

NO: ACB MDMS 01

PROGRAMME: MEDICAL DEVICES QUALITY MANAGEMENT SYSTEMS (MDQMS)

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CERTIFICATION BODY**LOCATION:****KGS CERTIFICATION SDN BHD****NO 15, LORONG BLM 5/4,
BANDAR LAGUNA MERBOK,
08000 SG. PETANI,
KEDAH
MALAYSIA****DATE OF INITIAL
ACCREDITATION:****15 OCTOBER 2014****ACCREDITATION CRITERIA:****ISO/IEC 17021-1:2015 & ACB-MDQMS****CERTIFICATION STANDARD(S):****ISO 13485:2016**

SCOPE OF ACCREDITATION	
Main Technical Areas	Technical Areas
Non-active Medical Devices	General non-active, non-implantable medical devices
	Non-active implants
	Devices for wound care
	Non-active dental devices and accessories
	Non-active medical devices other than specified above
Active Medical Devices (Non-implantable)	General active medical devices
	Devices for imaging
	Monitoring devices
	Devices for radiation therapy and thermo therapy
	Active (non-implantable) medical devices other than specified above
Active Implantable Medical Devices	General active implantable medical devices
	Implantable medical devices other than specified above
In Vitro Diagnostic Medical Devices	Reagents and reagent products, calibrators and control materials for: Clinical Chemistry Immunochemistry (Immunology) Haematology/Haemostasis/Immunohematology Microbiology Infectious Immunology Histology/Cytology Genetic testing
	In Vitro Diagnostic Instruments and software
	IVD medical devices other than specified above

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CERTIFICATION STANDARD(S): ISO 13485:2016

SCOPE OF ACCREDITATION	
Main Technical Areas	Technical Areas
Sterilization Method for Medical Devices	Ethylene oxide gas sterilization (EOG)
	Moist heat
	Aseptic processing
	Radiation sterilization (e.g. gamma, x-ray, electron beam)
	Sterilization method other than specified above
Devices incorporating/utilizing/specific substances/technologies	Medical devices incorporating medical substances
	Medical devices utilizing tissues of animal origin
	Medical devices incorporating derivatives of human blood
	Medical devices utilizing micromechanics
	Medical devices utilizing nanomaterials
	Medical devices utilizing biological active coatings and/or materials or being wholly or mainly absorbed
	Medical devices incorporating or utilizing specific substances/technologies/elements, other than specified above

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