



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

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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 0108	Non-active medical devices for disinfecting, cleaning, rinsing
(9)	MD 0202	Non-active orthopedic implants
(10)	MD 0301	Bandages and wound dressings
(11)	MD 0303	Other medical devices for wound care
(12)	MD 0401	Non-active dental equipment and instruments
(13)	MD 0402	Dental materials
(14)	MD 1111	Software
(15)	MD 1201	Imaging devices utilizing ionizing radiation
(16)	MD 1202	Imaging devices utilizing non-ionizing radiation
(17)	MD 1302	Monitoring devices of vital physiological parameters
(18)	MD 1402	Devices utilizing non-ionizing radiation
Conformity Assessment by Way of Verification		
(19)	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