



CI INTERNATIONAL CERTIFICATION SDN. BHD.

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CAB REGISTRATION NUMBER: **MDA/CAB-012**
VALIDITY: **10/04/2018 - 09/04/2021**

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 0107	Contraceptive medical devices
6	MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
7	MD 0202	Non-active orthopaedic implants
8	MD 0401	Non-active dental equipment and instruments
9	MD 0403	Dental implants
10	MD 1111	Software

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