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

Our Ref : (1) dlm. MDA. 100-1/7/2
Date : 6 April 2015

CIRCULAR LETTER OF THE MEDICAL DEVICE AUTHORITY NO. 7 YEAR 2015

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

FAST TRACK MEDICAL DEVICE REGISTRATION DURING TRANSITION PERIOD

PURPOSE

1) The purpose of this circular is to set the policy for implemention and enforcement under the Medical Device Act 2012 (Act 737) for fast track medical device registration during the transition period which is until 30 June 2015.

BACKGROUND

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

3) Section 7 of Act 737 also specifies that the Authority may register medical device upon receipt of application, and the Authority is satisfied that the medical device has undergone conformity assessment procedures conducted by a Conformity Assessment Body (CAB).

4) In accordance with Section 8(a) and (b), Act 737, the Authority may, at any time – impose any additional conditions on the registration of a medical device; or vary or revoke any of the conditions imposed on the registration of a medical device.

5) In accordance with Section 80(1) of Act also mentioned that a person who, prior to the appointed date, has imported, exported or placed in the market medical device shall, within twenty four months from the appointed date, apply for the registration of the medical devices.

6) To facilitate the establishment for expediting the registration of medical device, Medical Device Authority (MDA) has decided to implement the fast track registration.

POLICY DECISION FOR IMPLEMENTATION AND ENFORCEMENT

7) **The Medical Device Authority Meeting No. 1/2015 has decided to set a policy for implementation and enforcement to enable fast track registation during the transitional period which is until 30 June 2015 as follows:**

i) **Medical device that has obtained registration approval from at least one of five (5) reference countries (United States, Europe, Canada, Japan and Australia); or**

ii) **Medical device that has been registered in any country other than specified in 7(i) with additional conditions to be determined by MDA; or**

iii) **Class A medical device (sterile, active and has measuring function) which has not been registered in any country as specified in 7(i) and(ii);**

8) **Which comply with the following conditions:**

i) **Conformity assessment under Part II Regulation 4 of Medical Device Regulation 2012 shall be conducted by a CAB and the establishment shall obtain the certificate of conformity within five (5) years from 1 July 2015; and**

ii) **Establishment who has not obtained conformity assessment for medical device shall appoint a Conformity Assessment Body (CAB) within three (3) years from 1 July 2015 ; and**

iii) **The adequacy of the Declaration of Conformity (DOC) shall be reviewed and confirmed by the CAB within five (5) years in accordance with Item 9 Part III of Third Schedule of Medical Device Regulations 2012; and**

iv) **The establishment shall report to the Authority any on-going incident related to medical device during application for registration.**

9) **Registration of medical device will be cancelled / registration certificate will be suspended / revoked if:**

i) **The medical device detected or reported to be unsafe; or**

ii) **There is non-compliance to the conditions in 8(i), 8(ii), 8(iii) and 8(iv)**

10) **Registration of medical device will be put on-hold in the event of occurrence of any on-going incidents. Registration will only be considered after corrective / preventive actions have been taken.**

11) **The Authority may order the establishment to recall any medical device at any time due to patient safety and public health in accordance to Section 42 (4) Act 737.**

12) **Fast track registration of medical device is implemented through administrative method before order is published in the Gazette.**

USAGE AND EFFECTIVE DATE

13) This circular issued shall be used as part of the requirements under Act 737 and this circular shall be effective from the date it is issued. Any application for fast track medical device registration after transition period which is 30 June 2015 is not acceptable.

ENQUIRIES

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

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Medical Device Authority
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62675 Putrajaya, MALAYSIA
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Thank you.

"BERKHIDMAT UNTUK NEGARA"

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