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

Our Ref : (13) dlm. MDA. 100-1/7/2
Date : 8 August 2016

CIRCULAR LETTER OF THE MEDICAL DEVICE AUTHORITY NO. 3 YEAR 2016

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

CHANGE OF OWNERSHIP FOR MEDICAL DEVICE REGISTRATION

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 change of ownership for medical device registration in Malaysia.

BACKGROUND

2) Section 5(1) Act 737, no medical device shall be imported, exported or placed in the market unless the medical device is registered under this Act.

3) Section 6(1) requires an application for the registration of a medical device shall be made by an establishment to the Authority in the prescribed manner. In this context, the registration of medical device is the responsibility of local manufacturer or an authorized representative (AR) appointed by manufacturer having a principle place of business outside Malaysia.

4) Example of change ownership of medical device registration as follows:
- Manufacturer outside Malaysia who has set up a company in Malaysia and intends to obtain the ownership of medical device registration from AR.
- Replacing of existing AR to new AR by the manufacturer to place the medical device in the market
- Merging and acquisition activities
- Existing AR closed its business

5) Control over the change of ownership for medical device registration should be developed to encourage industries outside Malaysia doing business in Malaysia and assist the development of industry in the country and ensure the safety and effective of medical devices to users.

POLICY DECISION FOR IMPLEMENTATION AND ENFORCEMENT

6) **The Medical Device Authority Meeting No. 3/2016 has decided to allow Change of ownership for medical device registration with certain charges as may be specified by the Authority.**

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:

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Medical Device Authority
Ministry of Health Malaysia
Level 5, Menara Prisma, No. 26
Jalan Persiaran Perdana, Presint 3
62675 Putrajaya, MALAYSIA
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Thank you.

"BERKHIDMAT UNTUK NEGARA"

(YBHG. DATUK DR NOOR HISHAM BIN ABDULLAH)
Chairman
Medical Device Authority
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