

ISO 13485 ACCREDITED SCOPES

<u>Main Technical Areas</u>	<u>Technical Areas</u>	<u>Product Categories Covered by the Technical Areas</u>	<u>JAS-ANZ ACCREDITED</u>	
Non-active Medical Devices	General non-active, non-implantable medical devices	Non-active devices for anesthesia, emergency and intensive care	Y	
		Non-active devices for injection, infusion, transfusion and dialysis	Y	
		Non-active orthopedic and rehabilitation devices	Y	
		Non-active medical devices with measuring function	Y	
		Non-active ophthalmologic devices	Y	
		Non-active instruments	Y	
		Contraceptive medical devices	Y	
		Non-active medical devices for disinfecting, cleaning, rinsing	Y	
		Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	Y	
	Non-active implants		Non-active cardiovascular implants	Y
			Non-active orthopedic implants	Y
			Non-active functional implants	Y
			Non-active soft tissue implants	Y
	Devices for wound care		Bandages and wound dressings	Y
			Suture material and clamps	Y
			Other medical devices for wound care	Y
	Non-active dental devices and accessories		Non-active dental devices/equipment and instruments	Y
			Dental materials	Y
			Dental implants	Y
	Active Medical Devices (Non-	General active medical devices	Devices for extra-corporal circulation, infusion and haemopheresis	Y
Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia			Y	
Devices for stimulation or inhibition			Y	
Active surgical devices			Y	
Active ophthalmologic devices			Y	
Active dental devices			Y	
Active devices for disinfection and sterilisation			Y	
Active rehabilitation devices and active prostheses			Y	
Active devices for patient positioning and transport			Y	
Active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)			Y	
	Software	Y		

Implantable)	Devices for imaging	Devices utilizing ionizing rays	Y
		Devices utilizing non-ionizing rays	Y
	Monitoring devices	Monitoring devices of non-vital physiological parameters	Y
		Monitoring devices of vital physiological parameters	Y
	Devices for radiation therapy and thermo therapy	Devices utilising ionizing radiation	Y
		Devices utilising non-ionizing radiation	Y
		Devices for hyperthermia / hypothermia	Y
Devices for (extracorporeal) shockwave therapy (lithotripsy)		Y	
Active Implantable Medical Devices	General active implantable medical devices	Active implantable medical devices for stimulation / inhibition	NO
		Active implantable medical devices delivering drugs or other substances	NO
		Active implantable medical devices substituting or replacing organ functions	NO
In Vitro Diagnostic Medical Devices (IVD)	Reagents and reagent products, calibrators and control materials for:	_____>	NO
	Clinical Chemistry	_____>	NO
	Immunochemistry (Immunology)	_____>	NO
	Haematology/Haemostasis/Immunohe matology	_____>	NO
	Microbiology	_____>	NO
	Infectious Immunology	_____>	NO
	Histology/Cytology	_____>	NO
	Genetic Testing	_____>	NO
	In Vitro Diagnostic Instruments and software	_____>	NO
IVD medical devices other than specified above	_____>	NO	
Sterilization Method for Medical Devices	Ethylene oxide gas sterilization (EOG)	_____>	Y
	Moist heat	_____>	Y
	Aseptic processing	_____>	Y
	Radiation sterilization (e.g. gamma, x-ray, electron beam)	_____>	Y

<i>Devices incorporating/ utilizing specific substances / technologies</i>	Medical devices incorporating medicinal substances	_____>	NO
	Medical devices utilizing tissues of animal origin	_____>	NO
	Medical devices incorporating derivatives of human blood	_____>	NO
	Medical devices utilizing micromechanics	_____>	NO
	Medical devices utilizing nanomaterials	_____>	NO
	Medical devices utilizing biological active coatings and/or materials or being wholly or mainly absorbed	_____>	NO