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Validity **MDA/CAB-003: 21/11/2019 - 20/11/2022**

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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 0101	Non-active devices for anesthesia, emergency and intensive care
(4)	MD 0102	Non-active devices for injection, infusion, transfusion and dialysis
(5)	MD 0105	Non-active ophthalmologic devices

### Conformity Assessment of Medical Device Technical Areas

(6)	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*