



**CARE CERTIFICATION INTERNATIONAL (M) SDN. BHD.**  
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CAB REGISTRATION NUMBER: **MDA/CAB-009**  
VALIDITY: **12/02/2018 - 11/02/2021**

#### 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 0103	Non-active orthopaedic and rehabilitation devices
4	MD 0106	Non-active instruments
5	MD 0202	Non-active orthopaedic implants
6	MD 0107	Contraceptive medical devices
7	MD 1101	Devices for extra-corporal circulation, infusion and haemopheresis
8	MD 1102	Respiratory devices, including hyperbaric chambers for oxygen therapy, inhalation anesthesia
9	MD 1202	Imaging devices utilizing non-ionizing radiation
10	MD 1302	Monitoring devices of vital physiological parameters

  

Conformity Assessment by Way of Verification		
11	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**