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Validity **MDA/CAB-002**: **21/11/2016 - 20/11/2019**

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 0104	Non-active medical devices with measuring function
(6)	MD 0105	Non-active ophthalmologic devices
(7)	MD 0106	Non-active instruments
(8)	MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
(9)	MD 0202	Non-active orthopedic implants
(10)	MD 0301	Bandages and wound dressings
(11)	MD 0303	Other medical devices for wound care
(12)	MD 0401	Non-active dental equipment and instruments
(13)	MD 0402	Dental materials
(14)	MD 1111	Software
(15)	MD 1201	Imaging devices utilizing ionizing radiation
(16)	MD 1202	Imaging devices utilizing non-ionizing radiation
(17)	MD 1302	Monitoring devices of vital physiological parameters
(18)	MD 1402	Devices utilizing non-ionizing radiation

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