CIRCULAR LETTER OF THE MEDICAL DEVICE AUTHORITY
NO. 3 YEAR 2014

POLICY ON IMPLEMENTATION AND ENFORCEMENT UNDER THE MEDICAL DEVICE ACT 2012 (ACT 737):

EXEMPTION OF MEDICAL DEVICE FROM REGISTRATION REQUIREMENTS

PURPOSE

1) The purpose of this circular is to set the policy for implementation and enforcement under the medical device Act 2012 (Act 737) relating to exemption of medical device from registration under section 5 Act 737.

BACKGROUND

2) Section 5, Act 737 requires all medical devices to be registered before they can be imported, exported or placed in the market.

3) However, some medical devices are low risk, whilst some are custom-made devices needed for use by qualified medical practitioners for his patients or for use in emergency situations or in situations where all conventional treatments have failed, unavailable or unsuitable. Some devices are also only used for the purpose of clinical research, performance evaluation, demonstrations or education.

POLICY DECISION FOR IMPLEMENTATION AND ENFORCEMENT

4) Medical devices that are intended to be exempted from the registration requirements are low risk or only limited in its usage therefore it is possible to have a control by means of a notification.

5) Section 77 of Act 737 provides for the Minister to exempt any medical device from any provision of this Act, by order published in the Gazette if it is consistent with the purpose of this Act.

6) For the above reasons, the Medical Device Authority Meeting No. 2/2014 has decided to set the policy on implementation and enforcement as follows:

i) Exemption from registration requirements under the Medical Device Act 2012 (Act 737) for medical devices in the following categories subject to conditions to be imposed from time to time:
(a) Low-risk medical devices as listed in Appendix 1.
(b) Custom-made medical devices for the use of qualified medical practitioners for his patients.
(c) Medical devices for the use of qualified medical practitioners in emergency situations or in the events that all conventional treatment has failed, unavailable or unsuitable.
(d) Medical devices for the purpose of clinical research, performance evaluation, demonstration or education.

ii) Even though the medical devices are exempted from registration, Medical Device Authority shall be given notification before the medical device as specified in paragraph (i) are imported, exported or placed in the market.

iii) The exemption in paragraph (i) is made through administrative method before the exemption order is published in the Gazette.

USAGE AND EFFECTIVE DATE

7) Circular issued shall be used as part of requirements under Act 737 and this circular shall be effective from the date it is issued.

ENQUIRIES

8) Any enquiries relating to this Circular can be forwarded to:

Chief Executive
Medical Device Authority
Ministry of Health Malaysia
Level 5, Menara Prisma, No. 26
Jalan Persiaran Perdana, Presint 3
62675 Putrajaya, MALAYSIA
Tel: (+603) 8892 2400, Fax: (+603) 8892 2500
Email: mdb@mdb.gov.my

Thank you.

“BERKHIDMAT UNTUK NEGARA”

(Y. BHG. DATUK DR. NOOR HISHAM B ABDULLAH)
Chairman
Medical Device Authority
Ministry of Health Malaysia
Appendix 1 (Version 2)

Low-risk medical devices exempted from registration requirement under the Medical Device Act 2012 (Act 737)

All Class A medical devices that are non-active, non-sterile, and has no measuring function are considered to be low risk medical devices and are exempted from registration requirement.