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CAB REGISTRATION NUMBER: **MDA/CAB-003**
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 0105	Non-active ophthalmologic devices
7	MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
8	MD 0204	Non-active soft tissue implants
9	MD 0301	Bandages and wound dressings
10	MD 0303	Other medical devices for wound care
11	MD 0401	Non-active dental equipment and instruments
12	MD 1101	Devices for extra-corporal circulation, infusion and haemopheresis
13	MD 1102	Respiratory devices, including hyperbaric chambers for oxygen therapy, inhalation anaesthesia
14	MD 1103	Devices for stimulation or inhibition
15	MD 1104	Active surgical devices
16	MD 1106	Active dental devices
17	MD 1108	Active rehabilitation devices and active prostheses
18	MD 1109	Active devices for patient positioning and transport
19	MD 1301	Monitoring devices of non-vital physiological parameters
20	MD 1302	Monitoring devices of vital physiological parameters
21	MD 1403	Devices for hyperthermia / hypothermia
22	MD 1404	Devices for (extracorporeal) shock-wave therapy (lithotripsy)

Conformity Assessment by Way of Verification		
23	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