



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

	<p>TÜV RHEINLAND MALAYSIA SDN. BHD. NO. 27 JALAN PARA U8/103 METROPOLITAN BUSINESS PARK SEKSYEN U8 BUKIT JELUTONG 40150 SHAH ALAM SELANGOR DARUL EHSAN Tel. No.: +603-7859 8023 Fax. No.: +603-7859 8020</p>	<p>Person Responsible: MR. ABDUL RAHMAN BIN AB GHANI [abdul.rahman@tuv.com]</p> <p>Contact Person: MR. HONDA MANABU [manabu.honda@tuv.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 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)
Conformity Assessment by Way of Verification		
(36)	VERIFICATION	Conformity Assessment by Way of Verification