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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 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 non-vital physiological parameters
Conformity Assessment of Medical Device Technical Areas		
(9)	VERIFICATION	Conformity Assessment by Way of Verification

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