



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

	<p>SGS (MALAYSIA) SDN. BHD. UNIT 10-1 10TH FLOOR NO. 17 LORONG DUNGUN 50490 DAMANSARA HEIGHTS W. P. KUALA LUMPUR Tel. No.: +603-2095 9200 Fax. No.: +603-2095 9611</p>	<p>Person Responsible: MR. KENNY LOOI TUCK KIAN [kenny.looi@sgs.com]</p> <p>Contact Person: MR. KAMARRUZAIMISHAM BIN HARUN [zaimie.harun@sgs.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 0101	Non-active devices for anaesthesia, emergency and intensive care
(4)	MD 0102	Non-active devices for injection, infusion, transfusion and dialysis
(5)	MD 0105	Non-active ophthalmologic devices
(6)	MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
(7)	MD 0204	Non-active soft tissue implants
(8)	MD 0301	Bandages and wound dressings
(9)	MD 0303	Other medical devices for wound care
(10)	MD 1101	Devices for extra-corporal circulation, infusion and haemopheresis
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