

CAB REGISTRATION NUMBER: MDA/CAB-001
VALIDITY: 21/11/2022 – 20/11/2025



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SCOPE OF REGISTRATION

Conformity Assessment of Quality Management System (QMS) and Post-Market Surveillance System (PMSS)		
1	ISO 13485	Quality Management System for Medical Devices – Requirements for Regulatory Purpose
2	GDPMD	Good Distribution Practice for Medical Devices
Conformity Assessment of Technical Documentation		
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 0107	Contraceptive medical devices
6	MD 0301	Bandages and wound dressings
7	MDS 7005	Medical devices referencing the Directive 89/686/EEC on personal protective equipment (PPE)
Conformity Assessment by Way of Verification		
8	VERIFICATION	Conformity Assessment by Way of Verification

< End of List >

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