PIHAK BERKUASA PERANTI PERUBATAN
Medical Device Authority
KEMENTERIAN KESIHATAN MALAYSIA
Ministry of Health Malaysia

Our Ref : (42) dlm. MDA. 100-1/7/2
Date : 22 July 2019

CIRCULAR LETTER OF THE MEDICAL DEVICE AUTHORITY NO. 2 YEAR 2018 (REVISION 1)

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

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

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, healthcare facilities institution or any related facilities in Malaysia.

BACKGROUND

2) Orphaned medical device means an existing medical device in a hospital, healthcare facilities institution or any related facilities 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3) Obsolete medical device means outdated medical device, or no longer used due to design changes, evolution of new technologies and etc.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 distributed in the market or no longer 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) Section 15 (1) states that no establishment shall import, export or place in the market any registered medical device unless it holds an establishment licence granted under this Act.

8) Section 77, Act 737, states that, 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.

9) 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 which is not registered and still being used. Some of these medical devices can not be registered because the technical documentation of the medical device is unavailable and unable to comply with registration requirements.

10) Therefore, to impose certain controls to the healthcare facilities institution that are still continue to use such medical devices, as well as ensure that medical services in hospital or healthcare facilities institution are uninterrupted, there is a need to develop a policy to control this medical device.

POLICY DECISION FOR IMPLEMENTATION AND ENFORCEMENT

11) **The Medical Device Authority Meeting No 3/2019 has decided to set the implementation and enforcement control of orphaned, obsolete and discontinued medical device in hospital, healthcare facilities institution or any related facilities as follows:**

a) **An orphaned, obsolete and discontinued medical device is exempted from medical device registration and establishment licence requirement;**

b) **Establishment or healthcare facilities institution which have orphaned, obsolete or discontinued medical devices shall identify and provide the notification / listing to the Medical Device Authority.**

c) **The risk of using orphaned, obsolete and discontinued medical device is under the responsibility of establishment, users and healthcare facilities institution.**

d) **Establishment shall be responsible for post-market issues on any obsolete or discontinued medical device at least in accordance with the projected useful life of the medical device as determined by the manufacturer; and**

e) **Compliance with notification requirement with certain charges as may be specified by the Authority.**

12) **This exemption is implemented administratively before order is published in the Gazette.**

USAGE AND EFFECTIVE DATE

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

ENQUIRIES

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

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Medical Device Authority
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Block 3547, Persiaran Apec,
63000 Cyberjaya, Selangor, MALAYSIA
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Thank you

"BERKHIDMAT UNTUK NEGARA"

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