MEDICAL DEVICE ACT 2012

MEDICAL DEVICE REGULATIONS 2012

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MEDICAL DEVICE ACT 2012

MEDICAL DEVICE REGULATIONS 2012

In exercise of the powers conferred by subsection 79(2) of the Medical Device Act 2012 [*Act 737*], the Minister makes the following regulations:

PART I

PRELIMINARY

Citation and commencement

1. (1) These regulations may be cited as the **Medical Device Regulations 2012**.

(2) These Regulations come into operation on 1 July 2013.

Interpretation

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

"labelling" is a term used to cover all written, printed or graphic matter presented by a manufacturer meant to provide information concerning a medical device to the users and others, which may be attached to the medical device itself, on its packaging or as a packaging insert or may be made available by other means, for example by electronic means, when appropriate for the purpose as an additional, or alternative way of transmitting certain information regarding the medical device;

"licensee" means any person who obtains and holds an establishment licence under this Act;

"registration holder", in relation to a registered medical device, means an establishment on whose application the medical device is registered under the Act;

"conformity assessment" means the technical term given to the process of evaluation and evidence generated and procedures undertaken by the manufacturer, under the requirements established by the Authority, to determine that a medical device is safe and performs as intended by the manufacturer and, therefore, conforms to essential principles of safety and performance for medical devices.

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PART II

CONFORMITY ASSESSMENT PROCEDURE

Classification and grouping for the purpose of medical device registration

3. (1) All medical devices shall be—

(a) appropriately classified in accordance with the classification rules as specified in the First Schedule; and

(b) appropriately grouped using the rules of grouping as specified in Second Schedule.

(2) In the event of any dispute between an establishment and a conformity assessment body over a classification of a medical device, the establishment may request in writing to the Authority within thirty days from the date of dispute to decide on the matter.

(3) The Authority shall notify the establishment in writing of its decision on the classification of the medical device within thirty days from the date of request.

Requirement of conformity assessment for the purpose of medical device registration

4. (1) All medical devices shall be subjected to conformity assessment to demonstrate its conformity to the requirements as specified in Third Schedule.

(2) The manufacturer shall collect all the evidence of conformity and, depending on the class of a medical device, shall appoint a conformity assessment body to conduct the assessment on the conformity to the requirements in subregulation (1).

(3) Upon completion of the conformity assessment, and if the conformity assessment body is satisfied that all the requirements have been fulfilled, the conformity assessment body shall issue a report and certificate of the conformity assessment to the establishment as specified in Third Schedule.

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PART III

REGISTRATION OF MEDICAL DEVICE

Application for registration

5. (1) An application for registration of medical device shall be made to the Authority in forms to be determined by the Authority.

(2) An application to register medical devices shall be accompanied with the following:

(a) application fee as specified in Fifth Schedule;

(b) document or information as specified in forms to be determined by the Authority; and

(c) any other additional information, particulars, document on the application or sample of the medical device as may be required by the Authority.

(3) Any other additional information, particulars, document on the application or sample of the medical device as required in paragraph (2)*(c)* shall be submitted by the applicant within ninety days from the date of request by the Authority.

Registration

6. (1) If the Authority is satisfied that all requirements for medical device registration have been fulfilled, the Authority shall consider the application and may approve or refuse the application and shall notify the applicant in writing of its decision.

(2) The fee payable for the registration shall be as specified in Fifth Schedule.

(3) The Authority shall register the medical device and keep the medical device in the Register for a period of five years from the date of registration unless the registration is cancelled by the Authority before its expiry.

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Cancellation of registration

7. (1) The Authority shall notify the registration holder, in writing, on the cancellation of the registration of a medical device.

(2) The registration holder may submit a show cause in writing against the cancellation within ninety days from the date of receipt of notification.

(3) The registration holder may request for an extension of time to submit the show cause in writing as required under subregulation (2).

(4) The Authority shall consider the application for extension of time as requested by the applicant under subregulation (3) and may approve or refuse the application for extension of time and shall notify the applicant in writing of its decision.

(5) If the Authority is satisfied that the registration shall be cancelled, the Authority shall notify, in writing, the registration holder on its decision to cancel the registration.

(6) Where a registration is cancelled by the Authority pursuant to subregulation (1), the registration holder shall return the certificate without further notice to the Authority within fourteen days upon receipt of notification in writing of the cancellation.

(7) Any registration holder who contravenes subregulation (6) commits an offence and shall, on conviction, be liable to a fine not exceeding ten thousand ringgit or to imprisonment for a term not exceeding six months or to both.

PART IV

REGISTRATION OF CONFORMITY ASSESSMENT BODY

Application for registration

8. (1) Any person who intends to be a conformity assessment body shall comply with the requirements as specified in Fourth Schedule and shall apply for registration to the Authority.

(2) An application for registration of a conformity assessment body shall be made in forms to be determined by the Authority.

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(3) An application for registration of a conformity assessment body shall be accompanied with the following:

(a) application fee as specified in Fifth Schedule;

(b) documents or information as specified in forms to be determined by the Authority; and

(c) any additional information, particulars or documents as may be required by the Authority.

(4) Any additional information, particulars or documents required by the Authority under paragraph (3)*(c)* shall be provided by the applicant within thirty days from the date of request by the Authority.

Registration

9. (1) If the Authority is satisfied that all requirements for registration of a conformity assessment body have been fulfilled, the Authority shall consider the application and may approve or refuse the application and shall notify the applicant in writing of its decision.

(2) The fee payable for the registration of a conformity assessment body shall be as specified in Fifth Schedule.

(3) The Authority shall register the conformity assessment body and keep the conformity assessment body in the Register for a period of three years from the date of registration unless the registration is cancelled by the Authority before its expiry.

Cancellation of registration

10. (1) The Authority shall notify the registered conformity assessment body, in writing, on the cancellation of the registration of a medical device.

(2) The registered conformity assessment body may submit, in writing, a show cause against the cancellation within thirty days from the date of receipt of the notification.

(3) The registered conformity assessment body may request for an extension

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of time to submit the show cause in writing as required under subregulation (2).

(4) The Authority shall consider the application for extension of time as requested by the applicant under subregulation (3) and may approve or refuse the application for extension of time and shall notify the applicant in writing of its decision.

(5) If the Authority is satisfied that the registration shall be cancelled, the Authority shall notify, in writing, the registered conformity assessment body on its decision to cancel the registration.

(6) Where a registration is cancelled by the Authority pursuant to subregulation (1), the registered conformity assessment body shall return the certificate to the Authority within fourteen days after being notified in writing of the cancellation.

(7) Any registered conformity assessment body who contravenes subregulation (6) commits an offence and shall, on conviction, be liable to a fine not exceeding ten thousand ringgit or to imprisonment for a term not exceeding six months or to both.

PART V

ESTABLISHMENT LICENCE

Application for an establishment licence

11. (1) Any application for an establishment licence shall comply to the requirements as specified in Third Schedule.

(2) An application for an establishment licence shall be made to the Authority in forms to be determined by the Authority.

(3) An application for an establishment licence shall be accompanied with the following—

(a) application fee as specified in Fifth Schedule;

(b) such documents or information as specified in forms to be determined by the Authority; and

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(c) certificate and report of conformity assessment.

(4) Any additional information, particulars or documents required by the Authority shall be provided by the applicant within thirty days from the date of request by the Authority.

Grant and refusal of establishment licence

12. (1) If the Authority is satisfied that all requirements for an establishment license have been fulfilled, the Authority shall consider the application and may approve or refuse the application and shall notify the applicant in writing of its decision.

(2) The fee payable for the establishment licence shall be as specified in Fifth Schedule.

(3) The Authority shall issue a license to the establishment and keep the establishment in the Register for a period of three years from the date of issuance of the license unless the license is cancelled by the Authority before its expiry.

Renewal of establishment licence

13. (1) An application for renewal of establishment license shall be made to the Authority not later than one year before its expiry in forms to be determined by the Authority and shall be accompanied with the following—

(a) application fee as specified in Fifth Schedule;

(b) such documents or information as specified in forms to be determined by the Authority; and

(c) any other additional information, particulars or documents as may be required by the Authority.

(2) Any other additional information, particulars or documents required by the Authority under paragraph (1)*(c)* shall be provided by the establishment within thirty days from the date of request by the Authority.

(3) If the Authority is satisfied that all requirements for renewal of establishment license have been fulfilled, the Authority shall consider the application and may approve or refuse the application and shall notify the applicant in writing of its

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decision.

(4) The fee payable for renewal of establishment licence shall be as specified in Fifth Schedule.

(5) The Authority shall renew the establishment license and keep the establishment in the Register for a period of three years from the date of renewal of the license unless it is cancelled by the Authority before its expiry.

Suspension or revocation of establishment licence

14. (1) The Authority shall notify the establishment, in writing, on the suspension of the establishment license and shall require the establishment to remedy any contravention or breach that cause the suspension.

(2) The establishment shall remedy the contravention or breach that cause the suspension within fourteen days from the date of notification.

(3) The establishment may request for an extension of time to the Authority, in writing, to remedy as required under subregulation (2).

(4) The Authority shall consider the application for extension of time as requested by the establishment under subregulation (3) and may approve or refuse the application for an extension of time and shall notify the establishment in writing of its decision.

(5) The Authority shall revoke the establishment license if the establishment fails to remedy within the time specified under subregulation (2) or within the approved extension of time under subregulation (3), as the case may be.

(6) When the Authority decides to revoke an establishment license pursuant to subregulation (1), the Authority shall notify the establishment in writing on its decision and the establishment shall return the establishment license to the Authority within fourteen days from the date of notification of the revocation.

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PART VI

EXPORT PERMIT

Application for an export permit

15. (1) Any establishment who intends to apply for an export permit shall comply to the following criteria:

(a) the establishment is licensed under the Act;

(b) the medical device to be exported is registered under the Act; and

(c) any other additional information, particulars or documents as may be required by the Authority.

(2) An application for an export permit shall be made to the Authority in Form MDA1 and accompanied with the application fee as specified in Fifth Schedule.

(3) Any additional information, particulars or documents required by the Authority under paragraph (1)*(c)* shall be provided by the applicant within thirty days from the date of request by the Authority.

PART VII

LABELLING REQUIREMENTS

General provisions on labelling

16. (1) A manufacturer who—

(a) places any registered medical device in the market;

(b) uses or operates any registered medical device to another person; or

(c) uses or operates any registered medical device to another person for the purpose of any investigational testing,

shall ensure that the medical device is appropriately labelled according to labelling requirements as specified in Sixth Schedule.

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(2) The label shall not contain any statement to the effect, whether directly or indirectly, that the placement in the market, or usage or operation of the medical device is being promoted or endorsed by the Authority or the Ministry of Health or any of its organizational bodies.

(3) The label of a medical device shall be legible, permanent and prominent.

(4) Any manufacturer who contravenes subregulation (2) commits an offence and shall, on conviction, be liable to a fine not exceeding ten thousand ringgit or to imprisonment for a term not exceeding three months or to both.

PART VIII

APPEAL

Notice of appeal

17. (1) Any person who is aggrieved by a decision of the Authority under these Regulations shall send a duplicate notice of appeal to the Minister by registered post within thirty days from the date of the decision of the Authority.

(2) The notice of appeal submitted by the appellant shall state—

(a) the full name, address and other particulars of the appellant;

(b) the decision with which he is aggrieved;

(c) the grounds on which the appellant proposes to rely; and

(d) such information or such documents as may be necessary for the purposes of the appeal.

(3) The notice of appeal shall be accompanied with the appeal fee as specified in Fifth Schedule.

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Grounds of decision

18. The Authority shall cause to be prepared grounds of decision and shall be submitted to the Minister within thirty days from the date of receipt of the notice of appeal.

Determination of appeal

19. The Minister shall, as soon as is practicable, proceed to determine the appeal and may, in the event that—

(a) he requires further facts or evidence to be adduced or argument to be heard, set aside a date and time for the receiving of such facts or evidence or the hearing of such argument and shall inform the appellant and the Authority accordingly; or

(b) he requires expert advice or opinion, the Minister may set up an appeal committee to advise him in determining the appeal.

Withdrawal of appeal

20. Where the appellant decides not to pursue with the appeal, the appellant may withdraw the appeal at any time before the determination of the appeal whereupon the decision of the Minister shall be deemed to be final.

PART IX

REGISTER

Register

21. (1) The Authority shall, for the purpose of these Regulations, cause to be kept and maintained a Register.

(2) The Register shall contain any other matters or data as may be specified by the Authority which shall include, but not limited to, forms, technical requirements, guidance documents, guidelines and standards.

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Register for public access

22. (1) The Register shall be made available for public access.

(2) Public who wishes to make a search or to get copy of any information from the Register shall make a request to the Authority and shall pay a fee as specified in Fifth Schedule.

(3) Public shall be informed on any updates on the Register from time to time by any means as determined appropriate by the Authority.

FIRST SCHEDULE

RULES OF CLASSIFICATION OF MEDICAL DEVICE

[Paragraph 3(1)*(a)*]

PART I

PRELIMINARY

Application

1. This Schedule is made pursuant to paragraph 3(1)*(a)* of these Regulations pertaining to the rules to be applied to classify a medical device.

Definitions

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

"hazard" means potential source of harm;

"reusable surgical instrument" means 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;

"immediate danger" means 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;

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"intended use" means 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;

"harm" means physical injury or damage to the health of people or damage to property or the environment';

"body orifice" means 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;

"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";

"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;

"implantable medical device" means any medical 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 or any medical device intended to be partially introduced into the human body through

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surgical intervention and intended to remain in place after the procedure for at least thirty days is also considered an implantable device;

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

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

"life supporting or life sustaining medical device" means a medical 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;

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

"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;

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

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

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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;

"duration of use" are classified into—

(a) transient use which is normally intended for continuous use for less than sixty minutes;

(b) short term use which is normally intended for continuous use for between sixty minutes and thirty days;

(c) long term use which is normally intended for continuous use for more than thirty days.

(d) continuous use means —

(i) 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

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

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PART II

MEDICAL DEVICE CLASSIFICATION

Classification rules

3. (1) A manufacturer shall be responsible to classify its medical device.

(2) All medical devices shall be classified into four classes, namely, Class A, Class B, Class C and Class D depending on the level of risk it poses to patients, users and other persons.

(3) The manufacturer may use—

(a) the classification rules in APPENDIX 1 of this Schedule to classify medical device, excluding *in vitro* diagnostic medical devices; and

(b) the classification rules in APPENDIX 2 of this Schedule to classify *in vitro* diagnostic medical devices.

(4) Notwithstanding subparagraph (3), the manufacturer shall take the following considerations when classifying its medical device:

(a) the intended purpose and mechanism of action of the medical device;

(b) if more than one rule is applicable, the higher classification shall apply;

(c) the classification shall be consistent with the information accompanying the medical device, including its label, instruction for use, brochures and operating manuals;

(d) if a medical device is to be used in combination with other medical device, the classification shall be applied separately for each medical device;

(e) the duration of use shall be specified for all invasive medical devices;

(f) accessories shall be classified separately from the medical devices they are used with;

(g) if a medical device is not used in a specific part of the body, it shall be classified based on the most critical specified use;

(h) software intended to drive or influence the use of a medical device shall be classified the same classification as the medical device;

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(i) based on its intended purpose, a software may be a medical device in its own right.

APPENDIX 1

Classification rules to classify medical device, excluding *in vitro* diagnostic medical device

(1) NON-INVASIVE MEDICAL DEVICE

Rule	Explanation
Rule 1: All non-invasive medical devices which come into contact with injured skin—	Medical 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;	EXAMPLE: 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 medical devices principally intended to manage the microenvironment of a wound;	EXAMPLE: 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**.	Medical 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'. EXAMPLE: dressings for chronic ulcerated wounds, dressings for severe burns

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Rule	Explanation
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 are in **Class A**,	Such medical devices are 'indirectly invasive' in that they channel or store liquids that will eventually be delivered into the body (see explanation for **Rule 4**). EXAMPLE: administration sets for 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**; or	EXAMPLE: 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 medical device is influenced by the non-active medical device and *vice versa*.
unless they are intended for use of— *(a)* channelling blood; or *(b)* storing or channelling other body liquids; or	EXAMPLE: tubes used for blood transfusion; organ storage containers
(c) for storing organs, parts of organs or body tissues, in which case they are **Class B**; or	EXAMPLE: blood bags that do not incorporate an anti-coagulant
unless they are blood bags, in which case they are **Class C**.	

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Rule	Explanation
Rule 3: All non-invasive medical 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;** **unless** the treatment consists of filtration, centrifuging or exchanges of gas or of heat, in which case they are in **Class B**.	Such medical devices are indirectly invasive in that they treat or modify substances that will eventually be delivered into the body (see explanation for **Rule 4**). They are normally used in conjunction with an active medical device within the scope of either **Rule 9** or **Rule 11**. EXAMPLE: haemodialisers, 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. EXAMPLE: devices to remove carbon dioxide; particulate filters in an extracorporial circulation system
Rule 4: All other non-invasive medical devices are in **Class A**.	These medical devices either do not touch the patient or contact intact skin only. EXAMPLE: urine collection bottles; compression hosiery; non-invasive electrodes, hospital beds

(2) INVASIVE MEDICAL DEVICE

Rule	Explanation
Rule 5: All invasive medical devices with respect to body orifices (other than those which are surgically invasive) and which—	Such medical devices are invasive in body orifices and are not surgically invasive (refer to definition in subregulation 2 of PART I of these Regulations).

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Rule	Explanation
(a) are not intended for connection to an active medical device, or *(b)* are intended for connection to a **Class A** medical device only,	Medical 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; or	EXAMPLE: examination gloves; enema devices
are in **Class B** if they are intended for short-term use;	EXAMPLE: 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**,	EXAMPLE: dentures intended to be removed by the patient; dressings for nose bleeds
are in **Class C** if they are intended for long-term use; or	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**.	EXAMPLE: orthodontic wire, fixed dental prosthesis
All invasive medical 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**.	EXAMPLE: 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 medical devices intended for transient use are in **Class B**,	A majority of such medical devices fall into several major groups: those that create a conduit through

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Rule	Explanation
	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 **Class A**. NOTE: if the medical 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	EXAMPLE: Manually operated surgical drill bits and saws
unless intended to supply energy in the form of ionising 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	NOTE: *(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

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Rule	Explanation
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 case 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 medical 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**.	EXAMPLE: angioplasty balloon catheters and related guide wires; dedicated disposable cardiovascular surgical instruments
Rule 7: All surgically invasive medical devices intended for short-term use are in **Class B**,	Such medical devices are mostly used in the context of surgery or post-operative care, or are infusion devices, or are catheters of various types. EXAMPLE: infusion cannulae; temporary filling materials; non-absorbable skin closure devices; tissue stabilisers used in cardiac surgery NOTE: includes medical devices that are used during cardiac surgery but do not monitor or correct a defect. NOTE: if the medical device incorporates a medicinal substance in a secondary role, refer to **Rule 13**.

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Rule	Explanation
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 ionising 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**; or	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**.	EXAMPLE: cardiovascular catheters; temporary pacemaker leads; carotid artery shunts
Rule 8: All implantable medical devices, and long-term surgically invasive medical devices, are in **Class C**, or	Most of the medical 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

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Rule	Explanation
	internal sutures; posts to secure teeth to the mandibula bone (without a bioactive coating) NOTE: if the medical 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	EXAMPLES: 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**.	

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(3) ACTIVE MEDICAL DEVICE

Rule	Explanation
Rule 9(i): All active therapeutic medical devices intended to administer or exchange energy are in **Class B**; **unless** their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, including ionising radiation, taking account of the nature, the density and site of application of the energy, in which case they are in **Class C**.	Such medical devices are mostly electrically powered equipment used in surgery; medical devices for specialised treatment and some stimulators. EXAMPLE: muscle stimulators; TENS devices; powered dental hand pieces; hearing aids; neonatal phototherapy equipment; ultrasound equipment for physiotherapy EXAMPLE: lung ventilators; baby incubators; electrosurgical generators; external pacemakers and defibrillators; surgical lasers; lithotriptors; therapeutic X-ray and other sources of ionising radiation. NOTE: the term 'potentially hazardous' refers to the type of technology involved and the intended application.
Rule 9(ii): All active medical devices intended to control or monitor the performance of active therapeutic medical devices in **Class C**, or intended directly to influence the performance of such medical devices, are in **Class C**.	EXAMPLE: external feedback systems for active therapeutic medical devices

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Rule	Explanation
Rule 10(i):	
Active medical devices intended for diagnosis are in **Class B**;	Such medical 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**;	EXAMPLE: 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	EXAMPLE: monitors/alarms for intensive care; biological sensors; oxygen saturation monitors; apnoea monitors
(b) diagnosing in clinical situations where the patient is in immediate danger,	EXAMPLE: ultrasound equipment for use in interventional cardiac procedures
in which case they are in **Class C**.	

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Rule	Explanation
Rule 10(ii): Active medical devices intended to emit ionising 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 medical devices for the control, monitoring or influencing of the emission of ionising radiation
RULE 11: All active medical devices intended to administer and/or remove medicinal products, body liquids or other substances to or from the body are in **Class B**;	Such medical devices are mostly drug delivery systems or anaesthesia equipment. EXAMPLE: 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**.	EXAMPLE: 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 medical devices are in **Class A**.	EXAMPLE: examination lamps; surgical microscopes; powered hospital beds and wheelchairs; powered equipment for the recording, processing, viewing of diagnostic images; dental curing lights

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(4) ADDITIONAL RULES

Rule	Example
Rule 13: All medical 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. EXAMPLE: 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 medical devices manufactured from or incorporating animal or human cells, tissues or derivatives thereof, whether viable or non-viable, are in **Class D**; **unless** such medical 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**.	EXAMPLE: porcine heart valves; catgut sutures EXAMPLE: leather components of orthopaedic appliances
Rule 15: All medical devices intended specifically to be used for sterilising medical devices, or disinfecting as the end point of processing, are in **Class C;** **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: medical 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. EXAMPLE: washer disinfectors

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

APPENDIX 2

Classification rules to classify medical device for *in vitro* diagnostic medical device (IVD)

Rule	Explanation
Rule 1: IVD medical devices intended for the following purposes are classified as **Class D**: - Devices intended to be used to detect the presence of, or exposure to, a transmissible agent in blood, blood components, blood derivatives, cells, tissues or organs in order to assess their suitability for transfusion or transplantation; or - Devices intended to be used to detect the presence of, or exposure to, a transmissible agent that causes a life-	Tests to detect infection by HIV, HCV, HBV, HTLV. Pyrogenicity tests (endotoxin activity assay) marketed for detection of bacterial contamination of blood components. This rule applies to all types of assays, such as first-line assays, confirmatory assays and supplemental assays.

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Rule	Explanation
threatening often incurable disease with a high risk of propagation.	
Rule 2: IVD medical devices intended to be used for blood grouping, or tissue typing to ensure the immunological compatibility of blood, blood components, cells, tissue or organs that are intended for transfusion or transplantation, are classified as **Class C**; **except** for ABO, rhesus (C, c, D, E, e) and anti-Kell determination which are classified as **Class D**.	HLA, anti-Duffy, anti-Kidd (other Duffy systems except those classified as **Class D** in this rule).
Rule 3: IVD medical devices are classified as **Class C** if they are intended for use:	
- in detecting the presence of, or exposure to, a sexually transmitted agent;	Sexually transmitted diseases, such as chlamydia trachomatis, neisseria gonorrhoeae.
- in detecting the presence in cerebrospinal fluid or blood of an infectious agent with a risk of limited propagation;	Neisseria meningitidis or cryptococcus neoformans.
- in detecting the presence of an infectious agent where there is a significant risk that an erroneous result would cause death or severe disability to the individual or fetus being tested;	Diagnostic assay for CMV, chlamydia pneumoniae, methycillin resistant staphylococcus aureus.
- in pre-natal screening of women in order to determine their immune status towards transmissible agents;	Immune status tests for rubella or toxoplasmosis.
- in determining infective disease status or	Enteroviruses, CMV and HSV in transplant

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Rule	Explanation
immune status, and 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;	patients.
- in screening for selection of patients for selective therapy and management, or for disease staging, or in the diagnosis of cancer;	Personalised medicine.
- in human genetic testing;	Huntington's disease, cystic fibrosis.
- to monitor levels of medicines, substances or biological components, when 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;	Cardiac markers, cyclosporin, prothrombin time testing.
- in the management of patients suffering from a life-threatening infectious disease;	HCV viral load, HIV viral load and HIV and HCV geno- and subtyping.
- in screening for congenital disorders in the fetus.	Spina bifida or down syndrome.
Rule 4: IVD medical devices intended for self-testing are classified as **Class C;** **except** those devices from which the result is not determining a medically critical status, or is preliminary and requires follow-up with	- For self-testing class C: blood glucose monitoring; - For self-testing class B: pregnancy self-test, fertility testing, urine test-strips

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Rule	Explanation
the appropriate laboratory test in which case they are **Class B**. IVD medical devices intended for blood gases and blood glucose determinations for near-patient testing would be **Class C**. Other IVD medical devices that are intended for near-patient should be classified in their own right using the classification rules.	
Rule 5: The following IVD medical devices are classified as **Class A**. - reagents or other articles which possess specific characteristics, intended by the manufacturer to make them suitable for *in vitro* diagnostic procedures related to a specific examination; - instruments intended by the manufacturer specifically to be used for in vitro diagnostic procedures; - specimen receptacles.	Selective/differential microbiological media (excluding the dehydrated powders which are considered not to be a finished IVD medical device), identification kits for cultured microorganisms, wash solutions, instruments and plain urine cup.
Rule 6: IVD medical devices not covered in rules 1 to 5 are classified as **Class B**.	Blood gases, H. pylori and physiological markers such as hormones, vitamins, enzymes, metabolic markers, specific IgE assays and celiac disease markers.
Rule 7: IVD medical devices that are controls without a quantitative or qualitative assigned value will be classified as **Class B**.	

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SECOND SCHEDULE

RULES OF GROUPING OF MEDICAL DEVICE GROUPING
[Paragraph 3(1)*(b)*]

PART I

PRELIMINARY

Application

1. This Schedule is made pursuant to paragraph 3(1)*(b)* of these Regulations on the rules for grouping for the purpose of registration of medical devices.

Definitions

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

"accessory" means an article that is intended specifically by its manufacturer to—

(a) be used together with a medical device to enable that device to be used in accordance with its intended purpose as a medical device; or

(b) augment or extend the capabilities of that medical device in fulfillment of its intended purpose as a medical device;

and therefore should be considered as a medical device;

"reusable surgical instrument" means instrument intended for surgical use by cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or other surgical procedures, without connection to any active medical device and which are intended by the manufacturer to be reused after appropriate procedures for cleaning, disinfection and/or sterilization have been carried out;

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"component" means one of several possibly unequal subdivisions which together constitute the whole medical device to achieve the latter's intended purpose, which may also be known as a part but not a medical device in its own right;

"generic proprietary name" means a unique name given by the manufacturer to identify a medical device as a whole product, also known as the trade name or brand name;

"intended purpose" means the use for which the medical device is intended according to the specifications of its manufacturer as stated on any or all of the following:

(a) the label of the medical device;

(b) the instructions for use of the medical device;

(c) the promotional materials in relation to the medical device;

PART II

MEDICAL DEVICE GROUPING

General principles of grouping

3. (1) An application to register medical devices may be made according to their grouping.

(2) Medical devices may be grouped into one of the following categories:

(a) single;

(b) family;

(c) system;

(d) set;

(e) *in vitro* test kit; and

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(f) *in vitro* cluster.

(3) The basic rules of grouping consist of the following:

(a) one generic proprietary name;

(b) one manufacturer; and

(c) one common intended purpose.

(4) All rules shall be fulfilled when applying the grouping rules to medical devices.

(5) For the purpose of grouping, the corporate headquarters may be regarded as a manufacturer for its subsidiaries and regional manufacturing sites.

Rules of grouping

4. All medical devices shall be appropriately grouped using the rules as follows:

(1) *Single*

A medical device shall be grouped as a single medical device if its proprietary name is identified by the manufacturer with a specific intended use and it is sold as a distinct packaged entity and may be offered in a range of package sizes.

(2) *System*

A group of medical devices shall be grouped as a system if it consists of a number of constituent-components of medical devices that are—

(a) from the same manufacturer;

(b) intended to be used in combination to complete a common intended purpose;

(c) compatible when used as a system; and

(d) sold under a system name or the labelling, instruction-for-use, brochures or catalogues for each constituent-component states that the constituent-component is intended for use with the system.

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(3) *Family*

(a) A group of medical device shall be grouped as a family if it consists of a collection of medical devices, and each medical device in that collection—

(i) is from the same manufacturer;

(ii) is of the same risk classification;

(iii) has the same medical device proprietary name;

(iv) has a common intended purpose;

(v) has the same design and manufacturing process; and

(vi) has variations that are within the scope of the permissible variants.

(b) A permissible variant shall be a characteristic of a medical device if—

(i) the manufacturing processes for the medical devices are the same, or very similar;

(ii) the intended purpose of the medical devices is the same; and

(iii) the risk profile of the medical devices, taking into account the factors specified in subparagraphs *(b)*(i) and (ii), is the same.

(c) If a group of medical devices satisfy the conditions to be grouped as a family, but the proprietary names of the individual medical devices are different, the medical devices shall be listed separately on the Medical Device Register based on their proprietary names.

(d) The proprietary name of each individual medical device that is grouped as a family shall be put on the label of each of the member of medical device family and individual medical device names may contain additional descriptive phrase.

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(4) *Set*

(a) A group of medical devices shall be grouped as a set if it consists of a collection of two or more medical devices, assembled together as one package by a manufacturer and have—

(i) a single proprietary set name;

(ii) a common intended use;

(iii) a classification which is allocated based on the highest class of the device within the set.

(b) Information on all medical devices within a set shall be submitted as part of one medical device registration application.

(c) Medical devices shall be supplied on the market as a set that is listed on the Register.

(d) Medical devices that are registered as part of a set shall have a single medical device registration before they are sold separately as an individual medical device.

(e) If a medical device in a set is supplied for use in another set, such a medical device shall be included in the registration application of that other set.

(f) The set name indicated for the group of medical devices shall appear in the product label affixed on the external package of the set. Individual medical devices in the set shall not be labelled with that set name. Individual medical devices in the set may contain additional descriptive phrases.

(5) *In vitro test kit*

(a) An *in vitro* medical device shall be grouped as *in vitro* diagnostic test

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kit if it consists of reagents or articles that are—

(i) from the same manufacturer;

(ii) intended to be used in combination to complete a specific intended purpose;

(iii) sold under a single test kit name or the labelling, instructions-for-use, brochures or catalogues for each reagents or article states that the component is intended for use with the *in vitro* diagnostic test kit; and

(iv) compatible when used as a test kit.

(b) Information on all reagents or articles within an *in vitro* diagnostic test kit shall be submitted as part of one medical device registration application.

(c) Reagents or articles within an *in vitro* diagnostic test kit that are listed on the register shall be supplied on the market.

(d) If the reagents or articles in an *in vitro* diagnostic test kit are intended to be used in more than one *in vitro* diagnostic test, such reagents or articles shall be included in the medical device registration application of each of the other *in vitro* diagnostic test.

(e) Reagents or articles from another manufacturer may be registered with the *in vitro diagnostic* test group.

(6) *In vitro cluster*

(a) An *in vitro* medical device shall be grouped as *in vitro* diagnostic cluster if it comprises of a number of *in vitro* diagnostic reagents or articles that are—

(i) from the same manufacturer;

(ii) within risk classification A or B;

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(iii) of a common test methodology as listed in APPENDIX 1 of this Schedule; and

(iv) of the same *in vitro* diagnostic cluster category as listed in APPENDIX 1 of this Schedule**.**

(b) The *in vitro* diagnostic cluster may include analysers that are designed for use with the reagents in the *in vitro* diagnostic cluster.

(c) Information on all reagents or articles within an *in vitro* diagnostic cluster shall be submitted as part of one medical device registration application.

(d) Reagents or articles within an *in vitro* diagnostic cluster that are listed on the Register shall be supplied on the market.

(e) Individual reagents or articles that are listed as part of a cluster can be supplied separately.

(f) If a reagent or article is intended for multiple usage categories and can be grouped in more than one *in vitro* diagnostic cluster, the registrant can choose to group the reagent or article as part of any one of the *in vitro* diagnostic clusters it qualifies and information to support all the intended uses of the reagent or article must be submitted as part of the medical device registration application.

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APPENDIX 1

List of Methodology and Cluster Category for *In Vitro* Diagnostic Cluster

METHODOLOGY	CLUSTER CATEGORY (CLOSED LIST)	EXAMPLE OF ANALYTES (NON-EXHAUSTIVE LIST)
Clinical chemistry	Enzymes	Acid phosphatase; alpha-amylase; creatinekinase; gamma-glutamyltransferase; lactate dehydrogenase; lipase
	Substrates	Albumin; bilirubin; urea/blood urea nitrogen; cholesterol; creatinine; glucose
	Electrolytes reagents	Ammonia; bicarbonate; calcium; chloride; magnesium; phosphate inorganic/phosphorus
	Electrolyte electrodes	Ammonia electrodes; carbon dioxide (bicarbonate) electrodes; calcium electrodes; chloride electrodes; magnesium electrodes;potassium electrodes
	Substrate electrodes/ biosensors	Creatinineelectrodes; glucose electrodes; glycated hemoglobin; electrodes; lactate electrodes; urea electrodes; bilirubin electrodes
Immuno-chemistry	Immunoglobulins (without IgE).	Immunoglobulin A; immunoglobulin D; immunoglobulin G; immunoglobulin M; kappa and lambda chain; immunofixation kits
	Complement components	Complement component c1q; complement component C1 inactivator; complement component C3/C3c; complement component for Bb; complement component C4; complement component C5a
	Transport proteins	Albumin; ceruloplasmin; haptoglobin; hemopixin; lactoferrin; pre-albumin/transthyretin
	Lipoproteins	Apolipoprotein AI; apolipoprotein AII; apolipoprotein B; apolipoprotein E sub-typing; lipoprotein (a)
	Other specific proteins	a1-acid glycoprotein; a1-antitrypsin; a2-macroglobulin; a1-microglobulin; fibronectin;

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METHODOLOGY	CLUSTER CATEGORY (CLOSED LIST)	EXAMPLE OF ANALYTES (NON-EXHAUSTIVE LIST)
		immunoreactive trypsin
	Allergy	Immunoglobulin E–total; immunoglobulin E–screen; immunoglobulin E–specific, monotest/monoresult; allergene specific IgA; allergene specific IgG
	Cancer markers	BR-marker CA15-3; GI-marker CA19-9, CA242; carcinoembryonicantigen; total prostatic specific antigen; alphafetoprotein (AFP); p53
	Thyroid function markers	Free triiodothyronine; free thyroxine; thyroid stimulating hormone; T–uptake; thyroglobulin; neonatal thyroxine
	Fertility/pregnancy hormones/ proteins	Androstenedione; estradiol; prolactin; human chorionic; gonadotropin total; human placental lactogen; estriol
	Diabetes assays (hormones)	C-peptide; glucagon; insulin; glycosylated/glycatedhaemoglobin; islet cell Ab; proinsulin
	Renal metabolism assays	Aldosterone; angiotensin I/II; angiotensin converting enzyme; cortisol; renine
	Bone and mineral metabolism assays	Bone alkaline phosphatase; calcitonin; cross-linked C-telopeptides; cross-linked N-telopeptides; cyclic adenosine; monophosphate; hydroxyproline
	Endocrine hormones and peptides	Adrenocorticotropic hormone; human growth hormone; insulin-like growth factor I; insulin-like growth factor binding protein 1; vasointestinalpeptide; vasopressin
	Neuroendocrine function assays	Bombesin; 17-hydroxy-ketosterone; β-endorphin; neurotensin; somatostatin; substance P
	Other individual and	Gastrin; gonadotropin-releasing hormone;

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METHODOLOGY	CLUSTER CATEGORY (CLOSED LIST)	EXAMPLE OF ANALYTES (NON-EXHAUSTIVE LIST)
	specified hormones	melatonine; pepsinogen; adrenalin; dopamine
	Anaemia	Erythropoietin; ferritin; folate; iron; iron binding capacity; soluble transferrin receptor
	Vitamins	Vitamin B1; vitamin B2; vitamin B6; vitamin B12; vitamin D (cholecalciferol); intrinsic factor (blocking antibody)
	Non-immunosuppressive therapeutic drug monitoring	Phenobarbitol; digitoxin; gentamicin; valproic acid; caffeine; theophylline; methotrexate
	Immunosuppressive therapeutic drug monitoring	Cyclosporine; tacrolimus; rapamycin (sirolimus); mycophenolate
	Toxicology	Amphetamines; cocaine; barbiturates; morphines; phencyclidine; acetaminophen; catecholamines; ethanol; salicylate
	Auto-immune diseases	Anti-nuclear antibodies (ANAs); anti-topoisomerase; organ-specific autoantibodies; circulating immuno-complex; TSH receptor antibodies; anti-cardiolipinantibodies
	Rheumatoid-inflammatory diseases markers	Anti-streptococcal hyaluronidase; anti-streptokinase; anti-streptolysin O; C-reactive protein; anti-staphylolysin; anti-streptococcal screening
	Liver function	MEGX; carbohydrate deficient transferrin
	Cardiac markers	BNP/proBNP; creatine kinase-MB; myoglobin; troponin I/T; homocysteine; high-sensitivity C-reactive protein
	Bacterial infection - immunology	*Bacillus subtilis; escherichia coli*

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METHODOLOGY	CLUSTER CATEGORY (CLOSED LIST)	EXAMPLE OF ANALYTES (NON-EXHAUSTIVE LIST)
	Viral infection – immunology	Influenza virus
	Parasitic infection - immunology	*Entamoebahistolytica; leishmania*
	Fungal infection - immunology	*Candida albicans; aspergillus*
Haematology/ histology/cytology (Blood tests for transfusions excluded)	Hemoglobin testing	Hemoglobin determinations (totalHb); fractional oxyhemoglobin (FO2Hb); fractional carboxyhemoglobin(FCOHb); fractional methemoglobin(FMetHb); fractional deoxyhemoglobin(FHHb)
	General coagulation tests	Prothrombintime; thrombin time; activated clotting time; activated partial thromboplastin time
	Haemostasis (coagulation)	Prothrombin; thrombin; fibrinogen; protein C and protein S reagents; C1-inhibitors; heparin; alpha-antiplasmin; fibrin; factor XIII; platelet factor 4; plasminogen
	Other hematology tests	Complete blood count; hematocrit; erythrocyte; sedimentation rate
	Cytokines (lymphokines)/ immunomodulators	Interferons; soluble antigens/receptors; tumor necrosis factors; interleukins; colony stimulating factors; tumor necrosis factors receptors; interleukins receptors
	Histology/cytology reagents	Cytochemicalstaining; embedding, fixing, mounting media; stain solutions; immunohistology kits
Microbiology - culture (i) cytochemicalstaining (ii) embedding, fixing, mounting media	Culture media	Dehydrated culture media (DCM); additives for DCM; prepared media (tubes, bottles, plates); cells, media, serum for viral culture

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METHODOLOGY	CLUSTER CATEGORY (CLOSED LIST)	EXAMPLE OF ANALYTES (NON-EXHAUSTIVE LIST)
(iii) stain solutions (iv) immunohistology kits	Susceptibility testing Identification of bacteria by testing for the susceptibility of the bacteria to the certain antibiotics	Erythromycin susceptibility test for *staphylococcus aureus;* tobramycin susceptibility test for *pseudomonas aeruginosa;* Fungal susceptibility testing
	Biochemical culture identification (ID)	Gram negative manual ID; Gram positive manual ID; Other ID kits manual - anaerobes, fastidious; mycoplasma
	Immunological culture identification (ID)	Streptococci grouping slide tests; serotyping (E.coli, salmonella, shigella *etc*.)
	Nucleic acid (NA) based culture identification (ID)	NA identification – MRSA; NA identification – other resistance markers
	Serological identification (ID)	For parasitology and mycology (fungi and yeast)
Molecular biology	Oncogenes Genes, whose mutation or enhanced expression, turns a normal cell into a cancer cell.	p53; MYC (8q24) TERC (3q26)
	Bacterial infections (detection by NA reagents)	Staphylococcal detection; E.coli detection
	Viral infections (detection by NA reagents)	Influenza and para-influenza NA reagents
	Fungal infections	Fungi NA reagents

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THIRD SCHEDULE

CONFORMITY ASSESSMENT PROCEDURE

[Regulation 4]

PART I

PRELIMINARY

Application

1. This Schedule is made pursuant to regulation 4 of these Regulations on the requirement of conformity assessment procedure to demonstrate conformity to the requirements of the medical device law.

PART II

PROCEDURE FOR CONFORMITY ASSESSMENT

Collection of evidence of conformity by the manufacturer or authorised representative

2. A manufacturer shall collect and compile all the evidence to demonstrate conformity of the medical device to the requirements as determined by the Authority.

Conformity assessment by conformity assessment body

3. (1) Depending on the class of the medical device, the manufacturer shall appoint a conformity assessment body registered by the Authority under section 10 of the Act to conduct the conformity assessment.

(2) If the medical device manufacturer is not present in Malaysia, it shall—

(a) authorise an authorised representative to act on its behalf with regard to the conduct of the conformity assessment; and

(b) provide all the evidence of conformity and necessary support to the authorised representative for the purpose of the conformity

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assessment.

(3) The conformity assessment body shall conduct the conformity assessment in accordance with the requirements as prescribed in PART III of this Schedule.

Report and certificate of the conformity assessment

4. Upon completion of the conformity assessment, and if the conformity assessment body is satisfied that all the requirements have been fulfilled, the conformity assessment body shall issue a report and certificate of the conformity assessment to the manufacturer or the authorised representative.

PART III

ELEMENTS OF CONFORMITY ASSESSMENT

Elements of conformity assessment for the purpose of medical device registration

5. (1) Conformity assessment for the purpose of registration of a medical device shall comprise of the following elements:

(a) conformity assessment of quality management system;

(b) conformity assessment of post-market surveillance system;

(c) conformity assessment of technical documentation; and

(d) declaration of conformity.

(2) The level of evidence to be collected by the manufacturer shall be in accordance with the requirements as prescribed in paragraphs 6, 7, 8 and 9, respectively.

Conformity assessment of quality management system

6. (1) The medical device manufacturer shall establish, maintain and implement an appropriate quality management system in accordance with the recognised standard as determined by the Authority to ensure good manufacturing practice of its medical device.

(2) The extent of the quality management system to be established, maintained and implemented as required in subparagraph (1) shall be determined by the class of

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the medical device as follows:

(a) for a Class A medical device or *in vitro* diagnostic medical device—

(i) the manufacturer shall establish, maintain and implement a quality management system and may exclude design and development control, process control and inspection and testing; and

(ii) the manufacturer shall appoint a conformity assessment body to verify evidence on the aspects of manufacture concerned with —

(A) securing and maintaining sterile conditions if the medical device is to be supplied sterile; and/or

(B) conformity of the medical device with the metrological requirements if the medical device has a measuring function;

(b) for a Class B medical device or *in vitro* diagnostic medical device —

(i) the manufacturer shall establish and maintain a quality management system and may exclude design and development control, process control and inspection and testing; and

(ii) the manufacturer shall appoint a conformity assessment body who may review and conduct on-site audit, as it thinks fit, to verify evidence of compliance to the requirements as determined by the Authority; and

(c) for a Class C or Class D medical device or *in vitro* diagnostic medical device —

(i) the manufacturer shall establish, maintain and implement a full quality management system; and

(ii) the manufacturer shall appoint a conformity assessment body to review and conduct on-site audit to verify evidence of compliance to the requirements as determined by the

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Authority.

(3) Notwithstanding subparagraph (2), the conformity assessment body may require additional documents or information, as it thinks fit, to complete the conformity assessment procedure.

Conformity assessment of post-market surveillance system

7. (1) The manufacturer shall establish, maintain and implement a post-market surveillance system as part of the quality management system to ensure continued conformity of its medical device to essential principles of safety and performance throughout the post-market stage.

(2) During the conduct of the conformity assessment by the conformity assessment body,—

(a) for a Class A medical device or *in vitro* diagnostic medical device, the conformity assessment body may audit post-market surveillance system to investigate specific safety or regulatory concerns; and

(b) for a Class B, Class C or Class D medical device or *in vitro* diagnostic medical device, the conformity assessment body shall conduct an audit to ensure an appropriate post-market surveillance system is established, maintained and implemented by the manufacturer.

(3) Notwithstanding subparagraph (2), the conformity assessment body may require additional document or information as it thinks fit, to complete the conformity assessment procedure.

Conformity assessment of technical documentation

8. (1) The manufacturer shall—

(a) collect and examine evidence and undertake procedures to determine conformity of a medical device to essential principles of safety and performance as specified in APPENDIX 1 of this Schedule; and

(b) compile these evidence in a technical documentation.

(2) The manufacturer shall establish a summary of the technical documentation

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in the format as specified in APPENDIX 2 of this Schedule, for the purpose of the conformity assessment procedure.

(3) The extent of information to be included in the summary of the technical documentation as required in subparagraph (2) shall be determined by the class of the medical device as follows—

(a) for a Class A or Class B medical device or *in vitro* diagnostic medical device—

(i) the manufacturer shall prepare summary of technical documentation and shall make it available upon request by the conformity assessment body;

(ii) the manufacturer shall submit summary of technical documentation and other document or information to the conformity assessment body;

(iii) if the submission of the summary of technical documentation and/or other document or information is required, the conformity assessment body shall review the summary of technical documentation or and/other document or information.

(b) for a Class C or Class D medical device or *in vitro* diagnostic medical device —

(i) the manufacturer shall prepare and submit the summary of technical documentation for review by the conformity assessment body;

(ii) the conformity assessment body shall review the summary of technical documentation to determine and verify conformity to the requirements as determined by the Authority.

(4) Notwithstanding subparagraphs (2) and (3), the conformity assessment body may require additional document or information, as it thinks fit, to complete the conformity assessment procedure.

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Declaration of conformity

9. (1) The manufacturer shall be required to attest that its medical device complies fully with all essential principles for safety and performance and shall draw up a declaration of conformity in the format as specified in APPENDIX 3 of this Schedule.

(2) The conformity assessment body shall review and confirm the adequacy of the declaration of conformity by examining the supporting documents or other evidence.

(3) Notwithstanding subparagraphs (1) and (2), the conformity assessment body may require additional document or information, as it thinks fit, to complete the review.

Evidence of conformity for an imported medical device

10. (1) For an imported medical device, the authorised representative shall obtain the evidence of conformity as required under paragraphs (3) to (10) from its foreign manufacturer.

(2) Upon receipt of evidence of conformity in subparagraph (1) from the foreign manufacturer, the authorised representative shall be responsible to appoint a registered conformity assessment body to conduct conformity assessment procedure as required under paragraphs (3) to (10).

Quality management system requirement for a manufacturer, an authorised representative of a foreign manufacturer, importer and distributor of medical device

11. (1) For the purpose of placing a medical device in the market—

(a) a manufacturer;

(b) an authorised representative of foreign manufacturer;

(c) an importer; and

(d) a distributor,

shall establish, maintain and implement an appropriate quality management system that is commensurate with the role and function of the establishment and in compliance with the requirements in APPENDIX 4 of this Schedule**.**

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Registration and licensing

12. (1) Upon completion of the conformity assessment procedure, an establishment may apply for—

(a) establishment license to carry out its activity; and

(b) registration of its medical devices;

in accordance with the procedures and requirements as prescribed in these Regulations.

(2) The report and certificate of conformity assessment shall be submitted as one of the requirements for registration of medical device and licensing of establishment.

APPENDIX 1

Essential Principles of Safety and Performance of Medical Devices

Definitions

1. In this Schedule, unless the context otherwise requires—

"hazard" means potential source of harm;

"harm" means physical injury or damage to the health of people or damage to property or the environment;

"intended use/purpose" means 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;

"clinical evaluation" means review of relevant scientific literature and/or the review and assessment of data collected through clinical investigation;

"performance evaluation" means a review of the performance of a medical device based upon data already available, scientific literature and, where appropriate, laboratory, animal or clinical investigations;

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"medical device for self-testing/self-administration" means a medical device intended by the manufacturer to be able to be used by lay persons in a non-clinical environment;

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

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

"specimen" means 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.

GENERAL REQUIREMENTS

Medical device shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons

2. A medical device shall 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, the medical device shall 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 its 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.

Reduction of risk associated with a medical device

3. (1) The solutions adopted by the manufacturer for the design and manufacture of the devices shall conform to safety principles, taking account of the generally acknowledged state of the art.

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(2) When risk reduction is required, the manufacturer shall control the risk, so that the residual risk associated with each hazard is judged acceptable, according to the following principles—

(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.

Medical device shall achieve the performance intended by the manufacturer

4. A medical device shall 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.

Characteristics and performances of medical device shall not be adversely affected when it is subjected to normal stresses

5. The characteristics and performances of a medical device referred to in paragraphs 2, 3 and 4 shall 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 medical 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.

Characteristics and performances of medical device shall not be adversely affected under transport and storage conditions

6. A medical device shall be designed, manufactured and packed in such a way that its characteristics and performances during their intended use will not be adversely

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affected under transport and storage conditions, for example, fluctuations of temperature and humidity, taking into account of the instructions and information provided by the manufacturer.

Benefits shall outweigh side effects

7. The benefits of the use of a medical device shall be determined to outweigh any undesirable side effects for the performances intended.

DESIGN AND MANUFACTURING REQUIREMENTS

Chemical, physical and biological properties

8. (1) A medical device shall be designed and manufactured in such a way as to ensure the characteristics and performance referred to in paragraphs 2 to 7 of this Appendix, with particular attention 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;

(2) A medical device shall be designed, manufactured and packed in such a way—

(a) as to minimise 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 in which particular attention should be paid to tissues exposed and to the duration and frequency of exposure.

(b) 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

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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.

(c) as to reduce as far as reasonably practicable and appropriate the risks posed by substances that may leach or leak from the device.

(d) 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.

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

Infection and microbial contamination

9. (1) A medical device and its manufacturing processes shall be designed—

(a) 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;

(b) to allow easy handling and, where necessary—

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

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

(2) Where a medical device incorporates substances of biological origin, the risk of infection shall be reduced as far as reasonably practicable and appropriate by

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selecting appropriate sources, donors and substances and by using, as appropriate, validated inactivation, conservation, test and control procedures.

(3) Where a medical device incorporates tissues, cells or substances of nonhuman origin, such tissues, cells and substances shall originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues, cells or substances and the following requirements shall be adhered to—

(a) retention of information on the geographical origin of the animals;

(b) performance of appropriate processing, preservation, testing and handling of tissues, cells or substances of animal origin so as to ensure optimal safety, particularly, safety with regard to viruses and other transmissible agents shall be addressed by implementing validated methods of elimination or inactivation in the course of the manufacturing process.

(4) Where a medical device incorporates human tissues, cells or substances, the following requirements shall be adhered to:

(a) proper selection of sources, donors and/or tissues, cells or substances of human origin;

(b) performance of appropriate processing, preservation, testing and handling of tissues, cells or substances of such origin so as to ensure optimal safety, particularly, safety with regard to viruses and other transmissible agents shall be addressed by implementing validated methods of elimination or inactivation in the course of the manufacturing process.

(5) A medical device that is labelled as having a special microbiological state shall be designed, manufactured and packed to ensure it remain so when placed on the market and remain so under the transport and storage conditions specified by the manufacturer.

(6) A medical device that is delivered in a sterile state shall be designed, manufactured and packed in a non-reusable pack, and/or according to appropriate procedures, to ensure that it remains sterile when placed on the market and remains

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sterile, under the transport and storage conditions indicated by the manufacturer, until the protective packaging is damaged or opened.

(7) A medical device that is labelled either as sterile or as having a special microbiological state should have been processed, manufactured and, if applicable, sterilised by appropriate, validated methods.

(8) A medical device that is intended to be sterilised should be manufactured in appropriately controlled conditions.

(9) Packaging systems for non-sterile medical device shall be capable of keeping the medical device without deterioration at the level of cleanliness stipulated and, if the medical device is to be sterilised prior to use, the risk of microbial contamination shall be minimised and the packaging system should be suitable for the method of sterilisation indicated by the manufacturer.

(10) The packaging and/or label of a medical device shall distinguish between identical or similar products placed on the market in both sterile and non-sterile conditions.

Manufacturing and environmental properties

10. (1) If the medical device is intended for use in combination with other devices or equipment, the whole combination, including the connection system shall be safe and shall not impair the specified performance of the medical device.

(2) Any restrictions on use applying to such combinations referred to in subparagraph (1) shall be indicated on the label and/or in the instructions for use;

(3) A medical device shall be designed and manufactured in such a way as to remove or reduce as far as reasonably practicable and appropriate —

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

(b) risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and

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electromagnetic effects, electrostatic discharge, pressure, humidity, temperature or variations in pressure and acceleration;

(c) 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;

(d) the risks of accidental penetration of substances into the medical device;

(e) the risk of incorrect identification of specimens;

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

(4) A medical device shall be designed and manufactured in such a way as—

(a) to minimise the risks of fire or explosion during normal use and in single fault condition, with particular attention to medical device whose intended use includes exposure to or use in association with flammable substances or substances which could cause combustion; and

(b) to facilitate the safe disposal of any waste substances.

Medical device with a diagnostic or measuring function

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

(2) A diagnostic medical device shall be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for its intended use, based on appropriate scientific and technical methods; in particular the design 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 calibrators and/or control materials, the traceability of values assigned to such calibrators and/or control materials shall be assured through a quality management system.

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(4) Any measurement, monitoring or display scale shall be designed in line with ergonomic principles, taking account of the intended purpose of a medical device.

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

Protection against radiation

12. (1) A medical devices shall be designed, manufactured and packaged in such a way that exposure of patients, users and other persons to any emitted radiation shall 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.

(2) Where a medical device is 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, such medical device shall be designed and manufactured to ensure reproducibility of relevant variable parameters within an acceptable tolerance and it shall be possible for the user to control the emissions.

(3) Where a medical device is intended to emit potentially hazardous, visible and/or invisible radiation, it should be fitted, where practicable, with visual displays and/or audible warnings of such emissions.

(4) A medical device shall 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.

(5) The operating instructions for medical device emitting radiation shall provide detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and ways of avoiding misuse and of eliminating the risks inherent in installation.

(6) A medical device intended to emit ionising radiation shall be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry

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and energy distribution (or quality) of radiation emitted can be varied and controlled taking into account the intended use.

(7) A medical device emitting ionising radiation intended for diagnostic radiology shall 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.

(8) A medical device emitting ionising radiation, intended for therapeutic radiology shall 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 device connected to or equipped with an energy source

13. (1) A medical device incorporating electronic programmable system, including software, shall be designed to ensure the repeatability, reliability and performance of these systems according to the intended use.

(2) In the event of a single fault condition in the system referred to in subparagraph (1), appropriate means shall be adopted to eliminate or reduce as far as practicable and appropriate consequent risks.

(3) A medical device where the safety of the patients depends on an internal power supply shall be equipped with a means of determining the state of the power supply.

(4) A medical device where the safety of the patients depends on an external power supply shall include an alarm system to signal any power failure.

(5) A medical device intended to monitor one or more clinical parameters of a patient shall be equipped with appropriate alarm system to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.

(6) A medical device shall 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.

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(7) A medical device shall 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

14. A medical device shall 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 medical devices are installed and maintained as indicated by the manufacturer.

Protection against mechanical risks

15. A medical device shall be designed and manufactured in such a way as—

(a) to protect the patient and user against mechanical risks connected with, for example, resistance to movement, instability and moving parts;

(b) 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; and

(c) 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.

(2) 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 minimise all possible risks.

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

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

16. A medical device for supplying the patient with energy or substances shall—

(a) 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.

(b) be fitted with the means of preventing and/or indicating any inadequacies in the delivered amount which could pose a danger.

(c) incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source.

(d) clearly specify the function of any controls and indicators on the medical device;

(e) as appropriate, bear instructions required for its operation or indicate operating or adjustment parameters by means of a visual system, that shall be understandable to the user and, as appropriate to the patient.

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

17. (1) Medical device for self-testing or self-administration shall be designed and manufactured in such a way—

(a) 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;

(b) that the information and instructions provided by the manufacturer shall be easy for the user to understand and apply; and

(c) 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.

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

Information supplied by the manufacturer

18. (1) User of a medical device shall be provided with the appropriate information needed, to identify the manufacturer, to use the medical device safely and to ensure the intended performance, taking account of their training and knowledge.

(2) The information referred to in subparagraph (1) shall be easily understood by the user.

Performance evaluation including, where appropriate, clinical evaluation

19. (1) All data generated in support of performance evaluation of a medical device shall be obtained.

(2) Clinical investigations of a medical device on human subjects shall be carried out in accordance with the spirit of the Helsinki Declaration, which shall include every step in the clinical investigation from first consideration of the need and justification of the study to publication of the results.

APPENDIX 2

Common Submission Dossier Template ("CSDT")

Definitions

1. In this Schedule, unless the context otherwise, requires—

"technical documentation" means the documented evidence, normally an output of the quality management system that demonstrates conformity of a medical device to the essential principles of safety and performance as described in APPENDIX 1 of this Schedule on Essential Principles of Safety and Performance of Medical Devices.

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"essential principles" means essential principles of safety and performance of medical device as described in APPENDIX 1 of this Schedule on Essential Principles of Safety and Performance of Medical Devices;

"recognized standard" means standard deemed by the Authority to offer the presumption of conformity to specific essential principles of safety and performance;

Preparation of CSDT

2. (1) For the purpose of submission for conformity assessment as required under regulation 4 of these Regulations, a manufacturer of a medical device shall prepare a CSDT as a summary of the technical documentation of the medical device.

(2) The CSDT shall contain the elements as specified in Element of CSDT.

(3) Where any elements are not applicable to a particular medical device, the manufacturer shall provide justification for the non-applicability.

(4) The CSDT shall be prepared in Bahasa Malaysia or English.

(5) The depth and detail of the information contained in the CSDT shall depend on—

(a) the classification of the subject medical device;

(b) the complexity of the subject medical device;

(c) novel technology that is incorporated with the medical device;

(d) it is an already marketed medical device type that is now being offered for an intended use different from the original one;

(e) it is new to the manufacturer;

(f) the medical device type has been associated with a significant number of adverse events, including use errors;

(g) it incorporates novel or potentially hazardous materials;

(h) the medical device type raises specific public health concerns.

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(6) The information contained in the CSDT shall be supported by relevant supporting documents.

(7) The supporting documents referred to in subparagraph (6) that are referenced within the CSDT shall be—

(a) legible, within its validity period and submitted in full;

(b) signed-off and dates by an authorised person issuing the supporting documents; and

(c) submitted as annexes to the CSDT.

ELEMENTS OF CSDT

Executive summary

3. The CSDT shall contain an executive summary, which shall include the following information—

(a) an overview which covers an introductory descriptive information on the medical device, the intended uses and indications for use of the medical device, novel features and a synopsis of the content of the CSDT;

(b) commercial marketing history which covers the list of countries where the medical device is marketed and the dates of introduction into those countries;

(c) intended uses and indications in its label;

(d) list of regulatory approval or marketing clearance obtained including the registration status, intended use and indications of the medical device in other countries; copies of certificates or approval letters from each country and declaration on labelling, packaging and instructions for use;

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(e) status of any pending applications for regulatory approval or marketing clearance; and

(f) important safety and performance related information, which shall include—

(i) summary of reportable adverse events and field corrective actions;

(ii) a description of the medical device if the medical device contains animal or human cells, tissues and/or derivatives thereof, rendered non-viable cells, tissues and/or derivatives of microbial or recombinant origin and/or irradiating components, ionising or non-ionising.

Relevant essential principles and rule used to demonstrate conformity

4. (1) The manufacturer shall—

(a) determine all the relevant essential principles that are applicable to the medical device;

(b) take into account the intended purpose of the device when determining the essential principles;

(c) list all the relevant essential principles applicable to the medical device and rule used to demonstrate conformity to each applicable essential principle in the CSDT.

(2) The rules that may be used to demonstrate conformity to each applicable essential principle referred to in subparagraph (1)*(c)* include compliance with recognised or other standards, state of the art or internal industry rules, comparisons to other similar marketed medical devices, *etc.*.

(3) The specific documents shall be referenced in this element of CSDT to support the rule used to demonstrate conformity to the essential principles.

(4) The evidence of conformity shall be provided in tabular form with supporting documentation available for review as required using the format as in TABLE 1 of this Schedule.

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Description of medical device

2. (1) The CSDT shall contain a detailed description of the medical device attributes.

(2) The detailed description shall include the following information:

(a) a complete description of the medical device;

(b) principles of operation or mode of action;

(c) risk class and applicable classification rule for the medical device according to the rules of risk-based classification as specified in First Schedule on Medical Device Classification Rules;

(d) a description of the accessories, other medical devices and other products that are not medical devices, which are intended to be used in combination with the medical device;

(e) a description or complete list of the various configurations of the medical device to be registered using the format as in TABLE 2 of APPENDIX 2 of this Schedule;

(f) a complete description of the key functional elements, its formulation, its composition and its functionality;

(g) an explanation of any novel features;

(h) where appropriate, the information shall be supported by labelled pictorial representation of the medical device in the form of diagrams, photographs or drawings with sufficient explanation to understand the drawings and diagrams;

(i) intended use of the medical device which it is suited according to the data supplied by the manufacturer in the instructions as well as the functional capability of the medical device;

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(j) indications that the device will diagnose, treat, prevent, cure or mitigate and includes a description of the target patient population for which the medical device is intended;

(k) instruction for use;

(l) contraindications which the medical device should not be used because the risk of use clearly outweighs any possible benefit;

(m) warnings to inform on specific risk or hazard that a user needs to know before using the medical device;

(n) precautions to exercise special care necessary for the safe and effective use of the medical device;

(o) potential adverse effects or side effects from the use of the medical device, under normal conditions to the patient or user;

(p) alternative therapy for diagnosing, treating, curing or mitigating the disease or condition for which the medical device is intended;

(q) materials to describe their physical properties to the extent necessary to demonstrate conformity with the relevant essential principles;

(r) other relevant specifications and descriptive information.

Summary of design verification and validation documents

3. (1) The CSDT shall contain summary of design verification and design validation documents to the extent appropriate to the complexity and risk class of the medical device.

(2) The summary of design verification and design validation documents shall include—

(a) declarations or certificates of conformity to the standards recognized by the Authority as applied by the manufacturer; and/or

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(b) summaries or reports of tests and evaluations based on other standards, manufacturer rules and tests, or alternative ways of demonstrating compliance.

(3) The data summaries or tests reports and evaluations may cover, as appropriate to the complexity and risk class of the medical device—

(a) a listing of and conclusions drawn from published reports that concern the safety and performance of aspects of the medical device with reference to the essential principles;

(b) engineering tests;

(c) laboratory tests;

(d) biocompatibility tests;

(e) animal tests;

(f) simulated use; and

(g) software validation.

Pre-clinical studies

4. (1) The CSDT shall contain documentation on pre-clinical studies conducted for the medical device.

(2) The documentation referred to in subparagraph (1) shall include the report and/or certification and/or declaration of—

(a) biocompatibility tests conducted on materials used in a medical device,

(b) pre-clinical physical tests conducted on the medical device,

(c) pre-clinical animal studies to support the probability of effectiveness in humans.

(3) The report referred to in subparagraph (2) shall contain information on the objectives, methodology, results, discussion and conclusions of the testing.

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Software validation studies

5. (1) The CSDT shall contain documentation on software validation studies to verify the correctness of software in medical device.

(2) The manufacturer shall compile objective evidence that validates the software design and development process.

(3) The document shall include the results of all verification, validation and testing performed in-house and in a user's environment prior to final release, for all of the different hardware configurations identified in the labelling, and representative data generated from both testing environments.

Medical devices containing biological material

6. (1) If the medical device contains biological material, the documentation on the studies substantiating the adequacy of the measures taken with regards to the risks associated with transmissible agents shall be provided in the CSDT.

(2) The documentation shall contain the following information:

(a) a list of all materials of animal, human, microbial and/or recombinant origin used in the medical device and in the manufacturing process of the medical device, which includes animal or human cells, tissues and/or derivatives, rendered non-viable cells, tissues and/or derivatives of microbial or recombinant origin;

(b) detailed information concerning the selection of sources/donors;

(c) detailed information on the harvesting, processing, preservation, testing and handling of tissues, cells and substances;

(d) process validation results to substantiate that manufacturing procedures are in place to minimise biological risks, in particular, with regard to viruses and other transmissible agents; and

(e) full description of the system for record keeping allowing traceability from sources to the finished medical device.

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Clinical evidence

7. (1) The CSDT shall contain documentation on clinical evaluation to verify the clinical safety and performance of the medical device when used as intended by the manufacturer.

(2) The clinical evaluation may take the form of—

(a) a systematic review of existing bibliography;

(b) clinical experience with the same or similar medical devices; or

(c) clinical investigation.

Use of existing bibliography

8. (1) The CSDT shall contain copies of all literature studies, or existing bibliography, that the manufacturer is using to support safety and effectiveness.

(2) Bibliography shall be derived from relevant publications in a peer-reviewed scientific literature and shall include the objectives, methodology and results presented in context, clearly and meaningfully.

(3) The conclusions on the outcome of the clinical studies should be preceded by a discussion in context with the published literature.

Medical device labelling

9. (1) The CSDT shall contain documentation on medical device labelling that accompanies the device any time while it is held for sale or shipped.

(2) The documentation shall contain the following information—

(a) sample of labels on the device and its packaging;

(b) instructions for use;

(c) other literature or training materials;

(d) instructions for installation and maintenance (if applicable); and

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(e) any information and instructions given to the patient, including instructions for any procedure the patient is expected to perform, if applicable.

(3) The promotional material and product brochures shall be provided as part of CSDT to aid in the evaluation of the medical device.

(4) Samples of labels on the device and its packaging shall be in compliance with labelling requirements as specified by these Regulations.

Risk analysis

10. (1) The CSDT shall contain documentation on risk analysis conducted for the medical device.

(2) The documentation shall be provided in the form of a risk management report.

(3) The risk analysis shall be based upon standards recognized by the Authority, and shall be appropriate to the complexity and risk class of the medical device.

Manufacturer information

11. (1) The CSDT shall summarize or reference or contain documentation related to the manufacturing processes, including quality assurance measures, which is appropriate to the complexity and risk class of the medical device.

(2) The information of manufacturing process for the medical device shall be provided in the form of a list of resources and activities that transform inputs into the desired output.

Special requirement for medical device used in clinical investigation

12. (1) For medical device used in clinical investigation, the following elements are not applicable:

(a) clinical evidence; and

(b) use of existing bibliography.

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(2) The medical device shall be labelled to indicate that it is used in clinical investigation.

TABLE 1

EXAMPLE OF AN ESSENTIAL PRINCIPLES CONFORMITY CHECKLIST

Essential Principle	Applicable to the medical device	Rule of conformity	Identity of specific document
(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 construction of the devices should conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer should apply the following principles in the following order: (i) identify hazards and the associated risks arising from the intended use and			

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foreseeable misuse, (ii) eliminate or reduce risks as far as possible (inherently safe design and construction), (iii) where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated, (iv) inform users of the residual risks due to any shortcomings of the protection measures adopted.			

NOTE:

The essential principles conformity checklist is to be prepared based on the list of essential principles referred to in APPENDIX 1 of this Schedule on Essential Principles of Safety and Performance of Medical Devices. The medical device to which the essential principles conformity checklist is applicable should be identified on the checklist itself. Where applicable, the various configurations/variants of the medical device covered by the checklist are to be identified in the checklist. The columns in the recommended format for the checklist should be completed as follows:

(a) Applicable to the medical device — Either a 'Yes' or 'No' answer is required. If the answer is 'No' this should be briefly explained. For example: For a medical device that does not incorporate biological substances, the answer to it would be 'No – The medical device does not incorporate biological substances'.

(b) Rule of conformity—State the title and reference of the standard, industry or in-house test rule, comparison study or other rule used to demonstrate compliance. For standards, this should include the date of the standard and where appropriate, the clause that demonstrates conformity with the relevant essential principle. Where a standard is referred to more than once in the checklist, the reference number and date can be repeated. Conformity with the Essential Principles can be demonstrated by another means if the recognised standards are not available.

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(c) Identity of specific documents—This column should contain the reference to the actual technical documentation that demonstrates compliance to the essential principle, i.e. the certificates, test reports, study reports or other documents that resulted from the rule used to demonstrate compliance, and its location within the technical documentation.

TABLE 2

List of Configurations of Medical Device to be Registered

Name of medical device FAMILY/GROUP/SYSTEM:		
Proposed grouping for medical device (FAMILY/GROUP/SYSTEM):		
Name as per medical device label	*Identifier*	*Brief description of item*

Guides for Completing List of Configurations of Medical Device to be Registered

(1) For the "*Name as per medical device label*" column—

(i) for a medical device family, list the names of the constituent members in this column. Enter the identifier associated with each constituent member in the "Identifier" column.

(ii) for a medical device group, list the names of the constituent medical devices in this column. Enter the identifier associated with each constituent medical device in the "Identifier" column.

(iii) for a medical device system, list the names of every constituent component in this column. Enter the identifier associated with each constituent component in the "Identifier" column.

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(2) for the "*Identifier*" column, identifier refers to a unique series of letters or numbers or any combination of these or a bar code that is assigned to a medical device by the product owner and that identifies it and distinguishes it from similar devices. Examples of an identifier for a device are a barcode, catalogue, model or part number.

(3) for the "*Brief description of item*" column, give a brief description of the key distinguishing attributes or specifications of each item. Examples of a brief description of a constituent member of a family include the following:
For percutaneous transluminal coronary angioplasty (PTCA) catheters:
10 mm balloon length and 2 mm balloon diameter.

(4) A list of configurations is to be provided with each FAMILY/GROUP/SYSTEM medical device application.

APPENDIX 3

Declaration of Conformity

PART I

GENERAL PRINCIPLES

General principles of Declaration of Conformity

1. (1) For the purpose of registration of a medical device, a medical device manufacturer shall—

(a) attest that its medical device conform to all applicable essential principles for safety and performance of medical device;

(b) attest that its medical device complies fully with the requirements of the Act and its subsidiary legislations; and

(c) draw up a written Declaration of Conformity.

(2) Notwithstanding subparagraph (1), the manufacturer shall provide documents sufficient to support its Declaration of Conformity.

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PART II

FORMAT OF DECLARATION OF CONFORMITY

Contents of Declaration of Conformity

2. The Declaration of Conformity shall at least contain the following information—

(a) an attestation that each device that is subject to the declaration:

(i) complies with all the applicable essential principles for safety and performance as described in APPENDIX 1 of this Schedule on Essential Principles of Safety and Performance of Medical Devices;

(ii) has been classified according to the classification rules as specified in First Schedule on Rules of Classification of Medical Device; and

(iii) has met all the applicable conformity assessment elements.

(b) sufficient information to identify the device to which the Declaration of Conformity applies;

(c) nomenclature of the medical device, preferably using the Global Medical Device Nomenclature (GMDN) code and term;

(d) the risk class allocated to the medical device according to First Schedule on Rules of Classification of Medical Device;

(e) the conformity assessment elements as specified in Third Schedule of these Regulations have been applied;

(f) date from which the Declaration of Conformity is valid;

(g) name and address of the device manufacturer;

(h) name, position and signature of the responsible person who has been authorised to complete the Declaration of Conformity on behalf of the manufacturer.

Declaration of Conformity template

3. (1) The manufacturer may use Declaration of Conformity Template as appended in APPENDIX 1A of this Schedule.

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APPENDIX 1A

Declaration of Conformity Template

Name and Address of Manufacturer

[please print on Company Letterhead of Manufacturer]

DECLARATION OF CONFORMITY

I, *< please provide the name of person responsible for manufacturing the medical device>*, hereby declare that the below mentioned medical device—

(i) complies with all the requirements under the Act;

(ii) has been classified according to the classification rules as specified in First Schedule on Rules of Classification of Medical Device; and

(iii) conforms to requirements specified in APPENDIX 1 of Third Schedule on Essential Principles for Safety and Performance of Medical Devices under Medical Devices Regulations 2012.

(A) Particulars of medical device

Generic name:

Specified name:

Brand/model:

Manufacturer:

Country of origin:

Manufacturing site:

Risk-based classification:

Classification rule:

(Note: according to First Schedule on Rules of Classification of Medical Device)

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GMDN code:

Medical device registration number or any approval code:

(B) Quality Management System certificate ("QMS")

Conformity Assessment Body issuing the certificate:

Certificate number:

Issuance date:

Expiry date:

Note:

(i) For Class B, Class C and Class D medical devices, declaration of conformity to either of the following QMS standards is mandatory:

(a) MS ISO 13485; or

(b) Other quality management system standard recognised by the Medical Device Authority.

(ii) For Class A medical devices that are not manufactured under either of the above mentioned quality management system standards, certification obtained for alternative quality management system standards shall be listed in this section, if applicable.

(iii) For Class A medical devices with measuring function, conformity assessment certificate and calibration and metrology report, issue date, expiry date, calibration should be provided.

(iv) For Class A medical devices with sterilization, validation report and conformity assessment certificate number, issue date, expiry date should be provided.

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(C) Standards Applied

Please state and list all standards applicable for the above-mentioned medical device.

I am fully responsible with all the information provided in this declaration. This declaration of conformity is valid from …… (Day) …….. (Month) …….. (Year).

I fully understand and acknowledge that it is an offence under Section 76 of the Medical Device Act 2012 [*Act 737*] to make, sign or furnish any declaration, certificate or other document which is untrue, inaccurate or misleading.

Authorised Signatory:

_____ _____

Name/Position Date

Note: The Declaration of Conformity, all document and certificates and attestations shall be duly certified true copy by the Applicant.

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APPENDIX 4

Requirement on quality management system

Type of Establishment	Quality management system
(a) Manufacturer	ISO 13485 - Medical devices -- Quality management systems -- Requirements for regulatory purposes
(b) Authorised representative	Good Distribution Practice for Medical Devices (GDPMD)
(c) Importer	Good Distribution Practice for Medical Devices (GDPMD)
(d) Distributor	Good Distribution Practice for Medical Devices (GDPMD)

FOURTH SCHEDULE

REQUIREMENTS FOR THE REGISTRATION OF CONFORMITY ASSESSMENT BODIES
[Regulation 8]

PART I

PRELIMINARY

Application

1. This Schedule is made pursuant to regulation 8 of these Regulations to specify the requirements and conditions for any person to apply to be a registered conformity assessment body under section 10 of the Act.

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Definitions

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

"auditor" means the person employed by the conformity assessment body for the purpose of conducting conformity assessment against Medical Devices Regulations;

"client" of a conformity assessment body means any establishment who appoints the conformity assessment body to carry out conformity assessment under regulation 4 of these Regulations;

"essential principles of safety and performance" means the requirements for registration of medical devices as prescribed in APPENDIX 1 of the Third Schedule on Essential Principles of Safety and Performance of Medical Devices which is made pursuant to paragraph 4*(a)* of the Act and regulation 4 of these Regulations.

PART II

GENERAL

General requirements

3. Any person who wishes to be registered as a conformity assessment body under section 10 of the Act and PART IV of these Regulations shall be a sound organisation to enable it to carry out conformity assessment under regulation 4 of these Regulations and shall comply with, where applicable—

(a) requirements on organisation;

(b) requirements on resources and technical competency;

(c) requirements on independence and impartiality; and

(d) requirements on quality management system.

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PART III

REQUIREMENTS ON ORGANISATION

Organisation structure

4. (1) A conformity assessment body shall be a legally defined entity that is registered in Malaysia and shall be registered to the Authority to operate as a conformity assessment body in Malaysia.

(2) The person responsible for the management and operations of the conformity assessment body shall be a Malaysian citizen.

(3) The conformity assessment body shall identify and document its organisation structure showing duties, responsibilities, lines of authority, relationship and the reporting structure within its organisation, including committees established by the organisation.

(4) If a conformity assessment body is part of a larger organisation, the links and relationship between the conformity assessment body and the larger organisation shall be clearly defined and documented.

Responsibilities

5. (1) A conformity assessment body shall take full responsibility and shall retain authority for all tasks required in relation to the scope of the tasks for which it is being registered.

(2) The conformity assessment body shall conduct conformity assessment on its clients against the declared procedures and those required by these Regulations.

(3) The conformity assessment body shall—

(a) make adequate arrangements to ensure confidentiality of the information obtained in the course of carrying out its tasks; and

(b) ensure that no details, records, results or information of any kind are disclosed to any other party except Authority.

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(4) The conformity assessment body shall, without delay, inform the Authority of any changes regarding availability of resources, including subcontractors, and compliance with designation conditions which may have an impact on the maintenance of the designation and of the assignment of tasks.

PART IV

REQUIREMENTS ON RESOURCES AND TECHNICAL COMPETENCY

Requirements on resources

6. A conformity assessment body shall be a sound organisation with adequate competent staff and appropriate facilities, including test equipment, if applicable, to enable it to carry out the conformity assessment according to the scope for which it is being registered.

Requirements on technical competency

7. (1) A conformity assessment body shall determine the competence required for any personnel to undertake any assignment under its scope of registration and shall establish and implement procedures to ensure the competence level of its personnel.

(2) The conformity assessment body shall possess sufficient scientific and technical personnel within the organisation according to the technical areas as specified in APPENDIX 1 of this Schedule, or are supported by its associates with adequate experience and knowledge in order to be able to handle the technical and administrative tasks such as allocation of appropriate assessment personnel, review of assessment output and to advise on certification for the specific tasks and products it has been designated to cover.

(3) Depending on the scope of its registration, the qualification and experience of the technical personnel of the conformity assessment body as required in subparagraph (2) shall be in accordance with the requirements as specified in APPENDIX 2 of this Schedule.

(4) The conformity assessment body shall maintain records of qualification and experience of its personnel as prescribed in subparagraph (3).

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(5) The conformity assessment body shall ensure that when carrying out quality management system audits, the team of auditors shall comprise of at least one member who is experienced in the evaluation of the technologies used by the manufacturer.

(6) When conducting an audit of quality management system of an establishment, the conformity assessment body shall ensure that it is conducted by a team that includes at least a member who is competent in the review of specific technical areas or technologies pertaining to the medical device that the establishment is dealing with or specific processes involved in the production or handling of the medical devices.

Requirements on subcontractor

8. If a conformity assessment body uses the services of a subcontractor, the conformity assessment body shall—

(a) be responsible for all contracted tasks;

(b) be liable for the subcontractor as if the conformity assessment body itself performs the tasks;

(c) ensure that its subcontractors and their personnel conform to all the requirements of the regulations that would apply had the task is performed by the personnel of the conformity assessment body;

(d) establish and implement procedure and maintain records on the assessment of the subcontractor's qualifications and the tasks carried out by the subcontractor on behalf of the conformity assessment body;

(e) not subcontract the overall responsibility for reviewing the outcome of assessment and verification activities, which are the essential tasks for which it was registered;

(f) restrict the subcontractor to only perform the subcontracted tasks;

(g) draw up a documented agreement between the conformity assessment body and the subcontractor reflecting the requirements on the subcontracted tasks, including the requirements on confidentiality,

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impartiality, provision of access by the Authority and prohibition of the subcontractors from further subcontracting their duties;

(h) prohibit the subcontractor from further subcontracting its duties;

(i) ensure that the subcontracted tasks carried out by the subcontractor is carried out according to detailed documented procedures which are the same as, or judged by the conformity assessment body to be equivalent to, those followed by the conformity assessment body itself;

(j) ensure that that the subcontractor fulfils only an objective role, that is, one which is restricted to factual reporting and/or supported recommendations, on the basis of which the conformity assessment body shall make assessments and judgements in relation to the requirements of the regulation;

(k) inform the Authority of its intention to subcontract duties in relation to the task for which it was registered;

(l) maintain an up to date register of all its subcontractors, which shall be provided to the Authority without delay upon request;

(m) maintain documented evidence that the subcontractor has the necessary technical competence and facilities to carry out the subcontracted activities;

(n) maintain the relevant documents and records of assessment of the qualifications of the subcontractor in relation to the work contracted to the subcontractor;

(o) maintain subcontractor register which shall include the following information:

(i) the name of the subcontract organisation;

(ii) its legal status and details of any relationship with a parent company, group of companies, or any other organisation of which the subcontractor is a part;

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(iii) names of staff carrying out the subcontracted tasks and evidence that they are competent to do so;

(iv) the task performed by the subcontractor and details of the procedures used in carrying out the subcontracted task.

PART V

REQUIREMENTS ON INDEPENDENCE AND IMPARTIALITY

Independence and impartiality

9. (1) A conformity assessment body shall be independent and not related to its clients and shall not be involved in activities relating to designing, manufacturing, importing or distributing the product category for which the conformity assessment body has been registered.

(2) The conformity assessment body shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the result of the inspections, especially from persons or groups of persons with an interest in the results of the assessments.

(3) The conformity assessment body or its subsidiaries shall not—

(a) involve in consultancy activities relating to the scope of activities it is registered;

(b) provide consultancy services to establishment and seeking certification under its' own jurisdiction.

(4) The conformity assessment body shall establish and implement documented procedures and maintain records of the identification, review and resolution of all cases where conflict of interest is suspected or proven.

(5) The conformity assessment body shall require all staff acting on its behalf to declare any potential conflict of interest.

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(6) The conformity assessment body shall maintain records of such declarations required under subparagraph (5).

(7) The conformity assessment body shall guarantee the impartiality of all inspection and evaluation personnel and ensure that the remuneration of personnel shall not depend on the number of controls and verifications that they carry out, or on the results of their activities.

Liability

10. The conformity assessment body shall have public liability insurance commensurate with the scope of its services.

Confidentiality

11. (1) The conformity assessment body shall observe strict professional confidentiality with regard to all information obtained in carrying out their tasks.

(2) The professional confidentiality to be observed by the conformity assessment body shall not affect obligation of the conformity assessment body with regard to legally required reporting and dissemination of warnings, nor its obligation to provide information under criminal and/or civil law.

(3) The conformity assessment body shall make appropriate arrangements to ensure that no details, records, results or information of any kind are disclosed to any other party except to the Authority.

PART VI

QUALITY MANAGEMENT SYSTEM

Documentation

12. (1) A conformity assessment body shall establish, maintain and implement within its organisation an appropriate quality management system pertaining to its management and operations.

(2) The quality management system as required in subparagraph (1) shall include the following elements:

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(a) description of the legal status of the conformity assessment body, including the links and relationship with parent organisations, if relevant;

(b) responsible person;

(c) authorities, responsibilities and reporting structure within the conformity assessment body;

(d) the scope of the services provided and the fees for the conduct of conformity assessment;

(e) particulars of assessment personnel, both internal and subcontracted, which include—

(i) assessment responsibilities;

(ii) records of relevant training and experience; and

(iii) justification/rationale for the defined scope of assessment responsibilities;

(f) procedures to carry out assessment and verification during conformity assessment on the clients, which shall include—

(i) review on the completeness of application against the details provided under which conformity assessment has been sought;

(ii) review and verification on the compliance of the clients with the regulatory requirements;

(iii) conclusion of the assessment the compliance of the clients with the scope being assessed;

(iv) issuance, refusal, suspension, and withdrawal of, or restrictions placed on the certificate;

(v) communications with other organisations, including the Authority relating to issuance, refusal, suspension, and withdrawal of, or

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restrictions placed on a certificate, including records of all communications and action taken as a result of such communications;

(vi) assessment and monitoring of subcontractors, if used;

(vii) maintenance of record, including means to ensure security and confidentiality;

(viii) consideration of appeals against decisions made, including referral to the Authority where necessary;

(ix) means by which assessment and consultancy services are separated, whether these services are carried out by the conformity assessment body or any part of a larger organisation to which it is linked, or its subcontractors;

(g) records on the conclusions of assessment including a reasoned evaluation of the manufacturer's compliance with the standards specified;

(h) the conformity assessment body shall—

(i) establish and maintain a system to control all quality management system documentation and to ensure that current issues of procedures are available at all relevant locations; and

(ii) ensure that the defined quality management system is effectively implemented.

Product testing

13. (1) If the scope of the conformity assessment body covers product testing, relevant test equipment and testing protocols, standards used in-house facilities and any subcontractors the applicant proposes to use, including any relevant accreditations held by either the applicant or the subcontractor.

(2) If the testing is subcontracted, the conformity assessment shall ensure that the requirements on subcontractors as specified in paragraph 8 are adhered to.

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Conformity assessment process

14. (1) A conformity assessment body shall establish the following:

(a) Any documentation, including general terms and conditions, marketing materials, application forms and contracts, that an applicant would propose sending to potential new clients if registered;

(b) Procedures to assess clients' conformity with the appropriate conformity assessment requirements and essential principles of safety and performance, including as applicable, those procedures specific to—

(i) design dossier reviews;

(ii) assessment of clinical and bio-compatibility data;

(iii) medical device containing animal tissues;

(iv) sterile medical device;

(v) other specialised technologies; and

(vi) clinical pathology aspects of *in vitro diagnostics*, *etc.*;

(c) Procedures how to take account of existing certifications and registrations received by the applicant from other conformity assessment bodies or other regulatory authorities;

(d) Procedures to ensure conformity assessment certificates are only issued after a full assessment of all relevant information and that this assessment is subject to an independent check;

(e) Procedures aimed at ensuring the independence and impartiality of assessments and certification decisions.

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APPENDIX 1

Medical Device Technical Areas

Medical device technical areas listed in the following tables shall be referred to by the conformity assessment body when defining its scope of registration and areas of expertise of its technical personnel.

Code	Scope expression
(1) MEDICAL DEVICES, NON-ACTIVE	
MD 0100: GENERAL NON-ACTIVE, NON-IMPLANTABLE MEDICAL DEVICES	
MD 0101	Non-active devices for anaesthesia, emergency and intensive care
MD 0102	Non-active devices for injection, infusion, transfusion and dialysis
MD 0103	Non-active orthopaedic and rehabilitation devices
MD 0104	Non-active medical devices with measuring function
MD 0105	Non-active ophthalmologic devices
MD 0106	Non-active instruments
MD 0107	Contraceptive medical devices
MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
MD 0109	Non-active devices for *in vitro* fertilisation (IVF) and assisted reproductive technologies (ART)
MD 0200: NON-ACTIVE IMPLANTS	
MD 0201	Non-active cardiovascular implants
MD 0202	Non-active orthopaedic implants
MD 0203	Non-active functional implants
MD 0204	Non-active soft tissue implants
MD 0300: DEVICES FOR WOUND CARE	
MD 0301	Bandages and wound dressings
MD 0302	Suture material and clamps
MD 0303	Other medical devices for wound care
MD 0400: NON-ACTIVE DENTAL DEVICES AND ACCESSORIES	
MD 0401	Non-active dental equipment and instruments
MD 0402	Dental materials
MD 0403	Dental implants
(2) MEDICAL DEVICES, ACTIVE	
MD 1100: GENERAL ACTIVE MEDICAL DEVICES	

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Code	Scope expression
MD 1101	Devices for extra-corporal circulation, infusion and haemopheresis
MD 1102	Respiratory devices, including hyperbaric chambers for oxygen therapy, inhalation anaesthesia
MD 1103	Devices for stimulation or inhibition
MD 1104	Active surgical devices
MD 1105	Active ophthalmologic devices
MD 1106	Active dental devices
MD 1107	Active devices for disinfection and sterilisation
MD 1108	Active rehabilitation devices and active prostheses
MD 1109	Active devices for patient positioning and transport
MD 1110	Active devices for *in vitro* fertilisation (IVF) and assisted reproductive technologies (ART)
MD 1111	Software
MD 1200: DEVICES FOR IMAGING	
MD 1201	Imaging devices utilising ionizing radiation
MD 1202	Imaging devices utilising non-ionizing radiation
MD 1300: MONITORING DEVICES	
MD 1301	Monitoring devices of non-vital physiological parameters
MD 1302	Monitoring devices of vital physiological parameters
MD 1400: DEVICES FOR RADIATION THERAPY AND THERMO THERAPY	
MD 1401	Devices utilising ionizing radiation
MD 1402	Devices utilising non-ionizing radiation
MD 1403	Devices for hyperthermia / hypothermia
MD 1404	Devices for (extracorporal) shock-wave therapy (lithotripsy)
(3) ACTIVE IMPLANTABLE MEDICAL DEVICES	
AIMD 0100: GENERAL ACTIVE IMPLANTABLE MEDICAL DEVICES	
AIMD 0101	Active implantable medical devices for stimulation / inhibition
AIMD 0102	Active implantable medical devices delivering drugs or other substances
AIMD 0103	Active implantable medical devices substituting or replacing organ functions
(4) *IN VITRO* DIAGNOSTIC (IVD) MEDICAL DEVICES	
IVD 0100: LIST A REAGENTS AND REAGENT PRODUCTS, INCLUDING RELATED CALIBRATORS AND CONTROL MATERIALS, FOR DETERMINING THE FOLLOWING BLOOD GROUPS	
IVD 0101	AB0 system

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Code	Scope expression
IVD 0102	Rhesus (C, c, D, E, e)
IVD 0103	Anti-Kell
IVD 0200: LIST A REAGENTS AND REAGENT PRODUCTS, INCLUDING RELATED CALIBRATORS AND CONTROL MATERIALS, FOR THE DETECTION, CONFIRMATION AND QUANTIFICATION IN HUMAN SPECIMENS OF MARKERS OF	
IVD 0201	HIV infection (HIV 1 and 2)
IVD 0202	HTLV I and II
IVD 0203	Hepatitis B, C and D
IVD 0300: LIST B REAGENTS, REAGENT PRODUCTS AND DEVICES FOR SELF - DIAGNOSIS, INCLUDING RELATED CALIBRATORS AND CONTROL MATERIALS, FOR DETERMINING, DETECTION, QUANTIFICATION, DIAGNOSING, EVALUATING	
IVD 0301	Anti-Duffy and anti-Kidd
IVD 0302	Irregular anti-erythrocytic antibodies
IVD 0303	Congenital infections: rubella, toxoplasmosis
IVD 0304	Hereditary disease: phenylketonuria
IVD 0305	Human infections: cytomegalovirus, chlamydia
IVD 0306	HLA tissue groups: DR, A, B
IVD 0307	Tumoral marker: PSA
IVD 0308	Risk of trisomy 21 (incl. software)
IVD 0309	Device for self-diagnosis: device for the measurement of blood sugar
IVD 0400: DEVICES FOR SELF-TESTING	
IVD 0401	Clinical chemistry
IVD 0402	Haematology
IVD 0403	Immunology
IVD 0404	Molecular biology
IVD 0405	Pregnancy and ovulation
IVD 0406	Specimen receptacles
(5) SPECIFICS OF MEDICAL DEVICES AND ACTIVE MEDICAL DEVICES	
MDS 7000: MD / AIMD SPECIFICS	
MDS 7001	Medical devices incorporating medicinal substances, according to Directive 2001/83/EC
MDS 7002	Medical devices utilising tissues of animal origin, including Directive 2003/32/EC
MDS 7003	Medical devices incorporating derivates of human blood, according to Directive 2000/70/EC, amended by Directive 2001/104/EC
MDS 7004	Medical devices referencing the Directive 2006/42/EC on machinery

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Code	Scope expression
MDS 7005	Medical devices referencing the Directive 89/686/EEC on personal protective equipment (PPE)
(6) SPECIFICS OF *IN VITRO* DIAGNOSTIC (IVD) MEDICAL DEVICES	
MDS 7200: IVD SPECIFICS	
MDS 7206	IVDs in sterile condition
MDS 7207	IVDs utilising micromechanics
MDS 7208	IVDs utilising nanomaterials
MDS 7209	IVDs utilising biological active coating and/or material
MDS 7210	IVDs utilising material of human origin

APPENDIX 2

Requirements on Qualification And Experience Of The Technical Personnel Of The Conformity Assessment Body

1. **General**

The conformity assessment body shall employ technical personnel who possess the relevant qualification and experience to conduct conformity assessment in medical device technical areas as listed in APPENDIX 1 of this Schedule.

2. **Qualifications**

(1) The technical personnel who are involved in conducting conformity assessment tasks shall have the following qualification—

(a) have successfully completed a university or a technical college degree or equivalent qualification in one or more of the following fields—

(i) medical physics, biomedical engineering;

(ii) biology or microbiology or biotechnology;

(iii) chemistry or biochemistry;

(iv) computer or software technology;

(v) electrical, mechanical or bioengineering;

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(vi) human physiology;

(vii) medicine, dentistry, biomedical;

(viii) pharmacy;

(ix) physics or biophysics; or

(x) other relevant fields.

(b) have attended training sanctioned by the Authority on statutory requirements, including subsequent updates in the event of significant changes, in medical device regulation;

(c) have been awarded with the Certificate of Proficiency, which shall be valid for a duration as determined by the Authority, on statutory requirements, including subsequent updates in the event of significant changes, in medical device regulation;

(d) a quality management system auditor shall have passed appropriate training on auditing of relevant quality management system for medical device as determined by the Authority;

(e) a lead auditor shall be competent to plan and direct the team members so that in carrying out their separate tasks, the appropriate competence is applied effectively and fairly.

(f) all technical personnel of the conformity assessment body shall be registered with the Authority.

(2) The conformity assessment shall maintain the following records of its technical personnel—

(a) name of technical personnel;

(b) areas of competence and responsibility within the scope of activities for which the conformity assessment body has been registered;

(c) educational and professional qualifications;

(d) work experience relevant to the activities being performed; and

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(e) details of training received relating to assessment activities.

3. **Experience and knowledge**

(1) Technical personnel of a conformity assessment body most likely shall have experience in the following—

(a) Working in closely related industries and the workplace such as research and development and manufacturing;

(b) Working in the application of the device technology and its use in health care services and with patients;

(c) Testing of medical device concerned for compliance with the relevant national or international standards;

(d) Conducting performance testing, evaluation studies or clinical trials of medical device.

(e) Substantial relevant `experience in e.g. the diagnostic, medical devices or pharmaceutical industries, the health care professions, medical laboratories or test institutes,

(2) If the technical personnel have completed appropriate post tertiary education, the number of years for total experience may be reduced as follows:

(a) Masters - 1 year;

(b) PhD - 3 years

(3) The technical expert shall have a minimum of four years' work experience in medical devices related industry.

(4) As an equivalent to a degree in the relevant product or medical area, a lower level of tertiary qualification or a non-related degree supported by a minimum of eight years' experience in the technological area or by a minimum of five years' experience in the technological area when combined with further independently examined technical training is accepted.

(5) The knowledge of technical personnel would be most likely on the following:

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(a) Proven knowledge of medical devices law, other relevant regulations and relevant guidance documents;

(b) Proven knowledge of quality management procedures, especially of relevant standards acquired through successful participation in relevant training courses and/or practical experience;

(c) Knowledge of the current status of applicable and relevant product-related standards;

(d) Technical knowledge and experience of the design, manufacture, and quality control of medical devices and *in-vitro* diagnostics;

(e) Risk assessment and management as applied to medical devices, including relevant standards as well as the use of risk management tools encompassing the entire medical device lifecycle.

4. **Qualification for special technology areas**

A conformity assessment body whose scope of registration includes special technology areas relating certain types of medical device shall employ additional technical personnel who possess specific expertise in those special technology areas which, depending on the scope, may include—

(a) evaluation of biological and medical functionality and performance of medical devices;

(b) evaluation of medical devices containing animal tissues;

(c) evaluation of medical devices containing human blood derivatives, including blood borne infectious agents and their epidemiology;

(d) evaluation of bio-compatibility and clinical data used by manufacturers to demonstrate compliance with the essential principles of safety and performance;

(e) evaluation of electrical safety of medical devices;

(f) evaluation of software used in medical devices.

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(g) evaluation of performance characteristics of *in-vitro* diagnostic medical devices;

(h) assessment of the complexity and variability of biological test systems;

(i) development and use of standard methods for the evaluation and assessment of *in-vitro* diagnostics and medical devices for self-diagnosis

(j) experience in the development and use of reference methods, reference materials and standards used in batch testing;

(k) experience/training in the batch testing of *in-vitro* diagnostic medical devices;

(l) knowledge of the complexity and variability of pathogens in so far as they affect the performance of those *in-vitro* diagnostic medical devices (HIV 1 and 2, HTLV-1 and II, hepatitis B, C and D).

(m) knowledge of the fundamental principles behind the sourcing controls and validation of inactivation methods for medical devices containing tissues from animal origin;

(n) experience in medical device technology using tissues or derivatives and assessment of medical devices containing tissues from animal origin.

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FIFTH SCHEDULE

TABLE OF FEES
[Regulations 5, 6, 8, 9, 11, 12, 13, 15, 17 and 22]

Description of fees	Fee payable (RM)
1. PART III: REGISTRATION OF MEDICAL DEVICE	
(1) Medical device registration	
(a) Application fee [Paragraph 5(2)*(a)*]	
(i) a Class A medical device	100
(ii) a Class B medical device	250
(iii) a Class C medical device	500
(iv) a Class D medical device	750
(b) Registration fee [Subregulation 6(1)]	
(i) a Class A medical device	-
(ii) a Class B medical device	1,000
(iii) a Class C medical device	2,000
(iv) a Class D medical device	3,000
(v) a medical device that contains a medicinal product	5,000
2. PART IV: REGISTRATION OF CONFORMITY ASSESSMENT BODY	
(1) Application fee [Paragraph 8(3)*(a)*]	1,500
(2) Registration fee [Subregulation 9(1)]	8,000

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Description of fees	Fee payable (RM)
3. PART V: ESTABLISHMENT LICENCE	
(1) Licensing of establishment	
(a) Application fee [Paragraph 11(3)*(a)*]	
(i) Manufacturer	250
(ii) Authorised representative	250
(iii) Distributor	250
(iv) Importer	250
(b) Licensing fee [Subregulation 12(2)]	
(i) Manufacturer	4,000
(ii) Authorised representative	4,000
(iii) Distributor	2,000
(iv) Importer	2,000
(2) Renewal of establishment licence	
(a) Application for renewal fee [Paragraph 13(1)*(a)*]	
(i) Manufacturer	200
(ii) Authorised representative	200
(iii) Distributor	200
(iv) Importer	200
(b) Renewal fee [Subregulation 13(4)]	
(i) Manufacturer	2,000
(ii) Authorised representative	2,000

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Description of fees	Fee payable (RM)
(iii) Distributor	1,000
(iv) Importer	1,000
4. PART VI: EXPORT PERMIT	
Fee for export permit [Subregulation 15(2)]	100
5. PART VIII: APPEAL	
Appeal fee [Subregulation 16(3)]	250

SIXTH SCHEDULE

REQUIREMENTS FOR LABELLING
[Regulation 16]

PART I

PRELIMINARY

Application

1. This Schedule is made pursuant to regulation 16 of these Regulations on the labelling requirements for medical devices.

PART II

GENERAL PROVISIONS ON LABELLING

General

2. (1) No person shall—

(a) place any medical device in the market unless it has been appropriately labelled;

(b) use or operate any medical device to another person unless the appropriate label has been provided with the medical device when it is used on the other person;

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(c) use or operate any medical device to another person unless the appropriate label has been provided with the medical device when it is used to any other person in any investigational testing.

(2) A registered medical device shall be labelled to include a statement to the effect that the medical device has been registered under the Act.

(3) The label shall not contain any statement to the effect, whether directly or indirectly, that the placement in the market, or usage or operation of the medical device is being promoted or endorsed by the Authority or the Ministry of Health or any of its organisational bodies.

(4) The label of a medical device shall be legible, permanent and prominent.

Location of labelling

3. The label shall be appropriately located depending on a particular medical device and its intended use, in accordance with these following manners:

(a) where it is practical, the label shall be provided on or is attached to the medical device itself;

(b) if it is impractical to provide the label on or to attach the label to the medical device itself, the label shall be provided on the packaging of the individual medical device;

(c) in the case of medical devices that are packaged together because individual packaging of the medical devices is not practical, the label shall be provided as leaflet, packaging insert, document or other media supplied with a single or multiple medical devices; and

(d) if multiple medical devices are supplied to a single user and/or location or packaged together as one package, it may be appropriate to provide only a single copy of the label but more copies shall be supplied upon request.

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Format

4. (1) The format of labelling shall be in accordance with the international standard for medical device labelling as determined by the Authority.

(2) If a symbol or code in whatever form is used in the label of a medical device, an explanation of the symbol or code shall be provided.

Language

5. (1) The use of Bahasa Malaysia shall be required for home-used medical devices.

(2) The Authority may, as it thinks fit, require the use of Bahasa Malaysia for other types of medical devices.

PART III

CONTENTS OF LABELLING

General contents

6. The label of a medical device shall contain the following information:

(a) details of medical device to enable user to identify it, which include name, model, lot/batch or serial number, date of manufacturing and date of expiry;

(b) name, address and contact of the manufacturer of the medical device and where the medical device is manufactured outside Malaysia, the name, address and contact of the authorised representative of the medical device;

(c) technical details concerning the medical device;

(d) description and intended use of the medical device;

(e) instructions for use of the medical device;

(f) any undesirable side-effects, limitations, warnings and/or precautions on the safe use of the medical device;

(g) any necessary post-market servicing needs for the medical device;

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(h) any decommissioning or disposal information.

Specific contents

7. (1) For some medical devices, the following specific contents shall be included in the labelling:

(a) identification for a custom-made medical device or a special access medical device, and a statement that it shall be only used by a qualified practitioner for patient under his care;

(b) special storage and/or handling;

(c) verification that a medical device has been properly installed and can operate correctly and safely, the nature and frequency of preventative and regular maintenance, replacement of consumable components, and calibration needed to ensure optimal and safe operation of a medical device;

(d) further treatment or handling, such as sterilisation, calibration, etc., that is needed before a medical device can be used;

(e) identification for a sterile medical device, its indication for sterility and precautions and instructions if the sterile packaging is damaged, and where appropriate, description of re-sterilisation methods;

(f) the requirement for sterilisation of a medical device before it is used and instructions for cleaning and sterilisation processes;

(g) identification for a single-use medical devices;

(h) identification for a reusable medical device, information and instruction for cleaning, disinfecting, packaging and, where appropriate, the method of re-sterilisation, and any restriction on the number of reuse;

(i) identification for a medical device that is intended for clinical and/or performance investigations prior to placement on market and an

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indication that it shall be used by qualified investigator only and in the case of an *in vitro* diagnostic medical device, a statement to indicate that the performance specifications of the device have not been established;

(j) identification for a medical device is intended for presentation or demonstration purposes;

(k) sufficient details to obtain a safe combination for a medical device that is to be installed with or connected to other medical devices or equipment or with dedicated software, in order to operate as required for its intended purpose;

(l) particular risks in connection with implantation of an implantable medical device;

(m) the risks of reciprocal interference posed by a reasonably foreseeable presence of a medical device during specific investigation or treatment;

(n) the details of the nature, type, intensity and distribution of the radiation emitted by radiation emitting medical device;

(o) indication for custom-made medical device that it is for use by a single individual and has been manufactured according to a written prescription or pattern.

(2) The Authority may require any other additional information to be included as medical device labelling.

Instruction for use

8. An instruction for use shall contain the following details on any contra-indications, warnings and precautions to be taken:

(a) precautions to be taken if there are changes in the performance or malfunction of the medical device;

(b) precautions with respect to exposure to environmental conditions like magnetic fields, external electrical influences, electrostatic discharge,

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pressure or variations in pressure, temperature, humidity, acceleration, thermal ignition sources, proximity to other devices, *etc.*;

(c) where drugs or medicinal products are incorporated into the device as an integral part this should be indicated in the label;

(d) adequate information regarding the drug or medicinal products which a device is designed to administer, including any limitations in the choice of substances to be delivered;

(e) precautions to be taken against any special, unusual risks related to the disposal of the device;

(f) for medical device with measuring function, the degree of accuracy claimed by the manufacturer;

(g) requirements for special facilities, special training or particular qualifications for the medical device user.

Additional information for *in vitro* diagnostic medical devices

9. For an *in vitro* diagnostic medical devices, the following additional information shall be included in its label:

(a) indication of its intended use either for monitoring, screening or diagnostic;

(b) indication that it is for *in vitro* diagnostic use;

(c) test principle;

(d) specimen type, collection, handling and preparation;

(e) reagent description and any limitation (e.g. use with a dedicated instrument only);

(f) assay procedure including calculations and interpretation of results;

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(g) information on interfering substances that may affect the performance of the assay;

(h) analytical performance characteristics, such as sensitivity, specificity, accuracy (trueness and precision);

(i) reference intervals;

(j) use of drawings and diagrams.

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P.U. (A) 500

Form MDA1

MEDICAL DEVICE ACT 2012

MEDICAL DEVICE REGULATIONS 2012

APPLICATION FORM FOR EXPORT PERMIT

[Regulation 15]

This Form MDA1 is made pursuant to regulation 15 of the Medical Device Regulations 2012 for the purpose of application for export permit under Medical Device Act [*Act 737*].

This application form shall be completed and submitted together with an application fee as prescribed in Fifth Schedule of the Medical Device Regulations 2012 to—

Chief Executive, Medical Device Authority, Level 5, Menara Prisma, Boulevard Plot 3C4, Jalan Persiaran Perdana, Presint 3, 62675 Putrajaya, Malaysia
Tel Number: 03-88850778
Fax Number : 03-88850758

Notes

Please read carefully before filling the form

(1) Please note that general information may be included in Medical Device Register and uploaded to the Authority's website if this application is approved

(2) Please check the boxes as appropriate

(3) Please note that the submitted information may be forwarded to third parties (such as but not limited to foreign regulatory authority or conformity assessment body) for validation purposes

(4) All relevant certificates where necessary shall be notarized

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FOR OFFICIAL USE ONLY

Date received_____ Application no. _____ Officer _____

Date approved/rejected _____

PART A: PARTICULARS OF ESTABLISHMENT

1. Establishment license no. : _____

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2. Contact person and address of establishment:_____

3. Authorised agent name and business address (if applicable): _____

PART B: PARTICULARS OF MEDICAL DEVICE

4. Medical device registration no. : _____

Type of Device (please tick (√) the appropriate box)

[ ] General device

[ ] *In-vitro* diagnostic device (IVD)

Class of Device (please tick (√) the appropriate box)

[ ] Class A

[ ] Class B

[ ] Class C

[ ] Class D

Classification Rules :_____

Generic name :_____

Manufacturer specified name :_____

Intended use of device :_____

Device description :_____

Grouping of medical device (please tick (√) the appropriate box)

[ ] Single

[ ] System

[ ] Family

[ ] Set

[ ] IVD Test Kit

[ ] IVD Cluster

Name of manufacturer :_____

GMDN Category (please tick (√) the appropriate box)

[ ] 01 – Active implantable device

[ ] 02 – Anaesthetic and respiratory device

[ ] 03 – Dental devices

[ ] 04 – Electro mechanical medical devices

[ ] 05 – Hospital hardware

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[ ] 06 – *In-vitro* diagnostic devices
[ ] 07 – Non-active implantable devices
[ ] 08 – Opthalmic and optical devices
[ ] 09 – Reusable instruments
[ ] 10 – Single-use devices
[ ] 11 – Technical aids for disable persons
[ ] 12 – Diagnostic and therapeutic radiation devices
[ ] 13 – Complementary therapy devices
[ ] 14 – Biologically-derived devices
[ ] 15 – Healthcare facility products and adaptations
[ ] 16 – Laboratory equipment
[ ] 17 – Medical software

GMDN Code:_____

PART C: PARTICULARS OF EXPORT

5. Country requesting: _____

6. Quantity/number and value (RM): _____

7. Place/port of loading: _____

Made 31 December 2012
[KKM/PUU/R/U2/MDA; PN(PU2) 711]

DATO' SRI LIOW TIONG LAI
Minister of Health

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