No. S 000 -

HEALTH PRODUCTS ACT 2007
(ACT OF 2007)

HEALTH PRODUCTS (MEDICAL DEVICES) REGULATIONS 2007

ARRANGEMENT OF REGULATIONS

PART VII

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

In exercise of the powers conferred by section 72 of the Health Products Act 2007, the Health Sciences Authority, with the approval of the Minister for Health, hereby makes the following Regulations:

Citation and commencement

1. These Regulations may be cited as the Health Products (Medical Devices) Regulations 2007 and shall come into operation on 2007.

PART I

PRELIMINARY MATTERS

Definitions

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

"accessory" means an article which, whilst not itself being a medical device, is intended specifically by its manufacturer to be used together with a medical device so as to enable that medical device to be used for its intended purpose;

"authorised representative", in relation to the manufacturer of a medical device who is resident outside Singapore and who manufactures the medical device outside Singapore, means a person in Singapore who is appointed by that manufacturer to represent and act on his behalf in Singapore;

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

(*a*) differs from medical devices generally available for sale to the public; and

(*b*) is specially fabricated or imported for the sole use of a particular person, whether in accordance with the specifications of qualified practitioner or otherwise;

"*in vitro* diagnostic product" means any reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination, that is intended by its manufacturer to be used *in vitro* for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information —

(*a*) concerning a physiological or pathological state;

(*b*) concerning a congenital abnormality;

(*c*) to determine the safety and compatibility of donations, including blood and tissue donations, with potential recipients; or

(*d*) to monitor therapeutic measures,

and includes a specimen receptacle but not a product for general laboratory use, unless that product, in view of its characteristics, is specifically intended by its manufacturer to be used for *in vitro* diagnostic examination;

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

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

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

"qualified practitioner" means —

(*a*) a person registered 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 person registered under the Dentists Act (Cap. 76) whose name appears in the first division of the dentists register kept under that Act, when acting in the course of providing dental treatment to a patient under his care;

"special access medical device" means a medical device that is intended to be used by a qualified practitioner, in an emergency or in a case where all conventional therapies have

failed, to meet any special needs arising in the course of his practice.

Application of these Regulations to certain *in vitro* diagnostic products

3. These Regulations shall apply to any *in vitro* diagnostic product that is a drug or that contains a drug, as if the product were itself an *in vitro* diagnostic medical device.

PART II

MANUFACTURE AND IMPORT OF MEDICAL DEVICES

Fabrication of custom-made medical devices

4. A manufacturer's licence is not required for the fabrication of any custom-made medical device if the fabrication of the custom-made medical device is carried out at a private hospital, medical clinic or healthcare establishment licensed under the Private Hospitals and Medical Clinics Act (Cap. 248) pursuant to the order of any qualified practitioner practising thereat for the use of any person who is a patient thereat.

Import of medical devices for personal use

5. The Authority may, subject to such conditions as it thinks fit, permit any person who does not hold an importer's licence to import any medical device for his personal use or for the use of any member of his family.

PART III

SUPPLY OF MEDICAL DEVICES

Supply of unregistered medical devices with Authority's approval

6.—(1) Any person may, with the approval in writing of the Authority, supply or procure the supply of an unregistered medical device —

(*a*) solely for export to a party outside Singapore;

(*b*) for use in a clinical trial;

(*c*) for use by a qualified practitioner as a special access medical device; or

(*d*) for such other purposes as the Authority thinks fit.

(2) An application for the Authority's approval under paragraph (1) shall be made in such form and shall be accompanied by such information, documents and samples of the unregistered medical device as the Authority may require.

(3) The Authority may grant its approval under paragraph (1) for the supply of an unregistered medical device subject to such conditions as it thinks fit.

Supply of custom-made devices

7. The prohibition under section 15(1) of the Act against the supply of an unregistered health product shall not apply in the case where the unregistered health product is a custom-made medical device.

Prohibition against supply of unregistered refurbished medical devices

8.—(1) Subject to paragraph (2), the prohibition under section 15(1) of the Act against the supply of an unregistered health product shall apply in relation to the supply of a refurbished medical device that is unregistered, as if the refurbished medical product were a new medical device.

(2) The prohibition under section 15(1) of the Act against the supply of an unregistered health product shall not apply in relation to the case where a medical device belonging to a hospital, medical clinic, clinical laboratory or healthcare establishment licensed under the Private Hospitals and Medical Clinics Act (Cap. 248) is sent for refurbishment and thereafter returned to that hospital, medical clinic, clinical laboratory or healthcare establishment for its own use.

(3) For the purposes of this regulation, "refurbished medical device" means a medical device of which the whole or any part thereof has been substantially rebuilt, renovated, 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 manufacturer of the original medical device or for the purpose intended by the manufacturer who refurbished the medical device.

Testing of registered medical devices before supply

9.—(1) No person shall supply any registered medical device taken from a lot or consignment of such registered medical devices, unless —

(*a*) samples of the registered medical devices in that lot or consignment have been tested or analysed in accordance

with the requirements specified by the Authority when registering that medical device;

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

(*c*) the Authority is satisfied from the information received under sub-paragraph (*b*) that the registered medical device continues to meet the requisite standards of quality, safety and efficacy.

(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.

Prohibition on use of medical devices that have been changed or modified

10.—(1) No person shall, for the purpose of promoting or demonstrating the use of any medical device, make or cause to be made to the medical device any change or modification that causes the medical device to depart from the specifications of its manufacturer in relation to its intended purpose, design, components or method of installation or operation.

(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.

Supply of 'professional use only' medical devices

11. For the purpose of section 17(1) of the Act —

(*a*) a licensed wholesaler of medical devices shall not supply any medical device that has been registered as a 'professional use only' medical device to any other person who obtains that medical device for the purposes of supplying it again unless that other 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 to or application in any other person, any medical device that has been registered as a 'professional use only' medical device unless the person doing so is, or acts under the supervision of, a qualified practitioner.

PART IV

PRESCRIBED LABELLING REQUIREMENTS FOR PURPOSES OF SECTION 18(1) OF ACT

Information to be provided with medical devices

12.—(1) For the purposes of section 18(1) of the Act, no person shall supply any medical device to another person unless the following information is provided with the medical device when it is supplied to that other person:

(*a*) the name and description of the medical device;

(*b*) the name, address and contact particulars of the manufacturer of the medical device;

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

(*d*) instructions on how to use the medical device safely;

(*e*) where the medical device is supplied to any other person for use in any investigational testing —

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

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

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

(*f*) where the medical device is a custom-made medical device or a special access medical device, a statement to the effect that the medical device is a custom-made medical device or a special access medical device, as the case may be.

(2) The information referred to in paragraph (1) shall be provided in the following manner:

(*a*) where it is practical to do so, the information shall be provided on a label that appears on or is attached to the medical device itself;

(*b*) if it is impractical to comply with sub-paragraph (*a*), the information shall be provided —

(i) on the packaging of the medical device; or

(ii) in the case of medical devices that are packaged together because individual packaging of the medical devices is not practical — on the outer packaging used for the medical devices;

(*c*) if it is impractical to comply with sub-paragraph (*a*) or (*b*), the information shall be provided on a leaflet, a document or any other appropriate medium supplied with the medical device.

Labelling of registered medical devices

13.—(1) The label of a registered medical device may include —

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

(*b*) the registration number assigned to the registered medical device by the Authority.

(2) For the purposes of section 18(1) of the Act, no person shall supply to another person any medical device with a label that contains any statement to the effect, whether directly or indirectly, that the supply or use of the medical device is being promoted or endorsed by the Authority.

General provisions as to labelling

14.—(1) All information on the label of a medical device shall be provided in the English language, but nothing in this regulation shall prevent such information from being provided in any other language as well.

(2) All numbers, letters and symbols used in providing the information on the label of a medical device shall be legible, permanent and prominent.

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

PART V

ADVERTISEMENT OF MEDICAL DEVICES

Advertisement of medical device

15. For the purposes of section 21 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 such statement have been verified by objective evidence and such verification and objective evidence have been furnished to the Authority at the time when the application for the registration of the medical device was made;

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

(i) may include —

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

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

(ii) shall not contain any statement to the effect, whether directly or indirectly, that the use of the medical device is being promoted or endorsed by the Authority.

PART VI

REGISTRATION OF MEDICAL DEVICES

Requirements for registration of medical device

16.—(1) The Authority shall not register any medical device unless the Authority is satisfied, on the basis of objective evidence provided by the applicant, as to —

(*a*) the safety of the medical device;

(*b*) the quality of the medical device (having regard to the specifications of the medical device, the method of its manufacture and the measures proposed for ensuring that the medical device, whenever supplied, will be of that quality); and

(*c*) the efficacy of the medical device for its intended purpose.

Classification of medical devices

17.—(1) The Authority shall register a medical devices under the appropriate class in accordance with the classification rules specified in the First Schedule.

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

(*a*) the Authority shall have regard to the intended purpose of a medical device when determining the class under which to register the medical device;

(*b*) if a medical device may be registered under more than one class, the Authority shall register the medical device under the class representing the higher risk;

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

(*d*) any accessory to a medical device shall be classified separately from the medical device;

(*e*) if a medical device is driven or influenced by any software item, the software item shall have the same classification as the medical device; and

(*f*) if a medical device is not designed to be used solely or principally in a specific part of a patient's body, the medical device shall be classified having regard to the most critical specified use of the medical device.

Registration of medical device manufactured outside Singapore

18. The Authority shall not, on the application of any person, register any medical device that is manufactured outside Singapore by a person who is resident outside Singapore unless the Authority is satisfied that that applicant for the registration of the medical device is the authorised representative of the manufacturer of the medical device.

Certificates of registration of medical devices

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

Certification of medical devices intended for export

20. The Authority may, on the application of a person who intends to export a medical device, issue to that person a certificate certifying —

(*a*) that the medical device is registered under the Act; or

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

PART VII

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

Duties and obligations of licensees and registrants of medical device

21.—(1) A licensee or the registrant of any medical device shall —

(*a*) on being required by the Authority or an enforcement officer —

(i) produce his licence or certificate of registration to the Authority or enforcement officer for inspection; or

(ii) furnish the Authority or enforcement officer with such information as the Authority or enforcement officer may require in relation to the compliance by the licensee or registrant with the requirements of the Act; and

(*b*) attend at such place as the Authority or an enforcement officer may specify to produce such document or furnish such information as the Authority or enforcement officer may specify for the purpose of ensuring compliance with the Act.

(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.

Duty of manufacturer to ensure compliance with essential principles

22.—(1) A licensed manufacturer of a medical device shall —

(*a*) ensure that the medical device he manufactures conforms with the essential principles specified in the Second Schedule; and

(*b*) keep objective evidence to establish that the medical device conforms with those essential principles.

(2) A licensed manufacturer of any medical device who fails to comply with paragraph (1) shall be liable to have his manufacturer's licence suspended or cancelled under section 27 of the Act.

Duty of importer to ensure compliance with essential principles

23.—(1) A licensed importer of any medical device shall —

(*a*) ensure that the medical device he imports conforms with the essential principles specified in the Second Schedule; and

(*b*) keep objective evidence to establish that the medical device conforms with those essential principles.

(2) A licensed importer of any medical device who fails to comply with paragraph (1) shall be liable to have his importer's licence suspended or cancelled under section 27 of the Act.

Practitioners to keep records of implant

24.—(1) A qualified practitioner who has placed into the body of a person a medical device that is an implant listed in the Third Schedule shall keep proper records of the following matters:

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

(*b*) the date on which the implant was placed into the body of that person;

(*c*) the name and description of the implant; and

(*d*) the lot or batch number of the implant.

(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 kept by him; or

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

25.—(1) The manufacturer, importer, wholesaler and registrant of a medical device shall each establish and implement, in accordance with such written directives as the Authority may issue, a procedure for the receipt, review and evaluation, by a formally designated committee, of complaints pertaining to the medical device.

(2) Any person who fails to comply with paragraph (1) shall be liable to have his licence suspended or cancelled under section 27 of the Act, or any registration granted to him suspended or cancelled under section 37 of the Act.

Reporting of defects and adverse effects

26.—(1) For the purposes of section 42(1) of the Act, the manufacturer, importer, supplier or registrant of a medical device shall, upon becoming aware of any event or other occurrence that reveals any defect in the medical device or that concerns any adverse effect arising from the use thereof, report the event or occurrence to the Authority within the following period:

(*a*) if the information relates to an event or other occurrence that represents a serious threat to public health — 48 hours after the manufacturer, importer, supplier or registrant becomes aware of the event or occurrence; and

(*b*) if the information relates to an event or other occurrence 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 — 10 days after the manufacturer, importer, supplier or registrant becomes aware of the event or occurrence; and

(*c*) if the information relates to an event or other occurrence 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 — 30 days after the manufacturer, importer, supplier or registrant becomes aware of the event or occurrence.

(2) For the purposes of paragraph (1)(*a*), an event or other occurrence, in relation to a medical device, represents a serious threat to public health if —

(*a*) the event or other occurrence is a hazard arising from a systematic failure of the medical device that becomes known to the manufacturer, importer, supplier or registrant of the medical device;

(*b*) the event or other occurrence may lead to the death of, or a serious injury to, a patient, a user of the medical device or any other person;

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

(*d*) it becomes necessary for the manufacturer of the medical device to take prompt action to eliminate, or reduce the risk of, the hazard.

(3) For the purposes of paragraph (1)(*b*) and (*c*), an event or other occurrence leads to a serious deterioration in the state of health of a person if the event or other occurrence causes, or contributes to —

(*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 the structure of the body of that person; or

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

Licensee to notify Authority of changes concerning licence

27.—(1) Every licensee shall notify the Authority if there is any change to any of the particulars declared by him to the Authority at the time when he applied for 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; and

(*d*) 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) Where the change relates to any matter that may significantly affect the operations of the licensee, which may include (but not be limited to) any matter relating to —

(*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; or

(*d*) the personnel responsible for supervising the operations and processes,

the licensee shall not effect, or operate according to, the change unless the Authority has given its approval for the change.

(4) 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.

(5) Any licensee who —

(*a*) in compliance or purported compliance with paragraph (1), furnishes the Authority with any information 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.

Registrant to notify Authority of changes concerning registered medical device

28.—(1) The registrant of a registered medical device shall notify the Authority if there is any change to any matter in relation to the registration 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; and

(*d*) 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 the change relates to any significant matter that may affect the safety, quality or efficacy of the registered medical device, the registrant shall take all necessary steps to ensure that no supply is made of any such medical device to which the change has been made until such time the Authority has given its approval for the change.

(4) 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.

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

(*a*) in compliance or purported compliance with paragraph (1), furnishes the Authority with any information 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.

FIRST SCHEDULE

Regulation 17(1)

MEDICAL DEVICES CLASSIFICATION RULES

Definitions

"active medical device" means any medical device, the operation of which depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy but does not include medical devices intended to transmit energy, substances or other elements between an active medical device and the patient without any significant change.

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

"active device intended for diagnosis" means any active medical device, whether used alone or in combination with other medical devices, to supply information for detecting, diagnosing or monitoring, or to support the treatment of treating physiological conditions, states of health, illnesses or congenital deformities.

"central circulatory system" means the major internal blood vessels, including the following: pulmonary veins, pulmonary arteries, cardiac veins, coronary arteries, carotid arteries (common, internal and external), cerebral arteries, brachiocephalic artery, aorta (includes all segments of the aorta), inferior and superior vena cava and common iliac arteries.

"central nervous system" means brain, meninges and spinal cord.

"self-testing" means any device intended by the manufacturer to be able to be used by lay persons in a home environment.

Duration of use

Transient: Normally intended for continuous use for less than 60 minutes.

Short term: Normally intended for continuous use for between 60 minutes and 30 days.

Long term: Normally intended for continuous use for more than 30 days.

Continuous use means —

(*a*) the entire duration of use of the device without regard to temporary interruption of use during a procedure or temporary removal for purposes such as cleaning or disinfection of the device; or

(*b*) the accumulated use of a device that is intended by the manufacturer to be replaced immediately with another of the same type.

Harm: Physical injury or damage to the health of people or damage to property or the environment.

Hazard: Potential source of harm.

Immediate danger: A situation where the patient is at risk of either losing his life or an important physiological function if no immediate preventative measure is taken.

Intended use: The objective intent of the manufacturer regarding the use of a product, process or service as reflected in the specifications, instructions and information provided by the manufacturer.

Invasive devices

Invasive device: A device, which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body.

Body orifice: Any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma or permanent tracheotomy.

Surgically invasive device: An invasive device which penetrates inside the body through the surface of the body, with the aid or in the context of a surgical operation.

Devices other than those referred to in the previous subparagraph and which produce penetration other than through an established body orifice, shall be treated as surgically invasive devices.

Implantable device: Any device, including one that is partially or wholly absorbed or which is intended to be totally introduced into the human body, or to replace an epithelial surface or the surface of the eye, by surgical intervention and which is intended to remain in place after the procedure. Any device intended to be partially introduced into the human body through surgical intervention and intended to remain in place after the procedure for at least 30 days is also considered an implantable device.

Life supporting or life sustaining: A device that is essential to, or that yields information that is essential to, the restoration or continuation of a bodily function important to the continuation of human life.

Reusable surgical instrument: 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 are intended by the manufacturer to be reused after

appropriate procedures for cleaning and/or sterilisation have been carried out.

Risk: Combination of the probability of occurrence of harm and the severity of that harm.

CLASSIFICATION RULES FOR MEDICAL DEVICES
(EXCLUDING IN VITRO DIAGNOSTIC PRODUCTS)

RULE	*ILLUSTRATIVE EXAMPLES OF DEVICES THAT MAY CONFORM WITH A RULE*
NON-INVASIVE DEVICES	
Rule 1. All non-invasive devices which come into contact with injured skin:	Devices covered by this rule are extremely claim sensitive.
(*a*) are in Class A if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates only, i.e. they heal by primary intent;	Examples: simple wound dressings; cotton wool.
(*b*) are in Class B if they are intended to be used principally with wounds which have breached the dermis, including devices principally intended to manage the microenvironment of a wound.	Examples: non-medicated impregnated gauze dressings.
unless they are intended to be used principally with wounds which have breached the dermis and can only heal by secondary intent, in which case they are in Class C.	Devices used to treat wounds where the subcutaneous tissue is as least partially exposed and the edges of the wound are not sufficiently close to be pulled together. To close the wound, new tissue must be formed within the wound prior to external closure. The device manufacturer claims that they promote healing through physical methods other than 'primary intent'. Examples: dressings for chronic ulcerated wounds; dressings for severe burns.
Rule 2. All non-invasive devices intended for channelling or storing	
(*a*) body liquids or tissues, (*b*) liquids or (*c*) gases for the purpose of eventual infusion, administration or introduction into the body	Such devices are 'indirectly invasive' in that they channel or store liquids that will eventually be delivered into the body (see comment for Rule 4). Examples: administration sets for

are in Class A,	gravity infusion; syringes without needles.
unless they may be connected to an active medical device in Class B or a higher class, in which case they are Class B;	Examples: syringes and administration sets for infusion pumps; anaesthesia breathing circuits. **NOTE:** "Connection" to an active device covers those circumstances where the safety and performance of the active device is influenced by the non-active device and *vice versa*.
unless they are intended for use of (*a*) channelling blood, or (*b*) storing or channelling other body liquids, or (*c*) for storing organs, parts of organs or body tissues, in which case they are Class B.	Examples: tubes used for blood transfusion, organ storage containers.
unless they are blood bags, in which case they are Class C.	Example: Blood bags that do not incorporate an anti-coagulant.
Rule 3. All non-invasive devices intended for modifying the biological or chemical composition of (*a*) blood, (*b*) other body liquids, or (*c*) other liquids intended for infusion into the body are in Class C,	Such devices are indirectly invasive in that they treat or modify substances that will eventually be delivered into the body (see note to comment for Rule 4). They are normally used in conjunction with an active device within the scope of either Rule 9 or 11. Examples: haemodializers; devices to remove white blood cells from whole blood. **NOTE**: for the purpose of this part of the rule, 'modification' does not include simple, mechanical filtration or centrifuging which are covered below.
unless the treatment consists of filtration, centrifuging or exchanges of gas or of heat, in which case they are in Class B.	Examples: devices to remove carbon dioxide; particulate filters in an extracorporial circulation system.
Rule 4. All other non-invasive devices are in Class A.	These devices either do not touch the patient or contact intact skin only. Examples: urine collection bottles; compression hosiery; non-

	invasive electrodes, hospital beds.
INVASIVE DEVICES	
Rule 5. All invasive devices with respect to body orifices (other than those which are surgically invasive) and which: (*a*) are not intended for connection to an active medical device, or (*b*) are intended for connection to a Class A medical device only.	Such devices are invasive in body orifices and are not surgically invasive (refer to definition in Section 4). Devices tend to be diagnostic and therapeutic instruments used in ENT, ophthalmology, dentistry, proctology, urology and gynaecology. Classification depends on the duration of use and the sensitivity (or vulnerability) of the orifice to such invasion.
- are in Class A if they are intended for transient use;	Examples: examination gloves; enema devices.
- are in Class B if they are intended for short-term use;	Examples: urinary catheters, tracheal tubes.
unless they are intended for short-term use in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity, in which case they are in Class A,	Examples: dentures intended to be removed by the patient; dressings for nose bleeds.
- are in Class C if they are intended for long-term use;	Example: urethral stent; contact lenses for long-term continuous use (for this device, removal of the lens for cleaning or maintenance is considered as part of the continuous use).
unless they are intended for long-term use in the oral cavity as far as the pharynx, in an ear canal up to the ear-drum or in a nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are in Class B.	Examples: orthodontic wire, fixed dental prosthesis.
All invasive devices with respect to body orifices (other than those which are surgically invasive) that are intended to be connected to an active medical device in Class B or a higher class, are in Class B.	Examples: tracheal tubes connected to a ventilator; suction catheters for stomach drainage; dental aspirator tips. **NOTE:** independent of the time for which they are invasive.
Rule 6. All surgically invasive devices intended for transient use are in Class B,	A majority of such devices fall into several major groups: those that create a conduit through the skin (e.g. syringe needles; lancets), surgical instruments (e.g. single-use scalpels; surgical staplers; single-use aortic punch); surgical gloves; and various types

	of catheter/sucker etc. **NOTE**: a surgical instrument (other than those in Class D) is in Class A if reusable and in Class B if supplied sterile and intended for single use. Also, a surgical instrument connected to an active device is in a higher class than A. **NOTE:** if the device incorporates a medicinal substance in a secondary role, refer to Rule 13.
unless they are reusable surgical instruments, in which case they are in Class A; or	Examples: Manually operated surgical drill bits and saws.
unless intended to supply energy in the form of ionizing radiation, in which case they are in Class C; or	Example: catheter incorporating/containing sealed radioisotopes.
unless intended to have a biological effect or be wholly or mainly absorbed, in which case they are in Class C; or	**NOTES**: (a) the 'biological effect' referred to is an intended one rather than unintentional. The term 'absorption' refers to the degradation of a material within the body and the metabolic elimination of the resulting degradation products from the body. (b) This part of the rule does not apply to those substances that are excreted without modification from the body. Example: Insufflation gases for the abdominal cavity.
unless intended to administer medicinal products by means of a delivery system, if this is done in a manner that is potentially hazardous taking account of the mode of application, in which they are in Class C; or	Example: insulin pen for self-administration. **NOTE**: the term 'administration of medicines' implies storage and/or influencing the rate/volume of medicine delivered and not just channelling. The term 'potentially hazardous manner' refers to the characteristics of the device and not the competence of the user.
unless they are intended specifically for use in direct contact with the central nervous system, in which case they are in Class D; or	

unless intended specifically to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class D.	Examples: angioplasty balloon catheters and related guide wires; dedicated disposable cardiovascular surgical instruments.
Rule 7. All surgically invasive devices intended for short-term use are in Class B,	Such devices are mostly used in the context of surgery or post-operative care, or are infusion devices, or are catheters of various types. Examples: infusion cannulae; temporary filling materials; non-absorbable skin closure devices; tissue stabilisers used in cardiac surgery. **NOTE:** includes devices that are used during cardiac surgery but do not monitor or correct a defect. **NOTE:** if the device incorporates a medicinal substance in a secondary role, refer to Rule 13.
unless they are intended to administer medicinal products, in which case they are in Class C; or	**NOTE**: the term 'administration of medicines' implies storage and/or influencing the rate/volume of medicine delivered and not just channelling.
unless they are intended to undergo chemical change in the body (except if the devices are placed in the teeth), in which case they are in Class C; or	Example: surgical adhesive.
unless they are intended to supply energy in the form or ionizing radiation, in which case they are in Class C; or	Example: brachytherapy device.
unless they are intended to have a biological effect or to be wholly or mainly absorbed, in which case they are in Class D; or	Example: absorbable suture; biological adhesive. **NOTE**: the 'biological effect' referred to is an intended one rather than unintentional. The term 'absorption' refers to the degradation of a material within the body and the metabolic elimination of the resulting degradation products from the body.
unless they are intended specifically for use in direct contact with the central nervous system, in which case they are in Class D;	Example: neurological catheter.

unless they are intended specifically to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class D.	Examples: cardiovascular catheters; temporary pacemaker leads; carotid artery shunts.
Rule 8. All implantable devices, and long-term surgically invasive devices, are in Class C,	Most of the devices covered by this rule are implants used in the orthopaedic, dental, ophthalmic and cardiovascular fields. Example: maxilla-facial implants; prosthetic joint replacements; bone cement; non-absorbable internal sutures; posts to secure teeth to the mandibula bone (without a bioactive coating). **NOTE:** if the device incorporates a medicinal substance in a secondary role, refer to Rule 13.
unless they are intended to be placed into the teeth, in which case they are in Class B; or	Examples: bridges; crowns; dental filling materials.
unless they are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class D; or	Examples: prosthetic heart valves; spinal and vascular stents.
unless they are intended to be life supporting or life sustaining, in which case they are in Class D; or	
unless they are intended to be active implantable medical devices, in which case they are Class D; or	Example: pacemakers, their electrodes and their leads; implantable defibrillators.
unless they are intended to have a biological effect or to be wholly or mainly absorbed, in which case they are in Class D; or	Example: implants claimed to be bioactive. **NOTE**: hydroxy-apatite is considered as having biological effect only if so claimed and demonstrated by the manufacturer.
unless they are intended to administer medicinal products, in which case they are in Class D; or	Example: rechargeable non-active drug delivery system.

unless they are intended to undergo chemical change in the body (except if the devices are placed in the teeth), in which case they are in Class D; or	**NOTE**: bone cement is not within the scope of the term 'chemical change in the body' since any change takes place in the short rather than long term.
unless they are breast implants, in which case they are in Class D.	
ACTIVE DEVICES	
Rule 9(i). All active therapeutic devices intended to administer or exchange energy are in Class B,	Such devices are mostly electrically powered equipment used in surgery; devices for specialised treatment and some stimulators. Examples: muscle stimulators; TENS devices; powered dental hand pieces; hearing aids; neonatal phototherapy equipment; ultrasound equipment for physiotherapy.
unless their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, including ionizing radiation, taking account of the nature, the density and site of application of the energy, in which case they are in Class C.	Examples: lung ventilators; baby incubators; electrosurgical generators; external pacemakers and defibrillators; surgical lasers; lithotriptors; therapeutic X-ray and other sources of ionizing radiation. **NOTE**: the term 'potentially hazardous' refers to the type of technology involved and the intended application.
Rule 9(ii). All active devices intended to control or monitor the performance of active therapeutic devices in Class C, or intended directly to influence the performance of such devices, are in Class C.	Examples: external feedback systems for active therapeutic devices.
Rule 10(i). Active devices intended for diagnosis are in Class B:	Such devices include equipment for ultrasonic diagnosis/imaging, capture of physiological signals, interventional radiology and diagnostic radiology.
(*a*) if they are intended to supply energy which will be absorbed by the human body (except for devices used solely to illuminate the patient's body, with light in the visible or near infra-red spectrum, in which case they are Class A), or	Examples: magnetic resonance equipment; diagnostic ultrasound in non-critical applications; evoked response stimulators.

(*b*) if they are intended to image *in vivo* distribution of radiopharmaceuticals, or	Example: gamma/nuclear cameras.
(*c*) if they are intended to allow direct diagnosis or monitoring of vital physiological processes,	Example: electronic thermometers, stethoscopes and blood pressure monitors; electrocardiographs.
unless they are specifically intended for: (*a*) monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient, for instance, variations in cardiac performance, respiration, activity of central nervous system, or (*b*) diagnosing in clinical situations where the patient is in immediate danger, in which case they are in Class C.	Example: monitors/alarms for intensive care; biological sensors; oxygen saturation monitors; apnoea monitors. Example: ultrasound equipment for use in interventional cardiac procedures.
Rule 10(ii). Active devices intended to emit ionizing radiation and intended for diagnostic and/or interventional radiology, including devices which control or monitor such devices, or those which directly influence their performance, are in Class C.	Example: these include devices for the control, monitoring or influencing of the emission of ionizing radiation.
Rule 11. All active devices intended to administer and/or remove medicinal products, body liquids or other substances to or from the body are in Class B,	Such devices are mostly drug delivery systems or anaesthesia equipment. Examples of Class B devices: suction equipment; feeding pumps; jet injectors for vaccination; nebuliser to be used on conscious and spontaneously breathing patients where failure to deliver the appropriate dosage characteristics is not potentially hazardous.
unless this is done in a manner that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode and route of administration, in which case they are in Class C.	Examples: infusion pumps; anaesthesia equipment; dialysis equipment; hyperbaric chambers; nebuliser where the failure to deliver the appropriate dosage characteristics could be hazardous.

Rule 12. All other active devices are in Class A.	Examples: examination lamps; surgical microscopes; powered hospital beds & wheelchairs; powered equipment for the recording, processing, viewing of diagnostic images; dental curing lights.
ADDITIONAL RULES	
Rule 13. All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, and which is liable to act on the human body with action ancillary to that of the devices, are in Class D.	These medical devices incorporate medicinal substances in an ancillary role. Examples: antibiotic bone cements; heparin-coated catheters; wound dressings incorporating antimicrobial agents to provide ancillary action on the wound; blood bags incorporating an anti-coagulant.
Rule 14. All devices manufactured from or incorporating animal or human cells/tissues/derivatives thereof, whether viable or non-viable, are in Class D,	Examples: porcine heart valves; catgut sutures.
unless such devices are manufactured from or incorporate non-viable animal tissues or their derivatives that come in contact with intact skin only, in which case they are in Class A.	Examples: leather components of orthopaedic appliances.
Rule 15. All devices intended specifically to be used for sterilising medical devices, or disinfecting as the end point of processing, are in Class C.	Examples: devices for disinfecting or sterilising endoscopes; disinfectants intended to be used with medical devices. **NOTE:** This rule does not apply to products that are intended to clean medical devices by means of physical action e.g. washing machines.
unless they are intended for disinfecting medical devices prior to end point sterilisation or higher level disinfection, in which case they are in Class B; or	Example: washer disinfectors.
unless they are intended specifically to be used for disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses, in which case they are in Class C.	

Rule 16. All devices used for contraception or the prevention of the transmission of sexually transmitted diseases are in Class C,	Examples: condoms; contraceptive diaphragms.
unless they are implantable or long-term invasive devices, in which case they are in Class D.	Example: intrauterine contraceptive device.

CLASSIFICATION RULES FOR IN VITRO DIAGNOSTIC PRODUCTS

(1) List A

(*a*) Reagents and reagent products, including related calibrators and control materials, for determining the following blood groups: ABO system, rhesus (C, c, D, E, e) anti-Kell,

(*b*) reagents and reagent products, including related calibrators and control materials, for the detection, confirmation and quantification in human specimens of markers of HIV infection (HIV 1 and 2), HTLV I and II, and hepatitis B, C and D.

(2) List B

(*a*) Reagents and reagent products, including related calibrators and control materials, for determining the following blood groups: anti-Duffy and anti-Kidd,

(*b*) reagents and reagent products, including related calibrators and control materials, for determining irregular anti-erythrocytic antibodies,

(*c*) reagents and reagent products, including related calibrators and control materials, for the detection and quantification in human samples of the following congenital infections: rubella, toxoplasmosis,

(*d*) reagents and reagent products, including related calibrators and control materials, for diagnosing the following hereditary disease: phenylketonuria,

(*e*) reagents and reagent products, including related calibrators and control materials, for determining the following human infections: cytomegalovirus, chlamydia,

(*f*) reagents and reagent products, including related calibrators and control materials, for determining the following HLA tissue groups: DR, A, B,

(*g*) reagents and reagent products, including related calibrators and control materials, for determining the following tumoral marker: PSA,

(*h*) reagents and reagent products, including related calibrators, control materials and software, designed specifically for evaluating the risk of trisomy 21,

(*i*) the following device for self-diagnosis, including its related calibrators and control materials: device for the measurement of blood sugar.

(3) IVD's for Self-Testing

(a) the following device for self-testing, including its related calibrators and control materials: all devices not included as self-testing devices in List A and List B;

(4) General IVD

(*a*) all devices not included in List A, List B and self-testing devices.

DRAFT

SECOND SCHEDULE

Regulations 22(1)(*a*) and 23(1)(*a*)

ESSENTIAL PRINCIPLES OF SAFETY AND PERFORMANCE OF MEDICAL DEVICES

DEFINITIONS

Clinical evaluation: The review of relevant scientific literature and/or the review and assessment of data collected through clinical investigation.

Clinical investigation: Any designed and planned systematic study in human subjects undertaken to verify the safety and/or performance of a specific device.

Device for self-testing/self-administration: Any device intended by the manufacturer to be able to be used by lay persons in a non-clinical environment.

Harm: Physical injury or damage to the health of people or damage to property or the environment.

Hazard: Potential source of harm.

Intended use / purpose: The objective intent of the manufacturer regarding the use of a product, process or service as reflected in the specifications, instructions and information provided by the manufacturer.

Performance evaluation: Review of the performance of a medical device based upon data already available, scientific literature and, where appropriate, laboratory, animal or clinical investigations.

Regulatory Authority (RA): A government agency or other entity that exercises a legal right to control the use or sale of medical devices within its jurisdiction, and may take enforcement action to ensure that medical products marketed within its jurisdiction comply with legal requirements.

Risk: Combination of the probability of occurrence of harm and the severity of that harm.

Specimen: The discrete portion of a body fluid or tissue or other sample associated with the body taken for examination, study, or analysis of one or more quantity or characteristic to determine the character of the whole.

SECTION I

GENERAL REQUIREMENT

1. Medical devices should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training of intended users, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.

2. The solutions adopted by the manufacturer for the design and manufacture of the devices should conform to safety principles, taking account of the generally acknowledged state of the art. When risk reduction is required, the manufacturer should control the risk(s) so that the residual risk(s) associated with each hazard is judged acceptable. The manufacturer should apply the following principles in the priority order listed:

(*a*) identify known or foreseeable hazards and estimate the associated risks arising from the intended use and foreseeable misuse;

(*b*) eliminate risks as far as reasonably practicable through inherently safe design and manufacture;

(*c*) reduce as far as is reasonably practicable the remaining risks by taking adequate protection measures, including alarms;

(*d*) inform users of any residual risks.

3. Devices should achieve the performance intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions within the scope of the definition of a medical device applicable in each jurisdiction.

4. The characteristics and performances referred to in Clauses 1, 2 and 3 should not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.

5. The devices should be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected under transport and storage conditions (for example, fluctuations of temperature and humidity) taking account of the instructions and information provided by the manufacturer.

6. The benefits must be determined to outweigh any undesirable side effects for the performances intended.

SECTION II

DESIGN AND MANUFACTURING REQUIREMENTS

7. Chemical, physical and biological properties

The devices should be designed and manufactured in such a way as to ensure the characteristics and performance referred to in Section I, the 'General Requirements'. Particular attention shall be paid to —

(*a*) the choice of materials used, particularly as regards toxicity and, where appropriate, flammability;

(*b*) the compatibility between the materials used and biological tissues;

(*c*) cells, body fluids, and specimens, taking account of the intended purpose of the device;

(*d*) the choice of materials used should reflect, where appropriate, matters such as hardness, wear and fatigue strength;

The devices should be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to patients, taking account of the intended purpose of the product. Particular attention should be paid to tissues exposed and to the duration and frequency of exposure.

The devices should be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if the devices are intended to administer medicinal products they should be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use.

Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product/drug as defined in the relevant legislation that applies within that jurisdiction and which is liable to act upon the body with action ancillary to that of the device, the safety, quality and usefulness of the substance should be verified, taking account of the intended purpose of the device.

The devices should be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate the risks posed by substances that may leach or leak from the device.

Devices should be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate risks posed by the unintentional ingress or egress of substances into or from the device taking into account the device and the nature of the environment in which it is intended to be used.

8. Infection and microbial contamination

The devices and manufacturing processes should be designed in such a way as to eliminate or to reduce as far as reasonably practicable and appropriate the risk of infection to patients, users and, where applicable, other persons. The design should —

(*a*) allow easy handling;

and, where necessary

(*b*) reduce as far as reasonably practicable and appropriate any microbial leakage from the device and/or microbial exposure during use.

(*c*) prevent microbial contamination of the device, or specimen where applicable, by the patient, user or other person.

Where a device incorporates substances of biological origin, the risk of infection must be reduced as far as reasonably practicable and appropriate by selecting appropriate sources, donors and substances and by using, as appropriate, validated inactivation, conservation, test and control procedures.

In some jurisdictions products incorporating tissues, cells and substances of nonhuman origin may be considered medical devices. In this case, such tissues, cells and substances should originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues. National regulations may require that the manufacturer and/or the Regulatory Authority retain information on the geographical origin of the animals. Processing, preservation, testing and handling of tissues, cells and substances of animal origin should be carried out so as to provide optimal safety. In particular, safety with regard to viruses and other transmissible agents should be addressed

by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.

In some jurisdictions products incorporating human tissues, cells and substances may be considered medical devices. In this case, the selection of sources, donors and/or substances of human origin, the processing, preservation, testing and handling of tissues, cells and substances of such origin should be carried out so as to provide optimal safety. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.

Devices labelled as having a special microbiological state should be designed, manufactured and packed to ensure they remain so when placed on the market and remain so under the transport and storage conditions specified by the manufacturer.

Devices delivered in a sterile state should be designed, manufactured and packed in a non-reusable pack, and/or according to appropriate procedures, to ensure that they are sterile when placed on the market and remain sterile, under the transport and storage conditions indicated by the manufacturer, until the protective packaging is damaged or opened.

Devices labelled either as sterile or as having a special microbiological state should have been processed, manufactured and, if applicable, sterilized by appropriate, validated methods.

Devices intended to be sterilized should be manufactured in appropriately controlled (e.g. environmental) conditions.

Packaging systems for non-sterile devices should keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilized prior to use, minimize the risk of microbial contamination; the packaging system should be suitable taking account of the method of sterilization indicated by the manufacturer.

The packaging and/or label of the device should distinguish between identical or similar products placed on the market in both sterile and non-sterile condition.

9. Manufacturing and environmental properties

(*a*) If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system should be safe and should not impair the specified performance of the devices. Any restrictions on use applying to such combinations should be indicated on the label and/or in the instructions for use;

(*b*) Devices should be designed and manufactured in such a way as to remove or reduce as far as reasonably practicable and appropriate —

(i) the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features;

(ii) risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, pressure, humidity, temperature or variations in pressure and acceleration;

(iii) the risks connected to their use in conjunction with materials, substances and gases with which they may come into contact during normal conditions of use;

(iv) the risks of accidental penetration of substances into the device;

(v) the risk of incorrect identification of specimens;

(vi) risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of an measuring or control mechanism;

(*c*) Devices should be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and in single fault condition. Particular attention should be paid to devices whose intended use includes exposure to or use in association with flammable substances or substances which could cause combustion;

(*d*) Devices must be designed and manufactured in such a way as to facilitate the safe disposal of any waste substances.

10. Devices with a diagnostic or measuring function

(*a*) Devices with a measuring function, where inaccuracy could have a significant adverse effect on the patient, should be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended purpose of the device. The limits of accuracy should be indicated by the manufacturer;

(*b*) Diagnostic devices should be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended use, based on appropriate scientific and technical methods. In particular the design should address sensitivity, specificity, trueness, repeatability, reproducibility, control of known relevant interference and limits of detection, as appropriate;

(*c*) Where the performance of devices depends on the use of calibrators and/or control materials, the traceability of values assigned to such calibrators and/or control materials should be assured through a quality management system;

(*d*) Any measurement, monitoring or display scale should be designed in line with ergonomic principles, taking account of the intended purpose of the device;

(e) Wherever possible values expressed numerically should be in commonly accepted, standardised units, and understood by the users of the device;

11. Protection against radiation

General

Devices should be designed and manufactured and packaged in such a way that exposure of patients, users and other persons to any emitted radiation should be reduced as far as practicable and appropriate, compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.

Intended radiation

Where devices are designed to emit hazardous, or potentially hazardous, levels of visible and/or invisible radiation necessary for a specific medical

purpose the benefit of which is considered to outweigh the risks inherent in the emission, it should be possible for the user to control the emissions. Such devices should be designed and manufactured to ensure reproducibility of relevant variable parameters within an acceptable tolerance.

Where devices are intended to emit potentially hazardous, visible and/or invisible radiation, they should be fitted, where practicable, with visual displays and/or audible warnings of such emissions.

Unintended radiation

Devices should be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as practicable and appropriate.

Instructions for use

The operating instructions for devices emitting radiation should give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in installation.

Ionizing radiation

Devices intended to emit ionizing radiation should be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and energy distribution (or quality) of radiation emitted can be varied and controlled taking into account the intended use.

Devices emitting ionizing radiation intended for diagnostic radiology should be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimising radiation exposure of the patient and user.

Devices emitting ionizing radiation, intended for therapeutic radiology should be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the energy distribution of the radiation beam.

Requirements for medical devices connected to or equipped with an energy source

Devices incorporating electronic programmable systems, including software, should be designed to ensure the repeatability, reliability and performance of these systems according to the intended use. In the event of a single fault condition in the system, appropriate means should be adopted to eliminate or reduce as far as practicable and appropriate consequent risks.

Devices where the safety of the patients depends on an internal power supply should be equipped with a means of determining the state of the power supply.

Devices where the safety of the patients depends on an external power supply should include an alarm system to signal any power failure.

Devices intended to monitor one or more clinical parameters of a patient should be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health

Devices should be designed and manufactured in such a way as to reduce as far as practicable and appropriate the risks of creating electromagnetic interference which could impair the operation of this or other devices or equipment in the usual environment.

Devices should be designed and manufactured in such a way as to provide an adequate level of intrinsic immunity to electromagnetic disturbance to enable them to operate as intended.

Protection against electrical risks

Devices should be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided the devices are installed and maintained as indicated by the manufacturer.

Protection against mechanical risks

Devices should be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance to movement, instability and moving parts.

Devices should be designed and manufactured in such a way as to reduce to the lowest practicable level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.

Devices should be designed and manufactured in such a way as to reduce to the lowest practicable level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.

Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle should be designed and constructed in such a way as to minimize all possible risks.

Accessible parts of the devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings should not attain potentially dangerous temperatures under normal use.

Protection against the risks posed to the patient by supplied energy or substances

Devices for supplying the patient with energy or substances should be designed and constructed in such a way that the delivered amount can be set and maintained accurately enough to guarantee the safety of the patient and of the user.

Devices should be fitted with the means of preventing and/or indicating any inadequacies in the delivered amount which could pose a danger. Devices should incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source.

The function of the controls and indicators should be clearly specified on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information should be understandable to the user and, as appropriate, the patient.

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

Such devices should be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to users and the influence resulting from variation that can reasonably be anticipated in user's technique and environment. The information and instructions provided by the manufacturer should be easy for the user to understand and apply.

Such devices should be designed and manufactured in such a way as to reduce as far as practicable the risk of use error in the handling of the device and, if applicable, the specimen, and also in the interpretation of results.

Such devices should, where reasonably possible, include a procedure by which the user can verify that, at the time of use, that the product will perform as intended by the manufacturer.

Information supplied by the manufacturer

Users should be provided with the information needed to identify the manufacturer, to use the device safely and to ensure the intended performance, taking account of their training and knowledge. This information should be easily understood.

Performance evaluation including, where appropriate, clinical evaluation

All data generated in support of performance evaluation should be obtained in accordance with the relevant requirements applicable in each jurisdiction.

Clinical investigations on human subjects should be carried out in accordance with the spirit of the Helsinki Declaration. This includes every step in the clinical investigation from first consideration of the need and justification of the study to publication of the results. In addition, some countries may have specific regulatory requirements for pre-study protocol review or informed consent.

THIRD SCHEDULE

Regulation 24(1)

LIST OF IMPLANTS

1. Heart valve.
2. Annuloplasty ring.
3. The following active implantable device systems:
   (*a*) all models of implantable pacemakers and leads;
   (*b*) all models of implantable defibrillators and leads;
   (*c*) artificial heart;
   (*d*) implantable ventricular support system; and
   (*e*) implantable drug infusion system.
4. The following devices of human origin:
   (*a*) human dura mater; and
   (*b*) wound covering containing human cells.
5. All orthopaedic implant systems.

Made this day of 2007.

Chairman,
Health Sciences Authority,
Singapore.