



CARE CERTIFICATION INTERNATIONAL (M) SDN. BHD.
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CAB REGISTRATION NUMBER: **MDA/CAB-009**
VALIDITY: **12/02/2021 - 11/02/2024**

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 1101	Devices for extra-corporal circulation, infusion and haemopheresis
7	MD 1102	Respiratory devices, including hyperbaric chambers for oxygen therapy, inhalation anesthesia
8	MD 1202	Imaging devices utilizing non-ionizing radiation
9	MD 1302	Monitoring devices of vital physiological parameters
10	IVD 0402	Haematology
11	IVD 0403	Immunology

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

MDA Website: www.mda.gov.my • Email Address: cab.registration@mdb.gov.my