MEDCERT MALAYSIA SDN. BHD.
NO. 18 3RD FLOOR
JALAN SS19/1D
47500 SUBANG JAYA
SELANGOR DARUL EHSAN
TEL: **+603-5131 4773**
FAX: **+603-5124 7688**

PERSON RESPONSIBLE:
MR. SIEW YEW KONG
[siew.kong@medcert.de]

CONTACT PERSON:
MR. SIEW YEW KONG
[siew.kong@medcert.de]

CAB REGISTRATION NUMBER: **MDA/CAB-002**
VALIDITY: **21/11/2019 – 20/11/2022**

SCOPE OF REGISTRATION

Conformity Assessment of Quality Management System (QMS) and Post-Market Surveillance System (PMSS)		
1	GDPMD	Good Distribution Practice for Medical Devices

Conformity Assessment of Technical Documentation		
2	MD 0101	Non-active devices for anesthesia, emergency and intensive care
3	MD 0102	Non-active devices for injection, infusion, transfusion and dialysis
4	MD 0104	Non-active medical devices with measuring function
5	MD 0105	Non-active ophthalmologic devices
6	MD 0106	Non-active instruments
7	MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
8	MD 0202	Non-active orthopaedic implants
9	MD 0301	Bandages and wound dressings
10	MD 0303	Other medical devices for wound care
11	MD 0401	Non-active dental equipment and instruments
12	MD 0402	Dental materials
13	MD 1111	Software
14	MD 1201	Imaging devices utilizing ionizing radiation
15	MD 1202	Imaging devices utilizing non-ionizing radiation
16	MD 1302	Monitoring devices of vital physiological parameters
17	MD 1402	Devices utilizing non-ionizing radiation

Conformity Assessment by Way of Verification		
18	VERIFICATION	Conformity Assessment by Way of Verification

< End of List >

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