

CAB REGISTRATION NUMBER: **MDA/CAB-003**
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 0105	Non-active ophthalmologic devices
6	MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
7	MD 0204	Non-active soft tissue 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

Conformity Assessment by Way of Verification		
11	VERIFICATION	Conformity Assessment by Way of Verification

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