DQS CERTIFICATION (M) SDN. BHD.
SUITE 43-3, SETIA AVENUE
SU13/S SETIA ALAM
40170 SHAH ALAM
SELANGOR DARUL EHSAN
TEL: **+603-3342 3259**
FAX: **+603-3358 3299**

PERSON RESPONSIBLE:
MR. DANNY NG KIM YAU
[danny.ng@dqs.com.my]

CONTACT PERSON:
PN. NUR KHAIRUN HANIS BINTI ABU BAKAR
[hanis.bakar@dqs.com.my]

CAB REGISTRATION NUMBER: **MDA/CAB-006**
VALIDITY: **12/09/2020 – 11/09/2023**

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	GDPMD	Good Distribution Practice for Medical Devices

Conformity Assessment of Technical Documentation		
3	MD 0101	Non-active devices for anesthesia, emergency and intensive care
4	MD 0102	Non-active devices for injection, infusion, transfusion and dialysis
5	MD 0103	Non-active orthopaedic and rehabilitation devices
6	MD 0106	Non-active instruments
7	MD 0107	Contraceptive medical devices
8	MD 0202	Non-active orthopaedic implants
9	MD 0301	Bandages and wound dressings
10	MD 0403	Dental implants
11	MD 1101	Devices for extra-corporal circulation, infusion and haemopheresis
12	MD 1102	Respiratory devices, including hyperbaric chambers for oxygen therapy, inhalation anaesthesia
13	MD 1104	Active surgical devices
14	MD 1105	Active ophthalmologic devices
15	MD 1106	Active dental devices
16	MD 1107	Active devices for disinfection and sterilisation
17	MD 1201	Imaging devices utilising ionizing radiation
18	MD 1301	Monitoring devices of non-vital physiological parameters
19	MD 1302	Monitoring devices of vital physiological parameters
20	IVD 0404	Molecular biology
21	IVD 0405	Pregnancy and ovulation

Conformity Assessment by Way of Verification		
22	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