

**DQS CERTIFICATION (M) SDN. BHD.**

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CAB REGISTRATION NUMBER: **MDA/CAB-006**
VALIDITY: **12/09/2020 - 11/09/2023**

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 0101	Non-active devices for anesthesia, emergency and intensive care
4	MD 0102	Non-active devices for injection, infusion, transfusion and dialysis
5	MD 0107	Contraceptive medical devices
6	MD 0301	Bandages and wound dressings
7	MD 1101	Devices for extra-corporal circulation, infusion and haemopheresis
8	MD 1102	Respiratory devices, including hyperbaric chambers for oxygen therapy, inhalation anaesthesia
9	MD 1104	Active surgical devices
10	MD 1105	Active ophthalmologic devices
11	MD 1106	Active dental devices
12	MD 1107	Active devices for disinfection and sterilisation
13	MD 1201	Imaging devices utilising ionizing radiation
14	MD 1301	Monitoring devices of non-vital physiological parameters
15	MD 1302	Monitoring devices of vital physiological parameters
16	IVD 0404	Molecular biology
17	IVD 0405	Pregnancy and ovulation

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

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