



Our Ref : (46) dlm. MDA. 100-1/7/2

Date : 20th May 2020

**CIRCULAR LETTER OF THE MEDICAL DEVICE AUTHORITY
NO. 1 YEAR 2020**

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

TRANSITION PERIOD FOR MEDICAL DEVICE ADVERTISEMENT

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 establishment to comply with the advertising requirement for Medical Device in Malaysia.

BACKGROUND

2) Medical Device (Advertising) Regulation 2019 was gazetted on 15th November 2019 and will come into operation on 1st July 2020. However, there are some implementation issues that require more time to be resolved and require extension of the implementation date of this regulation.

3) The transition period will assist the industry and the MDA to specify the details for the implementation of the Medical Device (Advertising) Regulation 2019.

POLICY DECISION FOR IMPLEMENTATION AND ENFORCEMENT

4) **The Medical Device Authority has decided for implementation of a transitional period of 18 months (commencing from 1st July 2020 until 31st December 2021) for the implementation of Medical Device (Advertising) Regulation 2019.**

- 5) This transition period is implemented administratively before the Medical Device (Advertising) Regulation 2019 is revised.

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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Thank you.

"BERKHIDMAT UNTUK NEGARA"


(DATUK DR. NOOR HISHAM BIN ABDULLAH)

Chairman
Medical Device Authority
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