

ISO 13485 及管理体系认证

医疗行业审核认证

Intertek医疗器械审核认证领域广泛的服务范围，帮助您更快更有效地满足医疗行业要求。



正确的药方

对于正在寻求进入新市场的医疗制造商来说，符合法规要求是最常见的前提。想要有效地参与市场竞争的企业必需具备一个正确贯标并长期维护的质量管理体系(QMS)。为了符合并满足QMS要求，需要制造商开始发现选择Intertek作为认证伙伴的益处。作为一站式认证供应商，我们具有ISO 9001、ISO 13485/MDSAP以及医疗器械指令(MDD)附件2、5、6符合性审核的丰富经验和能力。

管理体系认证的益处

您的管理体系符合ISO 9001，ISO 13485或者ISO 14001将帮助您打开未开发的国内和国际商业机会，并受益于：

更广泛的市场准入——国内法规部门要求或者非常倾向于国内拥有第三方审核过和认证过管理体系的医疗产品制造商。对于体系的投资可以加快进入这些国家的速度且更利于进入其他区域。

减少销售成本——您的认证建立在您公司的信誉和对质量的承诺之上。认证是

更加直接的细节解释和确认质量体系有效性的方式，这将减少您获得客户信任和信心所需的时间。

改进绩效——基于一个一致的广泛接受的过程控制体系，您注册的管理体系将帮助您改善您的产品和过程。这将促进增进您与您供应商、商业伙伴和顾客的关系，并给予您真正的市场优势。

Intertek能做什么？

无论是对您的产品或者您的过程，Intertek都有足够资格来提供您进入国际市场所需要获得的信用。为帮助您进入欧盟市场，Intertek拥有多个MDD公告机构资质，我们在医疗行业极富经验的主任审核员网络可以确保您将与服务您需求的专家一起工作。当他们每年或者每半年审查您的管理体系对于标准的符合性时，您可以持续确认您的体系完全可以满足质量管理要求。除了管理体系认证之外，Intertek还可提供独立的产品安全测试以及认证来满足多样的安全要求，包括北美的ETL标志，欧盟的S标志和CE标志，以及全球CB认证测试。

Intertek在中国

Intertek是最早在国内开展医疗器械认证的认证机构之一，我们的一站式服务包括ISO 13485/CDMCAS，MDSAP单一审核程序，ISO 14971以及医疗器械质量管理体系标准及法规的培训、二方审核及差距分析等，满足您全方位的需求。

联系我们



021-5339 7720
400-886-9926



sc.china@intertek.com



intertek.com.cn

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 assessments 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

	UK	+44 116 296 1620
	AMER	+1 800 810 1195
	EMEA	+46 8 750 03 33
	ASIA	+86 21 53397720

 business.assurance@intertek.com

 intertek.com/auditing/medical