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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 0102	Non-active devices for injection, infusion, transfusion and dialysis
(4)	MD 0107	Contraceptive medical devices
(5)	MD 0202	Non-active orthopedic implants
(6)	MD 0204	Non-active soft tissue implants
(7)	MD 0301	Bandages and wound dressings
(8)	MD 0303	Other medical devices for wound care
(9)	MD 0402	Dental materials
(10)	MD 0403	Dental implants
(11)	IVD 0203	Hepatitis B, C and D
(12)	IVD 0303	Congenital infections: rubella, toxoplasmosis
(13)	IVD 0307	Tumoral marker: PSA
(14)	IVD 0401	Clinical chemistry
(15)	IVD 0404	Molecular biology
(16)	IVD 0405	Pregnancy and ovulation
(17)	MDS 7002	Medical devices utilizing tissues of animal origin, including Directive 2003/32/EC
(18)	MDS 7005	Medical devices referencing the Directive 89/686/EEC on personal protective equipment (PPE)

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

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