



Our Ref : (15) dlm. MDA. 100-1/7/2

Date : 8 August 2016

**CIRCULAR LETTER OF THE MEDICAL DEVICE AUTHORITY
NO. 5 YEAR 2016**

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

IMPOSITION OF CHARGES OR FEES FOR PRODUCT CLASSIFICATION

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 imposition of charges or fees for product classification in Malaysia.

BACKGROUND

2) Section 3(1) Act 737, a medical device shall be classified by an establishment based on the level of risk it poses, its intended use and the vulnerability of the human body in accordance with the prescribed manner.

3) Section 3(2) in the event of any dispute between an establishment and a conformity assessment body over a classification of a medical device, the matter shall be referred to the Authority, in the manner and within such period as may be specified by the Authority, for its decision.

4) Increased demand for product classification, indirectly has led to increased costs, time and labor for services rendered.

5) Medical Device Authority Act 2012 (Act 738) provides for Section 12(f) to impose fees or charges for services rendered by the Authority.

POLICY DECISION FOR IMPLEMENTATION AND ENFORCEMENT

6) **The Medical Device Authority Meeting No. 3/2016 has decided to set the policy for implementation and enforcement for product classification as follows:**

- i) **Charges of RM 300 / application;**
- ii) **A transitional period of 3 months is given prior to the charging of applications referred in (i).**

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:

Chief Executive
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
Ministry of Health Malaysia