

CAB REGISTRATION NUMBER: **MDA/CAB-007**  
VALIDITY: **11/09/2023 – 10/09/2026**



**TÜV RHEINLAND MALAYSIA SDN. BHD.**

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### 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 0106	Non-active instruments
7	MD 0107	Contraceptive medical devices
8	MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
9	MD 0202	Non-active orthopaedic implants
10	MD 0301	Bandages and wound dressings
11	MD 0401	Non-active dental equipment and instruments
12	MD 0402	Dental materials
13	IVD 0201	HIV infection (HIV 1 and 2)
14	IVD 0202	HTLV I and II
15	IVD 0203	Hepatitis B, C and D
16	IVD 0307	Tumoral marker: PSA
17	IVD 0309	Device for self-diagnosis: device for the measurement of blood sugar
18	IVD 0401	Clinical chemistry
19	IVD 0403	Immunology
20	IVD 0405	Pregnancy and ovulation
21	IVD 0406	Specimen receptacles
22	MDS 7005	Medical devices referencing the Directive 89/686/EEC on personal protective equipment (PPE)

Conformity Assessment by Way of Verification		
23	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**