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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 0103	Non-active orthopaedic and rehabilitation devices
(5)	MD 0106	Non-active instruments
(6)	MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
(7)	MD 0202	Non-active orthopaedic 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
(11)	MD 1107	Active devices for disinfection and sterilization

### Conformity Assessment of Medical Device Technical Areas

(12)	VERIFICATION	Conformity Assessment by Way of Verification
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*Section 10(1), Medical Device Act 2012 (Act 737) and Regulation 8, Medical Device Regulation 2012*