

CAB REGISTRATION NUMBER: **MDA/CAB-005**
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 0402	Dental materials
5	MD 1302	Monitoring devices of vital physiological parameters

**** means approval only for conformity assessment on dental dam.

Conformity Assessment by Way of Verification		
6	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