TÜV RHEINLAND MALAYSIA SDN. BHD.
NO. 27 JALAN U8/103
METROPOLITAN BUSINESS PARK
BUKIT JELUTONG, 40150 SHAH ALAM
SELANGOR DARUL EHSAN
TEL: **+603-7859 8000**
FAX: **+603-7859 8020**

PERSON RESPONSIBLE:
MR. ABDUL RAHMAN BIN AB GHANI
[abdul.rahman@tuv.com]

CONTACT PERSON:
MR. WAN AZIZUL HAFIZ BIN WAN ABDUL RAHMAN
[WanAzizul.Rahman@tuv.com]

CAB REGISTRATION NUMBER: **MDA/CAB-007**
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 0104	Non-active medical devices with measuring function
6	MD 0106	Non-active instruments
7	MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
8	MD 0301	Bandages and wound dressings
9	MD 0302	Suture material and clamps
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	IVD 0201	HIV infection (HIV 1 and 2)
15	IVD 0202	HTLV I and II
16	IVD 0203	Hepatitis B, C and D
17	IVD 0307	Tumoral marker: PSA
18	IVD 0309	Device for self-diagnosis: device for the measurement of blood sugar
19	IVD 0401	Clinical chemistry
20	IVD 0403	Immunology
21	IVD 0405	Pregnancy and ovulation
22	IVD 0406	Specimen receptacles

Conformity Assessment by Way of Verification		
23	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