Reference Number: **(9) MDA.600-1/1/18 JILID 5**
Revision Date: **NOVEMBER 16, 2022**

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CAB REGISTRATION NUMBER: **MDA/CAB-002**
VALIDITY: **21/11/2022 – 20/11/2025**

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 1111	Software
4	MD 1201	Imaging devices utilizing ionizing radiation
5	MD 1202	Imaging devices utilizing non-ionizing radiation
6	MD 1302	Monitoring devices of vital physiological parameters
7	MD 1402	Devices utilizing non-ionizing radiation

Conformity Assessment by Way of Verification		
8	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