



**MEDICAL DEVICE AUTHORITY (MDA)  
MINISTRY OF HEALTH MALAYSIA (MOH)**

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SCOPE OF REGISTRATION		
No.	Scope	Scope Expression
<b>Conformity Assessment of Quality Management System (QMS)</b>		
(1)	ISO 13485	Quality Management System for Medical Devices – Requirements for Regulatory Purpose
(2)	GDPMD	Good Distribution Practice for Medical Devices

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