Medical Device AUTHORITY MALAYSIA

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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 injection, infusion, transfusion and dialysis
(4)	MD 0102	Non-active orthopaedic and rehabilitation devices
(5)	MD 0107	Other medical devices for wound care
Conformity Assessment of Medical Device Technical Areas		
(6)	VERIFICATION	Conformity Assessment by Way of Verification

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