Medical Device AUTHORITY MALAYSIA

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ASI Certification

ASI CERTIFICATION SDN. BHD.
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Validity **MDA/CAB-019**: **08/11/2018 – 17/11/2021**

SCOPE OF REGISTRATION

Conformity Assessment of Quality Management System (QMS)		
(1)	GDPMD	Good Distribution Practice for Medical Devices
Conformity Assessment of Medical Device Technical Areas		
(2)	MD 0104	Non-active medical devices with measuring function
(3)	MD 0106	Non-active instruments
(4)	MD 1101	Devices for extra-corporal circulation, infusion and haemopheresis
(5)	MD 1102	Respiratory devices, including hyperbaric chambers for oxygen therapy, inhalation anesthesia
(6)	MD 1103	Devices for stimulation or inhibition
(7)	MD 1104	Active surgical devices
(8)	MD 1105	Active ophthalmologic devices
(9)	MD 1106	Active dental devices
(10)	MD 1107	Active devices for disinfection and sterilization
(11)	MD 1108	Active rehabilitation devices and active prostheses
(12)	MD 1109	Active devices for patient positioning and transport
(13)	MD 1201	Imaging devices utilizing ionizing radiation
(14)	MD 1202	Imaging devices utilizing non-ionizing radiation
(15)	MD 1301	Monitoring devices of non-vital physiological parameters
(16)	MDS 7004	Medical devices referencing the Directive 2006/42/EC on machinery
(17)	MDS 7005	Medical devices referencing the Directive 89/686/EEC on personal protective equipment(PPE)
Conformity Assessment of Medical Device Technical Areas		
(18)	VERIFICATION	Conformity Assessment by Way of Verification

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