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MEDIVICE CERTIFICATION SDN BHD

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Validity **MDA/CAB-020: 04/04/2019 – 03/04/2022**

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 0104	Non-active medical devices with measuring function
(6)	MD 0106	Non-active instruments
(7)	MD 0107	Contraceptive medical devices
(8)	MD 0301	Bandages and wound dressings
(9)	MD 1402*	Devise utilizing non-ionizing radiation

Conformity Assessment of Medical Device Technical Areas

(10)	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 Regulation 2012

Note: * means approval only for conformity assessment on aesthetics medical devices.