

NEWERA INTERNATIONAL CERTIFICATION SDN. BHD.

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CAB REGISTRATION NUMBER: **MDA/CAB-018**
 VALIDITY: **18/12/2020 - 17/12/2023**

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	GDPM	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 0403	Dental implants

Conformity Assessment by Way of Verification		
7	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