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CAB REGISTRATION NUMBER: **MDA/CAB-004**
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 0102	Non-active devices for injection, infusion, transfusion and dialysis
4	MD 0107	Contraceptive medical devices
5	MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
6	MD 0202	Non-active orthopaedic implants
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 0402	Dental materials
11	MD 0403	Dental implants
12	IVD 0203	Hepatitis B, C and D
13	IVD 0303	Congenital infections: rubella, toxoplasmosis
14	IVD 0307	Tumoral marker: PSA
15	IVD 0401	Clinical chemistry
16	IVD 0404	Molecular biology
17	IVD 0405	Pregnancy and ovulation
18	MDS 7002	Medical devices utilizing tissues of animal origin, including Directive 2003/32/EC
19	MDS 7005	Medical devices referencing the Directive 89/686/EEC on personal protective equipment (PPE)

Conformity Assessment by Way of Verification		
20	VERIFICATION	Conformity Assessment by Way of Verification

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