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SCOPE OF REGISTRATION

Conformity Assessment of Quality Management System (QMS)		
(1)	GDPMD	Good Distribution Practice for Medical Devices
(2)	ISO 13485	Quality Management Systems for Medical Devices – Requirements for Regulatory Purpose

Conformity Assessment of Medical Device Technical Areas		
(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 0105	Non-active ophthalmologic devices
(6)	MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
(7)	MD 0204	Non-active soft tissue implants
(8)	MD 0301	Bandages and wound dressings
(9)	MD 0303	Other medical devices for wound care
(10)	MD 1101	Devices for extra-corporal circulation, infusion and haemopheresis

Conformity Assessment of Medical Device Technical Areas		
(11)	VERIFICATION	Conformity Assessment by Way of Verification

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