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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 System for Medical Devices – Requirements for Regulatory Purpose
Conformity Assessment of Medical Device Technical Areas		
(3)	MD 0103	Non-active orthopaedic and rehabilitation devices
(4)	MD 0106	Non-active instruments
(5)	MD 0202	Non-active orthopaedic implants
(6)	MD 0403	Dental implants
Conformity Assessment of Medical Device Technical Areas		
(7)	VERIFICATION	Conformity Assessment by Way of Verification

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