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

Our Ref : (14) dlm. MDA. 100-1/7/2
Date : 5 August 2016

CIRCULAR LETTER OF THE MEDICAL DEVICE AUTHORITY NO. 4 YEAR 2016

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

TRANSITION PERIOD FOR MEDICAL DEVICE LABELING

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 transition period for medical device labeling in Malaysia.

BACKGROUND

2) Section 4(c) Medical Device Act 2012 (Act 737) requires a manufacturer to ensure that a medical device is labelled, packaged and marked in accordance with the prescibed manner.

3) Regulation 16(1) a manufacturer who –

(a) places any registered medical device in the market;
(b) uses or operates any registered medical device to another person; or
(c) uses or operates any registered medical device to another person for the purpose of any investigational testing,

shall ensure that the medical device is appropriately labelled according to labelling requirements as specified in Sixth Schedule Medical Device Regulation 2012.

4) The transitional period will assist industry in reducing the implementation cost of existing medical devices labeling in the market before compliance with the labeling requirements.

POLICY DECISION FOR IMPLEMENTATION AND ENFORCEMENT

5) **The Medical Device Authority Meeting No. 3/2016 has decided for implementation of a transitional period of two (2) years for establishment to comply with labeling requirements in accordance with the Sixth Schedule of the**

Medical Device Regulation 2012. The existing labeling shall be applied in the transition period.

USAGE AND EFFECTIVE DATE

6) 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

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

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Medical Device Authority
Ministry of Health Malaysia
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Jalan Persiaran Perdana, Presint 3
62675 Putrajaya, MALAYSIA
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Thank you.

"BERKHIDMAT UNTUK NEGARA"

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