



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

 <p>CERTIFICATION INTERNATIONAL MALAYSIA</p>	<p>CI INTERNATIONAL CERTIFICATION SDN. BHD. NO. 37-4 JALAN SP 2/2 TAMAN SERDANG PERDANA, SEKSYEN 2 43000 SERI KEMBANGAN SELANGOR DARUL EHSAN Tel. No.: +603-8942 9001 Fax. No.: +603-8942 9002</p>	<p>Person Responsible: MR. OOI SOO KANG [oosk@cimalaysia.com.my]</p> <p>Contact Person: MS. LIAU FEI LING [liau@cimalaysia.com.my]</p>
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SCOPE OF REGISTRATION		
No.	Scope	Scope Expression
Conformity Assessment of Quality Management System (QMS)		
(1)	ISO 13485	Quality Management System for Medical Devices – Requirements for Regulatory Purpose
(2)	GDPMD	Good Distribution Practice for Medical Devices
Conformity Assessment of Medical Device Technical Areas		
(3)	MD 0103	Non-active orthopaedic and rehabilitation devices
(4)	MD 0106	Non-active instruments
(5)	MD 0107	Contraceptive medical devices
(6)	MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
(7)	MD 0202	Non-active orthopaedic implants
(8)	MD 0401	Non-active dental equipment and instruments
(9)	MD 0403	Dental implants
(10)	MD 1111	Software
Conformity Assessment by Way of Verification		
(11)	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