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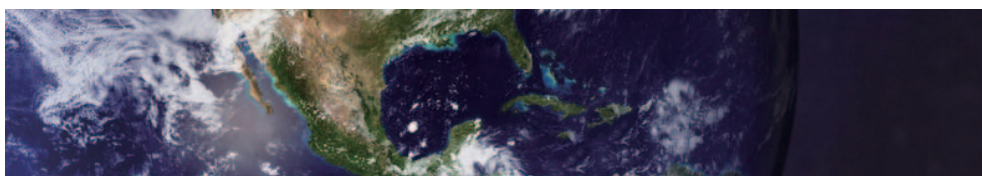
Global Approval

Globalization of Medical Device Approval

国际市场医疗器械准入

TÜV SÜD Group

TÜV®





Who is this applicable to?

Companies manufacturing or exporting medical devices and in vitro diagnostic medical devices for global markets.

TÜV SÜD facilitates market entry in many countries through agreements with local authorities and testing institutes. Manufacturers benefit from being able to submit fewer documents or from the consolidation of production monitoring.

USA

Class I and II medical devices require clearance for US market entry can only attain acceptance via a pre-market notification procedure, otherwise referred to as 510(k). The term 510(k) originates from section 510(k) of the Federal Food, Drug, and Cosmetic Act. A 510(k) submission is based on comparison of the new device with devices already legally marketed in the USA, which allows the US Food and Drug Administration (FDA) to determine whether a device is safe and effective. Medical device manufacturers are required to submit a 510(k) if they intend either to introduce a device for commercial distribution in the US for the first time, or to reintroduce a device that has been substantially modified. 510(k) was previously conducted by the FDA only.

Since 1996, the system was revised to allow several third parties to perform the review process on behalf of the FDA. TÜV SÜD was among those authorized to perform the third party review for all eligible devices. TÜV SÜD is able to perform pre-audits(i.e.mock audits) based on FDA regulations before a factory inspection.

适用对象是？

在全球市场从事医疗器械及体外诊断设备生产或出口的企业。

TÜV 南德意志集团与多国主管当局与检测机构签订了协议，可帮助企业更快地进入当地市场。制造商亦可从减少递交文件的数量，统一生产的监控中获益。

美国

I类和II类医疗器械需向美国食品与药品监督管理局提交上市前通告(又名510(k))并通过审核后方可在美国市场进行销售。510(k)这一名字源自于《食品、药品和化妆品法案》第510(K)章节，510(k)文件是参照已在美国合法上市的器械进行实质性等同说明的一套文件，以便美国食品与药品监督管理局(FDA)确定器械是否安全有效。在医疗器械首次投放美国市场，或上市器械作出重大更改时，制造商需提交510(k)申请。之前510(k)申请全部由FDA进行审核。

自1996年起，此系统开始允许指定的第三方机构可以代表FDA进行文件评审。TÜV南德意志集团就是其中之一。当FDA宣布要对您进行工厂检查时，我们也可根据FDA法规提供预审(如模拟审核)。





Moreover, TÜV SÜD is a Nationally Recognized Testing Laboratory (NRTL) for the US market and is able to provide testing services according to e.g. UL 60601-1. In addition, we will test your device according to the US-specific EMC requirements.

Canada

TÜV SÜD was the first registrar accredited by the Standards Council of Canada (SCC) to perform ISO 13485 CMDCAS certification. Specially trained and authorized auditors from TÜV SÜD support clients in achieving CMDCAS certification.

Japan

The revised Japanese Pharmaceutical Affairs Law (PAL) became effective on 1 April 2005. There are four classes of medical devices. TÜV SÜD is a Registered Certification Body (RCB) to certify class II medical devices. Products with a higher risk potential still need approval by the Pharmaceuticals and Medical Devices Agency (PMDA).

Hong Kong

The Medical Device Control Office (MDCO) regulates medical devices. On 26 November 2004, the DOH launched the Medical Device Administrative Control System (MDACS) as a regulatory framework for imported medical devices.

TÜV南德意志集团是美国劳动健康部授权的NRTL检测实验室，可为您提供如UL 60601-1等标准的检测。另外我们也可根据美国专用EMC标准为您提供检测服务。

加拿大

TÜV南德意志集团是第一家获得加拿大标准委员会 (SCC) 授权进行ISO 13485 CMDCAS认证的注册机构。我们审核员均接受过专业培训方获得授权，为所有客户提供CMDCAS认证。

日本

根据修订后的《日本药事法》于2005年4月1日起生效，医疗器械被分为四类。TÜV南德意志集团是日本注册认证机构(RCB)，可颁发二类医疗器械的相关证书。然而高风险产品仍然需要“药品和医疗器械综合管理机构”(PMDA)进行批准。

香港

香港卫生署医疗仪器管制办公室 (MDCO)负责医疗器械的管理。2004年11月26日，卫生署实施医疗仪器管制系统(MDACS)，作为对进口医疗器械进行管理的法规框架。



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TÜV SÜD has been recognized by the Department of Health as a Conformity Assessment Body (CAB) under the MDACS. Businesses can attain the CE marking & HK Registration with one assessment.

TÜV南德意志集团已按照MDACS要求成为卫生署授权的符合性评估机构(CAB)。客户进行一次评估便可获得CE标志及香港注册。

About TÜV SÜD

Established in Germany 140 years ago, TÜV SÜD is one of the world's leading technical services providers, offering knowledge services, inspections, testing, expert opinions, certification and training. Approximately 16,000 employees at over 600 locations worldwide provide technology, system and know-how optimization.

TÜV南德意志集团简介

140年前诞生于德国，TÜV南德意志集团是业内领先的技术服务公司，为您提供资讯，检验，测试，专家意见，认证和培训服务。16,000多名员工遍及全球600多个办事处，着力为您实现技术、体系和实际运作中的优化服务。

For more details of other countries, please refer to our website : www.tuv-sud.com

如需更多国家准入信息，可参考我们的网站：www.tuv-sud.com

For one stop German expertise in Greater China, please contact one of our branch offices, sales offices or representative offices:
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