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CAB REGISTRATION NUMBER: **MDA/CAB-001**
VALIDITY: **21/11/2019 - 20/11/2022**

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 0103	Non-active orthopaedic and rehabilitation devices
6	MD 0104	Non-active medical devices with measuring function
7	MD 0106	Non-active instruments
8	MD 0107	Contraceptive medical devices
9	MD 0109	Non-active devices for in vitro fertilization (IVF) and assisted reproductive technologies (ART)
10	MD 0301	Bandages and wound dressings
11	MD 0303	Other medical devices for wound care
12	MDS 7005	Medical devices referencing the Directive 89/686/EEC on personal protective equipment (PPE)

Conformity Assessment by Way of Verification		
13	VERIFICATION	Conformity Assessment by Way of Verification

< End of List >

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