedence in the use or administration of the medical device for the purpose of medical treatment, information on the outcome of that use or administration of the medical device.

Corrective measures in relation to contravening trade descriptions

18.—(1) Where any manufacturer, importer, supplier or registrant of a medical device has applied a trade description in contravention of regulation 14 or 17, the Authority may order that manufacturer, importer, supplier or registrant, as the case may be, to do any or all of the following at the manufacturer's, importer's, supplier's or registrant's own cost:

(*a*) to stop the trade description with immediate effect;

(*b*) to take such measures as may be reasonable and necessary in the circumstances to discontinue or remove any trade description that may already have been disseminated, used or published;

(*c*) to disseminate, apply or publish a corrective trade description in such manner and containing such information as the Authority may require.

(2) If a person to whom an order under paragraph (1) is directed fails to comply with the order —

(*a*) he shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both; and

(*b*) the Authority may take such steps as it thinks reasonable and necessary to implement the requirements of the order, and recover any costs and expenses reasonably incurred by it in so doing from that person.

PART V

ADVERTISEMENT OF MEDICAL DEVICES

Advertisement of medical device

19. For the purposes of section 21(1) of the Act, an advertisement of any medical device shall comply with the following requirements:

(*a*) if the medical device is intended for direct delivery to the general public or for direct use by the general public, the advertisement shall not contain any statement concerning the intended use and efficacy of the medical device, unless —

(i) such statement has been verified by objective evidence; and

(ii) such objective evidence has been furnished to the Authority at the time the application to register the medical device was made; and

(*b*) an advertisement of a medical device —

(i) may, in the case of a registered medical device, include —

(A) a statement to the effect that the medical device is registered under the Act; and

(B) the registration number assigned to the medical device by the Authority; but

(ii) shall not contain any statement which expressly or implicitly suggests that the use of the medical device is promoted or endorsed by the Authority.

Substantiation of assertions of uniqueness and prominence in advertisements

20.—(1) For the purposes of section 21(1) of the Act and without prejudice to regulation 19, where the advertisement of a medical device contains any statement, assertion, certification, award or feature of uniqueness or prominence differentiating the medical device from any other competing or similar medical device, the statement, assertion, certification, award or feature must be substantiated by facts or evidence.

(2) For the purposes of paragraph (1), the facts or evidence required for substantiation include —

(*a*) in relation to a certification or an award, the identity of the certifying or awarding body and the date the certification or award was granted; and

(*b*) in relation to any claim of historical precedence in the use or administration of the medical device for the purpose of medical treatment, information on the outcome of that use or administration of the medical device.

(3) Any facts or evidence referred to in paragraph (2)(*a*) must be indicated on the face of the advertisement.

Advertisement of "professional use only" medical devices

21. For the purposes of section 21(1) of the Act and without prejudice to regulation 19, no person shall advertise any registered "professional use only" medical device, unless the advertisement is distributed only to, or is contained in a publication intended for circulation mainly among, qualified practitioners.

Restriction on advertisements promoting medical devices for specified diseases and conditions

22. For the purposes of section 21(1) of the Act and without prejudice to regulation 19, an advertisement relating to a medical device shall not expressly or implicitly claim, indicate or suggest that the medical device will prevent, alleviate or cure any disease or condition specified in the Second Schedule, unless the advertisement is distributed only to, or is contained in a publication intended for circulation mainly among, one or more of the following classes of persons:

(*a*) qualified practitioners;

(*b*) registered pharmacists;

(*c*) registered nurses and registered midwives;

(*d*) persons undergoing training with a view to becoming qualified practitioners, registered pharmacists, registered nurses or registered midwives.

Power of Authority to require copies of advertisements

23. For the purposes of section 41(1) of the Act, the Authority may require the manufacturer, importer, supplier or registrant of a medical device to furnish to the Authority, within such time as may be specified in the notice, such number of copies, as may be specified in the notice, of any advertisement relating to any medical device which the manufacturer, importer, supplier or registrant has issued, or has caused to be issued, within the period of 12 months immediately preceding the date the notice is served.

PART VI

REGISTRATION OF MEDICAL DEVICES

Assignment of medical devices into classes

24.—(1) For the purposes of section 29(2)(*a*) of the Act, the classes of medical devices shall be as specified in the Third Schedule.

(2) For the purposes of assigning a medical device into a class of medical devices under section 29(2)(*b*) of the Act, the following principles shall apply:

(*a*) the Authority shall have regard to the intended purpose of the medical device;

(*b*) if the medical device may be assigned into 2 or more classes of medical devices, the Authority shall assign the medical device into such of those classes as represents the highest health risk posed to an end-user of the medical device;

(*c*) if the medical device is designed to be used in combination with another medical device, each of the medical devices shall be classified separately;

(*d*) if the medical device has 2 or more intended purposes, the medical device shall, subject to sub-paragraph (*b*), be assigned into a class of medical devices having regard to the most critical intended purpose of the medical device.

Requirements for registration of medical device

25. For the purposes of section 30(2)(*a*)(iii) of the Act, the prescribed requirements for the registration of a medical device are as follows:

(*a*) the medical device is safe to use;

(*b*) the medical device is of suitable quality, having regard to —

(i) the specifications of the medical device;

(ii) the method of its manufacture; and

(iii) the measures proposed for ensuring that the medical device, whenever supplied, will be of that quality; and

(*c*) the medical device is effective for its intended purpose.

Abridged evaluation process

26.—(1) For the purposes of section 33 of the Act, the Authority may, upon an application for the registration of a medical device, evaluate the medical device under an abridged evaluation process, if —

(*a*) any competent regulatory agency of a foreign jurisdiction has granted approval for the supply of the medical device in that jurisdiction; and

(*b*) the approval by the competent regulatory agency is of a type accepted by the Authority and identified on the Authority's website at the time of the application for the registration of the medical device.

(2) A medical device which does not qualify for evaluation under an abridged evaluation process referred to in paragraph (1) shall be evaluated under a full evaluation process.

(3) In paragraph (1), "competent regulatory agency" means any body or organisation which —

(*a*) exercises a legal right to control the use or sale of medical devices within a country or territory outside Singapore;

(*b*) may take enforcement action to ensure that medical devices advertised or supplied within that country or territory outside Singapore comply with the legal requirements applicable in that country or territory outside Singapore; and

(*c*) is recognised by the Authority and identified on the Authority's website at the time of the application for the registration of the medical device.

PART VII

CERTIFICATES

Certificates of origin for medical devices

27.—(1) The Authority may, on the application of a manufacturer of a medical device manufactured in Singapore, issue to the manufacturer a certificate of origin certifying that the medical device is manufactured in Singapore.

(2) Where the Authority has registered a medical device which is manufactured in Singapore, the Authority may, on the application of the manufacturer or registrant of the medical device, issue to the manufacturer or registrant a certificate of origin certifying that the

medical device is manufactured in Singapore and registered under the Act.

(3) An application for a certificate under paragraph (1) or (2) shall —

(*a*) be made in such form and manner as the Authority may specify on the Authority's website; and

(*b*) be accompanied by the relevant fee specified in the Fourth Schedule.

Certificates of issue of licences

28. Where the Authority has issued a licence in respect of a medical device, the Authority may, at the licensee's request and upon receiving the relevant fee prescribed in the Fourth Schedule, issue a certificate (including a certificate in an electronic form) confirming that the licence has been issued.

Certificates of registration and certificates of free sale

29.—(1) Where the Authority has registered a medical device, the Authority shall issue to the registrant of the medical device a certificate of registration in such form as the Authority may determine (including a certificate in an electronic form).

(2) The Authority may, at the registrant's request and upon receiving the relevant fee prescribed in the Fourth Schedule, issue to the registrant a hardcopy of the certificate of registration.

(3) Where the Authority has registered a medical device the product owner of which is a company registered under the Companies Act (Cap. 50), the Authority may, on the application of the product owner or registrant of the medical device, issue to the product owner or registrant a certificate of free sale, certifying that the medical device is registered under the Act and that it may be supplied in Singapore without any restrictions.

(4) An application for a certificate under paragraph (3) shall —

(*a*) be made in such form and manner as the Authority may specify on the Authority's website; and

(*b*) be accompanied by the relevant fee specified in the Fourth Schedule.

Certification of medical devices intended for export

30.—(1) The Authority may, on the application of a person who intends to export a medical device and upon receiving the relevant fee prescribed in the Fourth Schedule, issue to the person a certificate certifying —

(*a*) in a case where the medical device is registered under the Act, that it is so registered; or

(*b*) in a case where the medical device is not so registered, that it complies with such standards or requirements as may be specified in the certificate.

(2) An application for a certificate under paragraph (1) shall be made in such form and manner as the Authority may specify on the Authority's website.

PART VIII

DUTIES AND OBLIGATIONS OF MANUFACTURERS, IMPORTERS, ETC., OF MEDICAL DEVICES

Duty of licensees, suppliers and registrants to comply with enforcement orders

31.—(1) A licensee, supplier or registrant of a medical device shall, if required by the Authority or an enforcement officer —

(*a*) produce his licence or certificate of registration, or such other document as the Authority or enforcement officer may specify for ensuring compliance with the Act, to the Authority or enforcement officer for inspection;

(*b*) furnish the Authority or enforcement officer with such information as the Authority or enforcement officer may require for ensuring compliance with the Act; and

(*c*) attend at such place as the Authority or enforcement officer may specify to produce that licence, certificate or other document or furnish that information.

(2) An enforcement officer may conduct routine inspections of —

(*a*) any premises that are being used for the manufacture, supply or storage of medical devices; and

(*b*) any conveyances that are being used for the transport of medical devices.

(3) An enforcement officer conducting an inspection under paragraph (2) may, without payment, take for testing, examination or analysis a sample of any medical device that is found pursuant to the inspection.

(4) A licensee, supplier or registrant of a medical device whose premises are being used for the manufacture, supply or storage of medical devices, or whose conveyances are being used for the transport of medical devices, shall allow an enforcement officer —

(*a*) to conduct routine inspections of those premises or conveyances; and

(*b*) to take, without payment, for testing, examination or analysis a sample of any medical device that is found pursuant to the inspection.

(5) Any person who contravenes paragraph (1) or (4) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

Duty to comply with conditions of licence or registration

32.—(1) A manufacturer, importer, supplier or registrant of any medical device shall comply with such conditions, for the grant to the manufacturer, importer, supplier or registrant of any licence in respect of that medical device, or for the registration of that medical device, as the Authority may impose.

(2) Any person who contravenes paragraph (1) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

(3) Without prejudice to paragraph (2), the Authority may suspend or cancel the licence or registration, as the case may be, which the Authority has granted to a person, if that person contravenes paragraph (1).

Duty of manufacturer

33. A manufacturer of a medical device —

(*a*) shall ensure, and maintain objective evidence to establish, that the medical device complies with the First Schedule;

(*b*) if he holds a manufacturer's licence in respect of the medical device —

(i) shall provide and maintain such staff, premises and equipment or facilities as are necessary for carrying out, in accordance with his licence, such stages of the manufacture of the medical device as are undertaken by him;

(ii) shall not carry out any such stages of manufacture referred to in sub-paragraph (i) in any premises other than the premises specified in his licence;

(iii) shall provide and maintain such staff, premises, equipment and facilities for the handling, storage and distribution of the medical device as are necessary to prevent the deterioration of the medical device;

(iv) shall not use, for any purpose specified in sub-paragraph (iii), any premises other than the premises specified in his licence, or such other premises as may be approved from time to time by the Authority; and

(v) shall arrange for a testing laboratory approved by the Authority to carry out tests to ensure the safety, quality and performance of the medical device, and that the medical device complies with any standard set by the Authority for the medical device; and

(*c*) shall conduct all manufacturing operations in such a way as to ensure that the medical device is not wrongly labelled as another type of medical device.

Duty of importer

34. An importer of a medical device —

(*a*) shall ensure, and maintain objective evidence to establish, that the medical device complies with the First Schedule;

(*b*) if he is the holder of an importer's licence —

(i) shall provide and maintain such staff, premises, equipment and facilities for the handling and storage of the medical device as are necessary to prevent the deterioration of the medical device; and

(ii) shall not use, for any purpose specified in sub-paragraph (i), any premises other than the premises specified in his licence, or such other premises as may be approved from time to time by the Authority; and

(*c*) shall import only medical devices that are authorised to be imported by the registrant of the medical device or any other person approved by the Authority.

Duty of wholesaler to maintain premises and supply lawfully

35. A wholesaler of a medical device —

(*a*) shall only supply the medical device by wholesale to a person who may lawfully supply such medical devices in accordance with the Act and these Regulations; and

(*b*) if he is the holder of a wholesaler's licence —

(i) shall provide and maintain such staff, premises, equipment and facilities for the handling and storage of the medical device as are necessary to prevent the deterioration of the medical device; and

(ii) shall not use, for any purpose specified in sub-paragraph (i), any premises other than the

premises specified in his licence, or such other premises as may be approved from time to time by the Authority.

Duty of registrant to ensure compliance with First Schedule

36. A registrant of a medical device shall ensure, and maintain objective evidence to establish, that the medical device complies with the First Schedule.

Offence for contravention of duties

37. Any person who contravenes regulation 33, 34, 35 or 36 shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

Duty to maintain records of manufacture

38.—(1) A manufacturer of a medical device shall maintain records of —

(*a*) such information relating to the medical device and its manufacture or assembly as the Authority may specify; and

(*b*) the manufacture of each batch of the medical device and of the tests carried out thereon, in such manner as the Authority may specify.

(2) The manufacturer shall maintain the records referred to in paragraph (1) for the longer of the following periods:

(*a*) the projected useful life of the medical device; or

(*b*) 2 years after the date on which the medical device is supplied to another person.

(3) Any person who contravenes paragraph (1) or (2) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $10,000 or to imprisonment for a term not exceeding 6 months or to both.

(4) Any person who, in compliance or purported compliance with paragraph (1), furnishes the Authority or an enforcement officer with any record which he knows is false or misleading shall be guilty of an

offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

Duty to maintain records of supply

39.—(1) Every person who —

(*a*) is a manufacturer, an importer, a wholesaler or a registrant of a medical device;

(*b*) supplies a custom-made medical device referred to in regulation 6;

(*c*) supplies a refurbished medical device referred to in regulation 7; or

(*d*) supplies an unregistered medical device in accordance with regulation 8, 9, 10 or 11,

shall —

(i) maintain a record of every supply by him of the medical device; and

(ii) produce such record for inspection by the Authority or an enforcement officer as and when required by the Authority or enforcement officer.

(2) A person referred to in paragraph (1) shall ensure that every record referred to in that paragraph —

(*a*) contains, in relation to each supply by him of the medical device, the following information:

(i) the proprietary name or description of the medical device;

(ii) the date on which the medical device was supplied;

(iii) the name and address of the person to whom the medical device was supplied;

(iv) the quantity of the medical device supplied; and

(v) the identification number or mark (including the control number, lot number, batch number or serial number) of the medical device supplied; and

(*b*) is retained for the longer of the following periods:

(i) the projected useful life of the medical device; or

(ii) 2 years after the date on which the medical device is supplied to another person.

(3) Any person who contravenes paragraph (1) or (2) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $10,000 or to imprisonment for a term not exceeding 6 months or to both.

(4) Any person who, in compliance or purported compliance with paragraph (1), furnishes the Authority or an enforcement officer with any record which he knows is false or misleading shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

Qualified practitioners to maintain records of implantable medical devices

40.—(1) A qualified practitioner who has introduced into the body of a person an implantable medical device listed in the Fifth Schedule shall maintain proper records of the following matters:

(*a*) the name, address and national registration identity card number (if any) of that person;

(*b*) the date on which the implantable medical device was introduced into the body of that person;

(*c*) the name and description of the implantable medical device; and

(*d*) the lot or batch number of the implantable medical device.

(2) Any person who contravenes paragraph (1) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $10,000 or to imprisonment for a term not exceeding 6 months or to both.

(3) Any person who in compliance or purported compliance with paragraph (1) —

(*a*) wilfully makes, or causes to be made, a false entry in any record required to be maintained under that paragraph; or

(*b*) wilfully omits to make an entry required to be made by him in any such record,

shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

Duty to maintain records of complaints

41.—(1) Every person who —

(*a*) is a manufacturer, an importer, a supplier or a registrant of a medical device;

(*b*) supplies a custom-made medical device referred to in regulation 6;

(*c*) supplies a refurbished medical device referred to in regulation 7; or

(*d*) supplies an unregistered medical device in accordance with regulation 8, 9, 10 or 11,

shall —

(i) maintain a record of every complaint received by him pertaining to the medical device; and

(ii) produce such record for inspection by the Authority or an enforcement officer as and when required by the Authority or enforcement officer.

(2) A person referred to in paragraph (1) shall ensure that every record referred to in that paragraph —

(*a*) contains the following information:

(i) the proprietary name or description of the medical device that is the subject of the complaint;

(ii) the date on which the complaint was received;

(iii) the name and address of the complainant or, if unavailable, a unique identifier for the complaint;

(iv) the identification number or mark (including the control number, lot number, batch number or serial number) of the medical device; and

(v) the nature of the problem that is the subject of the complaint; and

(*b*) is retained for at least 5 years after the expiry of the projected useful life of the medical device.

(3) Any person who contravenes paragraph (1) or (2) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $10,000 or to imprisonment for a term not exceeding 6 months or to both.

(4) Any person who, in compliance or purported compliance with paragraph (1), furnishes the Authority or an enforcement officer with any record which he knows is false or misleading shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

Reporting of defects and adverse effects

42.—(1) For the purposes of section 42(1) of the Act, every manufacturer, importer, supplier or registrant of a medical device, whether registered or unregistered, shall, upon becoming aware of any defect in the medical device or any adverse effect that has arisen from the use thereof, inform the Authority of the defect or adverse effect within the following time delimited after the manufacturer, importer, supplier or registrant first becomes aware of the defect or adverse effect:

(*a*) within 48 hours, if the information relates to any defect or adverse effect that represents a serious threat to public health;

(*b*) within 10 days, if the information relates to an incident that has led to the death, or a serious deterioration in the state of health, of a patient, a user of the medical device or any other person; and

(*c*) within 30 days, if the information relates to an incident a recurrence of which might lead to the death, or a serious deterioration in the state of health, of a patient, a user of the medical device or any other person.

(2) For the purposes of paragraph (1)(*a*), a defect in, or an adverse effect that has arisen from the use of, a medical device, represents a serious threat to public health if —

(*a*) it is a hazard arising from a systematic failure of the medical device that the manufacturer, importer, wholesaler or registrant of the medical device has become aware of;

(*b*) it may lead to the death of, or a serious injury to, any person;

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

(*d*) it is necessary for the manufacturer or product owner of the medical device to take prompt action (including the recall of the medical device) to eliminate, or reduce the risk of, the hazard.

Reporting of information adversely affecting quality, safety or efficacy of medical device

43.—(1) Every licensee or registrant of a medical device shall, within 15 days after receiving any information which adversely affects the validity of any data furnished by him to the Authority relating to the quality, safety or efficacy of any medical device to which his licence or registration relates, inform the Authority of such information.

(2) Any person who contravenes paragraph (1) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $10,000 or to imprisonment for a term not exceeding 6 months or to both.

(3) Any person who, in compliance or purported compliance with paragraph (1), furnishes the Authority with any information which he knows is false or misleading shall be guilty of an offence and shall be

liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

Notification to Authority concerning recall

44.—(1) For the purposes of section 44(1) of the Act, every manufacturer, importer, supplier or registrant of a medical device who intends to recall the medical device shall notify the Authority of the intended recall at least 24 hours before the time of the intended recall.

(2) The notification referred to in paragraph (1) shall be made in such form and manner as the Authority may require.

(3) Where the Authority has been notified of the intended recall of a medical device under paragraph (1), the Authority may by notice in writing require the manufacturer, importer, supplier or registrant of the medical device to do either or both of the following:

(*a*) inspect the medical device and provide a report of the findings of the inspection;

(*b*) take such other measures as the Authority thinks necessary.

(4) Any person who fails to comply with a notice given to him by the Authority under paragraph (3) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $10,000 or to imprisonment for a term not exceeding 6 months or to both.

Duty to furnish report on recall

45.—(1) Every manufacturer, importer, supplier or registrant of a medical device shall —

(*a*) within 24 hours beginning at the time of the commencement of the recall of the medical device, furnish to the Authority a preliminary report stating the reasons for the recall; and

(*b*) within 21 days after the date of the commencement of the recall or such longer period as the Authority may allow in the particular case, furnish to the Authority a final report on the recall.

(2) The preliminary report and final report referred to in paragraph (1) shall be made in such form and manner, and shall

contain such information relating to the recall, as the Authority may require.

(3) Any person who contravenes paragraph (1) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $10,000 or to imprisonment for a term not exceeding 6 months or to both.

(4) Any person who, in compliance or purported compliance with paragraph (1), furnishes the Authority with any report which he knows is false or misleading shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

Notification to Authority concerning field safety corrective action

46.—(1) Every manufacturer, importer, supplier or registrant of a medical device shall, before carrying out any field safety corrective action in relation to a medical device, notify the Authority of the intended field safety corrective action.

(2) The notification referred to in paragraph (1) shall be made in such form and manner as the Authority may require.

(3) Where the Authority has been notified of any intended field safety corrective action in relation to a medical device under paragraph (1), the Authority may, by notice in writing, require the manufacturer, importer, supplier or registrant of the medical device to do either or both of the following:

(*a*) issue or cause to be issued, to such persons as the Authority may specify or to the general public, a statement informing them of the field safety corrective action;

(*b*) take such other measures as the Authority thinks necessary.

(4) Any person who contravenes paragraph (1) or fails to comply with a notice given to him by the Authority under paragraph (3) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $10,000 or to imprisonment for a term not exceeding 6 months or to both.

(5) Any person who, in compliance or purported compliance with paragraph (1), furnishes the Authority with any notification which he knows is false or misleading shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

Duty to furnish report on field safety corrective action

47.—(1) Every manufacturer, importer, supplier or registrant of a medical device shall —

(*a*) within 24 hours beginning at the time of the commencement of any field safety corrective action in relation to a medical device, furnish to the Authority a preliminary report stating the reasons for the field safety corrective action; and

(*b*) within 21 days after the date of the commencement of the field safety corrective action or such longer period as the Authority may allow, furnish to the Authority a final report on the field safety corrective action.

(2) The preliminary report and final report referred to in paragraph (1) shall be made in such form and manner, and shall contain such information relating to the field safety corrective action, as the Authority may require.

(3) Any person who contravenes paragraph (1) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $10,000 or to imprisonment for a term not exceeding 6 months or to both.

(4) Any person who, in compliance or purported compliance with paragraph (1), furnishes the Authority with any report which he knows is false or misleading shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

Changes affecting licence

48.—(1) Every licensee shall notify the Authority of —

(*a*) any change or proposed change to any particulars furnished by him to the Authority in relation to his application for his licence; and

(*b*) any change or proposed change that significantly affects the activities of the licensee that are authorised by his licence.

(2) A notification under paragraph (1) shall —

(*a*) be made in such form and manner as the Authority may require;

(*b*) be submitted within such time as the Authority may specify in the conditions of the licence;

(*c*) be accompanied by such particulars, information, documents and samples as the Authority may require;

(*d*) be accompanied by the relevant notification fee specified in the Fourth Schedule; and

(*e*) if required by the Authority, be accompanied by a statutory declaration by the licensee verifying any information contained in or relating to the notification.

(3) A licensee shall not, without the approval of the Authority, make any change that significantly affects the activities of the licensee that are authorised by his licence.

(4) An application for the Authority's approval under paragraph (3) shall be made in such form and manner as the Authority may specify on the Authority's website.

(5) For the purposes of paragraphs (1) and (3), a change that significantly affects the activities of a licensee that are authorised by his licence includes (but is not limited to) a change of one or more of the following:

(*a*) the premises where the licensee operates;

(*b*) the facilities and equipment used by the licensee;

(*c*) the operations and processes carried out by the licensee;

(*d*) the personnel responsible for supervising the operations and processes carried out by the licensee.

(6) Any licensee who contravenes paragraph (1) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $10,000 or to imprisonment for a term not exceeding 6 months or to both.

(7) Any licensee who —

(*a*) in compliance or purported compliance with paragraph (1), furnishes the Authority with any notification under paragraph (1) which he knows is false or misleading; or

(*b*) contravenes paragraph (3),

shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

Changes concerning registered medical device

49.—(1) The registrant of a registered medical device shall notify the Authority of —

(*a*) any change or proposed change to any particulars provided in relation to the registration of the medical device; and

(*b*) any change or proposed change that may affect the safety, quality or efficacy of the medical device.

(2) A notification under paragraph (1) shall —

(*a*) be made in such form and manner as the Authority may require;

(*b*) be submitted within such time as the Authority may specify in the conditions of the registration of the medical device;

(*c*) be accompanied by such particulars, information, documents and samples as the Authority may require;

(*d*) be accompanied by the relevant notification fee specified in the Fourth Schedule; and

(*e*) if required by the Authority, be accompanied by a statutory declaration by the registrant verifying any information contained in or relating to the notification.

(3) Where any change made to a registered medical device may affect the safety, quality or efficacy of the medical device, the registrant of the medical device shall ensure that the medical device is not supplied until after the Authority has given its approval for the change.

(4) An application for the Authority's approval under paragraph (3) shall be made in such form and manner as the Authority may specify on the Authority's website.

(5) Any registrant of a registered medical device who contravenes paragraph (1) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $10,000 or to imprisonment for a term not exceeding 6 months or to both.

(6) Any registrant of a registered medical device who —

(*a*) in compliance or purported compliance with paragraph (1), furnishes the Authority with any notification under paragraph (1) which he knows is false or misleading; or

(*b*) contravenes paragraph (3),

shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

PART IX

FEES

Applicable fees

50.—(1) The fee payable in respect of a matter specified in the first column of the Fourth Schedule shall be the corresponding fee specified in the second column of that Schedule.

(2) A fee for an application referred to in the Fourth Schedule shall be paid when the application is submitted to the Authority.

(3) For the purposes of section 31(*a*) of the Act, the retention fee for the retention of the registration of a medical device shall be payable on or before each anniversary of the date of registration of the medical device.

PART X

MISCELLANEOUS

51. [*Deleted by S 542/2011 wef 03/10/2011]*

Revocation

52. The Health Products (Medical Devices) Regulations 2007 (G.N. No. S 563/2007) are revoked.

Savings and transitional provision

53. Notwithstanding regulation 52, anything done under any provision of the revoked Health Products (Medical Devices) Regulations 2007 shall continue to have effect as from 10th August 2010 as if it had been done under the corresponding provision of these Regulations.

FIRST SCHEDULE

Regulations 11(1), 15, 33, 34 and 36

SAFETY AND PERFORMANCE REQUIREMENTS FOR MEDICAL DEVICES

PART I

PRELIMINARY

Definitions

1. In this Schedule —

"clinical investigation" means any designed and planned systematic study undertaken on human subjects to verify the safety or performance of a specific medical device;

"medical device for self-testing or self-administration" means any medical device intended by its product owner to be used in a non-clinical environment;

FIRST SCHEDULE — *continued*

"single fault condition" means a condition in which a medical device fails, but the backup feature for protection against fault in the medical device does not fail;

"transmissible agent" means any agent capable of being transmitted to a person as a communicable disease, an infectious disease or a contagious disease.

PART II

GENERAL REQUIREMENTS

Use of medical devices not to compromise health and safety

2. A medical device shall be designed and produced in a way that ensures that —

(*a*) the medical device will not compromise the clinical condition or safety of a patient, or the safety and health of any other person, when the medical device is used —

(i) under the conditions and for the purposes for which the medical device is intended; and

(ii) if applicable, by a user with the appropriate technical knowledge, experience, education or training; and

(*b*) any risk associated with the intended use of the medical device is —

(i) acceptable when weighed against the intended benefit to the patient; and

(ii) compatible with a high level of protection of health and safety.

Design and manufacture of medical devices to conform with safety requirements

3.—(1) Any solution adopted by a product owner for the design and manufacture of a medical device shall conform with this Schedule, having regard to the generally acknowledged state of the art.

(2) Without prejudice to sub-paragraph (1), in selecting an appropriate solution for the design and manufacture of a medical device so as to minimise any risks associated with the use of the medical device, the product owner shall —

(*a*) identify any hazard and associated risk arising from the use of the medical device for its intended purpose, and any foreseeable misuse of the medical device;

(*b*) eliminate or reduce those risks as far as possible by adopting a policy of inherently safe design and manufacture;

FIRST SCHEDULE — *continued*

(*c*) if appropriate, ensure that adequate protection measures are taken, including alarms if necessary, in relation to any risk that cannot be eliminated; and

(*d*) inform users of any residual risk that may arise due to any shortcomings of the protection measures adopted.

Medical devices to be suitable for intended purpose

4. A medical device shall —

(*a*) perform in the way intended by its product owner; and

(*b*) be designed, produced and packed in a way that ensures that it is suitable for one or more of the specific purposes mentioned in the description of a medical device in the second column of the First Schedule to the Act.

Long-term safety

5. A medical device shall be designed and produced in a way that ensures that the characteristics and performance mentioned in paragraphs 2, 3 and 4 are not adversely affected, if the medical device —

(*a*) is used within the period, as indicated by the product owner of the medical device, in which the medical device can be safely used;

(*b*) is not subjected to any stresses other than the stresses which may occur during normal conditions of the use of the medical device; and

(*c*) is regularly maintained and calibrated in accordance with the product owner's instructions.

Medical devices not to be adversely affected by transport or storage

6. A medical device shall be designed, produced and packed in a way that ensures that its characteristics and performance, when it is being used for its intended purpose, will not be adversely affected during its transport and storage, if the transport or storage is carried out in accordance with the instructions and information provided by its product owner.

Benefits of medical devices to outweigh any side effects

7. Any benefit to be gained from the use of a medical device for the performance intended by its product owner shall outweigh any undesirable side effect arising from its use.

FIRST SCHEDULE — *continued*

PART III

DESIGN AND MANUFACTURING REQUIREMENTS

CHEMICAL, PHYSICAL AND BIOLOGICAL PROPERTIES

Choice of materials

8. In ensuring that the requirements of Part II are met in relation to a medical device, particular attention shall be given, having regard to its intended purpose, to —

(*a*) the choice of any material used in the medical device, particularly as regards the toxicity and, where appropriate, the flammability of the material used;

(*b*) the chemical and physical properties of the material used;

(*c*) the compatibility between the material used and biological tissues, cells and body fluids; and

(*d*) where appropriate, matters such as hardness, wear and fatigue strength of the material used.

Minimisation of risks associated with contaminants and residues

9.—(1) A medical device shall be designed, produced and packed in a way that ensures the minimisation, having regard to the intended purpose of the medical device, of any risk associated with any contaminant or residue that may affect —

(*a*) a person who is involved in the transport, storage or use of the medical device; or

(*b*) a patient.

(2) In minimising risks, particular consideration shall be given to the likely duration and frequency of any tissue exposure associated with the transport, storage or use of the medical device.

Ability to be used safely with materials

10.—(1) A medical device shall be designed and produced in a way that ensures that it can be used safely with any material, substance or gas with which it may come into contact during normal use or use in a routine procedure.

(2) If the medical device is intended to be used to administer a medicinal product, the medical device shall be designed and produced in a way that ensures that it —

(*a*) is compatible with any provision or restriction applicable to the medicinal product; and

FIRST SCHEDULE — *continued*

(*b*) allows the medicinal product to perform as intended by the manufacturer of the medicinal product.

Verification of incorporated substance

11.—(1) If a medical device incorporates, or is intended to incorporate, as an integral part, a substance which, if used separately, might be considered to be a medicinal product, and which is intended to act on a patient in a way that is ancillary to the medical device, then —

(*a*) the safety and quality of the substance shall be verified in accordance with the requirements for issuing a product licence for that medicinal product under the Medicines Act (Cap. 176); and

(*b*) the ancillary action of the substance shall be verified, having regard to the intended purpose of the medical device, by adducing objective evidence, to the satisfaction of the Authority, that the substance acts in the intended way.

(2) For the purposes of this paragraph, "medicinal product" includes any stable derivative of human blood or human plasma.

Minimisation of risks associated with leaching substances

12. A medical device shall be designed and produced in a way that ensures that any risk associated with any substance that may leach from the medical device is minimised.

Minimisation of risks associated with ingress or egress of substances

13. A medical device shall be designed and produced in a way that ensures that any risk associated with any unintentional ingress of a substance into, or any unintentional egress of a substance out of, the medical device is minimised, having regard to the nature of the environment in which the medical device is intended to be used.

INFECTION AND MICROBIAL CONTAMINATION

Minimisation of risk of infection and contamination

14.—(1) A medical device shall be designed and produced in a way that ensures that any risk of infection to any person is eliminated or minimised.

(2) The medical device shall be designed in a way that —

(*a*) allows it to be easily handled;

(*b*) reduces, as far as reasonably practicable and appropriate, any microbial leakage from the medical device or microbial exposure during its use; and

(*c*) if appropriate, minimises contamination of the medical device by the patient, or contamination of the patient by the medical device, during its use.

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

15.—(1) This paragraph applies in relation to a medical device that contains —

(*a*) any tissue, cell or derivative that is of animal origin and rendered non-viable;

(*b*) any tissue, cell or derivative that is of human origin and rendered non-viable; or

(*c*) any tissue, cell or derivative of microbial or recombinant origin.

(2) If the tissue, cell or derivative originated from an animal —

(*a*) the animal shall have been subjected to appropriate veterinary controls and supervision, having regard to the intended use of the tissue, cell or derivative; and

(*b*) a record shall be kept of the country of origin of each animal from which the tissue, cell or derivative originated.

(3) The selection of the source, donor or substance of animal, human, microbial or recombinant origin, as the case may be, and the processing, preservation, testing and handling of the tissue, cell or derivative, shall be carried in a way that provides optimal safety to the patient or user of the medical device.

(4) Without prejudice to the generality of sub-paragraph (3), the risk of infection by any virus or other transmissible agent shall be addressed by the implementation of validated methods of elimination or inactivation of the virus or transmissible agent in the course of the manufacturing process.

Medical devices to be supplied in sterile state

16.—(1) A medical device that is intended by its product owner to be supplied in a sterile state shall be designed, produced and packed in a way that ensures that the medical device is sterile when it is supplied, and will remain sterile, if stored and transported in accordance with the directions of the product owner.

(2) The medical device shall be produced and sterilised using an appropriate validated method.

FIRST SCHEDULE — *continued*

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

Medical devices to be supplied in special microbiological state

17. A medical device that is intended by its product owner to be supplied in a special microbiological state shall be —

(*a*) labelled as having a special microbiological state; and

(*b*) designed, produced and packed to ensure that it remains so when placed on the market and under the transport and storage conditions specified by the product owner.

Medical devices to be supplied in non-sterile state

18.—(1) A medical device that is intended by its product owner to be supplied in a non-sterile state shall be packed in a way that ensures that the medical device maintains the level of cleanliness stipulated by the product owner.

(2) If the medical device is intended to be sterilised before it is used, it shall be packed in a way that —

(*a*) ensures that any risk of microbial contamination is minimised; and

(*b*) is suitable, having regard to the method of sterilisation that the product owner indicates is to be used for the medical device.

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

Distinction between medical devices supplied in sterile and non-sterile states

19. If a medical device is intended by its product owner to be supplied in both a sterile state and a non-sterile state, the information provided with the medical device shall clearly indicate whether the medical device is in a sterile state or a non-sterile state.

CONSTRUCTION AND ENVIRONMENTAL PROPERTIES

Medical devices intended to be used in combination with other devices or equipment

20.—(1) A medical device that is intended by its product owner to be used in combination with any other medical device or any equipment (including a connection system) shall be designed and produced in a way that ensures that —

(*a*) the medical device, and the other device or equipment with which it is used, operate in a safe way; and

FIRST SCHEDULE — *continued*

(*b*) the intended performance of the medical device, and the intended performance of the other device or equipment with which it is used, are not impaired.

(2) Any restrictions applying to such combined use shall be indicated on the label of the medical device or in the instructions for use.

Minimisation of risks associated with use of medical devices

21. A medical device shall be designed and produced in a way that ensures that, as far as practicable, the following risks are removed or minimised:

(*a*) the risk of injury arising from all or any of the physical features of the medical device, such as any magnetic field, external electrical and electromagnetic effects, electrostatic discharge, pressure, humidity, temperature or variation in pressure or acceleration;

(*b*) any risk associated with a reasonably foreseeable environmental condition;

(*c*) the risk of reciprocal interference involving other devices that are normally used in an investigation or treatment of the kind for which the medical device is intended to be used;

(*d*) any risk connected to the use of the medical device in conjunction with materials, substances and gases with which it may come into contact during normal conditions of use;

(*e*) any risk of accidental penetration of substances into the medical device;

(*f*) any risk of incorrect identification of specimens;

(*g*) any risk which may arise if maintenance or calibration of the medical device is not possible;

(*h*) any risk associated with the ageing of materials used in the medical device;

(*i*) any risk associated with loss of accuracy of any measuring or control mechanism of the medical device;

(*j*) any risk of fire or explosion occurring during normal use of the medical device, and in the event of a single fault condition, especially if the medical device is intended to be exposed to flammable substances or substances that can cause combustion.

Safe disposal of waste substances

22. A medical device shall be designed and produced in such a way as to facilitate the safe disposal of any waste substances.

FIRST SCHEDULE — *continued*

Medical devices with measuring functions

23.—(1) A medical device that has a measuring function shall be designed and produced in a way that ensures that it provides accurate, precise and stable measurements within the limits indicated by its product owner and having regard to the intended purpose of the medical device.

(2) Without prejudice to the generality of sub-paragraph (1), the design of a medical device shall address sensitivity, specificity, trueness, repeatability, reproducibility, control of known relevant interference and limits of detection, as appropriate.

(3) Where the performance of a medical device depends on the use of any calibrator or control material, the traceability of values assigned to that calibrator or control material shall be assured through a quality management system.

(4) The measurement, monitoring and display scale of a medical device shall be designed and produced in accordance with ergonomic principles, having regard to the intended purpose of the medical device.

(5) Wherever possible, values expressed numerically shall be in commonly accepted, standardised units, and understood by a user of the medical device.

PROTECTION AGAINST RADIATION

Minimisation of exposure to radiation

24. A medical device shall be designed and produced in a way that ensures that the exposure of a patient, or any other person, to radiation is minimised, having regard to the levels of radiation required to enable the medical device to perform its therapeutic and diagnostic functions and its intended purpose.

Medical devices intended to emit radiation

25.—(1) This paragraph applies in relation to a medical device that is intended by its product owner to emit hazardous levels of visible or invisible radiation because the emission is necessary for a specific medical purpose, the benefit of which is considered to outweigh any risk inherent in the emission.

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

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

(4) If practicable, the medical device shall be fitted with a visual indicator or an audible warning, or both, that operates if potentially hazardous levels of radiation are emitted.

FIRST SCHEDULE — *continued*

Minimisation of exposure to unintended radiation

26. A medical device shall be designed and produced in a way that ensures that the exposure of a patient, or any other person, to the emission of unintended, stray or scattered radiation is minimised.

Operating instructions

27. The operating instructions for a medical device that emits radiation shall include detailed information about the following matters:

(*a*) the nature of the radiation emitted;

(*b*) the means by which patients and users can be protected from the radiation;

(*c*) ways to avoid misusing the medical device;

(*d*) ways to eliminate any risks inherent in the installation of the medical device.

Additional requirements for medical devices intended to emit ionising radiation

28.—(1) This paragraph applies, in addition to paragraphs 24 to 27, in relation to a medical device that is intended by its product owner to emit ionising radiation.

(2) The medical device shall be designed and produced in a way that ensures that, if practicable, the quantity, geometry and energy distribution (or quality) of radiation emitted can be controlled and varied, having regard to the intended purpose of the medical device.

(3) If the medical device is intended to be used for diagnostic radiology, it shall be designed and produced in a way that ensures that, when used in relation to a patient for a purpose intended by its product owner —

(*a*) the medical device achieves an appropriate image or output quality for that purpose; and

(*b*) the exposure of the patient, or the user, to radiation is minimised.

(4) If the medical device is intended to be used for therapeutic radiology, it shall be designed and produced in a way that ensures that the delivered dose of radiation, the type and energy of the radiation beam and, if appropriate, the energy distribution of the radiation beam, can be reliably controlled and monitored.

FIRST SCHEDULE — *continued*

MEDICAL DEVICES CONNECTED TO OR EQUIPPED WITH AN ENERGY SOURCE

Medical devices incorporating electronic programmable systems

29. A medical device that incorporates an electronic programmable system shall be designed and produced in a way that ensures that —

(*a*) the performance, reliability and repeatability of the system are appropriate for the intended purpose of the medical device; and

(*b*) any consequent risks associated with a single fault condition in the system are minimised.

Safety dependent on internal power supply

30. If the safety of a patient on whom a medical device is to be used depends on an internal power supply for the medical device, the medical device shall be fitted with a means of determining the state of the power supply.

Safety dependent on external power supply

31. If the safety of a patient on whom a medical device is to be used depends on an external power supply for the medical device, the medical device shall be fitted with an alarm system that indicates whether a power failure has occurred.

Medical devices intended to monitor clinical parameters

32. A medical device that is intended by its product owner to be used to monitor one or more clinical parameters of a patient shall be fitted with an appropriate alarm system to warn a user if a situation has developed that could lead to the death, or a serious deterioration in the state of health, of the patient.

Minimisation of risk of electromagnetic fields

33.—(1) A medical device shall be designed and produced in a way that ensures that the risk of the medical device creating an electromagnetic interference, which could impair the operation of other devices or equipment being used in the vicinity of the medical device, is minimised.

(2) A medical device shall be designed and produced in such a way as to provide an adequate level of intrinsic immunity to electromagnetic disturbance to enable it to operate as intended.

Protection against electrical risks

34. A medical device shall be designed and produced in a way that ensures that, as far as possible, when it is installed correctly, and is being used for an intended

purpose under normal conditions of use and in the event of a single fault condition, a patient, or any other person, is protected against the risk of accidental electric shock.

Protection against mechanical risks

35. A medical device shall be designed and produced in a way that ensures that a patient, or any other person, is protected against any mechanical risk associated with the use of the medical device.

Protection against risks associated with vibration

36.—(1) A medical device shall be designed and produced in a way that ensures that any risk associated with vibrations generated by the medical device is minimised.

(2) If vibrations are not part of the intended performance of the medical device, particular attention shall be given to relevant technical progress, and the available means, for limiting vibrations, particularly at source.

Protection against risks associated with noise

37.—(1) A medical device shall be designed and produced in a way that ensures that any risk associated with noise emitted by the medical device is minimised.

(2) If noise is not part of the intended performance of the medical device, particular attention shall be given to relevant technical progress, and the available means, for reducing the emission of noise, particularly at source.

Protection against risks associated with terminals and connectors

38. A medical device that is intended by its product owner to be connected to any electric, gas, hydraulic, pneumatic or other energy supply shall be designed and produced in a way that ensures that any risk, in relation to the energy supply, to the user associated with the handling of a terminal or connector on the medical device, is minimised.

Protection against risks associated with heat

39. A medical device shall be designed and produced in a way that ensures that, during normal use, any accessible part of the medical device (other than any part intended by its product owner to supply heat or reach a given temperature), and any area surrounding an accessible part of the medical device, does not reach a potentially dangerous temperature.

FIRST SCHEDULE — *continued*

Protection against risks associated with administration of energy or substances

40.—(1) This paragraph applies in relation to a medical device that is intended by its product owner to be used to administer energy or a substance to a patient.

(2) The medical device shall be designed and produced in a way that ensures that —

(*a*) the delivered rate and amount of energy, or of the substance, can be set and maintained accurately to ensure the safety of any patient or user; and

(*b*) as far as possible, the accidental release of dangerous levels of energy or of the substance is prevented.

(3) The medical device shall be fitted with a means of indicating or, if appropriate, preventing inadequacies in the rate and amount of energy, or of the substance, administered that might cause danger to any person.

(4) The functions of each control and indicator on the medical device shall be clearly specified on the medical device.

(5) If the instructions for the operation of the medical device, or the operating or adjustment parameters for the medical device, are displayed by means of a visual system incorporated into the medical device, the instructions or parameters shall be able to be understood by a user and, if appropriate, the patient.

Active implantable medical devices

41.—(1) An active implantable medical device shall display a code that can be used to identify —

(*a*) the type of medical device;

(*b*) the product owner of the medical device; and

(*c*) the year of manufacture of the medical device.

(2) The code shall be readable without the need for surgery to the person in whom the medical device is implanted.

INFORMATION TO BE PROVIDED WITH MEDICAL DEVICES

General information to be provided with medical devices

42.—(1) The following information shall be provided with a medical device, having regard to the training and knowledge of potential users of the medical device:

FIRST SCHEDULE — *continued*

(*a*) information identifying the medical device;

(*b*) information identifying the product owner of the medical device;

(*c*) information explaining how to use the medical device safely.

(2) Without prejudice to the generality of sub-paragraph (1), the information required by paragraphs 44 and 45 shall be provided with a medical device.

(3) The information —

(*a*) shall be provided in English; and

(*b*) may, in addition, be provided in any other language.

(4) The format, content and location of the information shall be appropriate for the medical device and its intended purpose.

(5) Any number, letter or symbol, and any letter or number in a symbol, used in the information shall be legible and at least one millimetre high.

(6) If a symbol or an identification colour that is not included in a medical device standard is used in the information provided with the medical device, or in the instructions for use of the medical device, the meaning of the symbol or identification colour shall be explained in the information provided with the medical device or the instructions for the use of the medical device.

Location of information to be provided with medical devices

43.—(1) Unless it is impracticable or inappropriate to do so, the information required to be provided with a medical device shall be provided on the medical device itself.

(2) If it is not practicable to comply with sub-paragraph (1) in relation to the provision of the information, the information shall be provided —

(*a*) on the packaging used for the medical device; or

(*b*) in the case of medical devices that are packaged together because individual packaging of the medical devices for supply is not practicable, on the outer packaging used for the medical devices.

(3) If it is not practicable to comply with sub-paragraph (1) or (2) in relation to the provision of the information required under paragraph 44, the information shall be provided on a leaflet supplied with the medical device.

(4) If it is not practicable to comply with sub-paragraph (1) or (2) in relation to the provision of the information required under paragraph 45, the information shall be provided in a printed document or using other appropriate media.

FIRST SCHEDULE — *continued*

Particular requirements of information to be provided with medical devices

44. The information in the following table shall be provided with a medical device:

Item	*Information to be provided*
1	The product owner's name (or trading name) and address
2	The intended purpose of the medical device, the intended user of the medical device, and the kind of patient on whom the medical device is intended to be used (if this information is not obvious)
3	Sufficient information to enable a user to identify the medical device or, if relevant, the contents of its packaging
4	Any particular handling or storage requirements applicable to the medical device
5	Any warnings, restrictions or precautions that shall be taken in relation to the use of the medical device
6	Any special operating instructions for the use of the medical device
7	If applicable, an indication that the medical device is intended for a single use only
8	If applicable, an indication that the medical device has been custom-made for a particular individual and is intended for use only by that individual
9	If applicable, an indication that the medical device is intended to be used only for clinical or performance investigations before being supplied
10	For a sterile medical device, the word "STERILE" and information about the method that was used to sterilise the medical device
11	The batch code, lot number or serial number of the medical device
12	If applicable, a statement of the date (expressed in a way that clearly identifies the month and year) up to which the medical device can be safely used
13	If the information provided with the medical device does not include the information mentioned in item 12 — a statement of the date of manufacture of the medical device (this may be included in the batch code, lot number or serial number of the medical device, provided the date is clearly identifiable)
14	If applicable, the words "for export only".

FIRST SCHEDULE — *continued*

Instructions for use

45.—(1) Instructions for the use of a medical device shall be provided with the medical device.

(2) Instructions for the use of a medical device shall include the information in the following table that is applicable to the medical device:

Item	*Information to be provided*
1	The product owner's name (or trading name) and address
2	The intended purpose of the medical device, the intended user of the medical device, and the kind of patient on whom the medical device is intended to be used
3	Information about any risk arising because of other equipment likely to be present when the medical device is being used for its intended purpose (for example, electrical interference from electro-surgical devices or magnetic field interference from magnetic resonance imaging devices)
4	Information about the intended performance of the medical device and any undesirable side effects caused by use of the medical device
5	Any contra-indications, warnings, restrictions or precautions that may apply in relation to the use of the medical device
6	Sufficient information to enable a user to identify the medical device or, if relevant, the contents of its packaging
7	Any particular handling or storage requirements applicable to the medical device
8	If applicable, an indication that the medical device is intended for a single use only
9	If applicable, an indication that the medical device has been custom-made for a particular individual and is intended for use only by that individual
10	If applicable, an indication that the medical device is intended to be used only for clinical or performance investigations before being supplied
11	For a sterile medical device, the word "STERILE" and information about the method that was used to sterilise the medical device
12	For a medical device that is intended by its product owner to be supplied in a sterile state —

FIRST SCHEDULE — *continued*

(a) an indication that the medical device is sterile;

(b) information about what to do if sterile packaging is damaged; and

(c) if appropriate, instructions for re-sterilisation of the medical device

13 For a medical device that is intended by its product owner to be sterilised before use, instructions for cleaning and sterilising the medical device which, if followed, will ensure that the medical device continues to comply with the applicable provisions of this Schedule

14 Any special operating instructions for the use of the medical device

15 Information to enable the user to verify whether the medical device is properly installed and whether it can be operated safely and correctly, including details of calibration (if any) needed to ensure that the medical device operates properly and safely during its intended life

16 Information about the nature and frequency of regular and preventative maintenance of the medical device, including information about the replacement of consumable components of the medical device during its intended life

17 Information about any treatment or handling needed before the medical device can be used

18 For a medical device that is intended by its product owner to be installed with, or connected to, any other medical device or equipment so that the medical device can operate as required for its intended purpose, sufficient information about the medical device to enable a user to identify the appropriate medical device or equipment to be used in combination with it safely

19 For an implantable medical device, information about any risks associated with its implantation

20 For a reusable medical device —

(a) information about the appropriate processes to allow reuse of the medical device (including information about cleaning, disinfection, packaging and, if appropriate, re-sterilisation of the medical device); and

(b) an indication of the number of times the medical device may be safely reused

FIRST SCHEDULE — *continued*

21	For a medical device that is intended by its product owner to emit radiation for medical purposes, details of the nature, type, intensity and distribution of the radiation emitted
22	Information about precautions that shall be taken by a patient or user, if the performance of the medical device changes
23	Information about precautions that shall be taken by a patient or user, if it is reasonably foreseeable that use of the medical device will result in the patient or user being exposed to adverse environmental conditions
24	Adequate information about any medicinal product that the medical device is designed to administer, including any limitations on the substances that may be administered using the medical device
25	Information about any medicinal product (including any stable derivative of human blood or blood plasma) that is incorporated, or is intended to be incorporated, into the medical device as an integral part of the medical device
26	Information about precautions that shall be taken by a patient or user if there is any special or unusual risk associated with the disposal of the medical device
27	Information about the degree of accuracy claimed, if the medical device has a measuring function
28	Information about any particular facilities required for the use of the medical device, or about any particular training or qualifications required by the user of the medical device.

Protection against risks posed to patient for medical devices for self-testing or self-administration

46.—(1) A medical device for self-testing or self-administration shall be designed and produced in such a way that it performs appropriately for its intended purpose, taking into account the skills and the means available to any user and the influence resulting from variations that can reasonably be anticipated in the user's technique and environment.

(2) The information and instructions provided by the product owner of such a medical device shall be easy for the user to understand and apply.

(3) A medical device for self-testing or self-administration shall be designed and produced in such a way as to reduce, as far as practicable, the risks of —

FIRST SCHEDULE — *continued*

(*a*) user error in the handling of the medical device and, if applicable, the specimen; and

(*b*) error in the interpretation of results.

(4) A medical device for self-testing or self-administration shall, where reasonably possible, include a procedure by which a user can verify that, at the time of use, the medical device will perform as intended by its product owner.

Clinical evidence

47.—(1) Every medical device shall be supported by clinical evidence, appropriate for the use and classification of the medical device, demonstrating that the medical device complies with the applicable provisions of this Schedule.

(2) Any clinical investigation in relation to a medical device on any human subject, including every step in the clinical investigation from the consideration of the need and justification of the study to the publication of the results, shall be carried out in accordance with the spirit of the Declaration of Helsinki on Ethical Principles for Medical Research involving Human Subjects adopted by the 18th World Medical Association General Assembly in Helsinki in June 1964, as subsequently amended.

SECOND SCHEDULE

Regulation 22

DISEASES AND CONDITIONS SPECIFIED FOR PURPOSES OF REGULATION 22

1. Blindness.
2. Cancer.
3. Cataract.
4. Drug addiction.
5. Deafness.
6. Diabetes.
7. Epilepsy or fits.
8. Hypertension.
9. Insanity.
10. Kidney diseases.
11. Leprosy.

SECOND SCHEDULE — *continued*

12. Menstrual disorders.

13. Paralysis.

14. Tuberculosis.

15. Sexual function.

16. Infertility.

17. Impotency.

18. Frigidity.

19. Conception and pregnancy.

THIRD SCHEDULE

Regulation 24(1)

ASSIGNMENT OF MEDICAL DEVICES INTO CLASSES

PART I

CLASSES OF MEDICAL DEVICES

1. The classes of medical devices, listed in ascending order of the health risk posed to an end-user of a medical device assigned to the class, are as follows:

(*a*) Class A (low risk);

(*b*) Class B (moderately low risk);

(*c*) Class C (moderately high risk); and

(*d*) Class D (high risk).

PART II

RISK CLASSIFICATION RULES FOR MEDICAL DEVICES

OTHER THAN IN VITRO DIAGNOSTIC PRODUCTS

Definitions

2. In this Division, unless the context otherwise requires —

"active diagnostic medical device" means any active medical device used, whether alone or in combination with other medical devices, to supply information for detecting, diagnosing or monitoring, or to provide support in the treatment of, any physiological condition, state of health, illness or congenital deformity;

THIRD SCHEDULE — *continued*

"active therapeutic medical device" means any active medical device used, whether alone or in combination with any other medical device, to support, modify, replace or restore biological functions or structures, with a view to the treatment or alleviation of any illness, injury or handicap;

"central circulatory system" means the major internal blood vessels, including the following:

(*a*) *aorta abdominalis*;

(*b*) *aorta ascendens*;

(*c*) *aorta descendens* to the *bifurcatio aortae*;

(*d*) *aorta thoracica*;

(*e*) *arcus aorta*;

(*f*) *arteria carotis communis*;

(*g*) *arteria carotis externa*;

(*h*) *arteria carotis interna*;

(i) *arteriae cerebrates*;

(*j*) *arteriae coronariae*;

(*k*) *arteriae pulmonales*;

(*l*) *ilica communis*;

(*m*) *truncus brachiocephalicus*;

(*n*) *venae cava inferior*;

(*o*) *venae cava superior*;

(*p*) *venae cordis*;

(*q*) *venae pulmonales*;

"central nervous system" means the brain, meninges and spinal cord;

"continuous use", in relation to a medical device, means —

(*a*) the uninterrupted use of the medical device, not including any temporary interruption of its use during a procedure or any temporary removal of the medical device for purposes such as cleaning or disinfection; or

(*b*) the accumulated use of the medical device by replacing it immediately with another medical device of the same type, as intended by its product owner;

THIRD SCHEDULE — *continued*

"immediate danger" means a situation where a patient is at risk of losing his life or an important bodily function if no immediate preventative measure is taken;

"invasive (body orifice) medical device" means an invasive medical device, not being a surgically invasive medical device, which penetrates into a human body through a body orifice;

"invasive medical device" means a medical device which, in whole or in part, penetrates inside a human body, either through a body orifice or through the surface of the body;

"life supporting or life sustaining", in relation to a medical device, means that the medical device is essential to, or yields information that is essential to, the restoration or continuation of a bodily function important to the continuation of human life;

"long-term use", in relation to a medical device, means continuous use of the medical device for a period exceeding 30 days;

"non-invasive medical device" means a medical device other than an invasive medical device;

"primary intention", in relation to the healing of a wound, means the manner of healing where the wound edges directly touch each other with minimal granulation tissue being formed;

"reusable surgical instrument" means an instrument intended for surgical use by cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without connection to any active medical device, and which is intended to be reused after appropriate procedures for cleaning or sterilisation of the instrument have been carried out;

"short-term use", in relation to a medical device, means continuous use of the medical device for a period between 60 minutes and 30 days;

"surgically invasive medical device" means an invasive medical device which penetrates into the body through the surface of the body, with the aid or in the context of a surgical operation;

"transient use", in relation to a medical device, means continuous use of the medical device for a period not exceeding 60 minutes.

Non-invasive medical devices which come into contact with injured skin

3.—(1) A non-invasive medical device which comes into contact with injured skin shall be assigned to Class A, if it is intended by its product owner to be used as

THIRD SCHEDULE — *continued*

a mechanical barrier, for compression or for absorption of exudates only, for wounds which have not breached the dermis and can heal by primary intention.

(2) Subject to sub-paragraph (3), a non-invasive medical device which comes into contact with injured skin shall be assigned to Class B, if it is intended by its product owner to be used principally with wounds which have breached the dermis, or is principally intended for the management of the microenvironment of a wound.

(3) A non-invasive medical device which comes into contact with injured skin shall be assigned to Class C, if it is intended by its product owner to be used principally with wounds which have breached the dermis and cannot heal by primary intention.

Non-invasive medical devices for channelling or storing substances

4.—(1) Subject to sub-paragraphs (2) and (3), a non-invasive medical device shall be assigned to Class A, if it is intended by its product owner for channelling or storing, for the purpose of eventual infusion, administration or introduction into a human body —

(*a*) body liquids or tissues;

(*b*) liquids; or

(*c*) gases.

(2) A non-invasive medical device referred to in sub-paragraph (1) shall be assigned to Class B, if it is intended by its product owner —

(*a*) to be connected to an active medical device which is in Class B, C or D; or

(*b*) for —

(i) channelling blood;

(ii) storing or channelling other body liquids; or

(iii) storing organs, parts of organs or body tissues.

(3) A non-invasive medical device referred to in sub-paragraph (1) shall be assigned to Class C, if it is a blood bag that does not incorporate a medicinal product.

(4) For the purposes of sub-paragraph (2)(*a*), the circumstances when a non-invasive medical device is connected to an active medical device include circumstances where the safety and performance of the active medical device is influenced by the non-invasive medical device, or *vice versa*.

THIRD SCHEDULE — *continued*

Non-invasive medical devices for modifying compositions of substances

5.—(1) Subject to sub-paragraph (2), a non-invasive medical device shall be assigned to Class C, if it is intended by its product owner for modifying the biological or chemical composition of —

(*a*) blood;

(*b*) other body liquids; or

(*c*) other liquids intended for infusion into the body.

(2) A non-invasive medical device referred to in sub-paragraph (1) shall be assigned to Class B, if the intended modification is carried out by filtration, centrifuging or any exchange of gas or of heat.

Other non-invasive medical devices

6. A non-invasive medical device to which paragraphs 3, 4 and 5 do not apply shall be assigned to Class A, if it —

(*a*) does not come into contact with a person; or

(*b*) comes into contact with intact skin only.

Invasive (body orifice) medical devices for transient use

7.—(1) Subject to sub-paragraph (2), an invasive (body orifice) medical device shall be assigned to Class A, if —

(*a*) it is intended by its product owner for transient use; and

(*b*) either of the following applies:

(i) it is not intended by its product owner to be connected to an active medical device; or

(ii) it is intended by its product owner to be connected to a Class A medical device only.

(2) An invasive (body orifice) medical device referred to in sub-paragraph (1) shall be assigned to Class B, if —

(*a*) it is intended by its product owner for use on the external surface of any eyeball; or

(*b*) it is liable to be absorbed by the mucous membrane.

Invasive (body orifice) medical devices for short-term use

8.—(1) Subject to sub-paragraph (2), an invasive (body orifice) medical device shall be assigned to Class B, if —

THIRD SCHEDULE — *continued*

(*a*) it is intended by its product owner for short-term use; and

(*b*) either of the following applies:

(i) it is not intended by its product owner to be connected to an active medical device; or

(ii) it is intended by its product owner to be connected to a Class A medical device only.

(2) An invasive (body orifice) medical device referred to in sub-paragraph (1) shall be assigned to Class A, if —

(*a*) it is intended by its product owner only for use —

(i) in an oral cavity, as far as the pharynx;

(ii) in an ear canal, up to the ear drum; or

(iii) in a nasal cavity; and

(*b*) it is not liable to be absorbed by the mucous membrane.

Invasive (body orifice) medical devices for long-term use

9.—(1) Subject to sub-paragraph (2), an invasive (body orifice) medical device shall be assigned to Class C, if —

(*a*) it is intended by its product owner for long-term use; and

(*b*) either of the following applies:

(i) it is not intended by its product owner to be connected to an active medical device; or

(ii) it is intended by its product owner to be connected to a Class A medical device only.

(2) An invasive (body orifice) medical device referred to in sub-paragraph (1) shall be assigned to Class B, if —

(*a*) it is intended by its product owner only for use —

(i) in an oral cavity, as far as the pharynx;

(ii) in an ear canal, up to the ear drum; or

(iii) in a nasal cavity; and

(*b*) it is not liable to be absorbed by the mucous membrane.

THIRD SCHEDULE — *continued*

Invasive (body orifice) medical devices for connection to active medical devices

10. An invasive (body orifice) medical device shall be assigned to Class B, regardless of the duration of its use, if it is intended by its product owner to be connected to an active medical device which is in Class B, C or D.

Surgically invasive medical devices for transient use

11.—(1) Subject to sub-paragraphs (2) to (7), a surgically invasive medical device intended by its product owner for transient use (referred to in this paragraph as a transient use surgically invasive medical device) shall be assigned to Class B.

(2) Subject to sub-paragraphs (3) to (7), a transient use surgically invasive medical device shall be assigned to Class A, if it is a reusable surgical instrument.

(3) A transient use surgically invasive medical device shall be assigned to the same class as the active medical device to which it is intended by its product owner to be connected.

(4) A transient use surgically invasive medical device shall be assigned to Class C, if it is intended by its product owner for the supply of energy in the form of ionising radiation.

(5) A transient use surgically invasive medical device shall be assigned to Class C, if it is intended by its product owner —

(*a*) to have a biological effect; or

(*b*) to be wholly or mainly absorbed by the human body.

(6) A transient use surgically invasive medical device shall be assigned to Class C, if —

(*a*) it is intended by its product owner for the administration of any medicinal product by means of a delivery system; and

(*b*) such administration is done in a manner that is potentially hazardous.

(7) A transient use surgically invasive medical device shall be assigned to Class D, if it is intended by its product owner —

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

(*b*) for the diagnosis, monitoring or correction of a defect of the heart or of the central circulatory system through direct contact with these parts of the body.

THIRD SCHEDULE — *continued*

Surgically invasive medical devices for short-term use

12.—(1) Subject to sub-paragraphs (2), (4) and (5), a surgically invasive medical device intended by its product owner for short-term use (referred to in this paragraph as a short-term use surgically invasive medical device) shall be assigned to Class B.

(2) Subject to sub-paragraph (3), a short-term use surgically invasive medical device shall be assigned to Class C, if it is intended by its product owner to undergo a chemical change in the body.

(3) A short-term use surgically invasive medical device referred to in sub-paragraph (2) shall be assigned to Class B, if it is intended by its product owner to be placed into any tooth.

(4) A short-term use surgically invasive medical device shall be assigned to Class C, if it is intended by its product owner for —

(*a*) the administration of any medicinal product; or

(*b*) the supply of energy in the form of ionising radiation.

(5) A short-term use surgically invasive medical device shall be assigned to Class D, if it is intended by its product owner —

(*a*) to have a biological effect;

(*b*) to be wholly or mainly absorbed by the human body;

(*c*) to be used specifically in direct contact with the central nervous system; or

(*d*) for the diagnosis, monitoring or correction of a defect of the heart or of the central circulatory system through direct contact with these parts of the body.

Implantable medical devices and surgically invasive medical devices for long-term use

13.—(1) Subject to sub-paragraphs (2), (3) and (4), an implantable medical device or a surgically invasive medical device intended by its product owner for long-term use (referred to in this paragraph as a long-term use medical device) shall be assigned to Class C.

(2) A long-term use medical device shall be assigned to Class B, if it is intended by its product owner to be placed into any tooth.

(3) A long-term use medical device shall be assigned to Class D, if it is intended by its product owner —

THIRD SCHEDULE — *continued*

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

(*b*) to be life supporting or life sustaining;

(*c*) to be an active medical device;

(*d*) to be wholly or mainly absorbed by the human body;

(*e*) for the administration of any medicinal product; or

(*f*) to be a breast implant.

(4) Subject to sub-paragraph (2), a long-term use medical device shall be assigned to Class D, if it is intended by its product owner to undergo chemical change in the body.

Active therapeutic medical devices for administering or exchanging energy

14.—(1) Subject to sub-paragraph (2), an active therapeutic medical device shall be assigned to Class B, if it is intended by its product owner for the administration or exchange of energy to or with a human body.

(2) An active therapeutic medical device referred to in sub-paragraph (1) shall be assigned to Class C, if the administration or exchange of energy may be done in a potentially hazardous way (such as through the emission of ionising radiation), taking into account the nature, density and site of application of the energy and the type of technology involved.

Active therapeutic medical devices for controlling, monitoring or influencing other devices

15. An active therapeutic medical device shall be assigned to Class C, if it is intended by its product owner for the control or monitoring, or to be used to directly influence the performance, of a Class C active therapeutic device.

Active diagnostic medical devices

16.—(1) Subject to sub-paragraphs (2) and (3), an active diagnostic medical device shall be assigned to Class B, if it is intended by its product owner —

(*a*) to be used to supply energy which will be absorbed by the human body;

(*b*) to be used to capture any image of the *in vivo* distribution of radiopharmaceuticals; or

(*c*) for the direct diagnosis or monitoring of vital physiological processes.

THIRD SCHEDULE — *continued*

(2) An active diagnostic medical device referred to in sub-paragraph (1)(*a*) shall be assigned to Class A, if it is intended by its product owner to be used solely to illuminate a patient's body with light in the visible or near infrared spectrum.

(3) An active diagnostic medical device referred to in sub-paragraph (1) shall be assigned to Class C, if it is intended by its product owner specifically for —

(*a*) the monitoring of vital physiological parameters, where the nature of any variation is such that it could result in immediate danger to the patient (such as any variation in cardiac performance, respiration or activity of the central nervous system); or

(*b*) diagnosing in a clinical situation where the patient is in immediate danger.

Active diagnostic medical devices emitting ionising radiation, etc.

17.—(1) An active diagnostic medical device shall be assigned to Class C, if it is intended by its product owner —

(*a*) for the emission of ionising radiation; and

(*b*) to be used in diagnostic or interventional radiology.

(2) An active diagnostic medical device shall be assigned to Class C, if it is intended by its product owner for the control or monitoring, or to be used to directly influence the performance, of any active diagnostic medical device referred to in sub-paragraph (1).

Active medical devices for administering or removing medicinal products

18.—(1) Subject to sub-paragraph (2), an active medical device shall be assigned to Class B, if it is intended by its product owner for the administration, or removal of, any medicinal product, body liquid or other substance to or from a human body.

(2) An active medical device referred to in sub-paragraph (1) shall be assigned to Class C, if the administration or removal of the medicinal product, body liquid or other substance is done in a manner that is potentially hazardous, taking into account —

(*a*) the nature of the medicinal product, body liquid or substance;

(*b*) the part of the body concerned; and

(*c*) the mode and route of the administration or removal.

Other active medical devices

19. An active medical device to which paragraphs 14 to 18 do not apply shall be assigned to Class A.

THIRD SCHEDULE — *continued*

Medical devices incorporating medicinal products

20.—(1) Subject to sub-paragraph (2), a medical device shall be assigned to Class D, if it incorporates as an integral part a substance which —

(*a*) if used separately, may be considered to be a medicinal product; and

(*b*) is liable to act on a human body with an action ancillary to that of the medical device.

(2) A medical device referred to in sub-paragraph (1) shall be assigned to Class B, if the incorporated substance is a medicinal product exempted from the licensing requirements of sections 5 and 6 of the Medicines Act (Cap. 176).

Medical devices incorporating animal or human cells, tissues or derivatives

21.—(1) Subject to sub-paragraph (2), a medical device shall be assigned to Class D, if it is manufactured from or incorporates —

(*a*) cells, tissues or derivatives of cells or tissues, or any combination thereof, of animal or human origin, which are or have been rendered non-viable; or

(*b*) cells, tissues or derivatives of cells or tissues, or any combination thereof, of microbial or recombinant origin.

(2) A medical device referred to in sub-paragraph (1) shall be assigned to Class A, if it is manufactured from or incorporates non-viable animal tissues, or their derivatives, that come in contact with intact skin only.

Medical devices for sterilisation or disinfection

22.—(1) Subject to sub-paragraph (2), a medical device shall be assigned to Class C, if it is intended by its product owner to be used specifically for —

(*a*) the sterilisation of any other medical device;

(*b*) the end-point disinfection of any other medical device; or

(*c*) the disinfection, cleaning, rinsing or hydration of contact lenses.

(2) A medical device shall be assigned to Class B, if it is intended by its product owner for the disinfection of any other medical device before the latter is sterilised or undergoes end-point disinfection.

(3) In this paragraph, "end-point disinfection" means the disinfection of a medical device immediately before its use by or on a patient.

THIRD SCHEDULE — *continued*

Medical devices for contraceptive use

23.—(1) Subject to sub-paragraph (2), a medical device intended by its product owner to be used for contraception or the prevention of the transmission of any sexually transmitted disease shall be assigned to Class C.

(2) A medical device referred to in sub-paragraph (1) shall be assigned to Class D, if it is —

(*a*) an implantable medical device; or

(*b*) an invasive medical device intended by its product owner for long-term use.

DIVISION 2 — *Risk classification rules for in vitro diagnostic products*

Definitions

24. In this Division, unless the context otherwise requires —

"examination" means a set of operations having the object of determining the value of a property;

"near-patient testing" means any testing performed outside a laboratory environment by a qualified practitioner, registered nurse or registered pharmacist, generally near to, or at the side of, a patient.

***In vitro* diagnostic products for detecting transmissible agents, etc.**

25.—(1) An *in vitro* diagnostic product shall be assigned to Class D, if it is intended by its product owner to be used for detecting the presence of, or exposure to, a transmissible agent that —

(*a*) is in any blood, blood component, blood derivative, cell, tissue or organ, in order to assess the suitability of the blood, blood component, blood derivative, cell, tissue or organ, as the case may be, for transfusion or transplantation; or

(*b*) causes a life-threatening disease with a high risk of propagation.

(2) An *in vitro* diagnostic product shall be assigned to Class C, if it is intended by its product owner for use in —

(*a*) detecting the presence of, or exposure to, a sexually transmitted agent (e.g. *Chlamydia trachomatis* or *Neisseria gonorrhoeae*);

(*b*) detecting the presence in cerebrospinal fluid or blood of an infectious agent with a risk of limited propagation (e.g. *Cryptococcus neoformans* or *Neisseria meningitidis*);

THIRD SCHEDULE — *continued*

(*c*) detecting the presence of an infectious agent, where there is a significant risk that an erroneous result will cause death or severe disability to the individual or foetus being tested (e.g. a diagnostic assay for *Chlamydia pneumoniae*, *Cytomegalovirus* or Methicillin-resistant *Staphylococcus aureus*);

(*d*) pre-natal screening of women in order to determine their immune status towards transmissible agents (e.g. immune status tests for *Rubella* or *Toxoplasmosis*);

(*e*) determining infective disease status or immune status, where 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 being tested (e.g. *Cytomegalovirus*, *Enterovirus* or *Herpes simplex virus* in transplant patients);

(*f*) screening for disease staging, for the selection of patients for selective therapy and management, or in the diagnosis of cancer (e.g. personalised medicinal product);

(*g*) human genetic testing (e.g. for cystic fibrosis or Huntington's disease);

(*h*) monitoring levels of medicinal products, substances or biological components, where there is a risk that an erroneous result will lead to a patient management decision resulting in an immediate life-threatening situation for the patient being tested (e.g. cardiac markers, cyclosporin or prothrombin time testing);

(*i*) management of patients suffering from a life-threatening infectious disease (e.g. viral load of *Human immunodeficiency virus* or *Hepatitis C virus*, or genotyping and subtyping *Hepatitis C virus* or *Human immunodeficiency virus*); or

(*j*) screening for congenital disorders in the foetus (e.g. Down syndrome or spina bifida).

***In vitro* diagnostic products for blood grouping or tissue typing**

26.—(1) Subject to sub-paragraph (2), an *in vitro* diagnostic product shall be assigned to Class C, if it is intended by its product owner to be used for blood grouping or tissue typing to ensure the immunological compatibility of any blood, blood component, blood derivative, cell, tissue or organ that is intended for transfusion or transplantation, as the case may be.

(2) An *in vitro* diagnostic product referred to in sub-paragraph (1) shall be assigned to Class D, if it is intended by its product owner to be used for blood grouping or tissue typing according to —

THIRD SCHEDULE — *continued*

(*a*) the ABO system [A (ABO1), B (ABO2), AB (ABO3)];

(*b*) the Duffy system [FY1 (Fya), FY2 (Fyb)];

(*c*) the Kell system [Kel1 (K)];

(*d*) the Kidd system [JK1 (Jka), JK2 (Jkb)]; or

(*e*) the rhesus system [RH1 (D), RH2 (C), RH3 (E), RH4 (c), RH5 (e)].

In vitro diagnostic products for self-testing

27.—(1) Subject to sub-paragraph (2), an *in vitro* diagnostic product shall be assigned to Class C, if it is intended by its product owner to be used for self-testing.

(2) An *in vitro* diagnostic product referred to in sub-paragraph (1) shall be assigned to Class B, if it is intended by its product owner to be used to obtain —

(*a*) test results that are not for the determination of a medically-critical status; or

(*b*) preliminary test results which require confirmation by appropriate laboratory tests.

In vitro diagnostic products for near-patient testing

28.—(1) An *in vitro* diagnostic product shall be assigned to Class C, if it is intended by its product owner to be used for near-patient testing in —

(*a*) a blood gas analysis; or

(*b*) a blood glucose determination.

(2) Subject to sub-paragraph (1), an *in vitro* diagnostic product intended by its product owner to be used for near-patient testing shall be assigned to a class in accordance with this Division.

In vitro diagnostic products used in _in vitro_ diagnostic procedures

29. An *in vitro* diagnostic product shall be assigned to Class A, if it is —

(*a*) a reagent or an article which possesses any specific characteristic that is intended by its product owner to make it suitable for an *in vitro* diagnostic procedure related to a specific examination; or

(*b*) an instrument intended specifically by its product owner to be used for an *in vitro* diagnostic procedure.

THIRD SCHEDULE — *continued*

Specimen receptacles

30. An *in vitro* diagnostic product which is a specimen receptacle shall be assigned to Class A.

Other *in vitro* diagnostic products

31. An *in vitro* diagnostic product shall be assigned to Class B, if —

(*a*) paragraphs 25 to 30 do not apply to it; or

(*b*) it is a substance or device used for the assessment of the performance of an analytical procedure or a part thereof, without a quantitative or qualitative assigned value.

FOURTH SCHEDULE

Regulations 27 to 30, 48, 49 and 50

FEES

First column	*Second column*
Description of fees	*Fee payable*
1. Application fee for registration of —	
(a) a Class A medical device	$25
(b) a Class B medical device	$500
(c) a Class C medical device	$500
(d) a Class D medical device	$500
2. Application fee for evaluation of a medical device for registration, in a case where the medical device is proposed to be classified as —	
(a) a Class A medical device, by verification of the presentation of, and the conformity declaration for, the medical device	Nil
(b) a Class B medical device —	
(i) by evaluation under an abridged evaluation process referred to in regulation 26	$1,800
(ii) by evaluation under a full evaluation process	$3,500
(c) a Class C medical device —	

FOURTH SCHEDULE — *continued*

(i) by evaluation under an abridged evaluation process referred to in regulation 26	$3,500
(ii) by evaluation under a full evaluation process	$5,700
(d) a Class D medical device —	
(i) by evaluation under an abridged evaluation process referred to in regulation 26	$5,700
(ii) by evaluation under a full evaluation process	$11,400
(e) a medical device that contains a medicinal product —	
(i) by evaluation under an abridged evaluation process referred to in regulation 26	$10,000
(ii) by evaluation under a full evaluation process	$75,000
3. Annual retention fee under regulation 50(3) for —	
(a) a Class A registered medical device	$25
(b) a Class B registered medical device	$35
(c) a Class C registered medical device	$60
(d) a Class D registered medical device	$120
4. Notification fee under regulation 49(2) in respect of —	
(a) a Class A registered medical device	$25
(b) a Class B registered medical device	$500
(c) a Class C registered medical device	$500
(d) a Class D registered medical device	$500
5. Fee for application for the Authority's approval under regulation 49(3) in relation to —	
(a) a Class A registered medical device	Nil
(b) a Class B registered medical device	$600
(c) a Class C registered medical device	$1,200
(d) a Class D registered medical device	$2,300
6. Fee for application for, or application for renewal of —	
(a) a manufacturer's licence	$1,000

FOURTH SCHEDULE — *continued*

(b) an importer's licence (other than an importer's licence referred to in item 9 or 10)	$1,000
(c) a wholesaler's licence (other than a wholesaler's licence referred to in item 9 or 10)	$1,000
7. Notification fee under regulation 48(2) for changes to particulars in relation to —	
(a) a manufacturer's licence	$150
(b) an importer's licence	$150
(c) a wholesaler's licence	$150
8. Fee for application to change registrant of a medical device	$800
9. Fee for application for an importer's licence or a wholesaler's licence for the supply of an unregistered medical device —	
(a) by a private hospital, medical clinic or clinical laboratory licensed under the Private Hospitals and Medical Clinics Act (Cap. 248), or a person acting on its behalf, for the use of a patient of the private hospital, medical clinic or clinical laboratory	$500
(b) by a qualified practitioner, or a person acting on his behalf, for the use of a patient of the practitioner	$500
(c) solely for a non-clinical purpose	$500
10. Fee for application for an importer's licence or a wholesaler's licence for the supply of an unregistered medical device for the purpose of export or re-export only (being a medical device manufactured solely for export or imported solely for re-export)	$500
11. Fee for application for any certificate	$50
12. Processing fee —	
(a) in relation to a certificate of origin under regulation 27(1) or (2) —	
(i) for issue of a certificate of origin (for one medical device and addressed to one country)	$50
(ii) for inclusion of an additional medical device (per medical device)	$50

FOURTH SCHEDULE — *continued*

(iii) for inclusion of an additional country (per country)	$50
(b) for issue of a certificate under regulation 28 (per licence/per certificate)	$150
(c) for issue of a certificate of registration of a medical device under regulation 29(2) (per registered medical device/per certificate)	$150
(d) in relation to a certificate of free sale under regulation 29(3) —	
(i) for issue of a certificate of free sale (for one medical device and addressed to one country)	$50
(ii) for inclusion of an additional medical device (per medical device)	$50
(iii) for inclusion of an additional country (per country)	$50
(e) in relation to a certificate under regulation 30(1) for a medical device intended for export —	
(i) for issue of a certificate (for one medical device and addressed to one country)	$50
(ii) for inclusion of an additional medical device (per medical device)	$50
(iii) for inclusion of an additional country (per country)	$50.

FIFTH SCHEDULE

Regulation 40(1)

IMPLANTABLE MEDICAL DEVICES

1. Heart valve.
2. Annuloplasty ring.
3. The following active implantable medical 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.

FIFTH SCHEDULE — *continued*

4. The following medical devices of human origin:

   (*a*) human dura mater; and

   (*b*) wound covering containing human cells.

5. All orthopaedic implant systems.

SIXTH SCHEDULE

Regulation 10A

	First column	*Second column*
	Device identifier	**Description or intended purpose**
1.	**Adhesive bandage**	A piece of fabric or plastic material (not a strip) that is applied to a part of the body with a pressure-sensitive adhesive. It may or may not include an absorbent pad. It is used to cover and protect intact skin or wounds, to approximate the skin edges of a wound, to support an injured part of the body, or to secure objects to the skin. This is a single-use device.
2.	**Adhesive strip**	A small, narrow flexible band (of fabric, plastic, paper or other material) coated on one side with a pressure-sensitive adhesive, used to cover and protect intact skin or wounds or approximate the edges of superficial wounds or fix dressings to skin. The device may include an adhesive pad and have qualities such as hypoallergenic or waterproof. The device is usually supplied in pre-cut sizes or shapes. This is a single-use device.
3.	**Adhesive tape**	A very long and narrow flexible band (of fabric, plastic, paper or other material) coated on one side with a typically pressure-sensitive adhesive, used to cover a surface (e.g. small wound), fix a dressing, or bind/attach objects (e.g. a venflon to a patient's body part, an orthopaedic cast). The device may also be applied in several layers, one overlapping the other, to cover and exert pressure on a body part (e.g. a limb). The device may have additional properties (e.g. waterproof,

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
		hypoallergenic) and is typically supplied in rolls. This is a single-use device.
4.	**Adhesive tape remover**	A solvent material designed to remove adhesive tape and its residue from the skin or other surfaces. This is a single-use device.
5.	**Applicator, absorbent tipped**	A device used for making local applications to any accessible body surface. It is typically designed as a slender rod of wood, flexible metal or a synthetic material, to which is attached a non-sterile absorbent tip at one end. This is a single-use device.
6.	**Nasal aspirator, manual**	A portable, hand-held, manual suction device designed to enable gentle suction and clearing of excessive mucus from the nasal passages to facilitate easier breathing. It is available in a variety of forms including a compressible bulb with a tube that is inserted into the nares, or a syringe with a small bulb at its distal end that is applied to the nasal opening.
7.	**Ice bag**	A flexible container (a bag) designed to be filled with ice to provide dry cold therapy to a limited external surface area of the body. It is typically made of plastic or rubber materials with a detachable cap that can be threaded or fixed to the bag once it is filled with ice. It may include a holder or attachments to facilitate fixing or holding the device in place against the body surface of the patient. It can be used to alleviate pain and/or promote healing in minor injuries of the body, or for application around the neck or limbs.
8.	**Bandage, self-adherent**	A flexible piece, strip, or roll of fabric or plastic material that is applied to (typically wrapped around) a part of the body to secure a dressing, maintain pressure over a compress, or immobilise a limb or other body part. This is a single-use device.

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
9.	**Bandage, clavicle**	A strip or roll of fabric or webbed material that is wrapped around the shoulder girdle to maintain fixation and longitudinal extension of the clavicle during a period of treatment. This is a single-use device.
10.	**Bandage, elastic**	An elasticised fabric (e.g. polyamide, lycra) used to provide support or local pressure to a part of the body, especially a joint, while allowing movement. It may have various configurations (e.g. long flat strip, tubular) to accommodate various body parts (e.g. ankles, knees, wrists, neck). This is a single-use device.
11.	**Bandage, gauze**	A piece or strip of fabric made of open weave cotton or rayon fibres and of differing degrees of fineness used to cover and protect wounds. This is a single-use device.
12.	**Bandage, gauze, roller**	A long, layered gauze supplied in rolls that is used to bandage heads, limbs and wounds that are difficult to dress (e.g. burns, plastic surgery or orthopaedic wounds). This is a single-use device.
13.	**Bandage, traction**	A large strip of fabric or plastic material used to assist in exerting desirable tensile (*pulling*) forces on the body. This is a single-use device.
14.	**Sitz bath**	A tub that is filled with heated water and intended for use in external hydrotherapy to relieve pain or pruritus and to accelerate the healing of inflamed or traumatised tissues of the perianal and perineal areas. The patient immerses only the hips and buttocks, keeping the legs outside of the tub. It is typically used to maintain patient hygiene and to alleviate pain and discomfort caused by haemorrhoids, uterine cramps, labour and/or other diseases of the pelvic, abdominal and perineal area (e.g. prostate, bladder, bowel, vaginal disorders). This is a non-active medical device.

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
15.	**Bed, hospital**	A device upon which a patient rests or sleeps, or upon which a patient may be treated. It is used in hospitals, institutions and home care and is used in conjunction with a patient's admission and treatment, or for the disabled or infirm.
16.	**Bed, general-purpose, manually-operated**	A mechanically-designed bed to be used as a general-purpose patient bed in hospital wards with manual mechanisms to adjust the height and surface contour of the bed. This device may include movable and latchable side rails.
17.	**Bed, general-purpose, hydraulically-powered**	A bed designed to be used as a general-purpose patient bed in hospital wards with a hydraulic mechanism to adjust the height and surface contour of the bed. This device may include movable and latchable side rails.
18.	**Bed, general-purpose, electrically-powered**	A bed designed to be used as a general-purpose patient bed in hospital wards and which is electrically powered (*motorised*), providing the patient/nursing staff with touch button adjustment possibilities.
19.	**Bedpan, fracture**	A device used by a bedridden patient as receptacle for urine and faeces and which is designed to be used by a patient whose hips have been plastered. This device is reusable after the appropriate cleaning procedure has been done.
20.	**Bedpan, general-purpose**	A device used by a bedridden patient as receptacle for urine and faeces. This device is reusable after the appropriate cleaning procedure has been done.
21.	**Abdominal binder**	A strip or roll of fabric or plastic material applied to the abdomen to support relaxed abdominal walls.
22.	**Ankle binder**	A strip or roll of fabric or plastic material designed to support the ankle joint.

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
23.	**Breast binder**	A strip or roll of fabric or plastic material designed to support the breasts.
24.	**Chest binder**	A strip or roll of fabric or plastic material designed to support the ribs and chest.
25.	**Binder, sternum**	A strip or roll of fabric or plastic material designed to support the sternum.
26.	**Wrist binder**	A strip or roll of fabric or plastic material designed to support the wrist joint.
27.	**Blanket, rescue**	A large piece of fabric-material blanket specially designed to keep a patient warm and/or to prevent the further loss of body heat in an emergency situation.
28.	**Bite block**	A device inserted into a patient's mouth to maintain oral patency during an endoscopic procedure primarily to protect the endoscope, introduced via the mouth, from the patient's natural tendency to bite down on the instrument. The device will also protect the tongue and teeth of the patient during endoscopy. This is a single-use device.
29.	**Adaptor, blood collecting tube, reusable**	A non-sterile reusable device used to attach and hold a venous access device (i.e. needle, blood collection set) during venipuncture and to connect these devices to the blood collection tube.
30.	**Blood collection tray**	A device intended to hold syringes and other apparatus needed for blood collection.
31.	**Stripper, blood tubing**	A device specifically designed to strip, crimp and cut tubing in the preparation of blood segments from the blood collection and processing procedures.
32.	**Tube, blood collecting, open**	A non-sterile device designed as a tube which is used during the collection of blood. It is open-ended, allowing blood to fill the tube from, for example, a tubing that has been inserted. The

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
		tube may or may not be sealed using a cap or plug. This is a single-use device.
33.	**Tube, blood collecting, sealed, evacuated**	A non-sterile device designed as a tube which is used with a blood collection tube adaptor and a blood collection needle to draw blood. This device is a presealed tube which has been partially evacuated. The vacuum will make the tube fill with blood. This is a single-use device.
34.	**Board, arm**	A firm device in which a patient's arm is placed for stabilisation to maintain the patency of an intravascular catheter (e.g. those connected to an intravenous or intra-arterial line). It is typically constructed of expanded polystyrene with a plastic coating and can be straight or curved to accommodate the patient's arm/wrist.
35.	**Board, cardiac compression**	A flat, rigid device that is placed under a patient to instantly give the necessary support required for the application of cardiopulmonary resuscitation. This device is typically suitable for use when an acute situation has arisen and the patient is lying in his bed.
36.	**Board, spinal**	A flat, stiff device placed on a stretcher to ensure spinal immobilisation when a spinal injury is suspected.
37.	**Bottle, heating/cooling**	A flexible container, typically with a relatively narrow neck, that is usually filled with either hot or cold water or ice for the purpose of applying heat or cold therapy to an area of the body.
38.	**Contact lens case**	A container designed for the storage of contact lenses when the lenses are not being used. The container is composed of chemically inert material(s).
39.	**Chair, bath/shower**	A device designed to be sat upon by a person who is either bathing, showering, or using some washing facility where there is a need to sit,

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
		such as because the person is disabled or infirm, or because it is part of medical treatment.
40.	**Chair, blood donor**	A device used to position the patient in such a manner that a technician/nurse has easy access to the patient's arm for drawing blood. The arm board, that is attached to the chair, has lateral and height adjustments so that the patient's arm can be positioned in a location that is easily accessible to whoever is drawing the blood sample. This chair can typically be tilted/moved so that the patient lies in a reclining position.
41.	**Chair, examination/ treatment**	A device used to position the patient in a sitting, semi-sitting or reclined posture for easy access and patient comfort during an examination, treatment, or surgical intervention.
42.	**Chair, toilet**	A chair designed with a toilet-like seat that allows an immobilised person/patient to utilise a standard stationary toilet without leaving the chair.
43.	**Chair, MRI system**	A chair or stool specifically designed to support and position a patient during an examination involving the use of a diagnostic magnetic resonance imaging (MRI) system. For MRI system compatibility, these chairs/stools are made of ferromagnetically inactive materials.
44.	**Charger, battery**	A mains electricity (AC-powered) device designed to supply an electrical charge to the rechargeable batteries or battery pack of a medical device, restoring the batteries or battery pack to an appropriate working condition. This device is typically connected to the building's mains electricity power supply and can be used to charge the batteries either by themselves (removed from their parent device) or whilst they are still inside the parent device (in situ), e.g. a defibrillator, an ophthalmoscope, an otoscope. This device usually has current and

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
		voltage controls to meet the charge needs of different types of batteries.
45.	**Chart, eye, Amsler grid**	An ophthalmic device that consists of a series of charts with grids of different sizes that are held at a distance of 30 cm from the patient and intended to rapidly detect central and paracentral irregularities in the visual field.
46.	**Chart, eye, colour discrimination**	An ophthalmic chart with coloured figures printed on coloured backgrounds, used in testing colour vision.
47.	**Chart, visual acuity**	An ophthalmic chart imprinted with block letters or other symbols in gradually decreasing sizes, identified according to distances at which they are ordinarily visible; used in testing visual acuity. Such charts are often combined in a box where the individual letters or symbols are selected and highlighted by the optician/doctor with background electrical lighting.
48.	**Syringe, high performance/ calibration, liquid/gas chromatography**	A dedicated syringe used for injecting small volumes of accurately measured amounts of liquid or gas into a chromatograph system, such as for calibration or reference. This device is typically made of a glass cylinder with a steel plunger and made to high tolerances of accuracy. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
49.	**Indicator, cellulose fluorescent, TLC**	For use in thin layer chromatography. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
50.	**UV light, TLC**	For use in thin layer chromatography. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
51.	**Indicator, alumina fluorescent, TLC**	For use in thin layer chromatography. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
52.	**Indicator, silica gel fluorescent, TLC**	For use in thin layer chromatography. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
53.	**Plate, alumina, TLC**	For use in thin layer chromatography. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
54.	**Papers, ion exchange**	For use in ion exchange chromatography. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
55.	**Resins, ion exchange, liquid chromatography**	For use in ion exchange chromatography. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
56.	**Centrifuge, laboratory**	A device that is a laboratory centrifuge used to separate the components of suspensions by the application of centrifugal force. It typically consists of an electrically-powered drive unit with a vertical shaft and horizontal rotor attached to the upper end. This device is intended to centrifuge patient samples (e.g. body fluids) either alone or after the addition of reagents or other additives before measuring analytes. It is typically a low-speed (up to 6,000 rpm) or medium-speed (up to 12,000 rpm) machine. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
57.	**Centrifuge, ultra**	A device that is a laboratory centrifuge used to separate the components of suspensions by the

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
		application of centrifugal force. It typically consists of an electrically-powered drive unit with a vertical shaft and horizontal rotor attached to the upper end. This device is a specialised centrifuge that processes relatively small volumes of sample at very high speeds, typically up to 100,000 rpm and RCF 800,000 xg. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
58.	**Cover, microscope slide**	A device or material used as a physical barrier to protect the surface of a microscope slide upon which a sample has been placed from the effects of mechanical and/or environmental exposure. This is a single-use device. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
59.	**Slide, microscope**	A device, typically a thin flat piece of glass of given dimensions, whereupon samples (e.g. blood, tissue) can be placed for analysis, usually under a microscope. This is a single-use device. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
60.	**Petri dish processor**	A laboratory instrument that automatically processes petri dishes, feeding them from a magazine and filling them with a given quantity of substance, e.g. agar (a gelatine-like substance derived from seaweed used as a stabiliser and for nutrition) prior to the production of micro-organism cultures, for diagnostic purposes. This can be used together with an agar steriliser. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
61.	**Pipette, electronic/ manually-operated**	A device typically used in the laboratory to transfer discrete and consistent volumes of

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
		liquid substances, e.g. into a test tube or the wells of a microtitre plate. This device can operate mechanically, electronically, or through manual induction. The device may be factory pre-set to deliver a given volume, or may have user-selectable volumes within a useful volume range. It includes the pipette tips, safety mouthpiece and shield. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
62.	**Incubator, laboratory**	A device designed for use in a laboratory setting to provide controlled conditions for the incubation of biological and chemical materials. It will typically maintain a desired environment of, for example, temperature, gas concentrations or humidity. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
63.	**Inoculating loop**	A device consisting of a slender handle and an attached wire loop used to gather and hold specimen material (e.g. bacterial growth colonies) for the purpose of inoculating a culture medium (e.g. agar or broth). It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
64.	**Mixer, laboratory**	A device, typically used in the laboratory, for the mixing of 2 or more components by using a slow stirring/blending movement. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
65.	**Sample processing system**	An automated group of devices without analysers (e.g. robotic conveyors, handlers) controlled by a computer system used to alternate and treat clinical samples in preparation for analysis. It is a medical device

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
		that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
66.	**Sample alternating system**	An automated group of devices without analysers composed of robots/conveyors and a computer control system used to rotate clinical samples for processing and analysis. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
67.	**Sample processor**	An instrument without analysers used to automatically prepare a clinical sample for analysis. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
68.	**Sample processor, immunoassay**	An instrument or apparatus intended to homogenise a sample taken from human tissue and to prepare a portion of the sample for analysis by immunoassay analysers. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
69.	**Sample tube vacutip inserting device**	A laboratory instrument that introduces small tube-like tips (*vacutips*) into the rubber corks/plugs of sample tubes. This procedure will prevent the evaporation of the sample, and sampling (automatic or manual) can easily be performed through the inserted tip. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
70.	**Shaker, laboratory**	A device, typically used in the laboratory, that shakes or stirs samples/mixtures with a rapid and forceful movement. It is specially used to prevent substances comprising different components from separation or sedimentation because of their different densities. It is a medical device that is intended by the product

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
		owner for use as an in vitro diagnostic (IVD) product.
71.	**Thermostat, laboratory**	A device used in laboratories to regulate the temperature of various media in association with a parent device (e.g. water in water baths). It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
72.	**Washer**	A device used in the clinical laboratory to wash loosely adherent cells or to wash away residuals before diagnostic testing. It may have flexible washing options from simplicity of operation to digitally controlled aspiration and dispensing pumps. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
73.	**Clip, nose**	A device used to help prevent air movement through the nares. The device is typically constructed of plastic with rubber or foam tips and is used during pulmonary function studies to help ensure that airflow is conducted through the mouthpiece for accurate measurements.
74.	**Clip, spectacle, ophthalmic**	A device intended to hold prisms, spheres, cylinders, or occluders on a trial frame or set of spectacles during vision testing.
75.	**Collector, general**	A non-sterile small container for medical treatment purposes or intended for the purpose of short-term storage and/or transportation, to collect fluids, gas or other materials from the human body. This may also be for specimen or sample purposes.
76.	**Collector, sweat**	A non-sterile container used for collecting sweat typically for specimen or sample purposes.

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
77.	**Collector, urine**	A non-sterile small container used for collecting urine to obtain a specimen for analysis. This is a single-use device.
78.	**Compression dressing**	An elastic material that is designed to compress a local area (e.g. to stop bleeding, prevent oedema or provide support for varicose veins or ostomy aids).
79.	**Compression garment**	An elastic material that is contoured to fit over and apply pressure to one or more specific body parts (e.g. thighs, hips, buttocks), and is typically used after an invasive procedure (e.g. liposuction). In the case of significant subcutaneous tissue removal (e.g. fat removal after liposuction), the device may aid in the readjustment of overlying skin. This is a reusable device.
80.	**Sterilisation container**	A device used to hold surgical instruments, typically units (e.g. surgical powered drills, saws and their hoses) but also other instruments during sterilisation and for their subsequent storage. The container is permeable in order to allow moisture to escape from within after the sterilisation process is finished, whilst protecting the contents from being contaminated. It may have features such as expiry date, sterile breathing filter or stacking abilities.
81.	**Digital imaging cassette**	A device (e.g. a cassette or barrier envelope) used in medical imaging applications to hold and shield an attached storage phosphor screen from exposure to room light during transport and insertion into a diagnostic imaging X-ray system or a computed radiography scanner, in the process of producing a digital image of a patient radiation pattern.
82.	**X-ray film cassette, manual**	A device used in medical imaging applications to shield X-ray film from exposure to room light

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
		during transport and insertion into a diagnostic imaging system, film formatter or film processor. It is typically designed for use with a particular imaging system or image formatting unit and consists of a plastic or metal housing with removable metal or plastic inserts. Some film cassettes used in X-ray applications can incorporate an X-ray grid into the cassette design.
83.	**Cotton ball**	A spherical mass of cotton or man-made fibres used as a swab to apply medications to or remove liquid from various parts of the body.
84.	**Cotton roll, general-purpose**	A device usually made of medical cotton or sometimes man-made fibres that has a general-purpose use throughout hospitals and other areas of the healthcare sector.
85.	**Cover, thermometer**	A device used as a physical barrier for a thermometer to prevent cross-contamination between patients and/or environmental exposure. This is a single-use device.
86.	**Absorbent point, dental**	A non-medicated absorbent point used in endodontic procedures. This is a single-use device.
87.	**Mixer, dental, amalgam**	A dental amalgamator is a device intended to mix chairside, by shaking, mainly amalgam capsules containing mercury and dental alloy particles immediately before application to the teeth of the patient during dental procedures.
88.	**Articulating paper**	A strip or sheet of suitable material coated with pigment and used for marking areas of contact between opposite teeth, restorations or appliances. This is a single-use device.
89.	**Camera, dental, intra-oral**	A camera specially designed for use during dental surgery to obtain still picture documentation of surgical procedures and to photograph pathologies. This generic device

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
		group includes Polaroid, digital and photographic film cameras. This camera is not meant for a diagnostic purpose.
90.	**Chart, dental, colour discrimination**	A device used to determine the correct shade (*colour*) of filling materials, artificial crowns and teeth for matching to those of the patient.
91.	**Cotton roll, dental**	A device formed as a small, short, cotton roll that is used as a saliva absorber and intended to absorb moisture from the oral cavity during dental procedures. It is usually made of cotton and is disposable.
92.	**Cushion, dental**	A prefabricated or non-custom-made disposable device that is intended for use to improve the fit of a loose or an uncomfortable denture.
93.	**Dental teeth protector**	A curved device designed to fit over the upper and lower sets of teeth to protect them from damage during dental procedures. Such protection can be required when the patient is resisting the dental treatment by clenching his teeth which can be damaged against the metal or plastic materials of the dental instruments being used, and/or if the patient has bad teeth that are susceptible to inadvertent damage.
94.	**Dental ring**	A device used to hold a matrix band and wedge in place around the tooth.
95.	**Dental wedge**	A dental device that is positioned wedge-like at the interdental and cervical area of the teeth during routine intra-oral dental procedures. It is used to slightly separate the teeth during the placement of a filling material, or to stabilise and support other devices (e.g. a matrix band or a rubber dam).
96.	**Forceps, dental**	A hand-held dental instrument used in the mouth for different gripping applications. This is a single-use device.

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
97.	**Light, dental, polymerisation activator**	An electrically-powered lamp used to initiate the polymerisation of dental resin-based materials. The source for the activation should be ultraviolet light. It is used for curing of polymer-based materials in the laboratory.
98.	**Light, dental, intra-oral**	A dedicated light-conducting system with a very small dimension at the light delivery end designed for dental use and to be introduced into the oral cavity. It delivers light using fibre optic cables. The device is typically attached to a dental hand piece and is intended to directly illuminate a patient's oral structures.
99.	**Light, dental, general-purpose**	A dedicated light designed for general-purpose dental use that delivers intense focused lighting to the dental operating, examination or procedure site, which usually is the oral cavity.
100.	**Matrix band/strip, dental**	A matrix band or strip comprising strong material (typically stainless steel or transparent polyester) or a short tube that is used to form a mould around a tooth for the insertion of restorative materials. The device is held snugly around the tooth by a matrix retainer or tensioned around the tooth using a dedicated mechanical tensioning device. The matrix strip, retainer and tensioner may be supplied together or separately.
101.	**Mouth guard, preformed**	A prefabricated device designed to protect the teeth, bones, and tissues of the mouth, from the effects of grinding/clenching of teeth (e.g. bruxism). It is typically made of standard, preformed materials or items for adaptation/direct insertion in the mouth.
102.	**Mirror, dental, hand-held**	A dental instrument for intra-oral inspection, generally comprising the mirror head and the mirror handle.

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
103.	**Placers, dental**	Elastic placers provide an elastic hook on one end and a pusher on the other end to remove dental elastics.
104.	**Retractor, dental**	A dental instrument intended to be used to manually displace soft tissues (e.g. cheeks, lips, tongue) of the oral cavity to improve their visualisation and access, and to afford them protection during oral surgical procedures. This is a single-use device.
105.	**Scaler, dental, manual**	A hand-held dental instrument for removing calculus and other accretions from the surface of teeth during dental cleaning and periodontal therapy. This is a single-use device.
106.	**Aligner tray seater**	A device placed between the upper and lower sets of teeth and bitten down on, or chewed, to seat aligners in the right position.
107.	**Tray, dental**	A device intended to hold solutions, gels and foams for dental treatment.
108.	**Impression tray, dental**	A device intended to hold, support and control the impression material(s) used in making a dental impression (e.g. of a patient's teeth or alveolar process (bony tooth sockets) to produce the structure of a patient's teeth and gums). This device is typically preformed (e.g. horseshoe shaped) and made of metal or plastic materials.
109.	**Depressor, tongue**	An instrument intended to displace the tongue to facilitate examination of the surrounding organs and tissues.
110.	**Surgical drape, general-purpose**	A non-sterile (usually sterilised before use) protective covering made of natural or synthetic materials, or both, designed to isolate a site of surgical incision or a surgical field from contamination (e.g. microbial, substance) in various clinical settings (e.g. in an operating room or a catheterisation laboratory). The

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
		device may also be used to protect a patient from heat or flame during a surgical procedure.
111.	**Hammer, percussion**	A metal, usually stainless steel, instrument comprising a handle, shaft and head, used to deliver a force to the body to test reflexes. The handle is designed to fit into the palm of the hand and is usually round, tapering distally into a shaft which terminates at the head. A percussion hammer head comes in various shapes. Some heads are fitted on one or both ends with a material (e.g. rubber or plastic, of various shapes to absorb the shock of the impact). It is also possible for the entire head to be made of rubber or plastic. A percussion hammer is used in neurological examinations.
112.	**Bath, paraffin, laboratory**	A laboratory device used to heat paraffin wax so that it can be used in the fixation of laboratory specimens (e.g. tissue biopsies). It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
113.	**Bath, tissue flotation**	A water bath used in conjunction with a microtome during the production of tissue specimens. The tissue specimens float onto the surface of the bath as they are sliced by the operator of the microtome. This device is temperature controlled and is typically used in the laboratory. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
114.	**Cryo spray, histology**	A refrigerant (e.g. dimethyl ether and propane) typically contained in an aerosol dispenser and intended to be used in histology laboratories for freezing tissue specimens in paraffin blocks for sectioning. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
115.	**Microtome blade**	A device that is a flat wedge-shaped blade that has a cutting edge of extreme sharpness and which is mounted into a microtome used to cut micro-slices of tissues that have been fixed, and usually impregnated with paraffin wax. The resulting sections are mounted on glass slides for staining then viewing by microscope. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
116.	**Microtome, rotary, sliding or ultra**	An instrument used for cutting tissue samples into micro-slices in preparation for histological study (microscopic examination). Before cutting, the tissues are fixed (e.g. in paraffin wax, celloidin, plastic), and may be secured to a sample block (a base). For cutting, the sample is held by clamps and the microtome blade/knife is passed over it. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
117.	**Microtome, cryostat**	An instrument that consists of a microtome contained in a temperature controlled cabinet called a cryostat. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
118.	**Stain, microscopy**	An agent used to colour or refract the light of a sample of tissue, cells, blood, or micro-organisms in preparation for light, electron or fluorescence microscopy for diagnostic purposes in clinical laboratories. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
119.	**Tissue processor**	An instrument used in the laboratory for the preparation of tissue specimens prior to examination. It will typically utilise fixation (e.g. encapsulation in a paraffin wax),

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
		dehydration, and infiltration techniques to process the tissue samples. This device may be of a manual, semi-automated or fully-automated design. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
120.	**Freezer/dryer, laboratory**	A device typically used in the laboratory for the removal of all moisture (water content) using the process of dry freezing. It is typically constructed as a chamber or receptacle into which the sample or object is placed and the moisture is extracted. It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
121.	**Immobiliser, ankle**	A non-rigid device, usually made of a fabric, used to temporarily render the ankle immovable (strait-jacket effect) to support the healing of an injury or a surgical wound.
122.	**Immobiliser, arm**	A non-rigid device, usually made of a fabric, used to temporarily render the arm immovable (strait-jacket effect), typically at the shoulder and elbow, to support healing of an injury or a surgical wound.
123.	**Immobiliser, elbow**	A non-rigid device, usually made of a fabric, used to temporarily render the elbow immovable (strait-jacket effect) to support healing of an injury or a surgical wound.
124.	**Immobiliser, infant**	A device, usually made of fabric and/or plastic materials, used to temporarily render parts of an infant's body (e.g. the arms and/or feet) immovable (strait-jacket effect) while the patient undergoes therapeutic or diagnostic interventions. It will typically be used to prevent the patient from interrupting an intravenous (IV) infusion, pulling out a catheter, or interfering with wound care.

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
125.	**Immobiliser, knee**	A rigid support used to temporarily render the knee immovable (strait-jacket effect), either pre-operatively or following injury or arthroscopy.
126.	**Immobiliser, shoulder**	A non-rigid device used to temporarily immobilise or limit abduction of the shoulder joint (strait-jacket effect) to support healing of an injury or a surgical wound. It is typically used post-operatively and for post-traumatic treatment of injuries in the shoulder and upper arm areas (e.g. distortion/contusion, dislocation/luxation, post-operative support). It will typically consist of layered fabric, straps, buckles, fasteners and will eliminate most of the work involved with bandaging.
127.	**Immobiliser, whole body**	A device, usually made of fabric and/or plastic materials, used to temporarily render the patient's whole body immovable (strait-jacket effect) while the patient undergoes therapeutic or diagnostic interventions.
128.	**Immobiliser, wrist**	A rigid support designed to temporarily render the wrist immovable (strait-jacket effect) as therapy for non-displaced fractures, strains, sprains, and muscle injuries of the wrist. It comes in a variety of sizes.
129.	**Irrigator, nasal**	A device designed to dispense a solution intended to penetrate, clear, and clean the nasal passages and sinus cavity. It typically includes an irrigation bottle/canister, and sometimes actuator tips and adaptors for various solution-delivery applications. The solution may be self-administered for post-operative, preventative or symptomatic nasal care. The device does not include, or is not supplied together with, irrigation solution or medication.

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
130.	**Irrigation kit, eye**	A device that typically includes an application bottle, syringe or cup, used to flush the eye of irritating particulates/chemicals, or to help stimulate tired eyes. The device does not include, or is not supplied together with, irrigation solution or medication.
131.	**Knife, paraffin**	A dedicated knife designed to cut paraffin blocks. It will typically consist of a sturdy blade made of hard metal (e.g. beryllium copper) that retains the heat well and a shank that is permanently attached to a hand-held heat source. The heat, which may be regulated, penetrates into the blade from the heat source (e.g. electrical) through the shank. This device is used to cut/handle paraffin in clinical laboratories (histology and pathology embedding). It is a medical device that is intended by the product owner for use as an in vitro diagnostic (IVD) product.
132.	**Lens set, trial**	A set of ophthalmic lenses of various dioptric powers intended to be handled or inserted in a trial frame for vision testing to determine the required refraction.
133.	**Light, head-worn**	A device (a lamp) designed to be worn on an operator's head. It is mounted on a band or helmet frame and situated on the user's forehead providing a light directly into the field of vision during surgical, diagnostic or therapeutic procedures. The light typically consists of a magnifying lens, a reflector and a connection for the fibreoptic cable to transfer cold-light or power supply from a battery pack.
134.	**Light, surgical**	A device that provides a specialised light to illuminate a surgical site over a prolonged period of time providing the surgeon(s) with optimal visualisation of small, low-contrast objects at varying depths or through small

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
		incisions. In addition to providing enough illumination and minimising the emission of heat to the site, the light will reduce shadows and produce minimal colour distortion, which helps the surgeon evaluate tissues and structures. It typically consists of one or more light bulbs, which reflect the light via reflectors or mirrors depending upon the construction. This device will typically be part of a light system comprising more than one light head.
135.	**Light, examination, hand-held, battery-powered**	A small hand-held battery-powered light used as a personal light source to provide light for local examination, inspection and treatment of the patient. It may be torch-like in design and can have a magnifying lens to augment the lighting effect. It will typically be found in an examination room, doctor's surgery or office, on a medical trolley or as part of an emergency kit.
136.	**Light, examination**	A device that provides light to illuminate the site of examination or treatment of the patient. It typically consists of one or more light bulbs which reflect the light via reflectors or mirrors depending upon the construction. This device has a variety of uses and can be fixed (e.g. to a ceiling or wall, or supported on a mount). It can also be part of a light system comprising more than one light head.
137.	**Light, ear**	A dedicated device designed to illuminate the ear canal.
138.	**Loupe, binocular**	A system of lenses mounted onto a pair of spectacles worn by the surgeon during surgical intervention. These function as small telescopes and provide a magnified image of the working field. They can also be connected to an external light source supplying light directly through the field of vision.

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
139.	**Marker, skin**	A device used to make marks on the skin that allow measurement or identification.
140.	**Mask, resuscitation**	A malleable cone placed over the nose and mouth to administer air to a patient during cardiopulmonary resuscitation (CPR). The device is designed to replace mouth-to-mouth resuscitation, therefore avoiding cross-contamination. The device may include an airway, one-way valve or other component.
141.	**Face barrier, resuscitation shield**	A clear plastic sheet with a filter for mouth-to-mouth resuscitation. It does not provide absolute protection but reduces the risk of cross-contamination. The device does not include an airway, one-way valve or other component.
142.	**Mirror, ENT, hand-held**	An instrument with a surface sufficiently polished to reflect enough undiffused light to form a virtual image of an object placed before it, for the purposes of ear/nose/throat (ENT) examinations. This mirror is mounted on a long, slender handle, and is held by the doctor who can manipulate the mirror close to the site of interest.
143.	**Mirror, ENT, headband**	An instrument with a circular concave mirror attached to a headband acting as a reflector that is used to project a beam of deflected light to a body cavity (e.g. the nose or larynx) for the purposes of ear/nose/throat (ENT) examinations. The doctor will wear this device on his head, place the reflector in front of one eye, and view the site through a small hole in the centre of the reflector.
144.	**Mirror, general or plastic surgery**	A device designed to be used to assist practitioners during general or plastic surgery that displays a virtual image of an object placed before it.

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
145.	**Mirror, headband, ophthalmic**	An ophthalmic instrument with a circular concave mirror attached to a headband used to project a beam of light to allow examination of the eye and its associated structures.
146.	**Orthosis, shoulder/elbow/ wrist/hand**	An externally applied orthopaedic appliance or apparatus used to support, align or prevent deformities/injuries of the shoulder, elbow, wrist and/or hand.
147.	**Orthosis, hip/knee/ankle/foot**	An externally applied orthopaedic appliance or apparatus used to support, align or prevent deformities/injuries of the hip, knee, ankle and/or foot. The device may be an articulated single item or a collection of compatible units specific for various parts of the leg.
148.	**Orthosis, finger**	An externally applied orthopaedic appliance or apparatus used to support, align or prevent deformities/injuries of the finger.
149.	**Orthosis, footwear insert**	A specially designed footwear insert intended to provide support for the base of the foot.
150.	**Orthosis, sacroiliac spine**	An externally applied orthopaedic appliance or apparatus that encompasses the sacroiliac spine region of the trunk and is used to support or immobilise deformities, fractures, sprains, or strains of the spine.
151.	**Orthosis, thoracic spine**	An orthopaedic corset that encompasses the thoracic spine region of the trunk and is used to support or immobilise deformities, fractures, sprains or strains of the spine through compression of the abdomen.
152.	**Orthosis, cervicothoracic spine**	An externally applied orthopaedic appliance or apparatus used to support or immobilise deformities, fractures, sprains or strains of the cervicothoracic spine.
153.	**Orthosis, cervical spine**	An externally applied orthopaedic appliance or apparatus used to support or immobilise

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
		deformities, fractures, sprains or strains of the cervical spine.
154.	**Orthosis, lumbosacral spine**	An externally applied orthopaedic appliance or apparatus that encompasses the lumbosacral spine region of the trunk and is used to support or immobilise deformities, fractures, sprains or strains of the spine.
155.	**Paper, recording**	A device prepared from a thin sheet of fibrous material specially produced for recording the output of devices measuring physiologic parameters (e.g. electrocardiogram (ECG), electroencephalogram (EEG), or for ultrasound imaging).
156.	**Intravenous pole**	A pole or rod with 2 or more hooked bars extending horizontally from its top from which various fluid delivery devices (bags or bottles) can be suspended for the administration of intravenous (IV) fluids or medication to the patient. Commonly known as an IV pole or drip pole, it can be a fixed or side-swinging, adjustable, vertical pole attached to a bed or operating table, ceiling-mounted or, more commonly, an independent floor-standing IV pole for bedside use. It may have wheels to allow patient mobility.
157.	**Pressure alleviation pad**	A device designed to prevent pressure sores (e.g. bed sores or decubitus ulcers) occurring on the parts of the patient's body which are prone to this. It can equally be used as an underlay for the patient when he/she is undergoing a long treatment where the body is immobilised, or for disabled, infirm persons who are confined to sitting/lying positions. This device is usually constructed as an underlay but can also be formed to accommodate the patient's body shape, prominent or unprotected bony parts

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
		(e.g. as mattresses (both active and passive), pads or skins of different materials).
158.	**Finger protector**	A device intended to be used to protect an injured finger from further trauma during the healing process. It will typically be made of durable materials (e.g. plastic, rubber, reinforced metal).
159.	**Protector, foot**	A device designed to cover a part of the body, or to be worn over the foot to protect that part of the foot from friction against surfaces and knocks against objects. It is typically made of soft padded materials, and supplied in pre-cut sizes or shapes. It may have additional properties (e.g. waterproof, lubricating, hypoallergenic). It is typically used by persons who suffer from common foot ailments such as bunions, corns, blisters, calluses, ingrown toe nails, hammer toes, overlapping toes or spurs.
160.	**Projector, visual acuity**	An ophthalmic device, a kind of slide projector/beamer throwing block letters or other symbols on a screen/wall in gradually decreasing sizes, identified according to distances at which they are ordinarily visible; and used in testing visual acuity.
161.	**Prosthesis, arm, non-active**	An artificial substitute for a missing or dysfunctional used to restore some degree of the appearance and/or function of the normal anatomy. The device may be used as part of an upper limb prosthetic system. This is a non-active medical device.
162.	**Prosthesis, ankle/foot, external, non-active**	An artificial substitute for an ankle and/or foot, or foot part, used to restore some degree of the appearance and/or function of the normal anatomy. The device may be used as part of a lower limb prosthetic system. This is a non-active medical device.

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
163.	**Prosthesis, breast, external, non-active**	An external device used to replace the breast typically after a mastectomy, intended to restore some degree of the appearance and/or function of the normal anatomy. It is made of various materials to simulate the appearance and texture of a breast and is typically fitted into a brassiere. This is a non-active medical device.
164.	**Prosthesis, elbow, external, non-active**	An artificial substitute for the upper limb missing at the elbow joint used to restore some degree of the appearance and/or function of the normal anatomy. The device moves as the result of connecting straps/cables or other mechanism powered by the movement of body segments, or it moves as the result of a connection with another functional limb component. The position of the device may be maintained through a manual or automatic locking mechanism. The device may be used as part of an upper limb prosthetic system. This is a non-active medical device.
165.	**Prosthesis, hand, non-active**	An artificial substitute for a missing hand used to restore some degree of the appearance and/or function of the normal anatomy. The device moves as the result of connecting straps/cables or other mechanism powered by the movement of body segments. The position of the device may be maintained through a manual or automatic locking mechanism. The device may be used as part of an upper limb prosthetic system. The device is external. This is a non-active medical device.
166.	**Prosthetic hand range-of-motion aid, non-active**	A device positioned on the arm and maintained by friction used to increase the flexion range of the elbow allowing a prosthetic hand to reach the face of the wearer. This is a non-active medical device.

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
167.	**Prosthesis, hip, external, non-active**	An artificial substitute for a missing hip used to restore some degree of the function of the joint. The device is used as part of a lower limb prosthetic system. This is a non-active medical device.
168.	**Prosthesis, knee, external, non-active**	An artificial substitute for a missing knee used to restore some degree of the appearance and/or function of the joint. The device is used as part of a lower limb prosthetic system. This is a non-active medical device.
169.	**Prosthesis, leg, non-active**	An artificial substitute for a missing or dysfunctional leg used to restore some degree of the appearance and/or function of the normal anatomy. The device may be used as part of a lower limb prosthetic system. This is a non-active medical device.
170.	**Prosthesis, shoulder, external, non-active**	An artificial substitute for a missing shoulder used to restore some degree of the appearance and/or function of the joint. The device may be used as part of an upper limb prosthetic system. This is a non-active medical device.
171.	**Prosthesis, wrist, external, non-active**	An artificial substitute for a missing wrist used to restore some degree of the function of the joint. The device moves as the result of connecting straps/cables or other mechanism powered by the movement of body segments, or it moves as the result of a connection with another functional limb component. The position of the device can be maintained by a locking mechanism that is body-powered. The device is used as part of an upper limb prosthetic system. This is a non-active medical device.
172.	**Prosthetic socket, non-active**	A device that fits over the terminal end of a residual limb (*stump*) and serves as an interface between the limb and prosthesis. This is a non-active medical device.

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
173.	**Patient restraint**	A non-rigid device, typically a strap or band made of various materials (e.g. fabric, nylon, leather, foam), used to temporarily secure the arm or leg of an adult patient to prevent injury or hazards. The device is typically wrapped around the patient's arms or feet and anchored to a fixture or furniture part (e.g. a bedrail), restricting movement of the patient and preventing the patient from interfering with treatment (e.g. removing an intravenous or urinary catheter, handling a dressed wound).
174.	**Restraint, fingers**	A device designed to restrict finger mobility and prevent potential injury.
175.	**Restraint, body**	A device designed to secure a patient's arms to the torso to prevent self-inflicted injury.
176.	**Retainer, bandage**	A device used to stabilise, attach or fix a bandage/dressing in a desired location. This device can be a fastener/clasp (e.g. an elastic strip with opposing gripping teeth/hooks) or tubular elastic net. It is typically used on patients sensitive or allergic to adhesive tape.
177.	**Self-exam pad, breast**	A device for use as an aid in performing breast self-examination. It consists of 2 plastic sheets with liquid sealed in between and is to be placed onto the breast. It reduces friction between the fingers and breast.
178.	**Shield, eye**	A mechanical shield, usually plastic or metallic used for protection of one or both eyes following surgery or trauma.
179.	**Shield, face**	A clear, transparent guard worn over the face/eyes to protect the healthcare worker from blood and other body fluid splashes while performing a clinical procedure.
180.	**Shield, hip**	A mechanical guard worn over the hip area to prevent against hip fractures in the event of a patient fall.

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
181.	**Shield, wound**	A mechanical shield that is designed to form a protective structure over a wound. It may be cage-like and will allow exposure to air and permit access to the injured area while protecting against accidental damage.
182.	**Shield, radiation, apron**	A full-length or half-length apron-like garment intended to shield portions of the body of a patient from exposure to radiation during medical or dental procedures. Some include attached or detachable collars for neck and thyroid protection. The device typically consists of a fluid-resistant outer covering surrounding a thin sheet of lead or lead equivalent material. Those used for neutron attenuation are composed of hydrogenous materials; those used in mixed beta-gamma radiation field may have layers of both hydrogenous and lead equivalent materials.
183.	**Shield, radiation, bib**	A personal protective device intended to shield the chest area of a patient from unnecessary exposure to radiation from diagnostic or therapeutic medical and dental procedures. Some have either attached or detachable collars used for neck and thyroid protection. Bibs used in diagnostic X-ray and nuclear medicine typically consist of a fluid-resistant outer covering that surrounds a thin sheet of lead or lead equivalent material. Bibs used for neutron attenuation are composed of hydrogenous materials; those used in mixed beta-gamma radiation field may have layers of both hydrogenous and lead equivalent materials.
184.	**Shield, radiation, blanket**	A personal protective device intended to shield the selected body parts of a patient, or others, from unnecessary exposure to radiation during diagnostic or therapeutic medical or dental procedures. Radiation protection blankets used

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
		in diagnostic X-ray and nuclear medicine typically consist of a fluid-resistant outer covering that surrounds a thin sheet of lead or lead equivalent material. Blankets intended to attenuate neutrons are composed of hydrogenous materials instead of lead. Blankets used in mixed beta-gamma radiation field may have layers of both hydrogenous and lead equivalent materials.
185.	**Shield, radiation, eye**	A personal protective device used to cover the patient's eyes and shield them from unnecessary exposure to primary and scattered radiation associated with diagnostic and therapeutic medical procedures. Eye shields can come in various shapes and are typically made of lead glass, lead or tungsten when attenuating photons, or hydrogenous materials when attenuating neutrons.
186.	**Shield, radiation, thyroid**	A radiation protection device specifically designed to shield the thyroid of a patient from unnecessary exposure to radiation from diagnostic medical and dental procedures. The thyroid shield provides an attenuating barrier between the individual's thyroid and the source of primary or scattered radiation. Structural thyroid shields may be attached to the wall, ceiling or radiation delivery device by an articulating arm that can be adjusted to shield the thyroid area of the throat. Others may be more flexible and fit over the patient's thyroid. It typically consists of a fluid-resistant outer covering that surrounds a thin sheet of lead material.
187.	**Shield, shower**	A device designed to form a protective structure to cover part of the body in order to protect these while the user is taking a bath or shower. The device is made of waterproof materials.

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
188.	**Anti-slip shoe, slipper, boot**	A device designed to be worn or applied to the outer sole of the shoes of an elderly person or a person with a disability to provide such person with greater grip on the surface upon which he is walking. It is typically used to assist mobility and help prevent slipping. This include any anti-slip devices attached to the shoe, such as clips, bands or springs, that are used to help prevent slipping.
189.	**Orthotic shoe**	Orthopaedic footwear that is intended to support, align, or prevent or correct deformities of, the feet to help improve their function.
190.	**Cast boot**	A boot-like cover for a foot enclosed in a leg cast. This device is generally equipped with a waterproof covering, an outer sole for walking, and closures for easy application and removal.
191.	**Shoe, cast**	A shoe designed to be worn over a foot/ankle that is encased in a cast, in order to protect the cast material and provide support.
192.	**Sling**	A hanging bandage or other material that is usually suspended from the body or another structure, and used to support and limit the range of motion of an injured limb during the healing period, or to support and limit the range of motion of a body in transport.
193.	**Spectacles**	An optical/ophthalmic device consisting of a spectacle frame that contains a pair of spectacle lenses (*eyeglasses*).
194.	**Splint**	A rigid or semi-rigid device that serves to immobilise an injured limb or body part. It is generally placed externally along the injured limb or body part. It is typically made of plastic, mouldable plastic, wood or metal.
195.	**Splint, nasal, external**	A rigid or partially rigid device intended for use externally for the immobilisation of parts of the

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
		nose typically after a fracture or treatment. It may function as a truss-like support on the outside of the nose.
196.	**Stethoscope, mechanical**	A mechanical listening device used for listening to sounds from the heart and lungs. It typically comprises a membrane at the listening head connected by a split "Y" tube to the headgear with ear olives that are placed into the user's ears. Mechanical stethoscopes are typically found in 2 variants: (*a*) a general-purpose stethoscope used for clinical/ward activities; or (*b*) a reinforced stethoscope used by cardiologists.
197.	**Cast stockinette**	A knitted, seamless tube of material, typically cotton, designed to stretch and fit any contour of the body. The device is typically used as padding under a cast or splint.
198.	**Stocking, stockinette**	A knitted, seamless tubing, typically of cotton, that is open at both ends. The device is typically used to hold bandages in place, to place uniform pressure on a leg, finger, arm or other part of an extremity, to pad the area under a cast or splint, or to cover a stump when a prosthesis is worn.
199.	**Stocking, medical support**	An elastic limb support shaped as a stocking that is worn on the upper or lower extremity to support, correct or prevent deformity, or to align body structures for functional improvement.
200.	**Stretcher**	A device on which a patient lies for transport or reclines after treatment. It may have a wheeled undercarriage, which can be foldable.
201.	**Stretcher, ambulance**	A stretcher specially adapted for use with an ambulance vehicle, including aeroplanes, helicopters or boats. It will typically have an undercarriage which folds automatically when

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
		it meets the ambulance vehicle as it is being pushed in, as well as locking devices that match up with the docking devices of the ambulance vehicle.
202.	**Stretcher, portable**	A device designed for transporting the patient from an emergency site, which is not readily accessible for standard ambulance stretchers. It can be used in mountain or marine rescue, or difficult indoor situations (e.g. narrow corridors or extremely steep stairways). It is designed to be lightweight, simple in operation and easily transported (e.g. ideally by one or 2 persons). The patient is often strapped to the device to keep him secure during transportation.
203.	**Stretcher, bathroom**	A stretcher specially designed for the purpose of washing a patient whilst the patient lies on the stretcher. It will typically be used for patients who are disabled or incapable of supporting themselves and it may be submersed in an appropriate bath.
204.	**Reusable surgical instrument**	An instrument intended for surgical use by cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or other surgical procedures, without connection to any active medical device and which is intended by the product owner to be reused after appropriate procedures for cleaning and/or sterilisation have been carried out.
205.	**Swab**	A piece of absorbent material (e.g. cotton or foam) attached to the end of a stick made of wood, plastic or wire. It is used for the application of medication or the removal of material (save for the purpose of sample collection). This is a single-use device.
206.	**Table, examination/ treatment**	A table or bed for examination and/or treatment purposes. It is typically of the construction where the patient lies upon it, i.e. as an

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
		operating table, but some may be designed so that the patient sits beside the table and is examined with instruments placed upon the table. This device can be manually operated or powered. It may be fitted with some basic functions (e.g. raise, lower or tilt) and is used in examination rooms, doctors' surgeries and minor operating rooms.
207.	**Table, instrument**	A table used for laying out sterile surgical instruments, sutures, and other utensils/items required during an operation or intervention. It is designed to include an appropriate (e.g. stainless steel) top or surface with no crevices, screws or rivets and may include telescoping pedestals for height adjustment and swivel castor bases. This table is used in the so-called "sterile area" of the operation site and in some cases may be attached to the operating table.
208.	**Table, operation**	A device used to support the patient's body during surgical procedures, stabilising the patient's position and providing for optimal exposure of the surgical field. It is also designed to protect the patient from excessive manipulation, trauma and abrasion. It will typically include an appropriate top surface supported by a fixed pedestal or a movable, swivel castor base and may be divided into 3 or more hinged sections (e.g. head, body and legs) which are raised and lowered by mechanical, electro-mechanical or hydraulic systems using manual or electric controls.
209.	**Table, birthing**	An adjustable table designed to support a woman's body in an appropriate position during labour and delivery and in other examination/treatment procedures related to pregnancy. This table will typically include

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
		leg holders, traction handles, and a receptacle for afterbirth.
210.	**Tourniquet strap**	A device that is a strip of material of uniform breadth which is applied to a limb in order to compress the arteries and regulate the blood flow. This is typically used when taking blood samples, but may be used for other purposes. It has a fastening mechanism (e.g. Velcro or a self-locking buckle) used for adjustment.
211.	**Traction unit, non-active**	A device used to apply a tensile force in order to create a distraction on body parts by means of harnesses attached to the head or pelvic area. It is non-active (*static*) in operation. It consists of a rigid frame with non-powered traction accessories, such as cords, pulleys or weights, and is intended to apply a therapeutic pulling force to the skeletal system.
212.	**Traction unit, non-invasive component**	A non-invasive traction device (e.g. a head halter, pelvic belt or a traction splint) that does not penetrate the skin and is intended to assist in connecting a patient to a traction apparatus so that a therapeutic pulling force may be applied to the patient's body.
213.	**Transfer aid, person**	A technical aid used by attending personnel to assist in the physical transfer of a person/patient (e.g. ill, disabled or infirm) from one position to another. The device has typically no lifting capabilities and uses sliding/turning techniques. This device may be used to change the person's position, especially for those incapable of achieving this on their own, and thus prevent bedsores, or to move the person between, for example, an operating table and a bed, a wheelchair and a bath, or a chair and the toilet.
214.	**Transfer belt**	A hand-held device used by attending personnel to lift a person/patient (e.g. up from the floor onto a bed). It may be used to provide additional

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
		leverage while assisting patients in walking or in short-distance transfer activities. The device can be constructed like a carrying chair, harness, basket or lifting canvas and usually requires more than one person to operate it, thereby alleviating unnecessary strain upon each person's back.
215.	**View box, blood grouping**	A device with a glass or plastic viewing surface, which may be illuminated and heated, that is used to view cell reactions in antigen-antibody testing.
216.	**View box, diagnostic imaging, non-motorised**	A non-motorised device used to support and illuminate one or more medical images (e.g. X-ray, magnetic resonance imaging (MRI), computed tomography (CT), ultrasound or nuclear medicine) which are recorded on radiographic film (e.g. an X-ray or X-ray film) for direct viewing. This kind of radiographic view box is a simple non-motorised wall-mounted or table-mounted design. The device has a defined illumination uniformity and an attachment that is used to hold as many sheets of film in place as there is room for during viewing.
217.	**Walking crutch**	A mobility aid used to assist a disabled or an infirm user in walking by providing a means of support and increasing his ability to move around without attendance from another person. It has one leg, a handle, and a padded platform which is placed under the armpit or forearm for support.
218.	**Walking frame, standard, non-active**	A mobility aid used to assist a disabled or an infirm user in walking by providing a means of support and increasing his ability to move around without attendance from another person. It is a non-wheeled frame with built-in handgrips and legs which provide support

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
		whilst walking. It can be of fixed or adjustable height and be collapsible or non-collapsible. This is a non-active medical device.
219.	**Walking table, non-active**	A mobility aid used to assist a disabled or an infirm user in walking by providing a means of support and increasing his ability to move around without attendance from another person. It is a chest-height wheeled frame with a horizontal forearm support, which is pushed along using the arms and/or upper body. It can be of fixed or adjustable height and be collapsible or non-collapsible. This is a non-active medical device.
220.	**Walking frame, wheeled, non-active**	A mobility aid used to assist a disabled or an infirm user in walking by providing a means of support and increasing his ability to move around without attendance from another person. It is a wheeled frame with built-in handgrips and legs which provide support whilst walking. It can be of fixed or adjustable height and be collapsible or non-collapsible. This is a non-active medical device.
221.	**Walking stick**	A mobility aid used to assist a disabled or an infirm user in walking by providing a means of support and increasing his ability to move around without attendance from another person. It is a wooden or metal rod with either one leg, a tripod or quadripod base (3 or 4 legs). It has a handle and/or forearm support. It can be of fixed or adjustable length and be collapsible or non-collapsible.
222.	**Wrapper, sterilisation**	A device intended to enclose medical devices that are to be sterilised. It is designed to allow sterilisation of the enclosed medical device and also to maintain sterility of the device until the packaging is opened for use of the device, or until a predetermined shelf date is expired.

SIXTH SCHEDULE — *continued*

	First column	*Second column*
	Device identifier	**Description or intended purpose**
223.	**X-ray film**	A film specifically designed for medical or dental diagnostic imaging using X-ray. It is prepared as an emulsion of light and X-ray sensitive granules on one (single-emulsion film) or both (double-emulsion film) sides of a transparent film base made of cellulose acetate, polyester resin or other appropriate material. It can basically be separated into 2 major kinds: screen and non-screen film. Screen film is sensitive primarily to the wavelengths of light emitted from image-intensifying screens. Non-screen film is designed for direct exposure to X-rays and is relatively insensitive to the visible light emitted from screens. Screen film is not limited to use with X-ray imaging systems.

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Made this 5th day of August 2010.

EDISON LIU
Chairman,
Health Sciences Authority,
Singapore.

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