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Validity **MDA/CAB-013**: **27/09/2018 – 26/09/2021**

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 0102	Non-active devices for injection, infusion, transfusion and dialysis
(5)	MD 0103	Non-active orthopedic and rehabilitation devices
(6)	MD 0104	Non-active medical devices with measuring function
(7)	MD 0105	Non-active ophthalmologic devices
(8)	MD 0106	Non-active instruments
(9)	MD 0107	Contraceptive medical devices
(10)	MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
(11)	MD 0109	Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)
(12)	MD 0204	Non-active soft tissue implants
(13)	MD 0301	Bandages and wound dressings
(14)	MD 0302	Suture material and clamps
(15)	MD 0303	Other medical devices for wound care
(16)	MD 0401	Non-active dental equipment and instruments
(17)	IVD 0403	Immunology
(18)	IVD 0404	Molecular biology
(19)	IVD 0406	Specimen receptacles
(20)	MDS 7005	Medical devices referencing the Directive 89/686/EEC on personnel protective equipment (PPE)
Conformity Assessment of Medical Device Technical Areas		
(21)	VERIFICATION	Conformity Assessment by Way of Verification

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