Reference Number: **(1) MDA.600-1/1/18 JILID 4**
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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 0103	Non-active orthopaedic and rehabilitation devices
6	MD 0104	Non-active medical devices with measuring function
7	MD 0106	Non-active instruments
8	MD 0107	Contraceptive medical devices
9	MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
10	MD 0109	Non-active devices for in vitro fertilization (IVF) and assisted reproductive technologies (ART)
11	MD 0301	Bandages and wound dressings
12	MD 0401	Non-active dental equipment and instruments
13	**MD 1402	Devices utilizing non-ionizing radiation
14	MD 1101	Devices for extra-corporal circulation, infusion and haemopheresis
15	MD 1102	Respiratory devices, including hyperbaric chambers for oxygen therapy, inhalation anaesthesia
16	MD 1103	Devices for stimulation or inhibition
17	MD 1104	Active surgical devices
18	MD 1106	Active dental devices
19	MD 1108	Active rehabilitation devices and active prostheses
20	MD 1109	Active devices for patient positioning and transport
21	MD 1301	Monitoring devices of non-vital physiological parameters
22	MD 1302	Monitoring devices of vital physiological parameters
23	MD 1403	Devices for hyperthermia / hypothermia
24	MD 1404	Devices for (extracorporeal) shock-wave therapy (lithotripsy)
25	IVD 0309	Device for self-diagnosis: device for the measurement of blood sugar
26	IVD 0403	Immunology
27	IVD 0404	Molecular biology
28	IVD 0405	Pregnancy and ovulation
29	IVD 0406	Specimen receptacles
30	MDS 7206	IVDs in sterile condition
31	MDS 7210	IVDs utilizing material of human origin

Conformity Assessment by Way of Verification		
32	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