Reference Number: **(6) MDA.600-1/1/18 JILID 5**
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CAB REGISTRATION NUMBER: **MDA/CAB-017**
VALIDITY: **14/04/2020 – 13/04/2023**

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 0104	Non-active medical devices with measuring function
4	MD 0106	Non-active instruments
5	MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
6	IVD 0101	AB0 system
7	IVD 0102	Rhesus (C, c, D, E, e)
8	IVD 0103	Anti-Kell
9	IVD 0201	HIV infection (HIV 1 and 2)
10	IVD 0203	Hepatitis B, C and D
11	IVD 0309	Device for self-diagnosis: device for the measurement of blood sugar
12	IVD 0401	Clinical chemistry
13	IVD 0403	Immunology
14	IVD 0404	Molecular biology
15	IVD 0405	Pregnancy and ovulation

Conformity Assessment by Way of Verification		
16	VERIFICATION	Conformity Assessment by Way of Verification

< End of List >

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