



Our Ref : (28) dlm. MDA. 100-1/7/2

Date : 22 May 2018

**CIRCULAR LETTER OF THE MEDICAL DEVICE AUTHORITY
NO. 2 YEAR 2018**

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

**CONTROL OF ORPHANED, OBSOLETE AND DISCONTINUED MEDICAL DEVICE
IN HOSPITAL OR HEALTHCARE FACILITIES INSTITUTION**

PURPOSE

1) The purpose of this circular is to set the implementation and enforcement under the Medical Device Act 2012 (Act 737) relating to control of orphaned, obsolete and discontinued medical device in hospital or healthcare facilities institution in Malaysia.

BACKGROUND

- 2) Orphaned medical device means an existing medical device in a hospital or healthcare facilities institution that is not registered under this Act as it no longer has the manufacturer or authorized representative to register the medical device.
- 3) Obsolete medical device means outdated medical device, or no longer used due to design changes, evolution of new technologies and etc.
- 4) Discontinued medical device means medical device that is no longer available or being produced.
- 5) Section 5(1) no medical device shall be imported, exported or placed in the market unless the medical device is registered under this Act.
- 6) Section 5(2) any person who contravenes section 5(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.

7) All medical devices must be registered before being imported, exported or placed in Malaysian market. However, there are orphaned, obsolete and discontinued medical devices in hospitals or healthcare facilities institution not registered under this Act. Therefore, there is a need to develop a policy to control this medical device to meet the requirements in accordance with the purposes of this Act.

POLICY DECISION FOR IMPLEMENTATION AND ENFORCEMENT

8) **The Medical Device Authority Meeting No 1/2018 has decided to set the implementation and enforcement control of orphaned, obsolete and discontinued medical device in hospital or healthcare facilities institution as follows:**

- a) **Healthcare facilities institution which have orphaned medical devices shall identify and provide the notification / listing to the Medical Device Authority.**
- b) **The risk of using orphaned, obsolete and discontinued medical device prior to the effective date of Act 737 is under the liability of users and healthcare facilities institution.**
- c) **Any medical device placed in the market after the effective date of Act 737 and continues to be marketed is required to be registered under the Act.**

USAGE AND EFFECTIVE DATE

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

ENQUIRIES

10) Any enquiries relating to this circular can be forwarded to:

Chief Executive
Medical Device Authority
Ministry of Health Malaysia
Level 6, Prima 9, Prima Avenue II,
Block 3547, Persiaran Apec,
63000 Cyberjaya, Selangor, MALAYSIA
Tel.: (+603) 8230 0300, Fax: (+603) 8230 0200
Email: mdb@mdb.gov.my

Thank you

"BERKHIDMAT UNTUK NEGARA"



(YBHG. DATUK DR NOOR HISHAM BIN ABDULLAH)
Chairman
Medical Device Authority
Ministry of Health Malaysia