



**TÜV RHEINLAND MALAYSIA SDN. BHD.**  
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CAB REGISTRATION NUMBER: **MDA/CAB-007**  
 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 0104	Non-active medical devices with measuring function
6	MD 0105	Non-active ophthalmologic devices
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 0204	Non-active soft tissue implants
14	MD 0301	Bandages and wound dressings
15	MD 0302	Suture material and clamps
16	MD 0303	Other medical devices for wound care
17	MD 0401	Non-active dental equipment and instruments
18	MD 0402	Dental materials
19	MD 0403	Dental implants
20	MD 1101	Devices for extra-corporal circulation, infusion and haemopheresis
21	MD 1111	Software
22	MD 1201	Imaging devices utilizing ionizing radiation
23	MD 1202	Imaging devices utilizing non-ionizing radiation
24	MD 1301	Monitoring devices of non-vital physiological parameters
25	MD 1302	Monitoring devices of vital physiological parameters
26	IVD 0201	HIV infection (HIV 1 and 2)
27	IVD 0202	HTLV I and II
28	IVD 0203	Hepatitis B, C and D
29	IVD 0307	Tumoral marker: PSA
30	IVD 0309	Device for self-diagnosis: device for the measurement of blood sugar
31	IVD 0401	Clinical chemistry
32	IVD 0403	Immunology
33	IVD 0405	Pregnancy and ovulation

34	IVD 0406	Specimen receptacles
35	MDS 7005	Medical devices referencing the Directive 89/686/EEC on personal protective equipment (PPE)

<b>Conformity Assessment by Way of Verification</b>		
36	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**