

ADVISORY NOTE

Advertising of Medical Device

INTRODUCTION

The Medical Device Act 2012 (Act 737) has now been enforced as the transitional phase for registration comes to an end post June 2016. Therefore, The Medical Device Authority (MDA) is currently working towards establishing a comprehensive guideline for advertisement of medical device to facilitate the public.

ADVERTISING UNDER MEDICAL DEVICE ACT 2012 (ACT 737)

Based on Act 737, Section 44 states that “(1) No person shall advertise a medical device unless the medical device has been registered and complied with the requirements of this Act.” Moreover, Section 44(2) further states that “No person shall make any misleading or fraudulent claims in respect of a medical device in any advertisement”

OFFENCES AND PENALTIES UNDER ACT 737

Pursuant to Section 44(3) of Act 737, any person who contravenes subsection (1) or (2) commits an offence and shall, on, conviction, be liable to a fine not exceeding **RM300,000** or to imprisonment for a term not exceeding **3 YEARS** or to both.

ADVISE BY MEDICAL DEVICE AUTHORITY

Members of the public are therefore be reminded to take extra precautions with regards to representations and advertisements made by the unscrupulous parties that certain medical devices are encouraged and permissible by MDA.

Industry players are also be advised not to advertised its device unless the requirements under Section 44 has been complied with. Failure to comply will result in enforcement action being taken.

For more information, please contact:

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