ISO 13485 AND MANAGEMENT SYSTEMS CERTIFICATIONS

AUDITING FOR THE MEDICAL INDUSTRY

With a wide range of auditing services, reach medical industry requirements faster and more efficiently.

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 and ISO 13485/MDSAP, as well as conformity assements to Annexes II, V and VI of the Medical Devices Directive (MDD).

The Benefits of Management Systems Certification

Your management system's conformity with ISO 9001, ISO 13485, 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.

How Intertek can help

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

To help you get into the EU, Intertek has multiple Notified Bodies under the Medical Device Directive 93/42/EEC (MDD). 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.

In addition to management systems certification, Intertek 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).

FOR MORE INFORMATION

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