



**MEDICAL DEVICE AUTHORITY (MDA)
MINISTRY OF HEALTH MALAYSIA (MOH)**

	<p>TÜV NORD (MALAYSIA) SDN. BHD. NO. 9F-1A 9TH FLOOR, TOWER 2 @ PCFF JALAN PUTERI ½, BANDAR PUTERI PUCHONG 47100 PUCHONG SELANGOR DARUL EHSAN Tel. No.: +603-8600 4031 Fax. No.: +603-8600 4032</p>	<p>Person Responsible: MS. LIM POH CHING [pclim@tuv-nord.com]</p> <p>Contact Person: MS. LIM POH CHING [pclim@tuv-nord.com]</p>
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SCOPE OF REGISTRATION		
No.	Scope	Scope Expression
Conformity Assessment of Quality Management System (QMS)		
(1)	ISO 13485	Quality Management System for Medical Devices – Requirements for Regulatory Purpose
(2)	GDPMD	Good Distribution Practice for Medical Devices
Conformity Assessment of Medical Device Technical Areas		
(3)	MD 0101	Non-active devices for anaesthesia, emergency and intensive care
(4)	MD 0106	Non-active instruments
(5)	MD 0107	Contraceptive medical devices
(6)	MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
(7)	MD 1111	Software
(8)	MD 1301	Monitoring devices of vital physiological parameters
Conformity Assessment by Way of Verification		
(9)	VERIFICATION	Conformity Assessment by Way of Verification

Section 10(1) of Medical Device Act 2012 (Act 737) and Regulation 8 of Medical Device Regulations 2012