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

Our Ref : (30) dlm. MDA. 100-1/7/2
Date : 22 May 2018

CIRCULAR LETTER OF THE MEDICAL DEVICE AUTHORITY NO. 3 YEAR 2018

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

RECOGNITION AND LISTING OF INSTITUTE OR LABORATORY WHICH IS CAPABLE TO CARRYING OUT CLINICAL EVIDENCE OR PERFORMANCE EVALUATION FOR THE PURPOSE OF CONFORMITY ASSESSMENT

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 the recognition and listing of Institute or laboratory which is capable of carrying out and providing data or report of clinical evidence or performance evaluation of medical device. This further data or report may be used for conformity assessment by Conformity Assessment Bodies for the purpose of medical device registration.

BACKGROUND

2) Regulation 4(1) of Medical Device Regulation 2012, all medical device shall be subjected to conformity assessment to demostrate its conformity to the requirement of medical device law.

3) Regulation 4(2) requires the manufacturer to collect all evidence of conformity and, depending on the class of a medical device, shall appoint a conformity assessment body registered by Authority under Section 10 of the Act to conduct the assessment on the conformity.

4) Regulations 4(3) requires, upon completion of the conformity assessment, and if the conformity assessment body is satisfied that all the requirements have been fulfilled, the conformity assessment body shall issue a report and certificate of conformity to the establishment.

5) In accordance with Clause 5(1) in Third Schedule (Conformity Assessment Procedure) of the Medical Devices Regulation 2012, conformity assessment for the purpose of registration of a medical device shall comprise of the following elements:

(a) conformity assessment on quality management system;

(b) conformity assessment on post-market surveillance system;

(c) conformity assessment on technical documentation; and

(d) declaration of conformity

6) One of the conformity assessment for the purpose of medical device registration is the conformity assessment of technical documentation. The manufacturer shall collect and examine evidence and undertake procedures to determine conformity of a medical device to essential principles of safety and performance. One of the essential principles of safety and performance is data or report of clinical evidence / performance evaluation to be obtained to support the performance evaluation of medical device.

7) Currently, there are conformity assessment service with good quality and also comparable to global assessments or test carried out by local laboratories. This recognition and listing indirectly introduces and promotes local laboratories to the medical device industry.

8) This recognition is one of the initiatives to facilitate the establishment to reduce cost and time to gather clinical evidence or performance evaluation of medical devices compared to overseas.

9) This approach will also facilitate the local institutions or laboratories in its development, financial growth and recognition not only in Malaysia, but also globally.

POLICY DECISION FOR IMPLEMENTATION AND ENFORCEMENT

10) **The Medical Device Authority Meeting No. 2/2018 has decided to set the implementation and enforcement as follows:**

a) Recognize and listing Institute or laboratory which is capable of carrying out clinical evidence or performance evaluation for conformity assessment by Conformity Assessment Bodies for the purpose of medical device registration; and

b) Subject to such conditions as may be specified by the Authority.

USAGE AND EFFECTIVE DATE

11) 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

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

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Ministry of Health 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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