



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

	<p>NEWERA INTERNATIONAL CERTIFICATION SDN. BHD. PS-01-16 WISMA PJ5 SOHO NO. 4B JALAN SS5D/6 KELANA JAYA 47301 PETALING JAYA SELANGOR DARUL EHSAN Tel. No.: +603-7722 3882 Fax. No.: +603-7498 4456</p>	<p>Person Responsible: MR. JIMMY FOO SAIK KIN [marketing@neweracert.com]</p> <p>Contact Person: MR. KOK CHIN LON [sales1@neweracert.com]</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 0202	Non-active orthopaedic implants
(6)	MD 0403	Dental implants
Conformity Assessment by Way of Verification		
(7)	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