

Auditing Services for the Medical Industry



The right prescription

For medical manufacturers seeking access to new markets, conformity with regulatory requirements is most often a prerequisite. Those who want to compete effectively should also have in place a properly implemented and maintained quality management system (QMS). To satisfy these conformity and QMS needs, many manufacturers are discovering the benefits of working with Intertek. With our extensive experience and know-how, we are a single source for certification to ISO 9001, ISO 13485/CMDCAS, ISO 14971, and ISO 14001, as well as conformity assessments to Annexes II, V and VI of the Medical Devices Directive (MDD).

Quick Intertek Facts

- Trusted leader in Management Systems Certification
- As experts in the industries of our customers, we provide a complete quality and safety solution with the services that they need
- Intertek Group plc is listed on the London Stock Exchange – FTSE 100
- Our customers include some of the world's leading brands, major global and local companies and governments
- Operates in more than 100 countries with over 24,000 employees

The benefits of management systems certification

Your management system's conformity with ISO 9001, ISO 13485, ISO 14971, or ISO 14001 can help you open the door to untapped domestic and international business opportunities, and reap the benefits of:

Expanded market access – National regulatory authorities require or strongly prefer that manufacturers marketing medical products in their countries have a third-party audited and certified management system in place. Investing in such a system speeds access into those countries that require it, and expedites market entry into the others.

Reduced cost of sales – Your certification establishes your company's credibility and commitment to quality. Because the task of explaining the specifics and demonstrating the effectiveness of your quality system is more straightforward, it takes less time to earn your prospective customers' trust and confidence.

Improved performance – Based on a uniform and widely-accepted system of process control, your certified management system helps you improve your products and processes. This can foster improved relationships with your suppliers, business partners, and customers, and give you a real advantage in the marketplace.

Intertek – Your partner for global market access

Whether it's your product or your process, Intertek is well-qualified to provide the credentials you need to gain worldwide market access.

Worldwide recognition – To help you get into the EU, Intertek has multiple Notified Bodies under the Medical Device Directive 93/42/EEC (MDD). In North America, Intertek is qualified by the Standards Council of Canada (SCC) and Health Canada as a CMDCAS-recognized registrar, and is accredited by the FDA to perform inspections of eligible manufacturers. You can get it all with one single audit!

Knowledgeable, industry-specific auditors – Our network of medical industry-experienced lead auditors ensures that you will work with professionals dedicated to serving your needs. When they review your management system for compliance with the applicable standards on an annual or semi-annual basis, you can be continually assured that your system is robust enough to meet the demands of quality management.

Product testing expertise – In addition to management systems certification, Intertek delivers the benefit of more than 50 years of experience in medical device testing. We can provide independent product safety testing and certification to meet various safety requirements (from the ETL Listed Mark in North America, and the S Mark and CE Mark in the European Union, to testing for the global CB Scheme), as well as other services such as FDA 510(k) reviews, design reviews, and technical file reviews.

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To learn more about auditing and certification services for the medical industry, or to request a quote, visit www.intertek.com or e-mail intertek-sc@intertek.com.

To see a complete list of our offices, visit www.intertek.com/contact.