



**Your Global Testing,  
Inspection & Certification Partner**

# Testing and Certification Services for Active Medical Devices

STC is accredited by HOKLAS (Hong Kong), CNAS (China), FDA (USA), CE (Europe), DAkkS (Germany), and more.



## Scope of Services

- ▶ Safety and performance tests for medical electrical equipment: IEC/EN 60601 series standards
- ▶ Safety and EMC requirements for laboratory equipment: IEC/EN 61010, IEC/EN 61326 series standards
- ▶ Biocompatibility test: ISO 10993, ISO 18562 series standards
- ▶ Electromagnetic compatibility (EMC), Radio Frequency (RF) tests
- ▶ Performance test for medical face mask: ASTM F2100
- ▶ Hong Kong OFCA certification for RF medical devices

## General Requirements

- ▶ Safety requirements: IEC/EN 60601-1, IEC/EN 61010-1
- ▶ EMC requirements: IEC/EN 60601-1-2, IEC/EN 61326-1, IEC/EN 61326-2-6
- ▶ Requirements for alarm systems: IEC/EN 60601-1-8
- ▶ Home healthcare environment: IEC/EN 60601-1-11
- ▶ Emergency medical services environment: IEC/EN 60601-1-12
- ▶ OFCA type acceptance and type approval: HKCA 1007, 1052

## Particular Requirements

- ▶ Nerve and muscle stimulators: IEC/EN 60601-2-10
- ▶ Electromyographs and evoked response equipment: IEC/EN 60601-2-40
- ▶ Thermometers: ISO/EN ISO 80601-2-56, ASTM E 1965, ASTM E 1112
- ▶ Sphygmomanometers: IEC/EN 80601-2-30, IEC/EN 60601-2-34, ISO/EN ISO 81060-1
- ▶ Pulse oximeter equipment: ISO/EN ISO 80601-2-61
- ▶ Electrocardiographic equipment: IEC/EN 60601-2-25, IEC/EN 60601-2-27, IEC/EN 60601-2-47
- ▶ Electroencephalograph: IEC/EN 60601-2-26
- ▶ Multifunction patient monitors: IEC/EN 80601-2-49
- ▶ Heating pad or heating blanket: IEC/EN 80601-2-35
- ▶ Endoscopic equipment: IEC/EN 60601-2-18
- ▶ Medical beds: IEC/EN 60601-2-52
- ▶ Dental equipment: ISO/EN ISO 80601-2-60
- ▶ Light source equipment: IEC/EN 60601-2-22, IEC/EN 60601-2-57, IEC/EN 60601-2-83
- ▶ Hearing aids: IEC/EN 60601-2-66
- ▶ In Vitro Diagnostic (IVD) medical equipment: IEC/EN 61010-2-101



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