



**Choose certainty.
Add value.**



Quality – The Key To Market Success 质量—市场成功的关键

Medical devices certified according to
international regulations
依照国际标准认证的医疗器械

TÜV SÜD Group

TÜV®



Global success: More than a question of trust

Although the world is increasingly moving towards a global market, there is no global standard defining safety and quality. In the medical device sector, quality plays a more critical role than in almost any other industry. As a Notified Body, we aim to support you expertly and reliably, and provide experts to carry out all statutory tests and certifications on your behalf. We ensure that you can fully rely on our expertise and the quality of your medical devices – and so can your clients and patients.

全球成功： 不仅是信任问题

尽管全球一体化趋势日益显现，安全及质量方面的标准仍然未能统一。对于医疗器械而言，质量和其它领域相比占据了更重要的地位。作为公告机构，我们致力于提供专业可靠的支持，我们的专家为您实施全面的法规检测及认证。对于您及您的客户和患者，我们确信我们的专业能力能使您的产品更加值得信赖。



Canada 加拿大
 CMDCAS (ISO 13485),
 product testing as NRTL
 CMDCAS (ISO 13485)认证,
 NRTL 认证和工厂检查

Russia 俄罗斯
 Registration and GOST certification
 产品注册和GOST 认证

Taiwan 台湾
 Technical Cooperation Program
 技术合作协议

USA 美国
 FDA QSR inspections, FDA 510(k)
 approvals, product testing as NRTL
 FDA QSR 工厂检查 FDA 510(k)
 审批NRTL 认证和工厂检查

Japan 日本
 Registered certification body (RCB),
 JGMP, testing as per JIS 注册认证
 机构(RCB)、JGMP、JIS标准测试

Europe 欧洲
 Conformity assessment as per AIMDD,
 MDD, IVD (Notified Body No. 0123)
 AIMDD/MDD/IVD 符合性评价 (公
 告机构编号0123)

Brazil 巴西
 Nationally approved product certification
 国家授权产品认证

China 中国
 SFDA registration, CCC (China Compulsory
 Certification) SFDA 注册、CCC (中国强
 制认证)

Australia 澳大利亚
 Certification within the scope of a
 mutual recognition agreement (AUS
 EC-MRA)互认协议(AUS-EC-MRA)
 范围中的认证

Hong Kong 中国香港
 Conformity assessment according
 MDACS
 MDACS 符合性评价

Singapore 新加坡
 Certification Body (CB) for GDPMDS
 GDPMDS 认证

Statutory requirements: 法规要求： To comply with them 守法必先知法 you need to know them

Manufacturers of medical devices face enormous challenges. To have their medical devices approve for the market, they must comply with an almost limitless number of directives, statutory requirements and regulations regarding safety and quality. Who supports manufacturers in assuring the quality of their products? Who paves the way to their smooth market access? The experts at TÜV SÜD.

We do so irrespective of the risk class under which your medical device has been classified, irrespective of whether you manufacture disposable syringes, complex medical implants used in cardiac and neurosurgery or even large radiation equipment. As a Notified Body for AIMD, MDD and IVD, we employ specially trained experts who take care of the approval procedures on your behalf from beginning to end. We also hold special accreditations for medical devices which contain tissues or derivatives from animals for which a BSE/TSE risk is suspected, or blood products.

医疗器械制造商常面临各种各样的挑战。要获准在某个市场销售，该医疗器械必须符合各种安全与质量指令、法律和法规要求。谁能帮助制造商使其产品质量得到信任？谁能帮助制造商扫除进入市场的障碍？TÜV南德意志集团帮助您找到这样的产品专家。

无论您的产品是一次性注射器，还是复杂的心脏外科、神经外科植入设备，甚至大型放射性设备，无论产品风险等级如何，我们对您必须遵守的规定非常熟悉。我们为您产品成功进入市场铺平道路。作为AIMD（有源植入）、MDD（医疗器械）和IVD（体外诊断）的公告机构，我们的专家团队接受过专门培训，可帮助您协调整个产品的市场准入过程。对可能含有BSE/TSE的动物组织或衍生物的医疗器械、含有血液制品的医疗器械，我们也具备相应认证资质。



Client requirements: Safety is the key to market success

From the initial inspiration to market launch, medical devices often have a long way to go, which always involve finding answers to a host of questions: How do you ensure your product is launched into the market as quickly as possible? Where can you market your product? Will the product actually appeal to the customers? How do you ensure its correct use?

With long-standing experience and expertise in the medical sector, TÜV SÜD's specialists give positive answers to these and many more questions. And they do so throughout all phases of design and development – from the initial idea to marketing the finished product. With our assistance, test procedures run smoothly, cost-intensive development times are reduced and compliance with safety and quality standards is ensured, resulting in a fast and problem-free market launch for your medical device. Our worldwide experts provide support services that extend beyond market launch: they also monitor production facilities, ensure that user manuals are comprehensible, and provide tailored training and education measures – to ensure that you and your medical devices are safe winners in the medical sector and in all other aspects.

客户需求： 安全是市场成功的 关键

通常医疗器械从产品创意到产品上市需要经历一个漫长的过程。制造商经常面临一个又一个难题：产品如何尽快上市？在哪里上市？是否能够真正吸引客户？如何确保其能够被正确使用？

TÜV 南德意志集团专家在医疗器械领域拥有丰富经验和深厚知识，不仅可以为您解答以上问题，而且能做得更多。我们可以在整个设计研发过程提供支持，从最初的创意到最终销售的成品。在我们的帮助下，您能够顺利完成测试，减少研发的时间成本，确保产品符合安全和质量的要求，从而使好的产品迅速上市。此外，我们的 TÜV 南德意志集团专家还可以为您检查生产场地，确保使用说明清楚易懂，提供适合企业的培训—确保您和您的产品在医疗领域及其它方面都能成为赢家。



Our Service Flow 我们的服务流程

Enquiry review and quotation
需求的评估与报价

We will assign a professional sales team to communicate with you and evaluate your enquiry
我们会指派专业的销售人员与您联系，评估您的需求

Contract review and PM assigned
合同评审与项目经理的指派

We will assign the Project Manager supporting you to complete the Contract Review Process
我们会指派项目经理，配合您完成合同评审

Documentation review and compliance assessment
文件评审与符合性评价

We will review the submitted documentation as well as assessment, including test and audit
我们会评审递交的文件，安排检测及审核，进行符合性评价

Approval and release
批准与颁发

After handling of the procedures for international approvals, we will issue the relevant certificate or report
在满足审批流程之后，我们会为您颁发相应的证书或报告

Surveillance and maintenance
监督与维护

We will perform the maintenance of certificate and surveillance of quality management system
我们会为您提供证书的维护和监督质量管理体系的服务



Quality: Safety from beginning to end

Medical devices must guarantee a particularly high level of quality. But how to assure quality in times of ever-increasing cost pressure? How to increase efficiency while maintaining statutory quality standards? And how to safeguard compliance with them?

Simply rely on us. We support you throughout the entire value chain by providing flexible services which help you to supply the quality and efficiency expected by you and your clients—from beginning to end.

Tests and inspections

- Product testing and certification of medical devices
- EC conformity assessments
- CB certification
- EMC tests: verification of electromagnetic compatibility

质量： 安全贯穿始终

医疗器械必须保证高水平的质量要求。但是，在面对日益高涨的成本压力面前，如何能时刻保证产品的质量？如何在提高效率的同时满足法定的质量标准要求？又如何确保产品始终如一？

很简单，交给TÜV南德意志集团。通过提供多种服务，TÜV南德意志集团能在整个产品实现的价值链中为您提供支持，使您能始终满足您和您的客户对质量和效益的期望。

测试与检验

- 医疗器械检测与认证
- EC 符合性评估
- CB 认证
- EMC 检测：电磁兼容性验证





- Laboratory testing for ergonomics, electrical/mechanical/chemical/biological and functional safety, including testing for Software and data safety
- International approvals
- Target group- specific user testing

Clinical assessment

- Clinical assessment of medical devices, their safety and performance/fitness for use
- Review of plans for clinical trials

Management system certification

- Assessment and certification of management systems as per ISO 13485, ISO 9001, ISO 14001, TS 16949, SA8000 etc.

Training courses and seminars Free sales certificates

- 人体工程学、电气/机械/化学/生物/功能安全的实验室检测，包括软件及数据安全性的检测
- 国际市场准入
- 用户指定要求的检测

临床评估

- 医疗器械的临床评估，包括产品的安全、性能和适用性
- 评审临床试验计划

管理体系认证

- 按照ISO 13485、ISO 9001、ISO 14001、TS16949, SA8000等管理体系的要求进行评估和认证

培训课程与研讨会自由销售证书



www.tuv-sud.com

Competitive edge: Marked by success

竞争优势： 成功的标志

The medical devices market is characterized by fierce competition worldwide. How do you secure that all-important competitive edge? How do you stand out prominently and convincingly from your rivals? This is another area in which we can support you.

全球医疗器械市场竞争激烈。如何确保全面的竞争优势？如何自信地从竞争对手中脱颖而出？TÜV南德意志集团有能力在这一方面为您提供支持。



View our website to learn more our service at:
www.tuev-sued.de/medinfo

欲了解TÜV南德意志集团更多服务，
请浏览我们的网页：
www.tuev-sued.de/medinfo

For one stop German expertise in Greater China, please contact one of our branch offices, sales offices or representative offices:
欲在大中华区获得德国专家一站式服务，请联系以下分公司、销售处或联络处：

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