



Information of Medical Device Conformity Assessment Body Service Provider

(Should be filled in both **Chinese** and **English**)

1. **Company Name:** TÜV Rheinland Hong Kong Ltd.
香港德國萊茵技術監護顧問股份有限公司



(Please also send an additional copy of jpg file of your company logo as a separate attached file; < 300kbyte colour jpg file preferred.)

2. Company profile:

TÜV Rheinland Group China's compliance approval services for medical devices offer a wide spectrum of options, including performing safety testing and performance testing, conducting EMC testing, evaluating software, performing quality assurance management system audits, and handling CE marking requirements on behalf of the Notified Body TÜV Rheinland Product Safety GmbH.

Our role can be as basic as explaining the regulatory requirements and identifying the steps and documentation to meet them; or, we can help through the entire process, including testing to International, European and national standards, reporting the results and issuing compliance certificates and test mark licenses.

- [Safety Assessment](#)
- [Software Assessment](#)
- [EMC Assessment](#)
- [Performance Assessment](#)
- [CE Assessment](#)

Our Service Scope

Safety Assessment

Please note that the information provided by your company in this form may be used in the website of Hong Kong Medical and Healthcare Device Manufacturers Association (www.medicaldevice.org.hk). If you want to update the information in this form after the submission, you may send the updates by e-mail to: Dr. Theobald Chan, The Secretariat, HKMHDMA at: theobald@medicaldevice.org.hk.



With TÜV Rheinland's testing and certifications for Europe, the United States, Canada and Japan, your products have recognized and accepted test marks for key markets. As an added benefit, the same set of tests can be used to prepare a CB Certificate and Test Report, or to show compliance with essential requirements required by the European Directives for medical devices.

- GM Mark
- Type Approved Mark
- T Mark
- CB Certificate and Test Report
- cTUVus Mark
- FDA Third Party Review
- "Yakuji" Test Report
- Initial Design Support / Analysis
- International Approvals
- EC Verification
- EC Type Examination

Software Assessment

TÜV Rheinland's medical device auditors audit the software development process as part of the ISO 9001 / EN 46001 / ISO 13485 management system audits. Our medical device experts also evaluate medical device software in accordance with IEC 60601-1-4, the international norm covering software reliability requirements described in the Medical Device Directive, the Active Implantables Directive, the In-Vitro Diagnostic Directive or other countries' specific regulations.

EMC Assessment

TÜV Rheinland Group China offers EMC Testing and EMC Design Support as part of the product assessment procedure for medical devices. Our experts can evaluate your electro-medical devices according to IEC/EN 60601-1-2 and IEC/EN 60601-2-xx standards with particular requirements for various product categories.

CE Assessment

TÜV Rheinland Group China assists manufacturers to market their medical devices in the European Union (EU). Through our http://www.tuv.com/en/affiliates_en.tuv.com.php liation with TÜV Rheinland Product

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Safety GmbH in Cologne, Germany, which is recognized by the EU as a Notified Body 0197 for Product Compliance Approvals and Quality Management System Assessment, we are able to test, audit and certify a wide variety of medical products for the European market.

Assuring Directive Conformity

TÜV Rheinland Group China can help manufacturers meet the requirements of the EU's Medical Directives (AIMD: 90/385/EEC, MDD: 93/42/EEC and IVDD: 98/79/EEC), by assessment to the full scope of these directives. This includes all testing procedures and audits based on the EN 46001/2/3 series and ISO13485/8 series.

Selecting the Most Appropriate Certification Route

Medical auditors and experts of TÜV Rheinland Group China know the intricacies of the EU medical directives. They can assist you in classifying your products and recommend the most suitable assessment route.

- Classification of Medical Devices
- Preliminary Audits
- Technical File Review
- Essential Requirement Checklist
- Risk Analysis
- Test Reports according to harmonized standards
- Certificates for AIMD, MDD and IVDD

3. Contact Information

Contact Person in Hong Kong and/or PRC: Mr. Tony Lee, Sales Manager

Address(es):

Unit 8, 25/F., Skyline Tower, 39 Wang Kwong Road, Kowloon Bay, Kowloon, Hong Kong
香港九龍九龍灣宏光道 39 號宏天廣場 25 樓 8 室

Telephone No(s): 852-2192 1000

Fax No(s): 852-2192 1001

Email address(es): info@hk.chn.tuv.com

Website(s): *Please provide a direct hyperlink to your company webpage of medical device services.*

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ISO 13485 医疗器械指令内审员

ISO 13485 Medical Devices Directive Internal Auditor

课程助益

由于关系到人类本身的健康和安全，全球对医疗器械行业都有严格的要求。在欧洲市场上，医疗器械生产厂商早已被强制要求通过认证机构的CE认证。市场的压力使国内医疗器械企业深入了解这方面的要求成为迫切的需要。本课程将透彻的讲解医疗器械行业认证要求，使您全面掌握有关 ISO 13485: 2003 的相关要求，有效的进行体系内审工作。

参加对象

与ISO13485 体系相关人员

课程大纲

- 医疗器械行业质量管理体系基础
- ISO13485 医疗器械质量体系用于法规目的的体系要求
- ISO13485 在具体企业应用中的特点
 - 文件要求
 - 过程控制
- 医疗器械的指令要求
 - 指令与体系的关系
 - 指令与产品标准
- ISO13485 内部审核工作的策划
- 内部审核技巧
- 第三方质量体系认证过程和认证中常见的问题

Benefits to you and your organization

Due to an increasing global awareness to health and safety issues, higher regulatory requirements have been introduced especially to medical equipment manufacturers. In Europe, medical equipment manufacturers have already been required to obtain CE certification. Market pressure has prompted Chinese medical equipment manufacturers to fully comprehend according to these requirements. This course provides clear explanations to the newly introduced regulatory requirements outlined in ISO 13485:2003 and will equip participants with the tools to effectively implement internal audits.

Who should attend

All personnel involved in ISO 13485 quality management system

Course outline

- Basics of the medical devices quality management system
- ISO 13485 Medical devices quality management system - legal and regulatory requirements
- Special requirements for the practical implementation according to ISO 13485
 - Document requirements
 - Process control
- Medical devices directive requirements
 - Relationship between the quality system and the safety directive
 - Safety directives and product standards
- Internal auditing planning according to ISO 13485
- Internal auditing techniques
- Third party quality system certification process and frequently asked questions

时间: 3 天
费用: 2,500 人民币

Duration: 3 Days
Fee: RMB 2,500

	1月	2月	3月	4月	5月	6月	7月	8月	9月	10月	11月	12月
上海/Shanghai	11-13		4-6				18-20			10-12		
北京/Beijing			23-25								16-18	
大连/Dalian												
广州/Guangzhou			7-9						14-16			
深圳/Shenzhen			9-11						28-30			

具体培训时间请联系最近的 TÜV 公司或办事处，或参考莱茵 TÜV 中国通讯

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