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CAB REGISTRATION NUMBER: **MDA/CAB-004**
VALIDITY: **21/11/2022 – 20/11/2025**

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 0403	Dental implants
11	MD 1101	Devices for extra-corporal circulation, infusion and haemopheresis
12	MD 1102	Respiratory devices, including hyperbaric chambers for oxygen therapy, inhalation anaesthesia
13	MD 1104	Active surgical devices
14	MD 1106	Active dental devices
15	MD 1107	Active devices for disinfection and sterilisation
16	MD 1109	Active devices for patient positioning and transport
17	MD 1111	Software
18	IVD 0203	Hepatitis B, C and D
19	IVD 0303	Congenital infections: rubella, toxoplasmosis
20	IVD 0307	Tumoral marker: PSA
21	IVD 0401	Clinical chemistry
22	IVD 0404	Molecular biology
23	IVD 0405	Pregnancy and ovulation
24	MDS 7002	Medical devices utilizing tissues of animal origin, including Directive 2003/32/EC
25	MDS 7005	Medical devices referencing the Directive 89/686/EEC on personal protective equipment (PPE)

Conformity Assessment by Way of Verification		
26	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