CAB REGISTRATION NUMBER: **MDA/CAB-009**
VALIDITY: **12/02/2021 – 11/02/2024**

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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 0102	Non-active devices for injection, infusion, transfusion and dialysis
4	MD 1101	Devices for extra-corporal circulation, infusion and haemopheresis
5	MD 1102	Respiratory devices, including hyperbaric chambers for oxygen therapy, inhalation anesthesia
6	MD 1202	Imaging devices utilizing non-ionizing radiation
7	MD 1302	Monitoring devices of vital physiological parameters

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