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HEALTH PRODUCTS ACT
(CHAPTER 122D)

HEALTH PRODUCTS (MEDICAL DEVICES) REGULATIONS 2010

ARRANGEMENT OF REGULATIONS

Regulation

PART VII

CERTIFICATES

PART VIII

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

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;

[S 334/2016 wef 01/11/2016]

"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;

"clinical purpose" means any of the specific purposes described in the second column of item 1 of the First Schedule to the Act;

[S 334/2016 wef 01/11/2016]

"clinical research" has the same meaning as in regulation 2(1) of the Health Products (Therapeutic Products as Clinical Research Materials) Regulations 2016 (G.N. No. S 332/2016);

[S 334/2016 wef 01/11/2016]

"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;

"institutional review board" means an independent body which —

(*a*) is constituted of medical, scientific, and non-scientific members, whose responsibility is to ensure the protection of the rights, safety and wellbeing of

subjects by, among other things, reviewing, approving and providing continuing review of the protocol, amendments, and the methods and materials to be used in obtaining and documenting informed consent of the subjects; and

(*b*) when Part 4 of the Human Biomedical Research Act 2015 (Act 29 of 2015) comes into operation, is appointed under that Act;

[S 334/2016 wef 01/11/2016]

"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);

"regulated clinical trial" means any clinical research that is —

(*a*) authorised by the Authority, or notified to the Authority and the notification accepted by the Authority, under regulation 8 or 9 of the Health Products (Clinical Trials) Regulations 2016 (G.N. No. S 331/2016); or

(*b*) issued with a certificate under regulation 8 of the Medicines (Clinical Trials) Regulations 2016 (G.N. No. S 335/2016);

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"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;

"sponsor" means a person who takes responsibility for the initiation, management or financing of any clinical research;

[S 334/2016 wef 01/11/2016]

"sterile state", in relation to a medical device, means a state free of viable micro-organisms;

[S 169/2012 wef 01/05/2012]

"therapeutic product" means a health product categorised as a therapeutic product in the First Schedule to the Act;

[S 538/2016 wef 01/11/2016]

"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 device for use in clinical research

3A. A person may manufacture a medical device without holding a manufacturer's licence under section 12(1) of the Act, if the planned use for the medical device is a clinical purpose in any clinical research.

[S 334/2016 wef 01/11/2016]

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.

Import of medical devices for personal use

4A. A person may import, without holding an importer's licence as required under section 13(1) of the Act, any medical device for his personal use or for the personal use of any member of his family, subject to —

(*a*) such conditions; and

(*b*) such limits on quantity, not exceeding a total quantity of usage of the medical device for 3 months,

as the Authority thinks fit, based on the usage instructions recommended by the manufacturer or product owner of the medical device.

[S 426/2012 wef 01/09/2012]

Import of medical device licensed under Radiation Protection Act

4B. A person may import, without holding an importer's licence as required under section 13(1) of the Act, any medical device —

(*a*) in respect of which a licence to import the medical device is granted under the Radiation Protection Act (Cap. 262); and

(*b*) which is —

(i) registered under the Act;

(ii) listed on the Class A or B Medical Device Transition List as published on the Authority's website as at 1 January 2012; or

(iii) listed on the Class C or D Medical Device Transition List as published on the Authority's website as at 10 August 2010.

[S 334/2016 wef 01/11/2016]

Import of medical device for use in clinical research

4C. A person may import, without holding an importer's licence as required under section 13(1) of the Act, any medical device if —

(*a*) the planned use for the medical device is a clinical purpose in any clinical research; and

(*b*) the person imports the device —

(i) after the person has given notice to the Authority of the import in accordance with regulation 51; or

(ii) in accordance with a permission given by the licensing authority under the Medicines Act (Cap. 176) before 1 November 2016 for the import on or after that date.

[S 334/2016 wef 01/11/2016]

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.

Wholesaling of medical device licensed under Radiation Protection Act

5A. A person may carry out any activity that is a supply by wholesale, without holding a wholesaler's licence as required under section 14(1) of the Act, in relation to any medical device —

(*a*) in respect of which a licence is granted under the Radiation Protection Act (Cap. 262) for that activity; and

(*b*) which is —

(i) registered under the Act;

(ii) listed on the Class A or B Medical Device Transition List as published on the Authority's website as at 1 January 2012; or

(iii) listed on the Class C or D Medical Device Transition List as published on the Authority's website as at 10 August 2010.

[S 334/2016 wef 01/11/2016]

Wholesaling of medical device for use in clinical research

5B. A person may supply by wholesale, without holding a wholesaler's licence as required under section 14(1) of the Act, any medical device if —

(*a*) the planned use for the medical device is a clinical purpose in any clinical research; and

(*b*) where the person is the manufacturer of the medical device, the person gives the Authority notice in accordance with

regulation 51 of the supply by wholesale before so supplying the medical device.

[S 334/2016 wef 01/11/2016]

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 clinical research

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 by a person does not apply to the supply of a medical device if —

(*a*) the planned use for the medical device is a clinical purpose in any clinical research; and

(*b*) where the person is the manufacturer of the medical device, the person gives the Authority notice of the supply in accordance with regulation 51 before supplying the medical device.

[S 334/2016 wef 01/11/2016]

Exception for certain Class A medical devices

10B.—(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 Class A medical device —

(*a*) that is intended by its product owner to be supplied other than in a sterile state; and

(*b*) that is —

(i) manufactured under a valid manufacturer's licence;

(ii) imported by the supplier under a valid importer's licence; or

(iii) obtained by the supplier from a wholesaler who holds a valid wholesaler's licence.

(2) For the purposes of paragraph (1), a medical device shall be treated as a Class A medical device if it would have been assigned to Class A according to regulation 24 had the medical device been registered.

[S 169/2012 wef 01/05/2012]

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 (but not an unregistered Class A medical device supplied on or after 1st May 2012 in

accordance with the requirements specified in regulation 10B) —

(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;

[S 140/2012 wef 05/04/2012]

[S 169/2012 wef 01/05/2012]

(*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;

[S 140/2012 wef 05/04/2012]

(*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;

[S 140/2012 wef 05/04/2012]

[S 426/2012 wef 01/09/2012]

(*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;

[S 140/2012 wef 05/04/2012]

[S 426/2012 wef 01/09/2012]

(*g*) the supply on or after 1st September 2012 of an unregistered Class A or B medical device, not being an unregistered Class A medical device supplied in accordance with the requirements in regulation 10B, which is listed on the Class A or B Medical Device Transition List as published on the Authority's website; and

[S 426/2012 wef 01/09/2012]

(*h*) the supply on or after 1st September 2012 of an unregistered Class C or D medical device which is listed

on the Class C or D Medical Device Transition List as published on the Authority's website.

[S 426/2012 wef 01/09/2012]

(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.

Supply of medical devices for use in clinical research

13A.—(1) A person who manufactures a medical device under regulation 3A, imports a medical device under regulation 4C, or is supplied with a medical device under regulation 5B or 10A, may only supply the medical device —

(*a*) as one whose planned use is a clinical purpose in any clinical research; or

(*b*) as a medical device for some other purpose that the Authority has allowed and no other.

(2) To avoid doubt, as from the time that the Authority has allowed the supply mentioned in paragraph (1)(*b*), the medical device ceases to be a medical device whose planned use is a clinical purpose in any clinical research for the purposes of these Regulations; but continues to be subject to any applicable law relating to medical devices (including these Regulations).

(3) 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.

[S 334/2016 wef 01/11/2016]

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.

Requirement 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 the safety and performance requirements for the medical device specified in the First Schedule.

[S 426/2012 wef 01/09/2012]

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 —

(*a*) evaluate the medical device under —

(i) an abridged evaluation process;

[S 444/2017 wef 15/08/2017]

(ii) an expedited abridged evaluation process;

[S 444/2017 wef 15/08/2017]

(iii) a full evaluation process; or

[S 444/2017 wef 15/08/2017]

(iv) a priority full evaluation process; or

[S 444/2017 wef 15/08/2017]

(*b*) immediately register the medical device.

(2) A medical device may qualify for evaluation 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;

(*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; and

(*c*) the medical device complies with all other conditions specified on the Authority's website.

(3) A medical device, not being a Class D medical device, may qualify for evaluation under an expedited abridged evaluation process, if —

(*a*) at least one reference regulatory agency of a foreign jurisdiction has granted approval for the supply of the medical device in that jurisdiction;

(*b*) the approval by the reference 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; and

(*c*) the medical device complies with all other conditions specified on the Authority's website.

[S 646/2012 wef 01/01/2013]

(3A) A Class D medical device may qualify for evaluation under an expedited abridged evaluation process, if —

(*a*) at least 2 reference regulatory agencies, each of a foreign jurisdiction, have granted approval for the supply of the medical device in their jurisdictions;

(*b*) the approval by each of the reference regulatory agencies 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; and

(*c*) the medical device complies with all other conditions specified on the Authority's website.

[S 646/2012 wef 01/01/2013]

(3B) A medical device is to be evaluated under a full evaluation process where —

(*a*) the medical device does not qualify for evaluation under an abridged evaluation process mentioned in paragraph (2), for evaluation under an expedited abridged evaluation process mentioned in paragraph (3) or (3A), or for immediate registration under paragraph (4); or

(*b*) despite the medical device qualifying for an abridged evaluation process or expedited abridged evaluation process, an applicant who wishes to register the medical device under section 30 of the Act chooses to subject the medical device to a full evaluation process.

[S 444/2017 wef 15/08/2017]

(3C) A Class B, C or D medical device may qualify for evaluation under a priority full evaluation process if the medical device —

(*a*) is a medical device that is to be evaluated under a full evaluation process mentioned in paragraph (3B); and

(*b*) is, in the Authority's opinion, a novel medical device.

[S 444/2017 wef 15/08/2017]

(3D) Despite paragraph (3C), a Class B, C or D medical device that only satisfies the requirements of paragraph (3C)(*a*) may qualify for a priority full evaluation process if the appropriate fee specified in the Fourth Schedule is paid.

[S 444/2017 wef 15/08/2017]

(4) The Authority may immediately register a medical device, if —

(*a*) at least 2 reference regulatory agencies, each of a foreign jurisdiction, have granted approval for the supply of the medical device in their jurisdictions;

(*b*) the approval by each of the reference regulatory agencies 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; and

(*c*) the medical device complies with all other conditions specified on the Authority's website.

(5) [*Deleted by S 444/2017 wef 15/08/2017*]

(5A) For the purposes of paragraphs (3) and (3A), a medical device shall be treated as a Class D medical device if it would have been assigned to Class D according to regulation 24 upon the registration of the medical device.

[S 646/2012 wef 01/01/2013]

(6) In this regulation —

"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;

"infectious disease" has the same meaning as in the Infectious Diseases Act (Cap. 137);

[S 444/2017 wef 15/08/2017]

"novel medical device" means a medical device that —

(*a*) is intended for the purposes of the diagnosis, prevention, monitoring, treatment or alleviation of diabetes, or any disease in a specified branch of medicine, that has no other means of being diagnosed, prevented, monitored, treated or alleviated; or

(*b*) represents new medical technology, as compared to other registered medical devices, that provides a clinical advantage for the diagnosis, prevention,

monitoring, treatment or alleviation of diabetes, or any disease in a specified branch of medicine;

[S 444/2017 wef 15/08/2017]

"reference regulatory agency" means a competent regulatory agency specified on the Authority's website at the time of the application for the registration of the medical device for the purpose of an expedited abridged evaluation process under paragraph (3) or (3A) or immediate registration under paragraph (4);

[S 646/2012 wef 01/01/2013]

[S 426/2012 wef 01/09/2012]

[S 444/2017 wef 15/08/2017]

"specified branch of medicine" means any cardiovascular disease, cancer, infectious disease or ophthalmic disease.

[S 444/2017 wef 15/08/2017]

PART VII

CERTIFICATES

27. [*Deleted by S 426/2012 wef 01/09/2012*]

28. [*Deleted by S 426/2012 wef 01/09/2012*]

29. [*Deleted by S 426/2012 wef 01/09/2012*]

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 specified in the Fourth Schedule, issue to the person a certificate containing such statement relating to the medical device as the Authority may consider appropriate having regard to any applicable requirements (whether having the force of law or not) in the country to which the medical device is to be exported.

[S 426/2012 wef 01/09/2012]

(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.—(1) 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.

[S 334/2016 wef 01/11/2016]

(2) Paragraph (1)(*c*) does not apply to the import of any medical device under regulation 4C.

[S 334/2016 wef 01/11/2016]

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 supplier of unregistered Class A medical devices to furnish information

35A. Where a medical device would have been assigned to Class A according to regulation 24 had it been registered and the medical device is supplied without being registered in accordance with the requirements specified in regulation 10B, the Authority may, under section 41(1) of the Act, by notice in writing, require the supplier of the medical device to furnish to the Authority, within such time as may be specified in the notice, the name, address and licence number of the

manufacturer or wholesaler, as the case may be, from whom the supplier obtained the medical device.

[S 169/2012 wef 01/05/2012]

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.

Duties of sponsor, etc.

36A.—(1) This regulation applies in relation to any medical device manufactured under regulation 3A, imported under regulation 4C or supplied under regulation 5B or 10A.

(2) Without prejudice to regulation 13A, a person must not use the medical device, and the sponsor must ensure that no person involved in the clinical research uses the medical device except —

(*a*) for a clinical purpose in the research, and where the research requires approval of an institutional review board, with the approval of that board; or

(*b*) for some other use that the Authority has allowed and no other.

(3) To avoid doubt, as from the time that the Authority has allowed the other use mentioned in paragraph (2)(*b*), the medical device ceases to be a medical device whose planned use is, or which must be used, for a clinical purpose in any clinical research for the purposes of these Regulations; but continues to be subject to any applicable law relating to medical devices (including these Regulations).

(4) Unless the Authority otherwise allows, the sponsor must ensure that, within 6 months after the conclusion or termination of the clinical research, any unused medical device for that research is disposed of or exported.

(5) Any person who contravenes paragraph (2) 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.

(6) In this regulation, "unused medical device" means any medical device referred to in paragraph (1) that —

(*a*) is not used in the clinical research (including where the medical device cannot or can no longer be used in the research); or

(*b*) is reusable after the conclusion or termination of the clinical research.

[S 334/2016 wef 01/11/2016]

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.

(5) This regulation does not apply to a medical device which is supplied for a clinical purpose in any clinical research.

[S 334/2016 wef 01/11/2016]

Duty to maintain records of receipt and supply in relation to medical devices for clinical research

39A.—(1) Every person who supplies any medical device whose planned use is for a clinical purpose in any clinical research (including a person who manufactures or imports the medical device, and supplies the medical device) must —

(*a*) maintain a record relating to every receipt (where applicable) and every supply by the person of the medical device; and

(*b*) 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) must ensure that every record referred to in that paragraph —

(*a*) contains, in relation to (where applicable) each receipt, and each supply, by the person of the medical device, all of the following information:

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

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

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

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

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

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

(i) for any registered medical device used in a regulated clinical trial or any medical device used in any clinical research that is not a regulated clinical trial, the longer of the following periods:

(A) the projected useful life of the medical device;

(B) 2 years after the date on which the medical device is supplied;

(ii) for any unregistered medical device used in a regulated clinical trial, the period for which records must be kept under regulation 23(2)(*c*) of the Health Products (Clinical Trials) Regulations 2016 (G.N. No. S 331/2016) or regulation 23(2)(*c*) of the Medicines (Clinical Trials) Regulations 2016 (G.N. No. S 335/2016), as the case may be.

(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 the person 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.

[S 334/2016 wef 01/11/2016]

Duty to maintain records of use and disposal, etc., in relation to medical devices for clinical research

39B.—(1) The sponsor referred to in regulation 36A(2) or (4) must —

(*a*) maintain a record of the putting to some other use, disposal or export of a medical device under that provision; and

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

(2) The sponsor referred to in paragraph (1) must ensure that every record referred to in that paragraph —

(*a*) contains all of the following information in relation to each medical device which is put to some other use, disposed of or exported:

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

(ii) the date on which the medical device was put to the other use, disposed of or exported;

(iii) the name and address of the person responsible for the putting to the other use, disposal or export, of the medical device;

(iv) the quantity of the medical device put to the other use, disposed of or exported;

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

(*b*) is retained —

(i) for any registered medical device used in a regulated clinical trial or any medical device used in any clinical research that is not a regulated clinical trial, for 2 years after the time when the medical device is put to some other use, is disposed of or is exported, as the case may be; or

(ii) for any unregistered medical device used in a regulated clinical trial, for the period for which records must be kept under regulation 23(2)(*c*) of the Health Products (Clinical Trials) Regulations 2016 (G.N. No. S 331/2016) or regulation 23(2)(*c*) of the Medicines (Clinical Trials) Regulations 2016 (G.N. No. S 335/2016), as the case may be.

(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 the person 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.

[S 334/2016 wef 01/11/2016]

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.

(7) For the avoidance of doubt, any reference to a change or proposed change referred to in paragraph (1)(*a*) does not include any such change by reason only of the registered medical device ceasing to be registrable by virtue of regulation 10B.

[S 169/2012 wef 01/05/2012]

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.

(4) The Authority may, in any particular case or class of cases, waive or refund the whole or any part of any fee paid or payable under these Regulations.

[S 426/2012 wef 01/09/2012]

PART X

MISCELLANEOUS

Notices to Authority

51.—(1) A notice to be given to the Authority under these Regulations must be given in the form and manner, and within the time, specified on the Authority's website.

(2) Any person who, for the purposes of giving any notice to the Authority under these Regulations, furnishes the Authority with any particulars, information or document which the person 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.

[S 334/2016 wef 01/11/2016]

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, 25, 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;

"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.

FIRST SCHEDULE — *continued*

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;

(*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.

FIRST SCHEDULE — *continued*

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 therapeutic product or 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 therapeutic product or medicinal product; and

FIRST SCHEDULE — *continued*

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

[S 538/2016 wef 01/11/2016]

Verification of incorporated substance

11. If a medical device incorporates, or is intended to incorporate, as an integral part, a substance that —

(*a*) if used separately, might be considered to be a therapeutic product or medicinal product; and

(*b*) is intended to act on a patient in a way that is ancillary to the medical device,

then —

(i) the safety and quality of the substance must be verified in accordance with the requirements for registering that substance as a therapeutic product under the Act or for issuing a product licence for that substance as a medicinal product under the Medicines Act (Cap. 176), as the case may be; and

(ii) the intended ancillary action of the substance, having regard to the intended purpose of the medical device, must be verified to the Authority's satisfaction by objective evidence.

[S 538/2016 wef 01/11/2016]

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.

FIRST SCHEDULE — *continued*

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.

FIRST SCHEDULE — *continued*

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.

(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.

FIRST SCHEDULE — *continued*

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

(*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;

FIRST SCHEDULE — *continued*

(*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.

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.

FIRST SCHEDULE — *continued*

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.

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.

FIRST SCHEDULE — *continued*

(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.

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.

FIRST SCHEDULE — *continued*

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.

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

FIRST SCHEDULE — *continued*

(*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:

(*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

FIRST SCHEDULE — *continued*

(*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.

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

FIRST SCHEDULE — *continued*

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".

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

FIRST SCHEDULE — *continued*

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 — (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

FIRST SCHEDULE — *continued*

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

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 therapeutic product or 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 therapeutic product or medicinal product 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.

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FIRST SCHEDULE — *continued*

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 —

(*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.

SECOND SCHEDULE — *continued*

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

THIRD SCHEDULE — *continued*

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;

"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*;

THIRD SCHEDULE — *continued*

(*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;

"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;

THIRD SCHEDULE — *continued*

"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 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;

THIRD SCHEDULE — *continued*

(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 therapeutic product.

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(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*.

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

THIRD SCHEDULE — *continued*

(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 —

(*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.

THIRD SCHEDULE — *continued*

(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.

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 therapeutic product or medicinal product by means of a delivery system; and

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THIRD SCHEDULE — *continued*

(*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.

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 therapeutic product or medicinal product; or *[S 538/2016 wef 01/11/2016]*

(*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.

THIRD SCHEDULE — *continued*

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 —

(*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 therapeutic product or medicinal product;

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(*f*) to be a breast implant; or

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(*g*) to have a biological effect.

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(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.

THIRD SCHEDULE — *continued*

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.

(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).

THIRD SCHEDULE — *continued*

Active medical devices for administering or removing therapeutic products or 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 therapeutic product or medicinal product, body liquid or other substance to or from a human body.

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

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

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

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

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Other active medical devices

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

Medical devices incorporating therapeutic products or medicinal products

20. A medical device shall be assigned to Class D if it incorporates, as an integral part, a substance that is liable to act on a human body with an action ancillary to that of the medical device and the substance is —

(*a*) a therapeutic product; or

(*b*) a medicinal product subject to the licensing requirements of section 5 or 6 of the Medicines Act (Cap. 176).

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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

THIRD SCHEDULE — *continued*

(*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.

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;

THIRD SCHEDULE — *continued*

"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*);

(*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;

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

THIRD SCHEDULE — *continued*

(*h*) monitoring levels of therapeutic 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);

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(*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 —

(*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.

THIRD SCHEDULE — *continued*

***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.

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 26(3D), 30(1), 48(2), 49(2) and 50(1) and (2)

FEES

First column	*Second column*
Description of fees	*Fee payable*
1. Application fee for registration of —	

FOURTH SCHEDULE — *continued*

(*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(2)	$1,800
(ii) by evaluation under an expedited abridged evaluation process referred to in regulation 26(3)	$900
(iii) which is immediately registered under regulation 26(4)	$900
(iv) by evaluation under a full evaluation process	$3,500
(v) by evaluation under a priority full evaluation process mentioned in regulation 26(3C)	$4,100
(vi) by evaluation under a priority full evaluation process mentioned in regulation 26(3D)	$5,300
(*c*) a Class C medical device —	
(i) by evaluation under an abridged evaluation process referred to in regulation 26(2)	$3,500
(ii) by evaluation under a full evaluation process	$5,700

FOURTH SCHEDULE — *continued*

(iii) by evaluation under an expedited abridged evaluation process referred to in regulation 26(3)	$3,000
(iv) by evaluation under a priority full evaluation process mentioned in regulation 26(3C)	$6,600
(v) by evaluation under a priority full evaluation process mentioned in regulation 26(3D)	$8,600
(*d*) a Class D medical device —	
(i) by evaluation under an abridged evaluation process referred to in regulation 26(2)	$5,700
(ii) by evaluation under a full evaluation process	$11,400
(iii) by evaluation under an expedited abridged evaluation process referred to in regulation 26(3A)	$5,400
(iv) by evaluation under a priority full evaluation process mentioned in regulation 26(3C)	$13,200
(v) by evaluation under a priority full evaluation process mentioned in regulation 26(3D)	$17,100
(*e*) a medical device that contains a therapeutic product or medicinal product —	
(i) by evaluation under an abridged evaluation process referred to in regulation 26(2)	$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

FOURTH SCHEDULE — *continued*

(*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
(*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 relating to an unregistered medical device —	
(*a*) by a private hospital, medical clinic or clinical laboratory licensed under the Private Hospitals	$350

FOURTH SCHEDULE — *continued*

	and Medical Clinics Act (Cap. 248), or a person acting on its behalf, where the unregistered medical device is to be used by a patient of the private hospital, medical clinic or clinical laboratory	
	(*b*) by a qualified practitioner, or a person acting on his behalf, where the unregistered medical device is to be used by a patient of the practitioner	$150
	(*c*) where the unregistered medical device is to be used for a non-clinical purpose	$250
10.	Fee for application for an importer's licence or a wholesaler's licence relating to an unregistered medical device solely for export or re-export (being a medical device manufactured solely for export or imported solely for re-export)	$250
11.	Fee for application for any certificate	$50
12.	Processing fee in relation to a certificate under regulation 30(1) for a medical device intended for export (for one medical device and addressed to one country)	$50.

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[S 646/2012 wef 01/01/2013]

[S 426/2012 wef 01/09/2012]

[S 370/2012 wef 02/08/2012]

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;

FIFTH SCHEDULE — *continued*

(*b*) all models of implantable defibrillators and leads;

(*c*) artificial heart;

(*d*) implantable ventricular support system; and

(*e*) implantable drug infusion system.

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

[*Deleted by S 169/2012 wef 01/05/2012*]

Made this 5th day of August 2010.

EDISON LIU
Chairman,
Health Sciences Authority,
Singapore.

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(To be presented to Parliament under section 72(5) of the Health Products Act).