

LAWS OF MALAYSIA

Act 737

MEDICAL DEVICE ACT 2012

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MEDICAL DEVICE ACT 2012

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Act 737

MEDICAL DEVICE ACT 2012

An Act to regulate medical devices, the industry and to provide for matters connected thereto.

[ ]

ENACTED by the Parliament of Malaysia as follows:

PART I

PRELIMINARY

Short title and commencement

1. (1) This Act may be cited as the Medical Device Act 2012.

(2) This Act comes into operation on a date to be appointed by the Minister by notification in the *Gazette*.

Interpretation

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

"conformity assessment body" means the conformity assessment body registered under section 12;

"prescribed", unless otherwise specified, means prescribed by regulations made under this Act;

"establishment" means—

(a) a person who is either a manufacturer, importer, or distributor who is responsible for placing any medical device in the market but does not include a retailer; and

(b) an authorized representative appointed by a manufacturer having a principal place of business outside Malaysia,

and such person and authorized representative being—

(A) a person domiciled or resident in Malaysia; or

(B) a firm or company constituted under the laws of Malaysia,

and carrying on business or practice principally in Malaysia;

"place in the market" means to make available a medical device in return for payment or free of charge with a view to distributing, using, supplying or putting it into service, in Malaysia, regardless of whether it is new or reprocessed, but does not include to make available for use for clinical research or for performance evaluation of a medical device;

"Minister" means the Minister charged with the responsibility for health;

"manufacturer" means—

(a) a person who is responsible for—

(i) the design, production, fabrication, assembly, processing, packaging and labelling of a medical device whether or not it is the person, or a subcontractor acting on the person's behalf, who carries out these operations; and

(ii) assigning to the finished medical device under his own name, its intended purpose and ensuring the finished product meets the regulatory requirement; or

(b) any other person who—

(i) assembles, packages, processes, fully refurbishes, reprocesses or labels one or more ready-made medical devices; and

(ii) assigning to the ready-made medical device under his own name, its intended purpose and ensuring the finished product meets the regulatory requirement,

but shall not include the following persons:

(A) any person who assembles or adapts medical devices in the market that are intended for individual patients; and

(B) any person who assembles, packages or adapts medical devices in relation to which the assembling, packaging or adaptation does not change the purpose intended for the medical devices;

"medical device" means—

(a) any instrument, apparatus, implement, machine, appliance, implant, *in-vitro* reagent or calibrator, software, material or other similar or related article intended by the manufacturer to be used, alone or in combination, for human beings for the purpose of—

(i) diagnosis, prevention, monitoring, treatment or alleviation of disease;

(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury;

(iii) investigation, replacement or modification, or support of the anatomy or of a physiological process;

(iv) support or sustaining life;

(v) control of conception;

(vi) disinfection of medical device; or

(vii) providing information for medical or diagnostic purpose by means of *in-vitro* examination of specimens derived from the human body,

which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its intended function by such means; and

(b) any instrument, apparatus, implement, machine, appliance, implant, *in-vitro* reagent or calibrator, software, material or other similar or related article, to be used on the human body, which the Minister may, after taking into consideration issues of public safety, public health or public risk, declare to be a medical device by order published in the *Gazette*;

"designated medical device" means a medical device specified by the Minister to be a designated medical device by order published in the *Gazette*;

"Authority" means the Medical Device Authority established under the Medical Device Authority Act 2012 [*Act 738*];

"appointed date" means the date appointed by the Minister under subsection 1(2).

Part II

REGISTRATION OF MEDICAL DEVICE AND CONFORMITY ASSESSMENT BODY

Chapter 1

Registration of medical device

Classification of medical device

3. (1) A medical device shall be classified by an establishment based on the level of risk it poses, its intended use and the vulnerability of the human body in accordance with the prescribed manner.

(2) In the event of any dispute between an establishment and a conformity assessment body over a classification of a medical device, the matter shall be referred to the Authority, in the manner and within such period as may be specified by the Authority, for its decision.

Manufacturer's obligations

4. A manufacturer shall ensure that a medical device—

(a) conforms to the prescribed essential principles of safety and performance;

(b) is manufactured in accordance with good manufacturing practice and any written directive issued by the Authority; and

(c) is labelled, packaged and marked in accordance with the prescribed manner.

Requirement for registration of medical device

5. (1) No medical device shall be imported, exported or placed in the market unless the medical device is registered under this Act.

(2) Any person who contravenes subsection (1) commits an offence and shall, on conviction, be liable to a fine not exceeding two hundred thousand ringgit or to imprisonment for a term not exceeding three years or to both.

Application for registration of medical device

6. (1) An application for the registration of a medical device shall be made by an establishment to the Authority in the prescribed manner.

(2) An application may be withdrawn at any time by the applicant before it is approved or refused by the Authority.

(3) Every application under subsection (1) shall be accompanied by the prescribed application fee and such document or information as may be specified by the Authority.

(4) The Authority may, in writing, at any time after the receipt of an application under subsection (1), request the applicant to give to the Authority within the period specified in the request additional information, particulars or document on the application or sample of the medical device.

(5) If any additional information, particulars or document, or sample of the medical device required under subsection (4) is not given by the applicant within the period specified in the request or any extension of time granted by the Authority, the application shall be deemed to be withdrawn and shall not be further proceeded with, but without affecting the right of the applicant to make a fresh application.

Registration and refusal to register medical device

7. (1) Upon receipt of an application made under section 6 and the Authority being satisfied that—

(a) the medical device has been subjected to the conformity assessment procedures carried out by a conformity assessment body; and

(b) the applicant has complied with any requirement of the Authority made under subsection 6(4),

the Authority may, after such inspection of the premises in which the medical device is being manufactured as it considers proper and necessary to carry out and on payment of the prescribed registration fee, register the medical device for a prescribed period subject to such conditions as the Authority thinks fit to impose, assign a registration number to the medical device and issue to the applicant a certificate of registration.

(2) The Authority shall not register the medical device if it is not satisfied with any matter referred to in subsection (1).

Power to impose additional conditions and to vary or revoke conditions

8. The Authority may, at any time—

(a) impose any additional conditions on the registration of a medical device; or

(b) vary or revoke any of the conditions imposed on the registration of a medical device.

Power to cancel registration of medical device

9. (1) Subject to subsection (2), the Authority may cancel the registration of a medical device if the establishment on whose application a medical device is registered—

(a) has contravened any provision of this Act or any regulations made under this Act;

(b) has breached any condition of the registration; or

(c) has been convicted of an offence under this Act or any regulations made under this Act.

(2) Before the cancellation of the registration of a medical device under subsection (1), the Authority shall, by notice in writing, give the establishment on whose application the medical device is registered an opportunity to show cause against the cancellation, and pending the decision on the cancellation, all importation or supply of the medical device by that establishment shall be suspended from the date of the receipt of the notice by the establishment.

(3) An establishment whose registration of medical device is cancelled shall not be entitled to any compensation for any loss caused to it by the cancellation and shall not be entitled to any refund of the prescribed registration fee paid under section 7.

Chapter 2

Registration of conformity assessment body

Conformity assessment body

10. (1) A conformity assessment body shall be a body registered under this Act to carry out conformity assessment of a medical device to be registered under this Act.

(2) The person who is in charge of and has overall control over a conformity assessment body shall be a Malaysian citizen.

(3) A conformity assessment body shall be independent and shall not have, acquire or hold any interest, directly or indirectly, in relation to—

(a) any medical device under its assessment;

(b) any shares in the establishment whose medical device is assessed by it; or

(c) any related company of the establishment whose medical device is assessed by it.

(4) A conformity assessment body shall not disclose any information received during the conformity assessment procedures carried out on any medical device.

(5) A conformity assessment body shall be audited by the Authority from time to time as may be deemed necessary by the Authority.

Requirement for registration of conformity assessment body

11. (1) No conformity assessment body may carry out any conformity assessment related to a medical device unless it is registered under this Act.

(2) A conformity assessment body may apply for registration by submitting a written application to the Authority in the prescribed manner.

(3) An application may be withdrawn at any time by the applicant before it is approved or refused by the Authority.

(4) Every application under subsection (1) shall be accompanied by the prescribed application fee and such document or information as may be specified by the Authority.

(5) The Authority may, in writing, at any time after the receipt of an application under subsection (2), request the applicant to give to the Authority within the period specified in the request additional information, particulars or document on the application.

(6) If any additional information, particulars or document required under subsection (5) is not given by the applicant within the period specified in the request or any extension of time granted by the Authority, the application shall be deemed to be withdrawn and shall not be further proceeded with, but without affecting the right of the applicant to make a fresh application.

Registration and refusal to register conformity assessment body

12. (1) Upon receipt of an application made under subsection 11(2) and the Authority being satisfied of the compliance with any requirement under subsections 11(4) and (5), the Authority may, after such inspection of the premises of the conformity assessment body as it considers proper and necessary to carry out and on payment of the prescribed registration fee, register the conformity assessment body for a prescribed period subject to such conditions as the Authority thinks fit to impose, assign a registration number to the conformity assessment body and issue to the conformity assessment body a certificate of registration.

(2) The Authority shall not register the conformity assessment body if it is not satisfied with any matter referred to in subsection (1).

Power to impose additional conditions and to vary or revoke conditions

13. The Authority may, at any time—

(a) impose any additional conditions on the registration of a conformity assessment body; or

(b) vary or revoke any of the conditions imposed on the registration of a conformity assessment body.

Power to cancel registration of conformity assessment body

14. (1) Subject to subsection (2), the Authority may cancel the registration of a conformity assessment body that—

(a) has contravened any provision of this Act or any regulations made under this Act;

(b) has breached any condition of the registration; or

(c) has been convicted of an offence under this Act or any regulations made under this Act.

(2) Before the cancellation of the registration of a conformity assessment body under subsection (1), the Authority shall, by notice in writing, give the conformity assessment body an opportunity to show cause against the cancellation, and pending the decision of the cancellation, all assessment of any medical device by that conformity assessment body shall be suspended from the date of the receipt of the notice by the conformity assessment body.

(3) A conformity assessment body whose registration is cancelled shall not be entitled to any compensation for any loss caused to it by the cancellation and shall not be entitled to any refund of the prescribed registration fee paid under section 12.

Part III

LICENCE AND PERMIT

Chapter 1

Establishment licence

Requirement for establishment licence

15. (1) No establishment shall import, export or place in the market any registered medical device unless it holds an establishment licence granted under this Act.

(2) Any establishment who contravenes subsection (1) commits an offence and shall, on conviction, be liable to a fine not exceeding two hundred thousand ringgit or to imprisonment for a term not exceeding three years or to both.

Application for establishment licence

16. (1) An establishment may apply for an establishment licence to be granted under this Act by submitting a written application to the Authority in the prescribed manner.

(2) Every application under subsection (1) shall be accompanied by the prescribed application fee and such document or information as may be specified by the Authority.

(3) An application may be withdrawn at any time by the applicant before it is granted or refused by the Authority.

Additional information or document

17. (1) The Authority may, in writing, at any time after the receipt of an application under section 16, request the applicant to give to the Authority within the period specified in the request additional information, particulars or document.

(2) If any additional information, particulars or document required under subsection (1) is not given by the applicant within the period specified in the request or any extension of time granted by the Authority, the application shall be deemed to be withdrawn and shall not be further proceeded with, but without affecting the right of the applicant to make a fresh application.

Grant or refusal of establishment licence

18. (1) The Authority may, after considering the application for an establishment licence under section 16, and the additional information, particulars or document provided under section 17, grant the establishment licence for a prescribed period or refuse to grant the establishment licence.

(2) An establishment licence granted under subsection (1) shall be subject to the payment of the prescribed fee within the prescribed period and such conditions as the Authority thinks fit to impose.

Compliance with establishment licence conditions

19. (1) A licensee shall comply with the conditions imposed by the Authority on the establishment licence.

(2) Any licensee who contravenes subsection (1) commits an offence and shall, on conviction, be liable to a fine not exceeding one hundred thousand ringgit or to imprisonment for a term not exceeding one year or to both.

Power to impose additional conditions and to vary or revoke conditions

20. The Authority may, at any time—

(a) impose any additional conditions on the establishment licence; or

(b) vary or revoke any of the conditions imposed on the establishment licence.

Transfer of establishment licence

21. (1) The grant of an establishment licence under section 18 shall be personal to the licensee and the establishment licence shall not be assigned, sub-licensed or transferred to any other person except with the prior written approval of the Authority.

(2) A licensee who assigns, sub-licenses or transfers his establishment licence to any other person without the prior written approval of the Authority commits an offence 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.

Suspension or revocation of establishment licence

22. (1) The Authority may suspend or revoke an establishment licence if the licensee—

(a) has contravened any provision of this Act or any regulations made under this Act;

(b) has breached any condition of the licence; or

(c) has been convicted of an offence under this Act or any regulations made under this Act.

(2) If an establishment licence is suspended under subsection (1), the Authority may require the licensee to remedy the contravention or the breach within the period specified by the Authority.

(3) If the Authority is satisfied that the licensee has failed to remedy the contravention or breach as required under subsection (2), or the contravention or breach continues after the establishment licence is suspended under subsection (1), the Authority shall revoke the licence.

Surrender of establishment licence

23. (1) A licensee may, by notice in writing, surrender its licence by forwarding the establishment licence to the Authority.

(2) The surrender of the establishment licence shall take effect upon receipt of the establishment licence and the written notice under subsection (1) by the Authority.

(3) The surrender of an establishment licence under subsection (1) shall be irrevocable.

Renewal of establishment licence

24. (1) A licensee may apply for renewal of its establishment licence to the Authority not later than one year before the expiry date of the establishment licence.

(2) The Authority shall, upon payment of the prescribed fee, renew an establishment licence except in the following circumstances:

(a) the licensee has contravened any provision of this Act or any regulations made under this Act;

(b) the licensee has breached any condition of the establishment licence;

(c) the licensee had improperly or illegally obtained the establishment licence; or

(d) the licensee has been convicted of an offence under this Act or any regulations made under this Act.

(3) The Authority may request the licensee to provide any information, particulars or document as may be required for the renewal application within the period specified in the request.

(4) Notwithstanding subsection (2), if the information, particulars or document requested under subsection (3) is not provided by the licensee within the period specified in the request or any extension of time granted, the Authority may not renew the establishment licence.

Effect of suspension, revocation, surrender or non-renewal of establishment licence

25. (1) If an establishment licence is suspended or revoked under section 22, surrendered under section 23 or is not renewed under section 24, the licensee shall immediately cease to import, export or place in the market any registered medical device in respect of which the establishment licence was granted.

(2) Notwithstanding subsection (1), the Authority may, at any time after the suspension, revocation, surrender or non-renewal of an establishment licence, give such directions to the licensee as it may deem necessary in the interest of public health and safety, and the licensee shall comply with all such directions.

(3) A licensee whose establishment licence is—

(a) suspended, revoked or not renewed shall not be entitled to any compensation for any loss caused to it by the suspension, revocation or non-renewal of the establishment licence; and

(b) revoked shall not be entitled to any refund of the establishment licence fee paid under section 18.

(4) Any licensee who contravenes subsection (1) commits an offence and shall, on conviction, be liable to a fine not exceeding two hundred thousand ringgit or to imprisonment for a term not exceeding three years or to both.

Chapter 2

Designated medical device permit

Designated medical device

26. The Minister may, from time to time, after taking into consideration the risk level of a medical device, the exposure of medical device to public health, patient safety and the degree

of complexities of the medical device, specify a medical device to be a designated medical device by an order published in the *Gazette*.

Requirement for designated medical device permit

27. (1) No person shall use or operate any designated medical device unless the person holds a designated medical device permit granted under this Act.

(2) Any person who contravenes subsection (1) commits an offence and shall, on conviction, be liable to a fine not exceeding one hundred thousand ringgit or to imprisonment for a term not exceeding one year or to both.

Application for designated medical device permit

28. (1) A person may apply for a designated medical device permit to be granted under this Act by submitting a written application to the Authority in the prescribed manner.

(2) Every application under subsection (1) shall be accompanied by the prescribed application fee and such document or information as may be specified by the Authority.

(3) An application under this section may be withdrawn at any time by the applicant before it is granted or refused by the Authority.

Additional information or document

29. (1) The Authority may, in writing, at any time after the receipt of an application under section 28, request the applicant to give to the Authority within the period specified in the request additional information, particulars or document.

(2) If any additional information, particulars or document required under subsection (1) is not provided by the applicant within the period specified in the request or any extension of time granted by the Authority, the application shall be deemed to be withdrawn and shall not be further proceeded with, but without affecting the right of the applicant to make a fresh application.

Grant or refusal of designated medical device permit

30. (1) The Authority may, after considering the application for a designated medical device permit under section 28 and the additional information, particulars or document provided under section 29, grant the designated medical device permit for a prescribed period or refuse to grant the designated medical device permit.

(2) A designated medical device permit granted under subsection (1) shall be subject to the payment of the prescribed fee within the prescribed period and such conditions as the Authority thinks fit to impose.

Compliance with designated medical device permit conditions

31. (1) A permit holder shall comply with the conditions imposed by the Authority on the designated medical device permit.

(2) Any permit holder who contravenes subsection (1) commits an offence and shall, on conviction, be liable to a fine not exceeding fifty thousand ringgit or to imprisonment for a term not exceeding six months or to both.

Power to impose additional conditions and to vary or revoke conditions

32. The Authority may, at any time—

(a) impose any additional conditions on the designated medical device permit; or

(b) vary or revoke any of the conditions imposed on the designated medical device permit.

Suspension or revocation of designated medical device permit

33. (1) The Authority may suspend or revoke a designated medical device permit if the permit holder—

(a) has contravened any provision of this Act or any regulations made under this Act;

(b) has breached any condition of the designated medical device permit; or

(c) has been convicted of an offence under this Act or any regulations made under this Act.

(2) If a designated medical device permit is suspended under subsection (1), the Authority may require the permit holder to remedy the contravention or breach within the period specified by the Authority.

(3) If the Authority is satisfied that the permit holder has failed to remedy the contravention or breach as required under subsection (2), or the contravention or breach continues after the designated medical device permit is suspended under subsection (1), the Authority shall revoke the designated medical device permit.

Surrender of designated medical device permit

34. (1) A permit holder may, by notice in writting, surrender its designated medical device permit by forwarding the designated medical device permit to the Authority.

(2) The surrender of the designated medical device permit shall take effect upon receipt of the designated medical device permit and the written notice under subsection (1) by the Authority.

(3) The surrender of a designated medical device permit under subsection (1) shall be irrevocable.

Renewal of designated medical device permit

35. (1) A permit holder may apply for renewal of its designated medical device permit to the Authority not later than one year before the expiry date of the permit.

(2) The Authority shall, upon payment of the prescribed fee, renew a designated medical device permit except in the following circumstances:

(a) the permit holder has contravened any provision of this Act or any regulations made under this Act;

(b) the permit holder has breached any condition of the designated medical device permit;

(c) the permit holder had improperly or illegally obtained the designated medical device permit; or

(d) the permit holder has been convicted of an offence under this Act or any regulations made under this Act.

(3) The Authority may request the permit holder to provide any information, particulars or document as may be required for the renewal application within the period specified in the request.

(4) Notwithstanding subsection (2), if the information, particulars or document requested under subsection (3) is not provided by the permit holder within the period specified in the request or any extension of time granted, the Authority may not renew the designated medical device permit.

Effect of suspension, revocation, surrender or non-renewal of designated medical device permit

36. (1) If a designated medical device permit is suspended or revoked under section 33, surrendered under section 34 or is not renewed under section 35, the permit holder shall immediately cease to use or operate a designated medical device in respect of which the designated medical device permit was granted.

(2) Notwithstanding subsection (1), the Authority may, at any time after the suspension, revocation, surrender or non-renewal of a designated medical device permit, give such directions to the permit holder as it may deem necessary in the interest of public health and safety, and the permit holder shall comply with all such directions.

(3) A permit holder whose designated medical device permit is—

(a) suspended, revoked or not renewed shall not be entitled to any compensation for any loss caused to him by the suspension, revocation or non-renewal of the designated medical device permit; and

(b) revoked shall not be entitled to any refund of the designated medical device permit fee paid under section 30.

(4) Any permit holder who contravenes subsection (1) commits an offence and shall, on conviction, be liable to a fine of not less than one hundred thousand ringgit and not more than one million ringgit or to imprisonment for a term not exceeding seven years or to both.

Chapter 3

Duties and obligations of licensees or permit holders

Distribution records

37. (1) An establishment shall maintain a distribution record in respect of each medical device manufactured, imported, exported and placed in the market.

(2) The distribution record shall contain information as prescribed by the Minister.

(3) An establishment shall provide the distribution records to the Authority upon request.

Post-market surveillance and vigilance

38. (1) An establishment shall monitor the safety and performance of the medical device manufactured, imported, exported and placed in the market, and put in place a post-market surveillance system as prescribed by the Minister.

(2) An establishment shall ensure that any vigilance report of adverse incident involving its medical device in the market is properly recorded and fully evaluated.

Complaint handling

39. An establishment shall establish and implement documented procedures and maintain records of reported problems or complaints relating to the safety and the performance characteristics of its medical device.

Mandatory problem reporting

40. (1) An establishment shall report to the Authority any incident that comes to the establishment's attention occurring inside or outside Malaysia that—

(a) is related to the failure of the medical device or a deterioration in its effectiveness, or any inadequacy in its labelling or in its instructions for use and such report shall be made within thirty days from the discovery;

(b) has led to the death or serious deterioration in the state of health of a patient, user or other person, or could do so were the incident to recur and such report shall be made within ten days from the discovery; or

(c) is a serious threat to public health and such report shall be made within forty-eight hours from the discovery.

(2) Any person who contravenes subsection (1) commits an offence and shall, on conviction, be liable to a fine not exceeding two hundred thousand ringgit or to imprisonment for a term not exceeding two years or to both.

Field corrective action

41. An establishment shall undertake corrective or preventive action in relation to a medical device imported and placed in the market which may include—

(a) the return of the medical device to the establishment;

(b) modification of the medical device;

(c) exchange of the medical device;

(d) destruction of the medical device; or

(e) specific advice on the use of the medical device.

Recall

42. (1) An establishment may recall any defective medical device at any time.

(2) The establishment shall, on or before undertaking a recall of the medical device, provide information as may be specified by the Authority.

(3) The establishment shall, as soon as possible after the completion of a recall, report to the Authority the results of the recall and any action taken to prevent a recurrence of the problem.

(4) Notwithstanding subsection (1), the Authority may order the establishment to recall any medical device at any time due to patient safety and public health.

Chapter 4

General duty

Usage, operation, maintenance, *etc*., of medical device

43. (1) A person using or operating a medical device on a third party shall ensure that the medical device is—

(a) safe and efficacious;

(b) used in accordance with its intended purpose;

(c) used in accordance with the manufacturer's instructions; and

(d) properly installed, tested, commissioned and maintained.

(2) A person—

(a) using or operating a medical device on a third party; or

(b) installing, testing, commissioning, maintaining and disposing of a medical device,

shall have the qualification and competency as prescribed by the Minister.

(3) A person using or operating a medical device on a third party shall take the medical device out of operation when it is no longer safe and effective for use.

(4) A medical device which has been taken out of operation under subsection (3) shall be removed and disposed of in a safe manner which eliminates or reduces any—

(a) danger of injury;

(b) danger of contamination with biological material or other contaminants;

(c) danger of environmental damage; and

(d) danger of it being re-used.

(5) The Authority may issue directives, orders or guidelines to specify the measures to be taken in the event of an emergency or incident during the usage, operation, installation, testing, commissioning, maintenance and disposal of medical devices.

(6) Any person who contravenes subsection (1), (2), (3) or (4) commits an offence and shall, on conviction, be liable to a fine not exceeding one hundred thousand ringgit or to imprisonment for a term not exceeding one year or to both.

Advertising

44. (1) No person shall advertise a medical device unless the medical device has been registered and complied with the requirements of this Act.

(2) No person shall make any misleading or fraudulent claims in respect of a medical device in any advertisement.

(3) Any person who contravenes subsection (1) or (2) commits an offence and shall, on conviction, be liable to a fine not exceeding three hundred thousand ringgit or to imprisonment for a term not exceeding three years or to both.

Chapter 5

Export permit

Export permit

45. (1) An establishment may apply to the Authority for a permit to export a registered medical device in the prescribed form and accompanied by the prescribed fees.

(2) The Authority may, after considering the application under subsection (1), issue or refuse to issue a permit to export a registered medical device.

(3) If the Authority decides to issue an export permit, it may impose such conditions as it thinks fit.

(4) An establishment shall comply with the conditions imposed by the Authority on the export permit.

(5) Any establishment who contravenes subsection (4) commits an offence and shall, on conviction, be liable to a fine not exceeding fifty thousand ringgit or to imprisonment for a term not exceeding six months or to both.

Revocation of export permit

46. (1) The Authority may, at any time, revoke an export permit issued if it is satisfied that—

(a) the permit holder has contravened any provision of this Act or any regulations made under this Act;

(b) the permit holder has breached any condition of the permit;

(c) the export permit was issued as a result of false, misleading or inaccurate information;

(d) the permit holder had improperly or illegally obtained the permit; or

(e) the permit holder has been convicted of an offence under this Act or any regulations made under this Act.

(2) Upon the Authority notifying the permit holder of the revocation of its export permit, the permit holder shall immediately surrender the export permit.

(3) Any permit holder who contravenes subsection (2) commits an offence and shall, on conviction, be liable to a fine not exceeding fifty thousand ringgit or to imprisonment for a term not exceeding six months or to both.

(4) A permit holder whose export permit is revoked shall not be entitled to any compensation for any loss caused to him by the revocation of the export permit.

Part IV

APPEAL

Appeal against decision of Authority

47. (1) Any person who is aggrieved by the decision of the Authority under section 7, 9, 12, 14, 18, 22, 24, 30, 33, 35, 45 or 46 may appeal to the Minister in the prescribed manner and within the prescribed period.

(2) The Minister may confirm, reverse or vary the decision of the Authority.

(3) The Minister's decision on any appeal under subsection (1) shall be final and binding.

Part V

ENFORCEMENT

Authorized officers

48. (1) The Minister may, in writing, authorize any officer of the Authority or public officer to exercise the powers of enforcement under this Act.

(2) Any such officer shall be deemed to be a public servant within the meaning of the Penal Code [*Act 574*].

Authority card

49. (1) The Authority shall issue to each authorized officer an authority card which shall be signed by the Chief Executive of the Authority.

(2) Whenever the authorized officer exercises any of the powers of enforcement under this Act, he shall produce on demand to the person against whom the power is being exercised the authority card issued to him under subsection (1).

Power of investigation

50. (1) An authorized officer may investigate the commission of any offence under this Act.

(2) For the avoidance of doubt, it is declared that for the purposes of this Act, the authorized officer shall have all or any of the powers of a police officer of whatever rank in relation to police investigations in seizable cases as provided for under the Criminal Procedure Code [*Act 593*], and such powers shall be in addition to the powers provided for under this Act and not in derogation thereof.

Search and seizure with warrant

51. (1) If it appears to a Magistrate, upon written information on oath from the authorized officer and after such inquiry as the Magistrate considers necessary, that there is reasonable cause to believe that—

(a) any premises or conveyance has been used for; or

(b) there is in any premises or conveyance evidence necessary to the conduct of an investigation into,

the commission of an offence under this Act, the Magistrate may issue a warrant authorizing the authorized officer named in the warrant at any reasonable time by day or night and with or without assistance, to enter the premises or conveyance and if need be by force.

(2) Without affecting the generality of subsection (1), the warrant issued by the Magistrate may authorize the search and seizure of any medical device, book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form which is reasonably believed to furnish evidence of the commission of the offence.

(3) An authorized officer conducting a search under subsection (1) may, for the purpose of investigating into the offence, search any person who is in or on the premises or conveyance.

(4) An authorized officer making a search of a person under subsection (3) or section 52 may seize or take possession of, and place in safe custody all things other than the necessary clothing found upon the person, and any of those things of which there is reason to believe were the instruments or other evidence of the offence may be detained until the discharge or acquittal of the person.

(5) No person shall be searched except by another person of the same gender, and such search shall be conducted with strict regard to decency.

(6) If, by reason of its nature, size or amount, it is not practicable to remove any medical device, book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form seized under this section, the authorized officer shall by any means seal such medical device, book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form in the premises or conveyance in which it is found.

(7) A person who, without lawful authority, breaks, tampers with or damages the seal referred to in subsection (6) or removes any medical device, book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form under seal or attempts to do so commits an offence and shall, on conviction, be liable to a fine not exceeding five hundred thousand ringgit or to imprisonment for a term not exceeding three years or to both.

Search and seizure without warrant

52. If an authorized officer is satisfied upon information received that he has reasonable cause to believe that by reason of delay in obtaining a search warrant under section 51 the investigation would be adversely affected or evidence of the commission of an offence is likely to be tampered with, removed, damaged or destroyed, the authorized officer may enter the premises or conveyance and exercise in, upon and in respect of the premises

or conveyance all the powers referred to in section 51 in as full and ample a manner as if he were authorized to do so by a warrant issued under that section.

Access to computerized data

53. (1) An authorized officer conducting a search under sections 51 and 52 shall be given access to computerized data whether stored in a computer or otherwise.

(2) For the purposes of this section, "access"—

(a) includes being provided with the necessary password, encryption code, decryption code, software or hardware and any other means required to enable comprehension of computerized data; and

(b) has the meaning assigned to it in subsections 2(2) and (5) of the Computer Crimes Act 1997 [*Act 563*].

Warrant admissible notwithstanding defects

54. A search warrant issued under this Act shall be valid and enforceable notwithstanding any defect, mistake or omission therein or in the application for such warrant, and any medical device, book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form seized under such warrant shall be admissible in evidence in any proceedings under this Act.

List of medical device, book, document, *etc.*, seized

55. (1) Except as provided in subsection (2), where any medical device, book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form is seized pursuant to this Act, the authorized officer making the seizure—

(a) shall prepare—

(i) a list of the medical device, book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form seized and shall sign the list; and

(ii) a written notice of the seizure containing the grounds for the seizure and shall sign the notice; and

(b) shall as soon as practicable serve a copy of the list of the medical device, book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form seized and the written notice of the seizure to the occupier of the premises which have been searched, or to his agent or servant at those premises.

(2) The written notice of the seizure shall not be required to be served in pursuance of paragraph (1)*(b)* where the seizure is made in the presence of the person against whom proceedings under this Act are intended to be taken, or in the presence of the owner of such property or his agent, as the case may be.

(3) If the premises is unoccupied, the authorized officer shall post a copy of the list of the medical device, book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form seized conspicuously on the premises.

Release of medical device, book, document, *etc.*, seized

56. (1) If any medical device, book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form has been seized under this Act, the authorized officer who effected the seizure may, after referring to the Public Prosecutor, release the medical device, book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form to the person determined by him to be lawfully entitled to it, if the medical device, book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form is not liable to forfeiture under this Act, and is not otherwise required for the purpose of any proceedings under this Act or for the purpose of any prosecution under any other written law, and in such event neither the authorized officer effecting the seizure, nor the Federal Government, the Authority or any person acting on behalf of the Federal Government or Authority shall be liable to any proceedings by any person if the seizure and

the release of the medical device, book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form had been effected in good faith.

(2) A record in writing shall be made by the authorized officer effecting the release of the medical device, book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form under subsection (1) specifying in detail the circumstances of and the reason for the release, and he shall send a copy of the record to the Public Prosecutor within seven days of the release.

No costs or damages arising from seizure to be recoverable

57. No person shall, in any proceedings before any court in respect of any medical device, book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form seized in the exercise or the purported exercise of any power conferred under this Act, be entitled to the costs of such proceedings or to any damages or other relief unless such seizure was made without reasonable cause.

Cost of holding seized medical device, *etc*.

58. If any medical device, book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form seized under this Act is held in the custody of the Authority pending the completion of any proceedings in respect of an offence under this Act, the cost of holding it in custody shall, irrespective of whether any prosecution is instituted or otherwise against any person, be a civil debt due to the Government by such person and shall be recoverable accordingly.

Obstruction to search

59. Any person who—

(a) refuses any authorized officer access to any premises or conveyance which the authorized officer is entitled to have access to under this Act or in the execution of any duty imposed or power conferred by this Act;

(b) assaults, obstructs, hinders or delays any authorized officer in effecting any entry which the authorized officer is entitled to effect under this Act, or in the execution of any duty imposed or power conferred by this Act; or

(c) refuses any authorized officer any information relating to an offence or suspected offence under this Act or any other information which may reasonably be required of him and which he has in his knowledge or power to give,

commits an offence and shall, on conviction, be liable to a fine not exceeding five hundred thousand ringgit or to imprisonment for a term not exceeding three years or to both.

Power to require attendance of persons acquainted with case

60. (1) An authorized officer making an investigation under this Act may, by order in writing, require the attendance before himself of any person who appears to the authorized officer to be acquainted with the facts and circumstances of the case, and such person shall attend as so required.

(2) If any person refuses or fails to attend as so required, the authorized officer may report such refusal or failure to a Magistrate who shall issue a summons to secure the attendance of such person as may be required by the order made under subsection (1).

Examination of persons acquainted with case

61. (1) An authorized officer making an investigation under this Act may examine orally any person supposed to be acquainted with the facts and circumstances of the case.

(2) Such person shall be bound to answer all questions relating to the case put to him by the authorized officer, but he may refuse to answer any question the answer to which would have a tendency to expose him to a criminal charge or penalty or forfeiture.

(3) A person making a statement under this section shall be legally bound to state the truth, whether or not such statement is made wholly or partly in answer to questions.

(4) The authorized officer examining a person under subsection (1) shall first inform that person of the provisions of subsections (2) and (3).

(5) A statement made by any person under this section shall, whenever possible, be reduced into writing and signed by the person making it or affixed with his thumb print, as the case may be, after it has been read to him in the language in which he made it and after he has been given an opportunity to make any corrections he may wish.

Admission of statements in evidence

62. (1) Except as provided in this section, no statement made by any person to an authorized officer in the course of an investigation made under this Act shall be used in evidence.

(2) When any witness is called for the prosecution or for the defence, other than the accused, the court shall, on the request of the accused or the prosecutor, refer to any statement made by that witness to the authorized officer in the course of investigation under this Act and may then, if the courts thinks fit in the interest of justice, direct the accused to be furnished with a copy of it and the statement may be used to impeach the credit of the witness in the manner provided by the Evidence Act 1950 [*Act 56*].

(3) Where the accused had made a statement during the course of an investigation, such statement may be admitted in evidence in support of his defence during the course of the trial.

(4) Nothing in this section shall be deemed to apply to any statement made in the course of an identification parade or falling within section 27 or paragraphs 32(1)*(a), (i)* and *(j)* of the Evidence Act 1950.

(5) When any person is charged with any offence in relation to—

(a) the making; or

(b) the contents,

of any statement made by him to an authorized officer in the course of an investigation made under this Act, that statement may be used as evidence in the prosecution's case.

Forfeiture of seized medical device, *etc*.

63. (1) Any medical device, book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form seized in exercise of any power conferred by this Act shall be liable to forfeiture.

(2) An order for the forfeiture of the medical device, book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form seized and liable to forfeiture under this Act shall be made by the court before which the prosecution with regard thereto has been held if it is proved to the satisfaction of the court that an offence under this Act has been committed and that the medical device, book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form seized was the subject matter of or was used in the commission of the offence, notwithstanding that no person has been convicted of such offence.

(3) If there is no prosecution with regard to any medical device, book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form seized under this Act, such medical device, book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form shall be taken and deemed to be forfeited at the expiration of a period of one calendar month from the date of service of a notice to the last-known address of the person from whom the medical device, book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form was seized indicating that there is no prosecution in respect of such medical device, book, document, computerized data, apparatus,

equipment, device, machinery, vehicle, matter or thing including in digital form, unless before the expiration of that period a claim thereto is made in the manner set out in subsections (4), (5) and (6).

(4) Any person asserting that he is the owner of the medical device, book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form referred to in subsection (3) and that it is not liable to forfeiture may, personally or by his agent authorized in writing, give written notice to the authorized officer in whose possession such medical device, book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form is held that he claims the medical device, book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form.

(5) On receipt of the notice under subsection (4), the authorized officer shall refer the matter to a Magistrate for his decision.

(6) The Magistrate to whom the matter is referred under subsection (5) shall issue a summons requiring the person asserting that he is the owner of the medical device, book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form and the person from whom it was seized to appear before the Magistrate, and upon their appearance or default to appear, due service of the summons having been proved, the Magistrate shall proceed to the examination of the matter and, on proof that an offence under this Act has been committed and that medical device, book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form seized was the subject matter of or was used in the commission of such offence, the Magistrate shall order the medical device, book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form to be forfeited, and shall, in the absence of such proof, order its release.

(7) Any medical device, book, document, computerized data, apparatus, equipment, device, machinery, vehicle, matter or thing including in digital form forfeited or deemed to be forfeited shall be delivered to the Authority and shall be disposed of in such manner as the Authority thinks fit.

(8) The Authority may direct that any thing seized under this Act be sold at any time and the proceeds of the sale be held pending the result of any prosecution or claim under this section if—

(a) it is of a perishable nature or is subject to speedy and natural decay;

(b) the custody of the thing involves unreasonable expense and inconvenience; or

(c) it is believed to cause obstruction or hazard to the public.

Power of arrest

64. (1) An authorized officer or police officer may arrest without warrant any person whom he reasonably believes has committed or is attempting to commit an offence under this Act.

(2) An authorized officer making an arrest under subsection (1) shall without unnecessary delay make over the person so arrested to the nearest police officer or, in the absence of a police officer, take such person to the nearest police station, and thereafter the person shall be dealt with as is provided for by the law relating to criminal procedure for the time being in force as if he had been arrested by a police officer.

Power to take sample

65. (1) An authorized officer may demand, select, take or obtain samples of any medical device in the prescribed manner for the purposes of analysis—

(a) upon payment, from any person selling the medical device, or his or its agent or servant; or

(b) without payment, from any establishment of the medical device or its agent or servant.

(2) The analysis of the samples shall be done in the prescribed manner.

(3) Any person who refuses to comply with any demand made by an authorized officer under subsection (1) commits an offence and shall, on conviction, be liable to a fine not exceeding one hundred thousand ringgit or to imprisonment for a term not exceeding one year or to both.

Appointment of analyst

66. The Authority may appoint any qualified person to be an analyst for the purposes of carrying out an analysis under this Act.

PART VI

GENERAL

Register

67. (1) The Authority shall cause to be kept and maintained a register consisting of—

(a) all medical devices registered under this Act;

(b) all conformity assessment bodies registered under this Act;

(c) all licences and permits granted by the Authority;

(d) all decisions of the Authority to cancel the registration of a medical device or conformity assessment body;

(e) all decisions of the Authority to revoke and suspend licences or permits; and

(f) any other matters or data as may be specified by the Authority.

(2) The register shall be deemed to be a public document within the meaning of the Evidence Act 1950 and shall be open for public inspection and the public may make a search of and obtain extracts from the register upon payment of a prescribed fee.

Confidential business information

68. (1) A person making an application or furnishing any information under this Act may apply to the Authority for confidentiality of any particular information relating to the application or furnishing of information, as the case may be.

(2) The Authority may grant confidentiality based on the criteria under subsection (3), and where confidentiality is granted, such information shall not be made public.

(3) The Authority shall consider the claim for confidentiality according to the following criteria:

(a) that the information is not known generally among, or readily accessible to, persons within the circle that normally deals with the kind of information sought to be made confidential;

(b) that the information has commercial value;

(c) that reasonable steps have been taken to keep the information secret; and

(d) that the disclosure of the information will harm the competitive position of the person in a manner contrary to honest commercial practice.

(4) The Authority shall have the power to revoke the confidentiality granted in whole or in part in the interest of public health.

Public disclosure

69. Subject to the discretion of the Authority, the public may have access to such information relating to any application or furnishing of information under this Act, which has not been granted confidentiality under section 68 or in respect of which the Authority has revoked its confidentiality under subsection 68(4), in such manner as the Authority thinks fit.

Emergency response plan and assistance from multi-agencies in emergency

70. (1) The Authority may require, as part of the process of issuing a licence or designated medical device permit, or otherwise, any person to provide the necessary measures to be taken in the event of an emergency for the protection of the public from harm or damage caused by a medical device.

(2) The Authority shall forward the emergency response plan submitted under subsection (1) to all relevant agencies for their necessary action.

(3) In the event of any emergency involving any medical device, the Authority may seek the assistance and co-operation of the relevant agencies in implementing any emergency measures including those measures provided in the emergency response plan.

(4) Any costs incurred by any agency in implementing any emergency measure shall be borne by the licensee or designated medical device permit holder.

(5) Nothing in this section shall absolve or be deemed to absolve the licensee or designated medical device permit holder from any of his obligation to take all necessary measures in the event of any emergency.

Compounding of offences

71. (1) The Authority may, with the consent of the Public Prosecutor, compound any offence committed by any person under this Act and prescribed to be a compoundable offence by regulations made under this Act by making a written offer to such person to compound the offence upon payment to the Authority of such amount not exceeding fifty per centum of the amount of the maximum fine for that offence within such time as may be specified in the offer.

(2) An offer under subsection (1) may be made at any time after the offence has been committed, but before any prosecution for it has been instituted.

(3) If the amount specified in the offer made under subsection (1) is not paid within the time specified in the offer or within such extended period as the Authority may grant, prosecution for the offence may be instituted at any time after that against the person to whom the offer was made.

(4) Where an offence has been compounded under subsection (1), no prosecution shall be instituted in respect of the offence against the person to whom the offer to compound was made.

Prosecution

72. No prosecution for any offence under this Act or any regulations made under this Act shall be instituted except by or with the written consent of the Public Prosecutor.

Offence by body corporate

73. If a body corporate commits an offence under this Act, any person who at the time of the commission of the offence was a director, manager, secretary or other similar officer of the body corporate or was purporting to act in any such capacity or was in any manner or to any extent responsible for the management of any of the affairs of the body corporate or was assisting in such management—

(a) may be charged severally or jointly in the same proceedings with the body corporate; and

(b) where the body corporate is found guilty of the offence, shall be deemed to be guilty of that offence unless, having regard to the nature of his functions in that capacity and to all circumstances, he proves—

(i) that the offence was committed without his knowledge, consent or connivance; and

(ii) that he took all reasonable precautions and had exercised due diligence to prevent the commission of the offence.

Offence by partner, agent or servant

74. Any person who would have been liable to any penalty under this Act for any act, omission, neglect or default if the act, omission, neglect or default is committed by him personally shall be liable to the same penalty if the act, omission, neglect or default is committed by his partner, agent or servant unless he proves—

(a) that the act, omission, neglect or default was committed without his knowledge, consent or connivance; and

(b) that he took all reasonable precautions and had exercised due diligence to prevent the act, omission, neglect or default.

Service of document

75. (1) Service of documents on any person shall be effected—

(a) by delivering the document to that person or by delivering the document at the last-known place of residence of that person to an adult member of his family;

(b) by leaving the document at the usual or last-known place of residence or business of that person in a cover addressed to that person; or

(c) by forwarding the document by registered post addressed to that person at his usual or last-known place of residence or business.

(2) A document required to be served on the owner or occupier of any premises—

(a) shall be deemed to be properly addressed if addressed by the description of the "owner" or "occupier" of such premises; and

(b) may be served—

(i) by delivering the document to an adult person on the premises; or

(ii) if there is no such person on the premises to whom the document can with reasonable diligence be delivered, by advertisement at least in one local newspaper.

False declaration

76. (1) Any person who makes, orally or in writing, signs or furnishes any declaration, return, certificate or other document or information required under this Act which is untrue, inaccurate or misleading in any particular commits an offence and shall, on conviction, be liable to a fine not exceeding one hundred thousand ringgit or to imprisonment for a term not exceeding two years or to both.

(2) Any person who—

(a) without lawful authority alters, forges, mutilates or defaces any registration, licence or permit; or

(b) knowingly makes use of any registration, licence or permit which has been altered, forged, mutilated or defaced,

commits an offence and shall, on conviction, be liable to a fine not exceeding five hundred thousand ringgit or to imprisonment for a term not exceeding three years or to both.

Power to exempt

77. (1) The Minister may, if he considers it consistent with the purposes of this Act or in the interest of public health and safety, by order published in the *Gazette,* exempt any person or medical device from any of the provisions of this Act or any regulations made under this Act for such duration and subject to such conditions as the Minister may specify and he may alter or add the conditions so specified.

(2) The Minister may, at any time, by order published in the *Gazette,* revoke any order made under subsection (1) if he is satisfied that such exemption should no longer be granted.

General penalty

78. Any person who commits an offence under this Act for which no penalty is expressly provided shall, on conviction, be liable to a fine not exceeding five hundred thousand ringgit or to imprisonment for a term not exceeding three years or to both.

Regulations

79. (1) The Minister may make such regulations as may be expedient or necessary for the better carrying out of the provisions of this Act.

(2) Without prejudice to the generality of subsection (1), regulations may be made for the following purposes:

(a) to prescribe the manner of application for the registration of a medical device or conformity assessment body, licences or permits, and to provide for the cancellation of the registration, and suspension and revocation of the licence or permit;

(b) to prescribe the risk classification criteria, the manner of classification and the rules of classification of medical devices;

(c) to prescribe the design and manufacturing principles of medical devices, the good design principles in relation to risk elimination or minimization, and the good manufacturing principles in relation to standards, safety and efficacy of medical devices;

(d) to prescribe all matters relating to the packaging, labelling and marking of medical devices for the purpose of identification;

(e) to prescribe procedures and criteria for conformity assessment of medical devices;

(f) to prescribe the conformity assessment standards for various class or categories of medical devices;

(g) to prescribe the manner of keeping and maintaining the register;

(h) to prescribe matters relating to the contents of and conditions for advertising of medical devices;

(i) to prescribe the manner of maintenance and the contents of distribution records of medical devices;

(j) to prescribe the criteria, conditions and the procedures for post-market surveillance and vigilance, complaint handling, mandatory problem reporting, field corrective action and the usage, operation, installation, test, commission, maintenance and disposal of medical devices;

(k) to prescribe the procedure for voluntary recall by an establishment, the criteria, conditions and procedures for mandatory recall by the Authority, taking out of operation of medical devices and disposal of medical devices which are no longer safe to use;

(l) to prescribe matters relating to export permits including the criteria, conditions and the procedure for the application of export permits of medical devices;

(m) to prescribe the competency requirement of persons using, operating, installing, testing, commissioning, maintaining and disposing of medical devices; and

(n) to prescribe the fees and charges payable under this Act and the manner for collecting and dealing with such fees and charges.

(3) The regulations made under this Act may provide for any act or omission in contravention of the regulations to be an offence and may provide for penalties of a fine not exceeding two hundred thousand ringgit or to imprisonment for a term not exceeding two years or to both.

Savings and transitional

80. (1) A person who, prior to the appointed date, has imported, exported or placed in the market medical devices shall, within twenty four months from the appointed date, apply for the registration of the medical devices under section 6.

(2) A person who, prior to the appointed date, has been importing, exporting or placing in the market medical devices and intend to continue importing, exporting or placing in the market such medical devices shall, within twelve months from the appointed date, apply for an establishment licence under section 16.

(3) A person referred to in subsection (1) or (2) may continue to import, export or place in the market the medical devices pending determination of its application for registration of a medical device or for an establishment licence, as the case may be.

DICETAK OLEH
PERCETAKAN NASIONAL MALAYSIA BERHAD,
KUALA LUMPUR
BAGI PIHAK DAN DENGAN PERINTAH KERAJAAN MALAYSIA