Medical Device AUTHORITY MALAYSIA

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SCOPE OF REGISTRATION

Conformity Assessment of Quality Management System (QMS)		
(1)	GDPMD	Good Distribution Practice for Medical Devices
(2)	ISO 13485	Quality Management Systems for Medical Devices – Requirements for Regulatory Purpose
Conformity Assessment of Medical Device Technical Areas		
(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 orthopedic 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 anaesthesia
(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 sterilisation
(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 fertilisation (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 of Medical Device Technical Areas		
(33)	VERIFICATION	Conformity Assessment by Way of Verification

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