



DQS CERTIFICATION (M) SDN. BHD.

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CAB REGISTRATION NUMBER: **MDA/CAB-006**
 VALIDITY: **12/09/2017 - 11/09/2020**

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 0104	Non-active medical devices with measuring function
7	MD 0106	Non-active instruments
8	MD 0107	Contraceptive medical devices
9	MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
10	MD 0201	Non-active cardiovascular implants
11	MD 0202	Non-active orthopaedic implants
12	MD 0203	Non-active functional implants
13	MD 0301	Bandages and wound dressings
14	MD 0302	Suture material and clamps
15	MD 0303	Other medical devices for wound care
16	MD 0401	Non-active dental equipment and instruments
17	MD 0402	Dental materials
18	MD 0403	Dental implants
19	MD 1101	Devices for extra-corporal circulation, infusion and haemopheresis
20	MD 1102	Respiratory devices, including hyperbaric chambers for oxygen therapy, inhalation anesthesia
21	MD 1103	Devices for stimulation or inhibition
22	MD 1104	Active surgical devices
23	MD 1106	Active dental devices
24	MD 1108	Active rehabilitation devices and active prostheses
25	MD 1109	Active devices for patient positioning and transport
26	MD 1202	Imaging devices utilizing non-ionizing radiation
27	MD 1301	Monitoring devices of non-vital physiological parameters
28	MD 1302	Monitoring devices of vital physiological parameters
29	MD 1402	Devices utilizing non-ionizing radiation
30	AIMD 0101	Active implantable medical devices for stimulation/inhibition
31	AIMD 0102	Active implantable medical devices delivering drugs or other substances
32	MDS 7004	Medical devices referencing the Directive 2006/42/EC on machinery
33	MDS 7207	IVDs utilizing micromechanics

34	MDS 7209	IVDs utilizing biological active coating and/or material
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Conformity Assessment by Way of Verification		
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35	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