

MEDICAL DEVICE ACT 2012 (ACT 737)

MEDICAL DEVICE REGULATIONS 2012

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In exercise of the powers conferred by Section 79 of the Medical Device Act 2012, the Minister of Health hereby makes the following Regulations:

Citation and commencement

1. These Regulations may be cited as the Medical Device Regulations 2012 and shall come into operation on DD MM 2012.

PART I
PRELIMINARY MATTERS

Interpretation

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

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

“Act” means the Medical Device Act 2012 [Act 737];

“Authority” means the Medical Device Authority as established under the Medical Device Authority Act 2012 [Act 738];

“clinical investigation” means any systematic investigation or study in or on one or more human subjects, undertaken to assess the safety and/or performance of a medical device to assess the safety and performance of the medical device in question and evaluate whether it is suitable for the purpose(s) and the population(s) for which it is intended;

“conformity assessment” is 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;

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

- (a) is assembled or adapted in the market that are intended for individual patients; or
- (b) is specially fabricated or imported for the sole use of a particular person, whether in accordance with the specifications of a qualified practitioner or otherwise;

“field corrective action” means an action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use medical device that is already placed on the market;

“healthcare facility” means either—

- (a) hospital, medical clinic, dental clinic or health clinic under the Government of

Malaysia; or

- (b) private hospital, private medical clinic, dental clinic or healthcare establishment licensed under the Private Healthcare Facilities and Services Act 1998 [Act 586].

“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;

“medical device service provider” means—

- (a) a person domiciled or resident in Malaysia; and
- (b) a firm or company as defined under the Companies Act 1965 [Act 125];

whose business or practice in Malaysia is principally installing, testing, commissioning or maintaining a medical device but does not include manufacturing, importing, placing in the market of a medical device.

“objective evidence” means any information that can be proved true, based on facts obtained through observation, analysis, measurement, testing or other suitable means;

“performance test” means testing a medical device using test methods and equipment, as recommended by the manufacturer or standard practices, to yield qualitative test results;

“permit holder” means a holder of any permit issued by the Authority under the Act;

“qualified practitioner” means—

- (a) a person registered under the Medical Act 1971 [Act 50], when acting in the course of providing medical treatment to a patient under his care; or
- (b) a person registered under the Dental Act 1971 [Act 51] whose name appears in the first division of the dentists register kept under that Act, when acting in the course of providing dental treatment to a patient under his care;

“recognised standards” means standards deemed to offer the presumption of conformity to specific essential principles of safety and performance of medical devices

“registration holder”, in relation to a registered medical device, means a person who obtained the registration of a medical device under this Act.

“regulatory authority of a foreign jurisdiction” means an organisation which —

- (a) exercises a regulatory right to control the use or sale of medical devices within a country or territory outside Malaysia;
- (b) may take enforcement action to ensure that medical devices placed in the market within that country or territory outside Malaysia comply with the legal requirements applicable in that country or territory; and

“special access medical device” means a medical device that is intended to be used by a qualified practitioner, in an emergency or in a case where all conventional remedies have failed or unavailable or unsuitable, to meet any special needs arising in the course of his practice.

“technical documentation” means the documented evidence, normally an output of the

quality management system, that demonstrates compliance of a medical device to the essential principles of safety and performance of medical devices

PART II

CONFORMITY ASSESSMENT PROCEDURE

Requirement of conformity assessment for the purpose of medical device registration

3. —(1) For the purpose of **Sections 7(1) and 79(1)(e) of the Act**, any medical device shall be subjected to conformity assessment to demonstrate its conformity to the requirements as prescribed **in technical document TD1 listed in the Register**.

(2) The manufacturer shall collect all the evidence of conformity and shall appoint a conformity assessment body to conduct the assessment on the conformity to the requirements **in sub-regulation (1)**.

(3) Upon completion of the conformity assessment, and if the conformity assessment body is satisfied that all the applicable requirements have been fulfilled, the conformity assessment body shall issue a report and certificate of the conformity assessment to the establishment **in the format as specified in technical document TD2 listed in the Register**.

(4) Copies of the report and certificate of conformity assessment issued by the conformity assessment body **in sub-regulation (3)** shall be submitted to the Authority when applying for medical device registration.

PART III

REGISTRATION OF MEDICAL DEVICE

Classification and grouping for the purpose of medical device registration

4. —(1) For the purpose of registration of medical device under **Section 6 of the Act**, all medical devices shall be—

(a) appropriately classified in accordance with the classification rules specified in the **technical document TD3 listed in the Register**; and

(b) appropriately grouped using the rules of grouping specified in **technical document TD4 listed in the Register**.

(2) Subject to **Section 3 of the Act**, the establishment may **in writing**, request the Authority to decide on the dispute with the conformity assessment body relating to classification of a medical device and the Authority shall notify the establishment **in writing** of its decision on the classification of the medical device **within 30 days from** the date of request.

Procedure for application for medical device registration

5. —(1) For the purpose of **Section 6(1) of the Act**, an application to register medical devices shall be made by—

- (a) the manufacturer of medical device for any medical device that is manufactured in Malaysia;
- (b) the authorised representative appointed by a manufacturer having a principle place of business outside Malaysia for any medical device that is manufactured outside Malaysia; or
- (c) the manufacturer or the authorised representative or a person appointed by the manufacturer or the authorised representative, as the case may be, for any medical device to be used for clinical investigation in Malaysia.

(2) An application for registration of medical device shall be submitted to the Authority using **Form MDA1 listed in the Register**.

(3) An application to register medical devices shall be accompanied by the following—

- (a) application fee as prescribed in **Table of Fees in Schedule 1**;
- (b) information or document specified in **Form MDA1 listed in the Register**;
- (c) such other additional information, particulars, documents or samples of the medical device as the Authority may require in writing or pursuant to any instruction or directive issued by the Authority.

(4) Any other additional information, particulars, documents or samples of the medical device as required in **sub-regulation (3)** shall be submitted by the applicant **within 30 days** from the date requested by the Authority.

(5) An applicant may request for an extension of time granted to submit information, particulars, documents or samples of the medical device as required under **sub-regulation (4)**.

(6) Notwithstanding **sub-regulation (5)**, the Authority shall have the right to grant or not to grant the extension of time as requested by the applicant.

(7) The Authority shall consider the application for extension of time as requested by the applicant under **sub-regulation (5)** and may approve or refuse the application for extension of time and shall notify the applicant in writing of its decision.

(8) The Authority may withdraw an application if the applicant fails to submit additional information, particulars, documents or samples of the medical device as required under **sub-regulation (3)** within the specified time or within the approved extension of time, as the case may be.

(9) Any application fee paid to the Authority in respect of an application withdrawn under **sub-regulation (8)** shall not be refunded.

Abridged evaluation

6. —(1) For the purpose of medical device registration under **Section 6(1) of the Act**, the Authority may evaluate a medical device under an abridged evaluation process, if—

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

(b) the approval by the competent regulatory agency is of a type accepted by the Authority and notified by the Authority in the **Register** at the time of the application for the registration of the medical device.

(2) In **sub-regulation (1)**, “competent regulatory agency” means any body or organisation which—

(a) exercises a regulatory right to control the use or sale of medical devices within a country or territory outside Malaysia;

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

(c) is recognised by the Authority and notified by the Authority in the **Register** at the time of the application for the registration of the medical device.

(3) Notwithstanding **sub-regulations (1) and (2)**, the Authority may as it thinks fit, at any time, in writing, require such other information or document from the applicant to complete the evaluation.

Full evaluation

7. —(1) For the purpose of **Section 6(1) of the Act**, the Authority may, upon an application for the registration of a medical device, evaluate a medical device under a full evaluation route if the medical device —

(a) is not qualified for an abridged evaluation route referred to in **Regulation 6**;
or

(b) has not undergone conformity assessment under **Regulation 3**.

(2) Notwithstanding **sub-regulation (1)**, the Authority may, as it thinks fit, at any time evaluate a medical device under a full evaluation process, when the Authority is of the opinion that the medical device does not qualify for evaluation under an abridged evaluation route.

Registration of medical device

8. —(1) Upon receipt of the application forms and application fee and information, particulars, documents or samples of the medical device under **Regulation 14**, the Authority shall consider the application to register the medical device and may inspect the premises in which the medical device is being manufactured as it considers proper and necessary to verify any information, particulars, documents or samples of the medical device as provided by the applicant under **Regulation 14**.

(2) If the Authority is satisfied with all requirements pertaining to the application for medical device registration, the Authority shall notify its decision and request for registration fee as stipulated in the **Table of Fees in Schedule 1**.

(3) Upon receipt of the registration fee and if the Authority is satisfied that all requirements have been fulfilled, the Authority shall register the medical device and keep the medical device 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.

(4) The Authority shall assign a registration number and issue a certificate of registration for any registered medical device and impose conditions of medical device

registration as the Authority thinks fit.

Renewal of registration of medical device

9. —(1) An application for the renewal of a medical device registration shall be made not later than **sixty days before its expiry in Form MDA1 listed in the Register** and shall be accompanied by the following—

- (a) application fee as prescribed in **Table of Fees in Schedule 1**, and
- (b) information or document specified in the **Form MDA1 listed in the Register**;
- (c) such other information, particulars, documents or samples of the medical device as the Authority may require in writing or pursuant to any instruction or directive issued by the Authority.

(2) Any other additional information, particulars, documents or samples of the medical device required by the Authority under **sub-regulation (1)** shall be provided by the registration **holder within the 30 days from the date requested** by the Authority.

(3) A registration holder may request for an extension of time granted to submit information, particulars, documents or samples of the medical device as required under sub-regulation (1).

(4) Notwithstanding **sub-regulation (3)**, the Authority shall have the right to grant or not to grant the extension of time as requested by the registration holder.

(5) The Authority shall consider the application for extension of time as requested by the registration holder under **sub-regulation (3)** and may approve or refuse the application for extension of time and shall notify the applicant in writing of its decision.

(6) The Authority may withdraw an application if the registration holder fails to submit additional information, particulars, documents or samples of the medical device as required under **sub-regulation (1)** within the specified time or within the approved extension of time, as the case may be.

(7) Any fees paid to the Authority in respect of an application withdrawn under **sub-regulation (6)** shall not be refunded.

(8) Upon receipt of the application forms, application fee, information, particulars, documents or samples of the medical device under **sub-regulation (1)**, the Authority shall consider the application to renew the registration of a medical device and may inspect the premises in which the medical device is being manufactured as it considers proper and necessary to verify any information, particulars, documents or samples of the medical device as provided by the applicant **under sub-regulation (1)**.

(9) If the Authority is satisfied with all the requirements pertaining to the application for renewal of medical device registration, the Authority shall **notify in writing its decision** and request for renewal fee as stipulated in the **Table of Fees in Schedule 1**.

(10) Upon receipt of the renewal fee and if the Authority is satisfied that all requirements have been fulfilled, the Authority shall renew the registration of the medical device and maintain the medical device in the Register **for a period of two years from the date** of renewal of the registration unless the it is cancelled by the Authority before its expiry.

Changes concerning registered medical device

- 10.—(1) The registration holder shall notify the Authority of—
- (a) any proposed change to any particulars provided in relation to the registration of a medical device; and
 - (b) any proposed change that may affect safety or performance of the medical device.
- (2) A notification under **sub-regulation (1)** shall be—
- (a) made in using **Form MDA1 as set out in the Register**;
 - (b) submitted within such time as the Authority may specify in the conditions of the registration of the medical device;
 - (c) accompanied by such particulars, information, documents and samples of the medical device as the Authority may require;
 - (d) accompanied by the relevant application fee specified in the **Table of Fee in Schedule 1**; and
 - (e) accompanied by a statutory declaration by the registration holder verifying any information contained in or relating to the notification, as may be required by the Authority.
- (3) Upon receipt of the notification for change relating to a registered medical device, the Authority shall consider the proposed change and may inspect the establishment to verify any particulars, information or documents as provided by the registration holder under **sub-regulation (2)** and the registration holder shall not place the changed medical device into the market until the Authority has given its approval for the change.
- (4) Any registration holder who contravenes **sub-regulation (1)** shall be guilty of an offence and shall be liable on conviction to **a fine not exceeding ten thousand ringgit or to imprisonment for a term not exceeding six months or to both**.
- (5) Any registration holder who in compliance or purported compliance with **sub-regulation (1)**, furnishes the Authority with any notification under **sub-regulation (1)** which he knows is false or misleading shall be guilty of an offence and shall be liable on conviction to **a fine not exceeding fifty thousand ringgit or to imprisonment for a term not exceeding twelve months or to both**.

Certificate of registration of medical device

- 11.—(1) A certificate of registration of a medical device issued by the Authority under **Regulation 15(4)** shall be in such form as the Authority may determine.
- (2) A certificate of registration of a medical device shall not be assigned or transferred to any other person or classes of persons except with prior written approval from the Authority.
- (3) A registration holder commits an offence if he assigns or transfers his registration of the medical device to any other person or classes of persons without the prior written approval of the Authority, and shall, on conviction, be liable to **a fine of not less than fifty thousand ringgit and not more than five hundred thousand ringgit or to imprisonment for a term not exceeding three years or to both**.
- (4) A certificate of registration issued to a medical device shall remain the property

of the Authority, and shall be surrendered to the Authority without demand **within fourteen days** after the registration of the medical device is cancelled pursuant to **Section 9 of the Act**.

Duty to comply with conditions of registration of medical device

12.—(1) A registration holder shall comply with such **conditions**, for the grant of medical device registration, **as the Authority may impose**.

(2) Any person who contravenes **sub-regulation (1)** shall be guilty of an offence and shall be liable on conviction to **a fine not exceeding fifty thousand ringgit and not more than five hundred thousand ringgit or to imprisonment for a term not exceeding three years or to both**.

(3) Without prejudice to **sub-regulation (2)**, the Authority may suspend or cancel registration, which the Authority has granted to a person, if that person contravenes **sub-regulation (1)**.

Cancellation of registration of medical device

13.—(1) For the purpose of **Section 9(1) of the Act**, the Authority shall notify the registration holder, in writing, on the cancellation of the registration of a medical device.

(2) Upon receipt of the notification of cancellation, the registration holder may submit a show cause letter against the cancellation **within thirty days from the date** of notification.

(3) The registration holder may request for an extension of time granted to submit the show-cause letter as required under **sub-regulation (2)**.

(4) Notwithstanding **sub-regulation (3)**, the Authority shall have the right to grant or not to grant the extension of time as requested by the registration holder.

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

(6) Upon receipt of the show cause letter by the registration holder, the Authority shall consider the show cause letter and if the Authority is satisfied that the registration shall be cancelled, the Authority shall notify the registration holder on its decision to cancel the registration.

(7) Where a registration is cancelled by the Authority pursuant to **sub-regulation (1)**, the registration holder shall return the certificate without further notice to the Authority within fourteen days after being notified in writing of the cancellation.

(8) Any registration holder who contravenes **sub-regulation (7)** shall be guilty of an offence and shall be liable on conviction to **a fine not exceeding ten thousand ringgit or to imprisonment for a term not exceeding six months or to both**.

Additional requirements for registration of medical devices for clinical investigation

14.—(1) A medical device to be used for clinical investigation shall not be placed into the market to be used for patient management.

(2) A manufacturer or an authorised representative or a person appointed by a manufacturer or an authorised representative, as the case may be, who wishes to register the medical device to be used for clinical investigation on its medical device shall comply with the requirements **as specified in technical document TD5 listed in the Register**.

PART IV

REGISTRATION OF CONFORMITY ASSESSMENT BODY

Requirements for registration of conformity assessment body

15.—(1) For the purpose of **Sections 11 and 79(2)(a) of the Act**, any person who intends to be a conformity assessment body shall comply with requirements **as specified in technical document TD6 listed in the Register** and shall apply for registration to the Authority.

Application procedure for registration of conformity assessment body

16.—(1) For the purpose of **Section 11(2) of the Act**, an application for registration of a conformity assessment body shall be made to the Authority using **Form MDA2 as specified in the Register**.

(2) Notwithstanding **sub-regulation (1)**, an application for registration of a conformity assessment body shall be accompanied by the following—

- (a) application fee as prescribed in **Table of Fees in Schedule 1**;
- (b) such documents or information as specified in **Form MDA2 as specified in the Register**; and
- (c) such other additional information, particulars or documents as the Authority may require in writing or pursuant to any instruction or directive issued by the Authority.

(3) Any additional information, particulars or documents required by the Authority under **sub-regulation (2)(c)** shall be provided by the applicant **within 30 days** from the date requested by the Authority.

(4) An applicant may request for an extension of time granted under **sub-regulation (3) to submit additional information, particulars or documents as required under sub-regulation (2)(c)**.

(5) Notwithstanding **sub-regulation (4)**, the Authority shall have the right to grant or not to grant the extension of time as requested by the applicant.

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

(7) The Authority may withdraw an application if the applicant fails to submit additional information, particulars or documents as required under **sub-regulation (2)(c)** within the specified time or within the approved extension of time, as the case maybe.

(8) Any fees paid to the Authority in respect of an application withdrawn under **sub-regulation (7)** shall not be refunded.

Registration of conformity assessment body

17.—(1) Upon receipt of the application for registration of conformity assessment body, the Authority shall consider the application to register a conformity assessment body and may inspect the premises of the applicant as it considers proper and necessary to verify any information, particulars or documents as provided by the applicant under **Regulation (23)**.

(2) If the Authority is satisfied with all requirements pertaining to the application for

registration of a conformity assessment body, the Authority shall notify in writing its decision and request for fee for registration of conformity assessment body as stipulated in **Table of Fees in Schedule 1**.

(3) Upon receipt of registration fee and the Authority is satisfied with the result of the inspection made on the premises, 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.

(4) The Authority shall assign a registration number and issue a certificate of registration for any registered conformity assessment body and impose conditions of registration of a conformity assessment body as the Authority thinks fit.

Renewal of registration of conformity assessment body

18.—(1) An application for renewal of registration of conformity assessment body shall be made not later than six month before its expiry in **Form MDA5 as listed in the Register** and shall be accompanied by the following—

- (a) application fee as prescribed in **Table of Fees in Schedule 1**;
- (b) such document or information as specified in **Form MDA2 as listed in the Register**; and
- (c) such other information, particulars or documents as the Authority may require in writing or pursuant to any instruction or directive issued by the Authority.

(2) Any other additional information, particulars or documents required by the Authority under **sub-regulation (1)(c)** shall be provided by the conformity assessment body **within 30 days from the date requested** by the Authority.

(3) A conformity assessment body may request for an extension of time granted to submit information, particulars or documents as required under **sub-regulation (1)(c)**.

(4) Notwithstanding **sub-regulation (4)**, the Authority shall have the right to grant or not to grant the extension of time as requested by the conformity assessment body.

(5) The Authority shall consider the application for extension of time as requested by the conformity assessment body under **sub-regulation (4)** and may approve or refuse the application for extension of time and shall notify the conformity assessment body **in writing** of its decision.

(6) The Authority may withdraw an application if the conformity assessment body fails to submit additional information, particulars, or documents as required under **sub-regulation (1)(c)** within the specified time or within the approved extension of time, as the case may be.

(7) Any fees paid to the Authority in respect of an application withdrawn **under sub-regulation (9)** shall not be refunded.

(8) Upon receipt of the application to renew the registration of the conformity assessment body under **sub-regulation (1)**, the Authority shall consider the application and may inspect the premises of the conformity assessment body as it considers proper and necessary to verify any information as provided by the applicant under **sub-regulation (1)**.

(9) If the Authority is satisfied with all the requirements pertaining to the application for renewal of registration of the conformity assessment body, the Authority shall notify in

writing its decision and request for renewal fee as stipulated in **Table of Fees in Schedule 1**.

(10) Upon receipt of the renewal fee and the Authority is satisfied with the result of the inspection made on the premises, the Authority shall renew the registration of the conformity assessment body and maintain the conformity assessment body in the Register for **a period of two years from the date of renewal** of the registration unless it is cancelled by the Authority before its expiry.

Changes concerning registered conformity assessment body

19.—(1) A registered conformity assessment body shall notify the Authority of any proposed change to any particulars provided in relation to the registration of a conformity assessment body.

(2) A notification under **sub-regulation (1)** shall be—

(a) made using **Form MDA2 as listed in the Register**;

(b) submitted within such time as the Authority may specify in the conditions of the registration of conformity assessment body;

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

(d) accompanied by the relevant application fee specified in **Table of Fees in Schedule 1**; and

(e) accompanied by a statutory declaration by the registered conformity assessment body verifying any information contained in or relating to the notification, as may be required by the Authority.

(3) Upon receipt of the notification for change relating to a registered conformity assessment body under **sub-regulation (1)**, the Authority shall consider the proposed change and may inspect the conformity assessment body to verify any particulars, information or documents as provided by the conformity assessment body under **sub-regulation (2)** and the proposed change shall not take effect until the Authority has given its approval for the change.

(4) Any registered conformity assessment body who contravenes **sub-regulation (1)** shall be guilty of an offence and shall be liable on conviction to **a fine not exceeding ten thousand ringgit or to imprisonment for a term not exceeding six months or to both**.

(5) Any registered conformity assessment body who—

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

(b) contravenes **sub-regulation (3)**,

shall be guilty of an offence and shall be liable on conviction to **a fine not exceeding fifty thousand ringgit or to imprisonment for a term not exceeding twelve months or to both**.

Certificate of registration of conformity assessment body

20.—(1) A certificate of registration of a conformity assessment body issued by the Authority under **sub-regulation 25(4)** shall be in such form as the Authority may determine.

(2) A certificate of registration of a conformity assessment body shall not be assigned

or transferred to any other person or classes of persons except with prior written approval from the Authority.

(3) A registered conformity assessment body commits an offence if he assigns or transfers its registration to any other person or classes of persons without the prior written approval of the Authority, and shall, on conviction, be liable to **a fine of not less than fifty thousand ringgit and not more than five hundred thousand ringgit or to imprisonment for a term not exceeding three years or to both.**

(4) A certificate of registration issued to a registered conformity assessment body shall remain the property of the Authority, and shall be surrendered to the Authority without demand within fourteen days after the registration of the medical device is cancelled pursuant to **Section 14 of the Act.**

Duty to comply with conditions of registration of conformity assessment body

21.—(1) A registered conformity assessment body shall comply with such conditions, for the grant of the registration of conformity assessment body, as the Authority may impose.

(2) Any registered conformity assessment body who contravenes **sub-regulation (1)** shall be guilty of an offence and shall be liable on conviction to **a fine not exceeding fifty thousand ringgit or to imprisonment for a term not exceeding twelve months or to both.**

(3) Without prejudice to **sub-regulation (2)**, the Authority may suspend or cancel registration, which the Authority has granted to a conformity assessment body, if that conformity assessment body contravenes **sub-regulation (1).**

Cancellation of registration of a conformity assessment body

22.—(1) For the purposes of **Section 14 of the Act**, the Authority shall notify the registered conformity assessment body, in writing, on the cancellation of the registration of a medical device.

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

(3) Upon receipt of the show cause letter by the conformity assessment body, the Authority shall consider the show cause letter and 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.

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

Authority exempted from requirements applicable to a conformity assessment body

23.—(1) **Regulations (15), (16), (17), (18), (19), (20) (21) and (22)** shall not serve to bind and apply to the Authority when the Authority undertakes conformity assessment of a medical device.

PART V

ESTABLISHMENT LICENCE

Requirements for establishment licence

24.—(1) For the purpose of Sections 15, 16 and 79(2)(a) of the Act, any person who wishes to apply for an establishment licence shall comply to the requirements as set out in technical document TD7 listed in the Register.

Application procedure for establishment licence

25.—(1) For the purposes of Section 16 (1) of the Act, an application for an establishment licence shall be made to the Authority using Form MDA3 as specified in the Register.

(2) Notwithstanding sub-regulation (1), any person applying for an establishment licence shall submit the following details—

- (a) application fee as prescribed in Table of Fees in Schedule 1;
- (b) such documents or information as specified in Form MDA3 as specified in the Register;
- (c) certificate and report of conformity assessment; and
- (d) such other additional information, particulars or documents as the Authority may require in writing or pursuant to any instruction or directive issued by the Authority.

(3) Any additional information, particulars or documents required by the Authority under sub-regulation (2)(c) shall be provided by the applicant within 30 days from the date requested by the Authority.

(4) An applicant may request for an extension of time granted under sub-regulation (3) to submit additional information, particulars or documents as required under sub-regulation (2)(c).

(5) Notwithstanding sub-regulation (5), the Authority shall have the right to grant the extension of time as requested by the applicant.

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

(7) The Authority may withdraw an application if the applicant fails to submit additional information, particulars or documents as required under sub-regulation (2)(c) within the specified time.

(8) Any application fees paid to the Authority in respect of an application withdrawn and not further proceeded with under sub-regulation (8) shall not be refunded.

Grant and refusal of establishment licence

26.—(1) Upon receipt of the application for establishment licence under Regulation 36, the Authority shall consider the application and may inspect the premises of the establishment as it considers proper and necessary to verify any information, particulars or documents as provided by the applicant under Regulation 36.

(2) If the Authority is satisfied with all requirements pertaining to the application for an establishment license, the Authority shall notify **in writing** its decision and request for license fee as stipulated **in Table of Fee in Schedule 3**.

(3) Upon receipt of license fee and the Authority is satisfied with the result of the inspection made on the premises, the Authority shall issue a license to the establishment and keep the licensed 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.

(4) The Authority shall assign a license number and issue a license to the establishment and impose conditions of license as the Authority thinks fit.

Establishment licence

27.—(1) A license for an establishment issued by the Authority **under sub-regulation 12(4)** shall be in the format as the Authority may determine.

(2) A license for an establishment issued by the Authority **under sub-regulation 12(4)** shall not be assigned or transferred to any other person or classes of persons except with prior written approval from the Authority.

(3) A licensee commits an offence if it assigns or transfers its registration to any other person or classes of persons without the prior written approval of the Authority, and shall, on conviction, be liable to **a fine of not less than fifty thousand ringgit and not more than five hundred thousand ringgit or to imprisonment for a term not exceeding three years or to both**.

(4) An establishment licence issued to an establishment shall remain the property of the Authority, and shall be surrendered to the Authority without demand **within fourteen days** after the registration of the medical device is revoked **pursuant Section 22 of the Act**.

Renewal of establishment licence

28.—(1) An application for renewal of establishment license shall be made to the Authority **not later than six month before** its expiry in **Form MDA3 as list out in the Register** and shall be accompanied by the following—

- (a) application fee as prescribed in **Table of Fees in Schedule 1**;
- (b) such documents or information as specified in **Form MDA3 in the Register**; and
- (c) such other information, particulars or documents as the Authority may require in writing or pursuant to any instruction or directive issued by the Authority.

(2) Any other additional information, particulars or documents required by the Authority under **sub-regulation (1)(c)** shall be provided by the establishment **within 30 days** from the date requested by the Authority.

(3) An establishment may request for an extension of time granted to submit information, particulars or documents as required under **sub-regulation (1)(c)**.

(4) Notwithstanding **sub-regulation (4)**, the Authority shall have the right to grant or not to grant the extension of time as requested by the establishment.

(5) The Authority shall consider the application for extension of time as requested by

the establishment under **sub-regulation (4)** and may approve or refuse the application for extension of time and shall notify the establishment in writing of its decision.

(6) The Authority may withdraw an application if the establishment fails to submit additional information, particulars, or documents as required under **sub-regulation (1)(c)** within the specified time or within the approved extension of time, as the case may be.

(7) Any fees paid to the Authority in respect of an application withdrawn **under sub-regulation (9)** shall not be refunded.

(8) Upon receipt of the application to renew the establishment license under **sub-regulation (1)**, the Authority shall consider the application and may inspect the premises of the establishment as it considers proper and necessary to verify any information as provided by the applicant **under sub-regulation (1)**.

(9) If the Authority is satisfied with all the requirements pertaining to the application for renewal of establishment license, the Authority shall notify **in writing** its decision and request for renewal fee as prescribed in **Table of Fees in Schedule 1**.

(10) Upon receipt of the renewal fee and the Authority is satisfied with the result of the inspection made on the premises, the Authority shall renew the establishment license and maintain the establishment in the Register **for a period of two years from the date of renewal** of the license unless it is cancelled by the Authority before its expiry.

Changes concerning establishment licence

29.—(1) Any establishment shall notify the Authority of —

- (a) any proposed change to any information or particulars in relation to his establishment licence; and
- (b) any proposed change that significantly affects the activities that are authorised by the establishment licence.

(2) An establishment shall not, without the approval of the Authority, make any changes **under sub-regulation (1)**.

(3) For the purposes of **sub-regulations (1)**, a change that significantly affects the activities of an establishment that are authorised by his licence include (but is not limited to) a change of one or more of the following—

- (a) the premises of the establishment;
- (b) the quality system certification issued to the establishment by a conformity assessment body;
- (c) the conformity assessment body responsible for assessing and supervising the operations and processes carried out by the establishment; and
- (d) the list and type of medical device that he manufactures, imports, distributes, installs, tests, commissions, maintains or places in the market.

(4) A notification under **sub-regulation (1)** shall be—

- (a) made in using **Form MDA3 as listed in the Register**;
- (b) submitted within such time as the Authority may specify in the conditions of the registration of conformity assessment body;
- (c) accompanied by such particulars, information and documents as the

Authority may require;

(d) accompanied by the relevant application fee specified in **Table of Fees in Schedule 1**; and

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

(5) Upon receipt of the notification for change relating to a licensed establishment, the Authority shall consider the proposed change and may inspect the establishment to verify any particulars, information or documents as provided by the establishment under **sub-regulation (4)** and the proposed change shall not take effect until the Authority has given its approval for the change.

(6) Any establishment who contravenes **sub-regulation (1)** shall be guilty of an offence and shall be liable on conviction to **a fine not exceeding fifty thousand ringgit or to imprisonment for a term not exceeding twelve months or to both.**

(7) Any establishment who—

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

(b) contravenes **sub-regulation (3)**;

shall be guilty of an offence and shall be liable on conviction to **a fine not exceeding fifty thousand ringgit or to imprisonment for a term not exceeding twelve months or to both.**

Duty to comply with conditions of establishment licence

30.—(1) An establishment shall comply with such conditions, for the grant of the license to the establishment, as the Authority may impose.

(2) Any establishment who contravenes **sub-regulation (1)** shall be guilty of an offence and shall be liable on conviction to a fine not exceeding ten thousand ringgit or to imprisonment for a term not exceeding six months or to both.

(3) Without prejudice to **sub-regulation (2)**, the Authority may suspend or revoke the establishment licence which the Authority has granted to a person, if that person contravenes **sub-regulation (1)**.

Suspension or revocation of establishment licence

31.—(1) For the purposes of **Section 22 of the Act**, the Authority shall notify the establishment, **in writing**, on the suspension of the establishment license and shall require the establishment to submit a proposal to remedy any contravention or breach that cause the suspension.

(2) Upon receipt of the notification of suspension of license, the establishment shall submit, in writing, a proposal of remedy of the contravention or breach that cause the suspension within two weeks from the date of notification.

(3) The establishment may request for extension of time granted under **sub-regulation (2)** to submit the proposal for remedy as required under **sub-regulation (2)**.

(4) Notwithstanding **sub-regulation (3)**, the Authority shall have the right to grant the

extension of time as requested by the establishment.

(5) The Authority shall consider the application for extension of time as requested by the establishment under **sub-regulation (4)** and may approve or refuse the application for extension of time and shall notify the establishment of its decision.

(6) Upon receipt of the proposal of remedy by the establishment, the Authority shall consider the proposed remedy and if the Authority is satisfied with the proposal, the establishment shall carry out the remedial action on the contravention or breach that cause the suspension within a period of time specified by the Authority.

(7) The establishment may request for extension of time granted to complete the remedial action as required under **sub-regulation (6)**.

(8) Notwithstanding **sub-regulation (7)**, the Authority shall have the right to grant or not to grant the extension of time to complete the remedial action as requested by the establishment **sub-regulation (6)**.

(9) The Authority shall revoke the establishment license if—

(a) the establishment fails to submit the proposal for remedy within the time specified under **sub-regulation (2)** or within the approved extension of time under **sub-regulation (3)**, as the case may be;

(b) the establishment fails to complete the remedial action within the time specified in **sub-regulation (6)** or within the approved extension of time under **sub-regulation (7)**, as the case may be.

(10) When the Authority decides to revoke an establishment license pursuant to **sub-regulation (1)**, the Authority shall notify the establishment on its decision and the establishment shall return the establishment license to the Authority **within fourteen days** after being notified in writing of the revocation.

PART VI

EXPORT PERMIT

Export permit for exporting medical device

32.—(1) The Authority may, on the application of an establishment who intends to export a medical device, issue to that person an export permit certifying that—

(a) the medical device is registered under the Act; and

(b) the medical device complies with such requirements of the export permit as may be specified by the Authority;

and

(a) the establishment is licensed under the Act; and

(b) the establishment complies with such requirements as may be specified by the Authority.

Application procedure for an export permit

33.—(1) For the purposes of **Section 45 of the Act**, an application for an export permit shall be made to the Authority using **Form MDA4 as specified in the Register** and accompanied by the prescribed application fee as prescribed in **Table of Fees in Schedule 1**.

(2) Notwithstanding **sub-regulation (1)**, any establishment applying for an export permit shall submit the following details—

(a) such documents or information as specified in **Form MDA4 as specified in the Register**;

(b) such other additional information, particulars or documents as the Authority may require.

(3) Any additional information, particulars or documents required by the Authority under **sub-regulation (2)(b)** shall be provided by the applicant within 30 days from the date requested by the Authority.

(4) An applicant may request for an extension of time granted under **sub-regulation (3)** to submit additional information, particulars or documents as required under **sub-regulation (2)(b)**.

(5) Notwithstanding **sub-regulation (4)**, the Authority shall have the right to grant the extension of time as requested by the applicant.

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

(7) The Authority may withdraw an application if the applicant fails to submit additional information, particulars or documents as required under **sub-regulation (2)(b)** within the specified time.

(8) Any fees paid to the Authority in respect of an application withdrawn and not further proceeded with under **sub-regulation (7)** shall not be refunded.

Grant and refusal of export permit

34.—(1) Upon receipt of the information as requested under **Regulation 36**, the Authority shall consider the application for an export permit and may inspect the premises of the establishment as it considers proper and necessary to verify any information, particulars or documents as provided by the applicant under **Regulation 36**.

(2) If the Authority is satisfied with all requirements pertaining to the application for export permit, the Authority shall notify **in writing** its decision and request for export permit fee as prescribed in **Table Fees in Schedule 1**.

(3) Upon receipt of export permit fee and the Authority is satisfied with the result of the inspection made on the premises, the Authority shall issue the export permit to the establishment and keep the export permit in the Register **for a period of three years** from the date of issuance of the export permit unless the export permit is cancelled by the Authority before its expiry.

(4) The Authority shall assign a number, issue an export permit and impose conditions for the issuance of any export permit as the Authority thinks fit.

Export permit

35.—(1) An export permit issued by the Authority under **sub-regulation 31(4)** shall be in such form **as the Authority may determine**.

(2) An export permit shall not be assigned or transferred to any other person or classes of persons except with prior written approval from the Authority.

(3) An export permit holder commits an offence if it assigns or transfers its export permit to any other person or classes of persons without the prior written approval of the Authority, and shall, on conviction, be liable to **a fine of not less than fifty thousand ringgit and not more than five hundred thousand ringgit or to imprisonment for a term not exceeding three years or to both**.

(4) An export permit shall remain the property of the Authority, and shall be surrendered to the Authority without demand **within fourteen days** after the registration of the medical device is revoked pursuant **Section 22 of the Act**.

Duty to comply with conditions of export permit

36.—(1) An establishment shall comply with such conditions, for the grant of the export permit to the establishment, as the Authority may impose.

(2) Any establishment who contravenes **sub-regulation (1)** shall be guilty of an offence and shall be liable on conviction to **a fine not exceeding ten thousand ringgit or to imprisonment for a term not exceeding six months or to both**.

(3) Without prejudice to **sub-regulation (2)**, the Authority may suspend or revoke the export permit which the Authority has granted to an establishment, if that establishment contravenes **sub-regulation (1)**.

PART VII

LABELLING REQUIREMENTS

General provisions on labelling

37.—(1) For the purpose of **Section 4(c) and Section 79(2)(d) of the Act**—

(a) no person shall place any medical device in the market unless the it has been appropriately labelled;

(b) no person shall 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 that other person; and

(c) no person shall 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 according to labelling requirements as specified in **technical document TD8 listed in the Register**.

(3) A registered medical device shall be labelled to include a statement to the effect

that the medical device has been registered under the Act.

(4) 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.

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

PART VIII

DUTIES AND OBLIGATIONS OF LICENSEES

Duties and obligations of licensees and registration holders

38.—(1) A licensee shall conduct its operation in accordance with the provisions of the Act and shall comply with all the conditions of the licence issued by the Authority and on being required by the Authority or an authorised officer, the licensee shall—

- (a) produce or furnish his licence, certificate of registration or permit, as the case may be, to the Authority or the authorised officer for inspection;
- (b) produce or furnish the Authority or the authorised officer with such information, documents or samples of the medical device, as the Authority or the authorised officer may specify or require in relation to the compliance by the establishment with the requirements of the Act; and
- (c) attend at such place as the Authority or an authorised officer may specify or require to produce or furnish such information, documents or samples of the medical device, as the Authority or authorised officer may specify for the purpose of ensuring compliance with the Act.

(2) A licensee who contravenes sub-regulation (1) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding **fifty thousand ringgit or to imprisonment for a term not exceeding twelve months or to both.**

Duties and obligations of a manufacturer

39.—(1) A manufacturer shall—

- (a) ensure that the medical device he manufactures complies with the essential principles of safety and performance of the medical device;
- (b) ensure that proper records on compliance are maintained;
- (c) apply to register the medical device he manufactures;
- (d) be responsible for any post-market issues relating to its medical device in the market;
- (e) be responsible for any regulatory matters relating to its medical device with the Authority; and
- (f) apply for licence to carry out its activities in Malaysia.

(2) A manufacturer who operates outside Malaysia shall authorised an authorised representative in Malaysia to on its behalf relating to any matters as specified in **sub-regulation (1)** in Malaysia.

(3) A manufacturer who contravenes **sub-regulation (1)** shall be guilty of an offence and shall be liable on conviction **to have his establishment licence suspended or revoked under Section 22 of the Act.**

Duties and obligations of an authorised representative

40.—(1) An authorised representative shall obtain an appropriate authorisation from its foreign manufacture to represent the latter with regard to any duties and obligations pertaining to the placement of a medical device in the Malaysian market.

(2) The authorised representative shall be responsible to carry out the duties and obligations as specified in **Regulation 39** and shall act on behalf its foreign manufacturer relating to any regulatory matters with the Authority.

(3) An authorised representative who contravenes **sub-regulations (1) and (2)** shall be guilty of an offence and shall be liable on conviction **to have his establishment licence suspended or revoked under Section 22 of the Act.**

Duties and obligations of a distributor or importer

41.—(1) A distributor or an importer shall—

- (a) obtain an appropriate authorisation from a licensed manufacturer or a licensed authorised representative;
- (b) only distribute in the market or import into the market, registered medical device authorised by the licensed manufacturer or licensed authorised representative;
- (c) conduct its operations in accordance with **the requirements of an appropriate quality management system as specified by the Authority in the Register;**

(2) A distributor shall only distribute a registered medical device to a person who may lawfully place in the market such medical device in accordance with any laws in Malaysia.

(3) A distributor or an importer who contravenes **sub-regulations (1) and (2)** shall be guilty of an offence and shall be liable on conviction **to have his establishment licence suspended or revoked under Section 22 of the Act.**

(4)

Post-market surveillance and vigilance system

42.—(1) For the purpose of **Section 38 and sub-section 79(2)(j) of the Act**, a licensee shall establish, maintain and implement an appropriate and effective post-market surveillance and vigilance system of medical devices he is dealing with which shall include the following elements—

- (a) distribution records, including, where applicable, implant registration, **pursuant to Section 37 and sub-section 79(2)(i) of the Act;**

- (b) complaint handling, pursuant to Section 39 and sub-section 79(2)(j) of the Act;
 - (c) mandatory problem reporting, including investigation of problem or incident, pursuant to Section 40 and sub-section 79(2)(j) of the Act;
 - (d) field corrective action, pursuant to Section 41 and sub-section 79(2)(j) of the Act; and
 - (e) recall, pursuant to Section 42 and sub-section 79(2)(k) of the Act.
- (2) The post-market surveillance and vigilance system of medical device under **sub-regulation (1)** shall be established in accordance with the requirements as specified in technical document **TD9 listed in the Register**.
- (3) Any person who contravenes **sub-regulation (1)** shall be guilty of an offence and shall be liable on conviction to **a fine not exceeding ten thousand ringgit or to imprisonment for a term not exceeding six months or to both**.
- (4) Any person who, in compliance or purported compliance with **sub-regulation (1)**, furnishes the Authority or an authorised officer with any record which he knows is false or misleading, shall be guilty of an offence and shall be liable on conviction to **a fine not exceeding fifty thousand ringgit or to imprisonment for a term not exceeding twelve months or to both**.

PART IX

EXEMPTION OF ANY PERSON OR MEDICAL DEVICE FROM ANY PROVISION OF THIS ACT

Exemption from registration of medical devices for certain purpose

43.—(1) For the purpose of **Section 77(1) of the Act**, the Minister may exempt any person from the licensing requirements to import to distribute any medical device and may exempt any medical device from registration requirements if the medical device is intended to be used for the following purposes—

- (a) special access medical device;
- (b) medical device for the purpose of education or training;
- (c) medical device for personal use;
- (d) medical device for promotion or demonstration;
- (e) custom-made medical device to be used only by a qualified practitioner for patient under his care.

(2) Any person who intends to apply for the exemption pursuant to sub-regulation (1) shall notify the Authority using **Form MDA5 listed in the Register** and shall be accompanied by a processing fee as prescribed in **Table of Fees in Schedule 1** and such information, documents and samples of the medical device **as the Authority may require**.

(3) Upon receipt of the notification, the Authority shall consider the application and if the Authority is satisfied, the Authority may grant the exemption under **sub-regulation (1)**

subject to such conditions as the Authority thinks fit.

(4) The Authority, may at any time in writing, if the Authority thinks fit, require from the person that samples of the exempted medical devices be sent for appropriate conformity assessment, including, but not limited to, analysis or testing.

(5) The Authority shall not borne any expenses incurred for or arising out of the sampling, testing or analysis and for the detention of the medical devices pending the result of any such sampling, test or analysis pursuant to **sub-regulation (4)**.

(6) Notwithstanding **sub-regulations (1) and (2)**, the Authority may, if he considers it consistent with the purpose of this Act and in the interest of public health, exempt—

- (a) any person from the requirements for establishment licensing to import, export or distribute any medical device; or
- (b) any medical device from any registration requirements.

Prohibition on changes to medical devices for use in promotion and demonstration

44.—(1) Subject to **Regulation 43(1)(d)**, no person shall, for the purpose of promoting or demonstrating the use of any medical device, make or cause to be made to the medical device any change or modification that causes the medical device to depart from the specifications of its manufacturer in relation to its intended purpose, design, components or method of installation or operation.

(2) Any person who contravenes **sub-regulation (1)** shall be guilty of an offence and shall be liable on conviction to **a fine not exceeding fifty thousand ringgit or to imprisonment for a term not exceeding twelve months or to both**.

Fabrication of custom-made medical devices

45.—(1) Subject to **Regulation 43(1)(e)**, no person shall fabricate a custom-made medical device, unless that person—

- (a) is a qualified practitioner, and who shall fabricate the custom-made medical device only for the use of patient under his care; and
- (b) shall only fabricate a custom-made medical device either in—
 - (i) a hospital, medical clinic, dental clinic or health clinic under the Government of Malaysia; or
 - (ii) a private healthcare facility licensed under the Private Healthcare Facilities and Services Act 1998 [Act 586].

(2) The person referred to in **sub-regulation (1)** may be subjected to the duties and obligations under **Part VIII of this Regulation**.

(3) The prohibition under **Section 5(1) of the Act** pursuant to an unregistered medical device shall not apply in the case where the unregistered medical device is a custom-made medical device.

(4) Any person who contravenes **sub-regulation (1)** shall be guilty of an offence and shall be liable on conviction to **a fine not exceeding fifty thousand ringgit or to imprisonment for a term not exceeding twelve months or to both**.

Prohibition against placement in the market of refurbished medical devices

46.—(1) The prohibition under **Section 5(1) of the Act** shall apply to the placement in the market of a refurbished medical device, as if the refurbished medical device is a new medical device.

Sample of medical device for testing

47.—(1) The Authority, may at any time in writing if the Authority thinks fit, require from the establishment that new samples of the registered medical devices be sent for appropriate conformity assessment, including but not limiting to analysis or testing.

(5) Any expenses incurred for or arising out of the sampling, testing or analysis and for the detention of the medical devices pending the result of any such sampling, test or analysis shall be borne by the establishment.

PART X

USAGE, OPERATION, MAINTENANCE ETC

Usage, operation, maintenance, etc of medical device

48.—(1) For the purpose of **Section 43(1) of the Act**, a person using a medical device in a healthcare facility on a third party shall ensure that the medical device is used for its intended purpose and in accordance with manufacturer's instruction.

(2) A person using or operating a medical device in a healthcare facility on a third party shall put in place an appropriate maintenance management system within the healthcare facility which shall include the following requirements—

- (a) procurement of registered medical device;
- (b) inspection and verification of the safety and performance of the medical device prior to acceptance for use;
- (c) maintaining and keeping up to date an appropriate medical device assets inventory of all medical devices within the healthcare facility;
- (d) a procedure to ensure that the medical device is properly maintained and calibrated so as to ensure its safety and performance requirements are complied with;
- (e) a procedure that will enable the healthcare facility to response in a timely manner to any of the following incidents—
 - (i) medical device safety alerts, advisory notices, recalls;
 - (ii) adverse events due to the medical device; or
 - (iii) defective medical device;
 - (iv) that compromises the safety, quality and performance of the medical device;
- (f) a procedure for managing the proper disposal of the medical device; and

- (g) a procedure that will enable the person in the healthcare facility to report an adverse event relating to the medical device to the relevant manufacturer and the Authority as per the timeline required by **Regulations (52)**.
- (3) Where applicable, for the purposes of **sub-regulation (2)**, the requirements shall be in accordance to the manufacturer's requirements or recommendations, to any standards as determined by the Authority.
- (4) No person shall be a medical device service provider unless—
- (a) the person is competent to address any regulatory matters and issues arising from the safety, quality and performance of the medical device as approved by Authority;
 - (b) the person is competent in any regulatory matters and the safety, quality and performance of the medical device as determined by Authority;
 - (c) the person has put in place a quality management system as approved by Authority meeting the requirements as stipulated in the standard and code of practice, and other relevant or applicable documents as determined by the Authority; and
 - (d) the person shall install, test, commission, maintain and service a medical device in accordance with manufacturer's instruction and applicable or relevant qualitative and quantitative safety and performance parameters.
 - (e) the person has put in place—
 - (i) a system to maintain medical device inventory and maintenance records in respect of a medical device installed, tested, commissioned, maintain and service;
 - (ii) a post-market surveillance system in respect of a medical device installed, tested, commissioned, maintain and service;
 - (iii) a system to maintain record of reported problems or complaints relating to the safety and performance characteristics of a medical device installed, tested, commissioned, maintain and service;
 - (iv) a system to report incident occurring within Malaysia to the Authority in respect of a medical device installed, tested, commissioned, maintain and service; and
 - (v) a system to undertake corrective or preventive action in relation to a medical device installed, tested, commissioned, maintain and service.
- (5) Any person who contravenes **Regulation 56** shall be guilty of an offence and shall be liable on conviction to **a fine not exceeding fifty thousand ringgit or to imprisonment for a term not exceeding six months or to both**.

Practitioner to keep records of implant

- 49.—**(1) A qualified practitioner who has placed into the body of a person an implanted medical device shall maintain proper records of the following matters—
- (a) the name, address and identity card number (if any) of that person;
 - (b) the date on which the implant was placed into the body of that person;

- (c) the name and description of the implant; and
- (d) the lot or batch number of the implant.

(2) Any person who contravenes **sub-regulation (1)** shall be guilty of an offence and shall be liable on conviction **to a fine not exceeding ten thousand ringgit or to imprisonment for a term not exceeding three months or to both.**

(3) Any person who in compliance or purported compliance with **sub-regulation (1)**—

- (a) wilfully makes, or causes to be made, a false entry in any record required to be kept by him; or
- (b) wilfully omits to make an entry required to be made by him in such record;

shall be guilty of an offence and shall be liable on conviction **to a fine not exceeding fifty thousand ringgit or to imprisonment for a term not exceeding six months or to both.**

Qualification and competency of a person using or operating a medical device

50.—(1) No person shall use or operate a medical device on a third party unless the person is trained on the proper and correct usage, operation and application of the medical device.

(2) For the purposes of **Section 43(2) of the Act**, a person shall be trained by the manufacturer or its authorised representative or a competent trainer respectively duly recognised by the Authority on a case by case basis and based on **the appropriate conditions as listed in the Register**, on the following—

- (a) safety precautions in operating the medical device;
- (b) proper operating procedures, including but not limited to, features unique to the particular manufacturer or model of the medical device;
- (c) recognition and correction of common operational problems;
- (d) recognition of defective equipment and potential hazards;
- (e) user care and maintenance of the medical device;
- (f) relevant regulatory knowledge in relation to safety and performance of a medical device; and
- (g) proper procedures for conducting a basic safety and performance inspection, checking and test for the medical device, where applicable.

(3) The decision of the Authority on any doubt or dispute as to whether a particular usage or operation of a medical device shall be subjected to the requisite training under **sub-regulations (1) and (2)**, shall be final and binding.

Qualification and competency of a person installing, testing or maintaining a medical device

51.—(1) No person shall install, test, commission or maintain and calibrate a medical device unless the person is trained to properly install, test, commission or maintain and calibrate the medical device, as the case may be.

(2) For the purpose of **sub-regulation (1)**, and as the case may be, a person installing, testing, commissioning or maintaining and calibrating a medical device shall be trained on by the manufacturer or authorised representative or a competent trainer recognised by the

Authority—

- (a) safety precautions to properly install or test, as the case may be, of the medical device; and
 - (b) for the case of an active medical device, proper procedures for conducting an electrical and other relevant safety test and qualitative and quantitative performance test for the medical device.
- (3) For the purposes of **sub-regulation (1)**, a person installing, testing, commission or maintaining or calibrating a medical device shall be trained on—
- (a) proper procedures for decontaminating the medical device; and
 - (b) the appropriate **and relevant standards as determined by the Authority**.

Regulatory knowledge and technical competency for personnel assessing the safety and performance of a medical device or inspecting a healthcare facility, etc

52.—(1) No person shall —

- (a) inspect, test, audit or evaluate the safety, quality, efficacy or performance of a medical device;
- (b) inspect or audit an establishment or a medical device service provider; or
- (c) install, test, calibrate or maintain a medical device;

unless he has requisite knowledge of the medical device law, appropriate qualifications, relevant technical competencies pursuant to **sub-regulation (1)** and in accordance with **the requirements as determined by the Authority**.

(2) For the purposes **of sub-regulation (1)**, the following persons or classes of persons shall pass a competency test, administered by the Authority, on his requisite knowledge of medical device law on—

- (a) inspection and evaluation personnel of a conformity assessment body registered under **Section 10 of the Act**;
 - (b) installation, testing or maintenance personnel of an establishment or a medical device service provider as the case may be; and
 - (c) such other persons or classes of persons as may be decided by the Authority.
- (3) For the purpose of **sub-regulation (2)**,—
- (a) the competency test shall be in such form and manner as the Authority thinks fit;
 - (b) the criteria for passing the competency test shall be determined by the Authority;
 - (c) the frequency for administering the competency test shall be determined by the Authority; and
 - (d) the Authority shall issue a certificate of competency for any person who has passed the competency test and impose conditions of certificate as the Authority thinks fit.
- (4) An application to sit for the competency test under **sub-regulation (2)** shall—

- (a) be made in such form and manner as the Authority may require;
 - (b) be submitted within such time as the Authority may specify;
 - (c) be accompanied by such particulars, information, and documents as the Authority may require;
 - (d) be accompanied by an application fee as prescribed in **Table of Fees in Schedule 1**; and
 - (e) if required by the Authority, be accompanied by a statutory declaration by the person verifying any information contained in or relating to the application.
- (5) Any fees paid to the Authority in respect of an application withdrawn and not further proceeded with shall not be refunded.
- (6) The decision of the Authority on any matter under **sub-regulation (3)** shall be final and binding.

PART XI
**REQUIREMENTS FOR THE PROVISION OF AUDITING,
CONSULTING OR TRAINING RELATED TO MEDICAL DEVICE
REGULATORY MATTERS**

Requirements for the provision of auditing, consulting or training

53.—(1) For the purpose of this Regulation, an “auditor, consultant, or trainer” means—

- (a) a person domiciled or resident in Malaysia; and
- (b) a firm or company as defined under the Companies Act 1965 [Act 125];

(2) No person shall provide auditing, consultancy or training services related to medical device Regulation and all the relevant regulatory matters unless the person possesses the requisite knowledge, expertise, experience and competency related to medical device Regulation and all the relevant regulatory matters as approved by Authority.

(3) Any person providing auditing, consultancy or training services shall represent and communicate only accurate and factual information to an establishment, and shall not misrepresent to an establishment on his capacity, experience, competency and the provision of his auditing, consultancy or training services as an establishment have a regulatory obligations *vis-a-vis* the Medical Device Act 2012 [Act 737].

(4) Any person providing auditing, consultancy or training services shall at all times adhere to the code of professional conduct **as determined by the Authority** from time to time, and as made **available in the Register**.

(5) For the removal of doubt, this Regulation shall apply without prejudice to the generality and application of the Trade Descriptions Act 2011 [Act 730].

(6) Any person who contravenes **sub-regulation (1), (2),(3) or (4)** shall be guilty of an offence and shall be liable on conviction to **a fine not exceeding fifty thousand ringgit or to imprisonment for a term not exceeding six months or to both**.

PART XII

APPEAL

Notice of appeal

54.—(1) For the purpose of **Section 47 of the Act**, every appellant who is aggrieved by a decision of the Authority shall send a notice of appeal to the Minister and a copy of it to the Authority within 30 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 contain such documents as may be necessary for the purposes of the appeal.

(3) The notice of appeal shall be accompanied by the appeal fee as prescribed in **Table of Fees in Schedule 1**.

Grounds of decision

55.—(1) Upon receipt of the notice of appeal, the Authority shall cause to be prepared a statement stating the grounds on which he arrived at his decision and shall submit such grounds of decision to the Minister **within 30 days from the date receipt** of the notice of appeal.

Determination of appeal

56.—(1) 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.

(2) Every notice or document relating to an appeal—

- (a) shall be sent by registered post; and
- (b) shall be sent in duplicate to the Minister.

Appeal committee

57.—(1) The Minister may appoint an appeal committee for the purpose of considering any appeal made under **Regulation 68**.

(2) An appeal committee shall consist of a Chairman to be appointed by the Minister from among members of Authority and two other persons to be appointed by the Minister who, in his opinion, have wide experience and knowledge in matters relating to the subject matter of the appeal.

(3) Every member of an appeal committee may be paid an allowance at such rate as the Minister may determine.

Withdrawal of appeal

58.—(1) Where the appellant decides not to pursue his appeal he may withdraw the appeal at any time before the determination of the appeal whereupon the decision of the Authority shall be deemed to be final.

PART XIII REGISTER

Contents of the Register

59.—(1) For the purposes of **Sections 67 and 79(2)(g) of the Act**, the Authority shall establish and maintain a Register in such form as the Authority may determine.

(2) The Register shall contain information as specified under **sub-sections 67(1)(a) through (e) of the Act**.

(3) The Register shall also contain any other matters or data as may be specified by the Authority under **sub-section 67(1)(f) of the Act** which shall include, but not limited to, forms, technical requirements, guidance documents, guidelines and standards.

(4) Notwithstanding **sub-regulations (2) and (3)**, the Authority shall decide the information, data or matters that shall be made available for the public and put in the Register.

Register for public view

60.—(1) Subject to **sub-section 67(2) of the Act**, the Register shall be made available for public view.

(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 prescribed by the Authority in **Table of Fees in Schedule 1**.

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

PART XIV PRESCRIBED FEES

Fees

61.—(1) The fee payable in respect of a matter specified in the first column of the Table of

Fees in Schedule 1 shall be the corresponding fee specified in the second column of that Table.