CIRCULAR LETTER OF THE MEDICAL DEVICE AUTHORITY

NO. 3 YEAR 2017 (REVISION 1)

IMPLEMENTATION AND ENFORCEMENT OF GUIDELINE FOR REGISTRATION OF DRUG-MEDICAL DEVICE AND MEDICAL DEVICE-DRUG COMBINATIONS PRODUCTS

This Circular Letter was prepared by the Medical Device Authority (MDA) to facilitate the stakeholder and industry in the implementation of Medical Device Act (Act 737) Medical Device Act (Act 737) and the regulations under it.

This Circular Letter shall be read in conjunction with the current laws and regulations used in Malaysia, which include but not limited to the following;

a) Medical Device Act 2012 (Act 737); and

b) Medical Device Regulations 2012;

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In view of the problems faced by stakeholders, and an effort to facilitate the industry, Medical Device Authority (MDA) has taken into account the issues raised. After much deliberation the Authority has decided to alleviate and remove all obstacles in the implementation of Medical Device Act (Act 737) as part of our continued role in facilitating the industry.

We are pleased to inform that MDA has decided on new policies to facilitate the stakeholder and industry in the implementation of Medical Device Act (Act 737).

The policies are as follows:

NO	TITLE	LANGUAGE
1 / 2014	Establishment As Authorised Representative And Establishment Undertaking Multiple Activities	Malay / English
2 / 2014	Conformity Assessment Procedures For Medical Device Approved By Recognised Countries	Malay / English
3 / 2014	Exemption Of Medical Device From Registration Requirements *Note:The Circular Letter will* ***no longer effective.*** Please Refer to **Medical Device Exemption 2016**	Malay / English
4 / 2014	Medical Device For The Purpose Of Export And Transit And Medical Device For Import/Export From/To Countries Without Diplomatic Ties With Malaysia	Malay / English
5 / 2014	Certification Of Good Manufacturing Practice (GMP) For The Purpose Of Obtaining Establishment License	Malay / English
1 / 2016	Refurbishment of Medical Device	Malay / English
2 / 2016	Medical Device Procurement For Healthcare Institution	Malay
3 / 2016	Change Of Ownership For Medical Device Registration	Malay / English
4 / 2016	Transition Period For Medical Device Labeling	Malay / English
5 / 2016	Imposition Of Charges Or Fees For Product Classification	Malay / English
1 / 2017	Registration Requirement And Exemption From Labelling For Export Only Medical Device	Malay / English
2 / 2017	National Preparation To Ratify Minamata Convention On Mercury	Malay / English
3 / 2017	Implementation And Enforcement Of Guideline For Registration Of Drug-Medical Device And Medical Device-Drug Combinations Products	Malay / English
4 / 2017	Recognition Of Institute For Medical Research (IMR) To Provide The Report Or Data Of Clinical Evidence Or Performance Evaluation For The Purpose Of Conformity Assessment By Conformity Assessment Body	Malay / English

These circulars shall take effect immediately.