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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 0103	Non-active orthopaedic and rehabilitation devices
(6)	MD 0104	Non-active medical devices with measuring function
(7)	MD 0105	Non-active ophthalmologic devices
(8)	MD 0106	Non-active instruments
(9)	MD 0107	Contraceptive medical devices
(10)	MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
(11)	MD 0109	Non-active devices for in vitro fertilization (IVF) and assisted reproductive technologies (ART)
(12)	MD 0301	Bandages and wound dressings
(13)	MD 0303	Other medical devices for wound care
(14)	MD 0402	Dental materials
(15)	MDS 7005	Medical devices referencing the Directive 89/686/EEC on personal protective equipment (PPE)
Conformity Assessment by Way of Verification		
(16)	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