

医疗器械质量管理体系认证

ISO 13485

风险管理 | 法规合规 | 质量控制 | 文件化和可追溯



认证收益

- **加速生产流程与设备分配：**提高生产效率，缩短产品上市时间，抢占市场先机。
- **增强市场竞争力与买家信任：**通过国际认可的质量管理体系，树立企业品牌形象，赢得更多国内外客户的信赖与合作。
- **推动流程系统性优化：**建立并持续改进内部管理体系，减少浪费，提升整体运营效率。
- **确保供应链持续优化监控：**加强对供应商的管理与监督，确保原材料及零部件质量，降低供应链风险。
- **探索并实施高效运营策略：**引入先进管理理念与工具，不断创新运营模式，降低成本，提升利润空间。
- **质量管理改进：**帮助企业建立完善的质量管理体系，包括质量策划、质量控制、质量保证和质量改进等环节。

认证流程



联系我们获得方案和报价

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我们的优势

Amtivo集团获得国际认可机构UKAS（英国皇家认可委员会），ANAB（美国国家标准协会和美国质量协会），以及INAB（爱尔兰国家认可委员会）等认可，上海市凯瑞克质量体系认证有限公司（Amtivo China）依托集团资源能够在全中国范围内开展UKAS认证业务，拥有以下独特优势

- **国际背景与本地化服务：**依托Amtivo集团在全球40多个国家的资源，结合对中国本地市场的深入理解，为企业提供量身定制的解决方案，确保认证服务既符合国际标准又贴合实际需求。
- **专业团队与丰富经验：**拥有一支经验丰富的专业审核团队，认证过程科学、高效、公正，帮助企业顺利完成认证。
- **高客户推荐率：**和多家知名企业建立了长期合作关系，服务质量获得广泛认可。94% 的客户表示愿意推荐我们的服务。

欢迎联络我们获得报价

作为认证行业的专业机构，我们提供ISO 13485医疗器械质量管理体系认证服务，帮助企业确保其产品在生产、存储、分发、安装等各环节都符合用户和法律标准。

通过取得ISO 13485认证，将帮助企业改进质量管理，提高效率 and 安全性，让中企业能更好地进入更大的市场。



Medical Device Quality Management System Certification

ISO 13485



What Are the Benefits

- **Accelerate Production Processes and Equipment Allocation:** Enhance production efficiency, reduce time-to-market, and gain a competitive edge.
- **Strengthen Market Competitiveness and Buyer Confidence:** Build a strong brand image through an internationally recognized quality management system, earning trust and fostering partnerships with domestic and international clients.
- **Drive Systematic Process Optimization:** Establish and continuously improve internal management systems to minimize waste and improve overall operational efficiency.
- **Ensure Continuous Supply Chain Monitoring and Optimization:** Strengthen supplier management and oversight to guarantee the quality of raw materials and components, reducing supply chain risks.
- **Explore and Implement Efficient Operational Strategies:** Adopt advanced management principles and tools, innovate operational models, reduce costs, and maximize profit margins.
- **Quality Management Enhancement:** Support businesses in establishing a comprehensive quality management system, including quality planning, control, assurance, and improvement.

Certification Journey



Risk Management Regulatory Compliance Quality Control Documentation and Traceability



Why You Should Choose Amtivo

Amtivo Group is proud to hold accreditation from internationally respected bodies such as **UKAS** (United Kingdom Accreditation Service), **ANAB** (American National Standards Institute and American Society for Quality), and **INAB** (Irish National Accreditation Board). With the support of the Group's extensive resources, Amtivo China is equipped to deliver UKAS-accredited certification services worldwide,

- **Global Expertise with Localized Services:** Drawing on Amtivo Group's presence in over 40 countries worldwide and a deep understanding of the Chinese market, we provide tailored solutions that ensure certification services meet international standards while aligning with practical needs.
- **Professional Team with Extensive Experience:** Our team of experienced auditors ensures a scientific, efficient, and impartial certification process, helping businesses achieve certification smoothly.
- **High Customer Recommendation Rate:** Many renowned companies have established long-term partnerships with us, reflecting the high quality of our services. 94% of clients have expressed willingness to recommend our services.

Contact Us to Get a Quote

Amtivo as a professional certification body, offers ISO 13485 Medical Device Quality Management System certification services. This certification ensures that a company's products meet user and regulatory requirements across all stages, including production, storage, distribution, and installation.

By achieving ISO 13485 certification, Amtivo supports businesses in enhancing their quality management, improving efficiency and safety, and gaining better access to larger and more competitive markets.



Contact us

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