




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

	<p>SIRIM QAS INTERNATIONAL SDN. BHD. SIRIM COMPLEX, NO. 1 SEKSYEN 2 PERSIARAN DATO' MENTERI 40700 SHAH ALAM SELANGOR DARUL EHSAN Tel. No.: +603-5544 6489 Fax. No.: +603-5544 6473</p>	<p>Person Responsible: PN. NOR'AFIZA BINTI SAIM</p> <p>Contact Person: MR. MD ZAINI BIN MD JAI [mdzaini@sirim.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 0101	Non-active devices for anaesthesia, emergency and intensive care
(4)	MD 0102	Non-active devices for injection, infusion, transfusion and dialysis
(5)	MD 0103	Non-active orthopaedic and rehabilitation devices
(6)	MD 0104	Non-active medical devices with measuring function
(7)	MD 0106	Non-active instruments
(8)	MD 0107	Contraceptive medical devices
(9)	MD 0202	Non-active orthopaedic implants
(10)	MD 0203	Non-active functional implants
(11)	MD 0204	Non-active soft tissue implants
(12)	MD 0301	Bandages and wound dressings
(13)	MD 0302	Suture material and clamps
(14)	MD 0303	Other medical devices for wound care
(15)	MD 0401	Non-active dental equipment and instruments
(16)	MD 0402	Dental materials
(17)	MD 0403	Dental implants
(18)	MD 1301	Monitoring devices of non-vital physiological parameters
(19)	MD 1302	Monitoring devices of vital physiological parameters
(20)	MD 1403	Devices for hyperthermia / hypothermia
(21)	IVD 0203	Hepatitis B, C and D
(22)	IVD 0303	Congenital infections: rubella, toxoplasmosis
(23)	IVD 0307	Tumoral marker: PSA
(24)	IVD 0401	Clinical chemistry
(25)	IVD 0404	Molecular biology
(26)	IVD 0405	Pregnancy and ovulation
(27)	IVD 0406	Specimen receptacles
(28)	MDS 7002	Medical devices utilizing tissues of animal origin, including Directive 2003/32/EC
(29)	MDS 7005	Medical devices referencing the Directive 89/686/EEC on personal protective equipment (PPE)
Conformity Assessment by Way of Verification		
(30)	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