

Attached Table 2-2 Accreditation scopes (MD-QMS)

Main Technical Areas	Technical Areas	Product Categories Covered by the Technical Areas
1.Non-active Medical Devices	1-a General non-active, non-implantable medical devices	<ul style="list-style-type: none"> • Non-active devices for anesthesia, emergency and intensive care • Non-active devices for injection, infusion, transfusion and dialysis • Non-active orthopedic and rehabilitation devices • Non-active medical devices with measuring function • Non-active ophthalmologic devices • Non-active instruments • Contraceptive medical devices • Non-active medical devices for disinfecting, cleaning, rinsing • Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)
	1-b Non-active implants	<ul style="list-style-type: none"> • Non-active cardiovascular implants • Non-active orthopedic implants • Non-active functional implants • Non-active soft tissue implants
	1-c Devices for wound care	<ul style="list-style-type: none"> • Bandages and wound dressings • Suture material and clamps • Other medical devices for wound care
	1-d Non-active dental devices and accessories	<ul style="list-style-type: none"> • Non-active dental devices/equipment and instruments • Dental materials • Dental implants
	1-e Non-active medical devices other than specified above	

Main Technical Areas	Technical Areas	Product Categories Covered by the Technical Areas
2. Active Medical Devices (Non-Implantable)	2-a General active medical devices	<ul style="list-style-type: none"> • Devices for extra-corporal circulation, infusion and haemopheresis • Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia • Devices for stimulation or inhibition • Active surgical devices • Active ophthalmologic devices • Active dental devices • Active devices for disinfection and sterilisation • Active rehabilitation devices and active prostheses • Active devices for patient positioning and transport • Active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART) • Software
	2-b Devices for imaging	<ul style="list-style-type: none"> • Devices utilizing ionizing rays • Devices utilizing non-ionizing rays
	2-c Monitoring devices	<ul style="list-style-type: none"> • Monitoring devices of non-vital physiological parameters • Monitoring devices of vital physiological parameters
	2-d Devices for radiation therapy and thermo therapy	<ul style="list-style-type: none"> • Devices utilising ionizing radiation • Devices utilising non-ionizing radiation • Devices for hyperthermia / hypothermia • Devices for (extracorporal) shock-wave therapy (lithotripsy)
	2-e Active (non-implantable) medical devices other than specified above	

<p>3.Active Implantable Medical Devices</p>	<p>3-a General active implantable medical devices</p>	<ul style="list-style-type: none"> • Active implantable medical devices for stimulation / inhibition • Active implantable medical devices delivering drugs or other substances <p>Active implantable medical devices substituting or replacing organ functions</p>
	<p>3-b Implantable medical devices other than specified above</p>	

Main Technical Areas	Technical Areas	Product Categories Covered by the Technical Areas
4. In Vitro Diagnostic Medical Devices (IVD)	4-a Reagents and reagent products, calibrators and control materials for: Clinical Chemistry Immunochemistry (Immunology) Haematology/Haemostasis/Immuno hematology Microbiology Infectious Immunology Histology/Cytology Genetic Testing	
	4-b In Vitro Diagnostic Instruments and software	
	4-c IVD medical devices other than specified above	
5. Sterilization Method for Medical Devices	5-a Ethylene oxide gas sterilization (EOG)	
	5-b Moist heat	
	5-c Aseptic processing	
	5-d Radiation sterilization (e.g. gamma, x-ray, electron beam)	
	5-e Sterilization method other than specified above	
6. Devices incorporating/utilizing specific substances/ technologies	6-a Medical devices incorporating medicinal substances	
	6-b Medical devices utilizing tissues of animal origin	
	6-c Medical devices incorporating derivates of human blood	
	6-d Medical devices utilizing micromechanics	
	6-e Medical devices utilizing nanomaterials	
	6-f Medical devices utilizing biological active coatings and/or materials or being wholly or mainly absorbed	

NOTE : If seeking accreditation using an technical area without recourse to this attached table, the details of the technical area shall be described.