

Intertek

Medical Devices Testing and Certification International Standards, Local Service



As a medical device manufacturer, you are immersed in the world's most regulated industry. At times, it seems as if compliance requirements shift on a daily basis. Additionally, you must contend with globalisation and shorter product life cycles, allwhile trying to beat your competition to market.

At Intertek, we understand the challenges you face and offer a rather unique proposition to help you meet them. Speed and time to market has always been Intertek's philosophy world-wide. In Asia Pacific, Intertek stays committed to that philosophy in offering total solutions for our Medical Devices customers.

Intertek can quickly and efficiently assist you in obtaining market clearance to sell your medical devices.

Intertek Asia Pacific services for global market access

Imaging Equipment

- X-ray
- CT
- Magnetic Resonance Imaging (MRI)

Monitors

- Electrocardiographs (ECG)
- Blood pressure monitor
- Patient monitors
- Electronic Thermometer

Medical Equipment

- Hospital beds
- Surgical luminaries
- Dentist chairs / equipment
- Ultrasound equipment
- Muscle stimulators

Laboratory Equipment

- Handheld probe
- Mixing and stirring
- In-Vitro Diagnostics
- Sterilizers and disinfectors



▶ Management Systems Certification

Beyond opening doors to new markets, a third-party certified management system can improve your operational processes and give you a real advantage in the marketplace. We offer registration to ISO 13485, ISO 14971, and ISO 9001, among other standards. We are also recognized by Health Canada as a CMDCAS registrar for ISO 13485.



▶ FDA 510(k) Third Party Reviews

As a leading third-party reviewer, Intertek is able to complete your premarket review and submit our findings to the FDA, on average, in less than 30 days. Intertek's scope of device eligibility includes approximately 670 product types. Our expertise, combined with the FDA's comfort in our findings and accurate results, means you can reach your market faster.

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▶ CE Mark—Passport to EU CE0473 and CE0413

As the notified body of EU, Intertek can issue the compulsive CE mark for MDD and IVDD to EU marketplace.



▶ CB Scheme

As the NCB and CBTL, Intertek is able to guide you to pass the test and help your products entering the marketplace of more than 25 countries. Intertek is a leading body at the test scope and capability of CB Scheme. We have the test capability of IEC 60601-1, 3rd version and can take risk evaluation according the relevant standard ISO 14971.

Intertek

Full details on our global services for medical devices can be found at www.intertek.com/medical.

To start your project, please contact our expert right now!

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