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CAB REGISTRATION NUMBER: **MDA/CAB-013**
VALIDITY: **27/09/2018 – 26/09/2021**

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 0105**	Non-active ophthalmologic devices
8	**MD 0106**	Non-active instruments
9	**MD 0108**	Non-active medical devices for disinfecting, cleaning, rinsing
10	**MD 0301**	Bandages and wound dressings
11	**MD 0302**	Suture material and clamps
12	**MD 0303**	Other medical devices for wound care
13	**MD 0401**	Non-active dental equipment and instruments
14	**IVD 0403**	Immunology
15	**IVD 0404**	Molecular biology
16	**IVD 0406**	Specimen receptacles
17	**MDS 7005**	Medical devices referencing the Directive 89/686/EEC on personal protective equipment (PPE)

Conformity Assessment by Way of Verification		
18	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