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SCOPE OF REGISTRATION

Conformity Assessment of Quality Management System (QMS)		
(1)	GDPMD	Good Distribution Practice for Medical Devices
Conformity Assessment of Medical Device Technical Areas		
(2)	MD 0101	Non-active devices for anesthesia, emergency and intensive care
(3)	MD 0102	Non-active devices for injection, infusion, transfusion and dialysis
(4)	MD 0104	Non-active medical devices with measuring function
(5)	MD 0106	Non-active instruments
(6)	MD 0107	Contraceptive medical devices
(7)	MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
(8)	MD 0301	Bandages and wound dressings
(9)	MD 0302	Suture material and clamps
(10)	MD 0303	Other medical devices for wound care
(11)	IVD 0101	AB0 system
(12)	IVD 0201	HIV infection (HIV 1 and 2)
(13)	IVD 0202	HTLV I and II
(14)	IVD 0203	Hepatitis B, C and D
(15)	IVD 0303	Congenital infections: rubella, toxoplasmosis
(16)	IVD 0305	Human infections: cytomegalovirus, chlamydia
(17)	IVD 0307	Tumoral marker: PSA
(18)	IVD 0401	Clinical chemistry
(19)	IVD 0402	Haematology
(20)	IVD 0403	Immunology
(21)	IVD 0404	Molecular biology
(22)	IVD 0405	Pregnancy and ovulation
(23)	IVD 0406	Specimen receptacles
(24)	MDS 7002	MD utilising tissues of animal origin, inc. Commission Regulation (EU) No 722/2012
(25)	MDS 7206	IVDs in sterile condition
(26)	MDS 7210	IVDs utilizing material of human origin
Conformity Assessment of Medical Device Technical Areas		
(27)	VERIFICATION	Conformity Assessment by Way of Verification

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