MEDICAL DEVICE ACT 2012 (ACT 737)
Consists of 80 Sections and divided into 6 parts:

PART 1:
PRELIMINARY
Interpretation

PART II:

REGISTRATION OF MEDICAL DEVICE AND CONFORMITY ASSESSMENT BODY

Chap 1: Registration of medical device

Chap 2: Registration of conformity assessment body

PART III:

LICENSE AND PERMIT

Chap 1:Establishment licence

Chap 2:Dmd

Chap 3:Duties & obligation of licensees & permit holders ;provide requirements for POST MARKET-

Chap 4:General duties; specify the requirement on usage, operation, maintenance of medical devices & advertising of medical device

Part IV: APPEAL

provides requirements for APPEAL against decision of authority

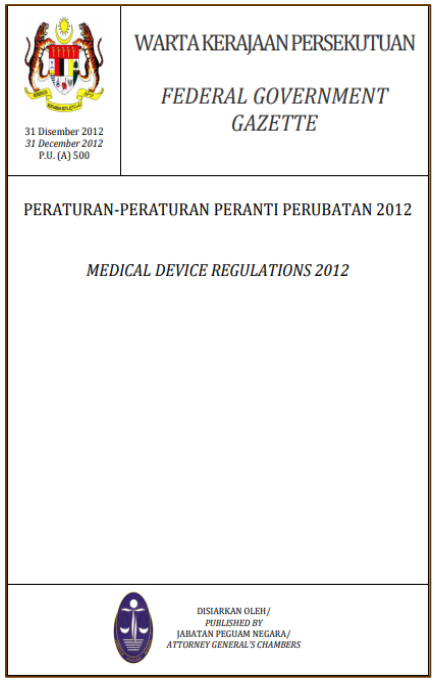
PART V: ENFORCEMENT

Section 48 – Section 66: provides requirements for enforcement activities

PART VI: GENERAL

Section 67 – Section 80 : provides general requirements in relation to the provision of the Act (Section 80 - Saving and transitional)

PHASE 1: PU(A) 500


WARTA KERAJAAN PERSEKUTUAN

FEDERAL GOVERNMENT GAZETTE

31 Disember 2012
31 December 2012
P.U. (A) 500

PERATURAN-PERATURAN PERANTI PERUBATAN 2012

MEDICAL DEVICE REGULATIONS 2012

DISIARKAN OLEH /
PUBLISHED BY
JABATAN PEGUAM NEGARA/
ATTORNEY GENERAL'S CHAMBERS

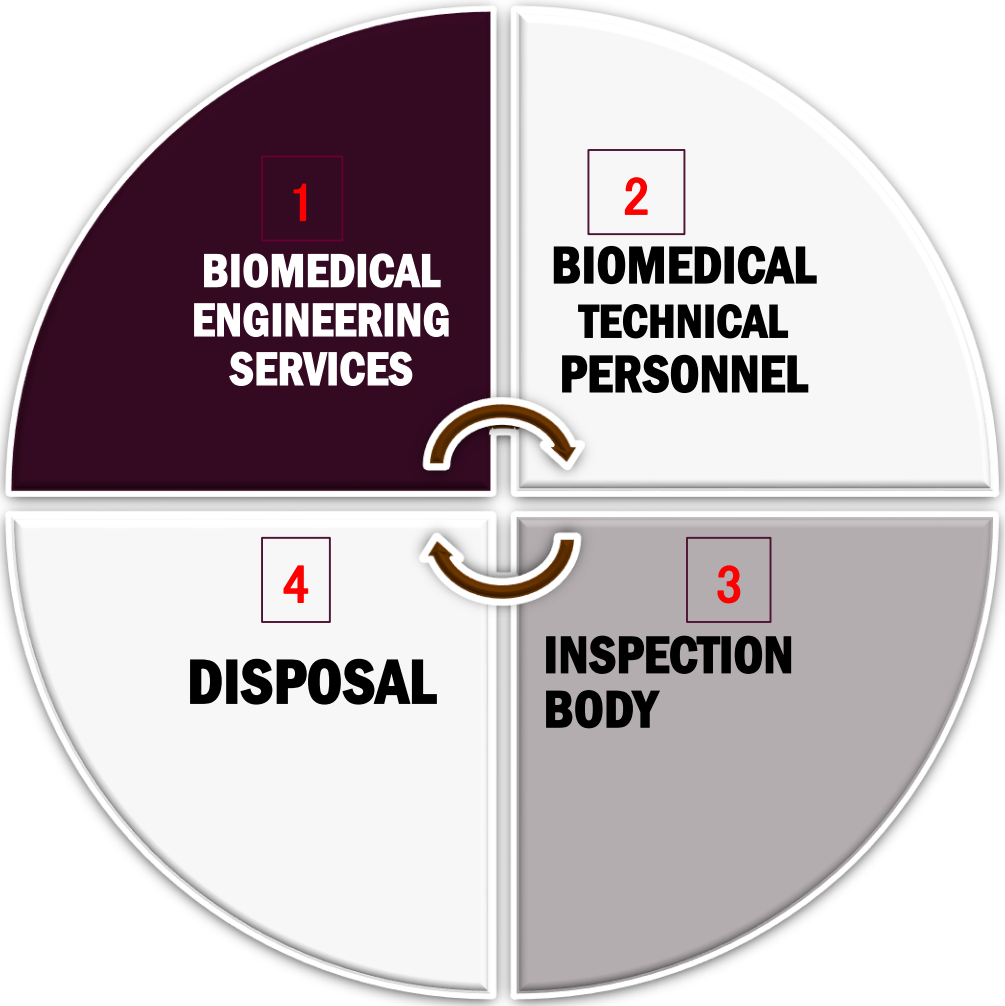
MEDICAL DEVICE REGULATION 2012: EFFECTIVE 1 JULY 2013

- Medical device registration under Section 5 of Act 737
- Establishment licensing under Section 15 of Act 737
- Registration of Conformity Assessment Body under Section 10 of Act 737

PHASE 2

- **PU(A) 317**: MEDICAL DEVICE (ADVERTISING) REGULATIONS 2019 EFFECTIVE DATE 1 JULY 2020
- **PU(A) 318**: MEDICAL DEVICE(DUTIES AND OBLIGATION OF ESTABLISHMENTS) REGULATIONS 2019 EFFECTIVE DATE 1 JULY 2020

PHASE 3 (SECTION 43)
REGULATION ON USAGE, OPERATION, INSTALLATION, TEST, COMMISSION, MAINTENANCE



PHASE 4 (SECTION 26-36)
REGULATION ON DESIGNATED MEDICAL DEVICE (DMD)

REGISTERED MEDICAL DEVICES-

- risk level
- exposure to public health
- patient safety
- degree of complexities

PERMIT TO USE DMD

- COMPETENT USER
- LOCATION/LAYOUT PLAN OF THE PREMISES/ROOM
- TC CERTIFIICATE & REPORT