Reference Number: **(48) MDA.600-1/1/18 JILID 3**
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CAB REGISTRATION NUMBER: **MDA/CAB-020**
VALIDITY: **04/04/2019 – 03/04/2022**

SCOPE OF REGISTRATION

Conformity Assessment of Quality Management System (QMS) and Post-Market Surveillance System (PMSS)		
1	ISO 13485	Quality Management System for Medical Devices – Requirements for Regulatory Purpose
2	GDPMD	Good Distribution Practice for Medical Devices

Conformity Assessment of Technical Documentation		
3	MD 0101	Non-active devices for anesthesia, emergency and intensive care
4	MD 0102	Non-active devices for injection, infusion, transfusion and dialysis
5	MD 0104	Non-active medical devices with measuring function
6	MD 0106	Non-active instruments
7	MD 0107	Contraceptive medical devices
8	MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
9	MD 0109	Non-active devices for in vitro fertilization (IVF) and assisted reproductive technologies (ART)
10	MD 0301	Bandages and wound dressings
11	**MD 1402	Devices utilizing non-ionizing radiation
12	IVD 0309	Device for self-diagnosis: device for the measurement of blood sugar
13	IVD 0404	Molecular biology
14	IVD 0405	Pregnancy and ovulation
15	IVD 0406	Specimen receptacles
16	MDS 7206	IVDs in sterile condition
17	MDS 7210	IVDs utilizing material of human origin

Conformity Assessment by Way of Verification		
18	VERIFICATION	Conformity Assessment by Way of Verification

** means approval only for conformity assessment on aesthetics medical devices.

< End of List >

Section 10(1), Medical Device Act 2012 (Act 737) and Regulation 8, Medical Device Regulations 2012