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

	KIWA INTERNATIONAL CERTIFICATIONS (M) SDN. BHD. 2A JALAN ASTANA 1D BANDAR BUKIT RAJA 41050 KLANG SELANGOR DARUL EHSAN Tel. No.: +603-3359 7583 Fax. No.: +603-3359 6583	**Person Responsible:** DR. KENNY CHAN TEIK KEN [kenny@kiwacert.com] **Contact Person:** MS. VENICE CHOOI SEE WEI [kiwa.auditing@gmail.com] [venice@kiwacert.com]

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 0102	Non-active devices for injection, infusion, transfusion and dialysis
(4)	MD 0103	Non-active orthopaedic and rehabilitation devices
(5)	MD 0106	Non-active instruments
(6)	MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
(7)	MD 0202	Non-active orthopaedic implants
(8)	MD 0301	Bandages and wound dressings
(9)	MD 0303	Other medical devices for wound care
Conformity Assessment by Way of Verification		
(10)	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