FRAMEWORK IN REGULATING MEDICAL DEVICE IN MALAYSIA

CONFORMITY ASSESSMENT
- Quality Management System (ISO 13485)
- Post Market Surveillance System
- Technical Documentation
- Declaration of Conformity

MEDICAL DEVICE REGISTRATION
- Assurance of safety & performance of medical device
- Marketing approval

SURVEILLANCE & VIGILANCE
- Monitoring of safety & performance of medical device
- Carry out post-market obligations (complaint handling, incident reporting, Field Corrective Action (FCA), recall)

PRE-MARKET | **PLACEMENT ON-MARKET** | **POST-MARKET**

CAB verifies evidence of conformity

ESTABLISHMENT LICENSING
- Compliance to Good Distribution Practice (GDP) & advertising requirements
- Approval to import / export / distribute medical devices

USAGE & MAINTENANCE
- Use, maintain & dispose off medical devices appropriately
- Apply for permit to use/operate designated medical devices

Monitoring by MDA

Home / Documents / Legislation

Legislation
Circular Letter
Guidance Document
Guideline
Standard
Annual Report
Strategic Plan
Slide Presentation

Legislations

List of legislations:

No	Legislation		Date of Gazette	Version
1	Medical Device Act 2012		09/02/2012	BM / English
2	Medical Device Authority Act 2012	Act 738	09/02/2012	BM / English
3	Medical Device Regulations 2012	P.U. (A) 500	31/12/2012	BM / English
4	Appointment of Date of Coming into Operation	P.U. (B) 73	15/03/2012	BM / English
5	Appointment of Date of Coming into Operation	P.U. (B) 126	22/04/2013	BM / English
6	Medical Device (Exemption) Order 2015	P.U. (A) 135	30/06/2015	BM / English
7	Medical Device (Exemption) Order 2016	P.U. (A) 103	18/04/2016	BM / English
8	Medical Device (Declaration) Order 2017	P.U. (A) 339	07/11/2017	BM / English