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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 0107	Contraceptive medical devices
10	MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
11	MD 0201	Non-active cardiovascular implants
12	MD 0202	Non-active orthopaedic implants
13	MD 0203	Non-active functional implants
14	MD 0204	Non-active soft tissue implants
15	MD 0301	Bandages and wound dressings
16	MD 0302	Suture material and clamps
17	MD 0303	Other medical devices for wound care
18	MD 0401	Non-active dental equipment and instruments
19	MD 0402	Dental materials
20	MD 0403	Dental implants
21	MD 1101	Devices for extra-corporal circulation, infusion and haemopheresis
22	MD 1102	Respiratory devices, including hyperbaric chambers for oxygen therapy, inhalation anesthesia
23	MD 1103	Devices for stimulation or inhibition
24	MD 1104	Active surgical devices
25	MD 1106	Active dental devices
26	MD 1107	Active devices for disinfection and sterilization
27	MD 1108	Active rehabilitation devices and active prostheses
28	MD 1109	Active devices for patient positioning and transport
29	MD 1110	Active devices for in vitro fertilization (IVF) and assisted reproductive technologies (ART)
30	MD 1111	Software
31	MD 1301	Monitoring devices of non-vital physiological parameters
32	MD 1302	Monitoring devices of vital physiological parameters

Conformity Assessment by Way of Verification		
33	VERIFICATION	Conformity Assessment by Way of Verification

< End of List >

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