

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



NEWERA INTERNATIONAL CERTIFICATION SDN. BHD.

PS-01-16 WISMA PJ5 SOHO
NO. 4B JALAN SS5D/6, KELANA JAYA
47301 PETALING JAYA
SELANGOR DARUL EHSAN
TEL: **+603-7498 4456**
FAX: **+603-7498 4456**

PERSON RESPONSIBLE:
MR. JIMMY FOO SAIK KIN
[marketing@neweracert.com]

CONTACT PERSON:
MR. JIMMY FOO SAIK KIN
[marketing@neweracert.com]

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 0403	Dental implants

Conformity Assessment by Way of Verification		
7	VERIFICATION	Conformity Assessment by Way of Verification

< End of List >

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