



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

	<p><b>CARE CERTIFICATION INTERNATIONAL (M) SDN. BHD.</b>                  NO. 3-16 IOI BOULEVARD                  JALAN KENARI 6                  BANDAR PUCHONG JAYA                  47170 PUCHONG                  SELANGOR DARUL EHSAN                  Tel. No.: +603-8073 2788                  Fax. No.: +603-8070 4900</p>	<p><b>Person Responsible:</b>                  MR. FLEMING TEO CHIN SIONG                  [flemingteo@outlook.com]</p> <p><b>Contact Person:</b>                  MR. FLEMING TEO CHIN SIONG                  [flemingteo@outlook.com]</p>
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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
<b>Conformity Assessment of Medical Device Technical Areas</b>		
(3)	MD 0107	Contraceptive medical devices
(4)	MD 0303	Other medical devices for wound care
<b>Conformity Assessment by Way of Verification</b>		
(5)	VERIFICATION	Conformity Assessment by Way of Verification

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