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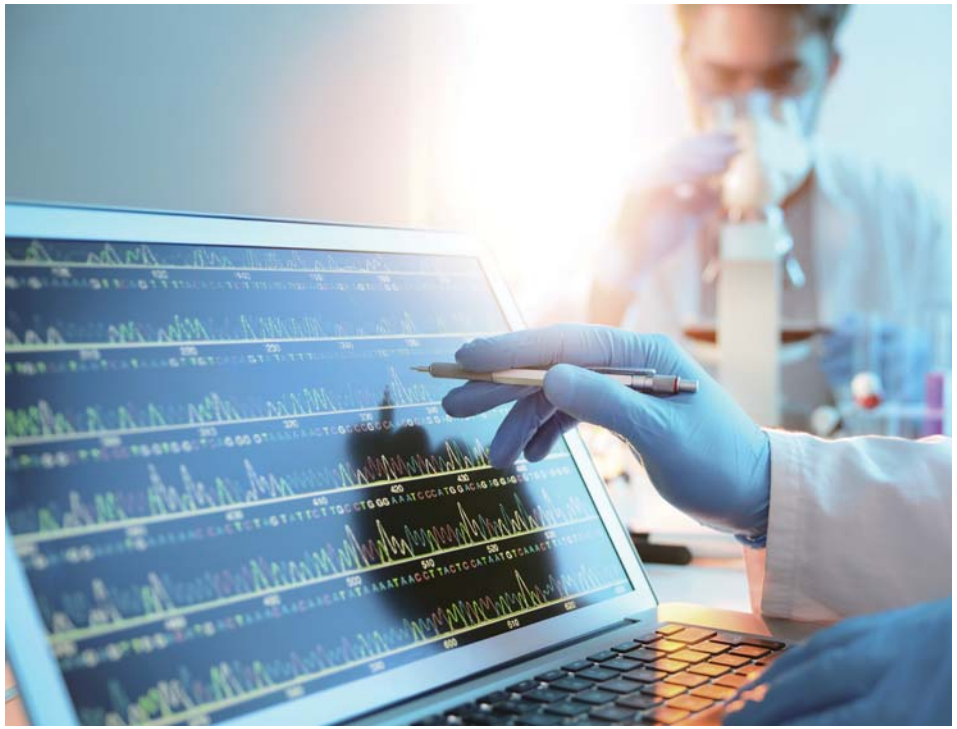
WHEN YOU NEED TO BE SURE



医疗器械产品一站式服务

ONE-STOP SERVICES FOR YOUR MEDICAL DEVICES

关于SGS ABOUT SGS

SGS是全球领先的检验、鉴定、测试和认证机构，也是公认的品质与诚信的全球基准。SGS集团在世界各地共有97,000多名员工，分布在2,600多个分支机构和实验室，服务网络遍及全球。

SGS is the world's leading inspection, verification, testing and certification company. Recognized as the global benchmark for quality and integrity, with more than 97,000 employees and operates a network of over 2,600 offices and laboratories around the world.

无论被支持机构规模如何，我们都能从供应链的每一环节确保医疗设备项目快速符合法规规定，以更快获得市场准入及更快实现利润。

Supporting organizations large and small, from every step of the supply chain, we ensure that medical device projects achieve quick regulatory compliance that translates in faster market access and faster profits realization.

作为医疗器械及体外诊断行业的领先服务提供商，SGS已在超过35个国家建立了由医疗器械专家及审核员构成的网络。由于熟知当地法规及市场，并能及时连接SGS的全球服务网络，您所在地区的SGS医疗器械专家能为您的医疗器械业务提供一站式解决方案。

As a leading service provider for the medical devices and IVD industries, SGS has developed a network of medical devices experts and auditors in over 35 countries. With knowledge of local regulations and markets and instant access to our global capabilities, the SGS medical device expert in your region has the one-stop-solution for your medical devices business.

在时机就是一切的行业中，SGS为医疗器械制造厂商提供全球性整合解决方案，促进新医疗器械更快进入市场。无论项目规模和目标市场的数量如何，SGS凭借范围广泛，资源丰富及专业技能的全球优势，来提高您的经营效率及价值。

For an industry where timing is everything, SGS offers medical device manufacturers a globally integrated solution to get their new devices to market faster. Regardless of the project size and number of markets targeted, SGS can improve the efficiency and value of your operation by combining in one global package the advantages of our worldwide reach, our wide range of accreditations and resources and global expertise.

认可资质及服务
OUR ACCREDITATIONS AND SERVICES

基于范围广泛的医疗器械认证及认可，SGS网络能针对几乎所有法规标准及市场提供完善的测试及认证服务。

Thanks to our wide range of medical devices certifications and approvals the SGS network can offer you complete testing and certification services for nearly all regulatory criteria and markets.

我们的资质包括

- 欧盟CE认证，SGS拥有欧洲合格认证的四个公告机构，其中三个公告机构(0598, 0120, 1639)可涵盖医疗设备的93/42/EEC指令及体外诊断医疗设备的98/79/EC指令
- 全球认证包括：UKAS ISO 13485:2003、加拿大CMDCAS；日本JPAL；美国食品及药物管理局现场检查；巴西卫生部注册要求的INMETRO认证、北美NRTL认证；台湾、澳大利亚及香港方案
- 公告机构及CB认证机构
- 欧盟指令认可包括：个人防护设备、压力设备、非自动称量设备及无线电与电信终端设备
- 更多

OUR ACCREDITATIONS INCLUDE

- Four notified bodies for CE marking. Three of them (0598, 0120, 1639) can cover 93/42/EEC for Medical Devices and 98/79/EC for In-vitro Diagnostic Medical Devices
- NATIONAL ACCREDITATIONS including: UKAS ISO 13485:2003, CMDCAS for Canada; JPAL for Japan; FDA siteinspections for USA; INMETRO for Brazil and schemes for Taiwan, Australia and Hong Kong
- NOTIFIED BODY as well as CB Certification Body
- Approval for OVERLAPPING EC DIRECTIVES including: Personal Protective Equipment; Pressure Equipment; Non Automatic Weighing Equipment; R&TTE
- AND MANY MORE

CE 0598 CE 0120 CE 1639

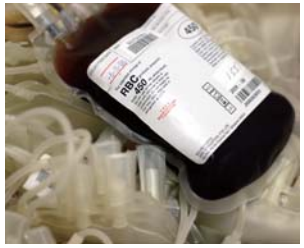
我们精锐的专业范畴
OUR EXPERTISE DELIVERS TRUST

SGS拥有完整的全球网络和医疗器械整包组合服务，为您的业务提供增值服务并能快速推进国际市场。我们通过以下途径为您完成：

- 更具灵活的解决方案 —— 时刻关注您的业务，随时为您解答测试认证等咨询，为您的产品授权多种认证，包括CB、CE、NRTL、SCC等
- 唯一项目负责人 —— 为您量身定制，并负责处理所有测试、认证及任何其它服务需求
- 完整的IEC 60601测试 —— 主要的医疗器械测试标准，以及IEC 61010的完整测试
- 多重法规支持 —— 满足MDD及IVD指令要求，并根据ISO 14971列出的风险管理要求

Our entire network and medical devices portfolio has been developed to bring added value to your business and fast track your market access. SGS achieves this through:

- FLEXIBLE SERVICE SOLUTIONS that keep your business in mind, putting test data to work, to grant you access to multiple accreditations, including: CB, CE, NRTL, SCC, etc.
- ONE PROJECT MANAGER located close to you, to handle all your testing, certification and any other service needs in a fashion uniquely suited to your business
- COMPLETE TESTING TO IEC 60601, the crucial medical devices standard, as well as testing to IEC 61010
- SUPPORT WITH COMPLEX REGUALTORY COMPLIANCE such as fulfilling the requirements of the MDD and IVD Directives or addressing risk management requirements as per ISO 14971



测试服务 TESTING SERVICES

电磁兼容、安规、性能和无线测试服务
EMC, SAFETY, PERFORMANCE AND WIRELESS TESTING SERVICES

SGS中国在广州、深圳、上海及天津已经投资建立医疗安规测试实验室、EMC和无线测试实验室，其中包括广州及深圳投资兴建的10m半电波暗室。我们的EMC测试实验室资质包括美国FCC(美国联邦通讯委员会)、加拿大工业部、日本VCCI(信息类设备干扰自愿控制委员会)、北美NVLAP(国家自愿性实验室认可体系)、SGS FIMKO CB/EMC测试实验室、中国CNAS(中国国家合格评定委员会)等，均可提供产品研发阶段的预测试，以及产品认证阶段的型式测试和产品测试失败时的整改服务。

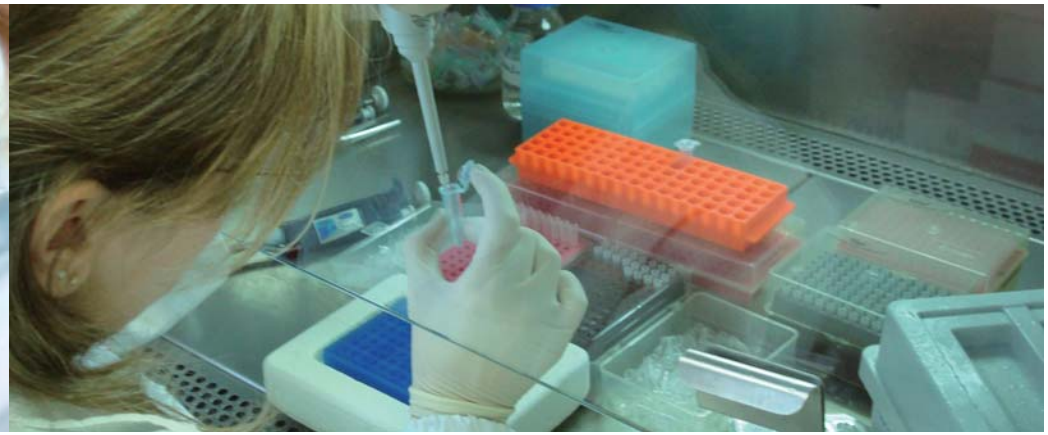
SGS has set up our own Medical safety testing labs, EMC and wireless testing labs in China Guangzhou, Shenzhen, Shanghai and Tianjin, where we have provided EMC and Wireless testing services, including 10m Semi-Anechoic chamber in Guangzhou and Shenzhen. Our testing facilities have registered in US FCC (US Federal Communication Commision), Canada IC (Industry Canada), Japan VCCI (Voluntary Control Council for Interference by Information Technology Equipments) and our labs have been accredited by US NVLAP (national Voluntary laboratory Accreditation Program), IECEE CBTL under the responsibility of SGS FIMKO Ltd., China CNAS etc. we can provide the pre-testing in product R&D stage, type testing and debug/modification services in product certification stage.

服务项目

- 欧盟/IEC产品安规和性能测试，包括根据IEC/EN 60601系列标准以及覆盖全球30多个国家要求的CB体系测试
- FDA510(K)支持服务包括：测试，咨询和工厂后续预审核
- EMC测试(用于医疗器械CE mark认证的IEC/EN 60601-1-2测试)符合加拿大SCC以及FDA的要求
- 无线产品相关测试以及无线产品涉及的全球准入性认证
- 电池测试及认证，包括IEC 62133 CB认证以及UL 1642/2054的SGS北美认证
- 电动轮椅等医疗康复类产品测试

TESTING SERVICES

- EU/international product safety and performance, including testing to the IEC/EN 60601 series and testing under the CB scheme that covers testing requirements of over 30 countries
- FDA510(K) support services for test data, consulting, and factory follow-up
- EMC testing (IEC/EN 60601-1-2, MDD – CE marking) - This testing can be used to support the SCC and FDA requirements
- Wireless testing/telemedicine and international type approval for wireless
- Battery testing, including IEC 62133 for CB Scheme and UL 1642/2054 for lithium cells and batteries for US Certification
- Medical rehabilitation products testing, such as electric wheelchair testing



生命科学 —— 微生物，理化测试服务
LIFE SCIENCE - MICROBIOLOGICAL, PHYSICAL & CHEMICAL TESTING LABS

SGS生命科学服务在美洲、欧洲与亚洲12个不同国家中具有16个尖端实验室。其中，位于上海的测试实验室获得中国CNAS认可，同时也是美国FDA注册的实验室，可提供微生物、无菌、化学、生物安全性评价、环境检测等相关测试服务。

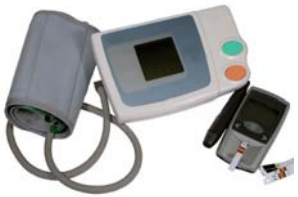
Our presence in Asia, Europe, America, totally 12 countries, among which Shanghai lab has accredited by CNAS and registrated in US FDA, can provide the microbiological, sterilization, biocompatibility and environment monitoring testing services.

服务项目

- 化学测试
- 灭菌测试
- 微生物测试
- 生物安全性测试，包括根据ISO 10993系列标准要求
- 环境监测
- 包装测试

TESTING SERVICES

- Chemical test
- Sterilization test
- Microbiological test
- Biocompatibility test, including the testing according to ISO 10993 series
- Environment monitoring Service
- Packaging Test



机械、功能测试服务
MECHANICAL AND FUNCTIONAL TESTING SERVICES

SGS 中国已经在广州、顺德和上海建立了机械包装以及功能测试实验室，均取得CNAS认可，包装运输可提供不同标准的测试服务，包括欧洲，澳洲，英国，美国等国家标准以及ISTA标准。

SGS China has established mechanical and packaging testing labs in Guangzhou, Shunde and Shanghai, all of which have accredited by CNAS and can provide the testing service according to different standards, such as Europe, Australia, British, ASTM, ISTA ect.

服务项目

- 材料分析
- 振动测试
- 盐雾测试
- 疲劳耐久性测试
- 机械冲击测试
- 包装模拟运输
- 金属材料材质分析
- 高分子材料材质分析
- 日照/紫外光老化测试
- 环境可靠性/温湿度循环测试
- 无音室声压、声功率量测试

TESTING SERVICES

- Material Analysis
- Vibration Test
- Salt Spray
- Durability Test
- Mechanical Shock Test
- Package Transportation Test
- Metal Analysis
- Polymer Analysis
- Deterioration Test
- Reliability / Condition Test
- Acoustics Test

限用物质测试服务
RESTRICTED SUBSTANCE TESTING SERVICES

RoHS 2.0(2011/65/EU) 于2011年7月1日在欧盟官方公报上正式发布并于20天后强制执行。适用于该指令的医疗器械包括了同时适用于93/42/EEC以及98/79/EC利用电能工作的医疗设备。SGS遍布中国的7个化学测试中心实验室，获得中国CNAS，韩国KSFDA，德国DAP(Deutsches Akkreditierungssystem Prufwesen GmbH)等资质认可，可提供指令要求的医疗设备限用物质测试服务以及针对企业限用物质管控的整体解决方案。

RoHS 2.0(2011/65/EU) was published on 1 July 2011 by Europe official journalist and come into force after 20 days. The applicable medical devices include those driven by electro power fall into 93/42/EEC and 98/79/EC. Medical devices and IVD medical devices shall comply with this directive. 7 related chemical test centers around SGS China, accredited by China CNAS, Korea KSFDA and Germany DAP(Deutsches Akkreditierungssystem Prüfwesen GmbH) ect., can cover all the testing services over the country and provide the restricted substance testing to ROHS 2.0 and the provide the complete one-stop solution services for restricted substance control.

服务项目

- 限用物质测试，包括RoHS 2.0, REACH针对医疗器械的要求
- 有害物质过程管理提升方案

TESTING SERVICES

- Restricted substance testing, including testing to RoHS 2.0 and REACH requirements
- Process management improving solution for Harzard substances

认证服务 CERTIFICATION SERVICES

欧盟指令93/42/EEC (修订 2007/47/EC)医疗器械指令
EC DIRECTIVE 93/42/EEC (AMENDED BY 2007/47/EC) MEDICAL DEVICES DIRECTIVE

按照93/42/EEC所修订的欧盟医疗器械指令2007/47/EC的要求，部分I类(灭菌/具测量功能)、IIa类、IIb及III类器械制造商，在使用CE标志及产品投放市场以前，都需要获得公告机构的认证证书。SGS公告机构可以认证93/42/EEC指令所包含的医疗器械，包括药物/器械结合体及相关的指令2003/32/EC、2005/50/EC指令的认证。SGS全球分支机构根据以上指令提供的服务，包括附录II、V、VI及现场审核和/或技术文件评估。

EC Directive 93/42/EEC as amended by 2007/47/EC for medical devices requires manufacturers of Class I (sterile/measuring), IIa, IIb and III devices to obtain certification from a Notified Body before using the CE mark and placing the product on the market. SGS Notified Bodies can certify medical devices under directive 93/42/EEC, including drug/device combinations and associated directives 2003/32/EC and 2005/50/EC. The certification options under this directive offered globally by SGS affiliates include Annex II, V and VI comprising site audits and/or assessments of technical documentation.

欧盟指令98/79/EC体外诊断医疗器械指令
EC DIRECTIVE 98/79/EC IN VITRO DIAGNOSTIC MEDICAL DEVICES DIRECTIVE

根据欧盟体外诊断医疗器械指令98/79/EC要求，中/高风险的体外诊断医疗器械制造商(List A、list B及自我检测用体外诊断医疗器械)在使用CE标志及产品投放市场前，必须通过公告机构的认证。SGS UK(公告号0120)获得指令98/79/EC授权，SGS全球分支机构可以提供的服务，包括附录III、IV、VII及现场审核和/或技术文件评估。

EC Directive 98/79/EC for in vitro diagnostic medical devices requires manufacturers of medium and high risk devices (List A, List B and self test devices) to obtain certification from a Notified Body before using the CE mark and placing product on the market. SGS UK is Notified Body 0120 under directive 98/79/EC. The certification options under this directive offered globally by SGS affiliates include Annex III, IV and VII comprising site audits and/or assessments of technical documentation.

CB

CB是世界五大洲各国广泛采纳的产品认证互认计划，它标志着被认证之电器产品符合IEC标准，CB计划得到全球CB成员国或非CB成员国家和地区的共同认可。CB制度极大地有助于节省重复测试的时间和成本，例如，厂商在取得SGS颁发的CB测试报告和证书的基础上，加上进口地的国家差异就可以方便转换为进口地所接受的测试报告。

CB (Certification Bodies) is a mutual recognition scheme of products certification which widely adopted by countries around the world. It symbolizes the IEC conformity of certified electrical products. CB scheme is of great benefit to saving time and costs of repeated testing, e.g. a company applies the national deviation of import country based on CB testing report and certificate issued by SGS, which conveniently convert the testing report into the one accepted by the import country.

巴西有源医疗器械INMETRO认证
BRAZIL ELECTRO-MEDICAL MEDICAL DEVICES INMETRO CERTIFICATION

巴西卫生部(ANVISA)颁布了一系列监管医疗器械的RDCs法规，其中RDC 32/2007规定了对于有源医疗器械INMETRO的认证要求，INMETRO认证包括认可机构的测试要求、对生产厂家按照部分ISO 13485要求和产品常规测试要求进行工厂审核。SGS巴西是INMETRO授权可以进行测试、审核和出具INMETRO证书的机构，通过SGS全球网络可以为有源医疗器械制造商提供便捷服务。

The Brazilian Health Agency is known as ANVISA and the regulation of medical devices is through a series of resolutions or RDCs. Among those, RDC 32/2007 on the certification of active medical devices. Electro-medical medical devices require an INMETRO certificate which must include test reports and an annual audit at the manufacturing site covering parts of ISO 13485 and routine testing. SGS Brazil is approved to undertake testing and audits, and issue INMETRO certificates. This service is available through the global network of SGS medical devices offices and auditors.

北美NRTL　U.S. NRTL

OSHA/NRTL认可计划，由美国职业安全与健康管理局(OSHA)制定，目的是确保美国境内所有在工作场合使用的产品符合特定的安全要求标准。美国并没有针对工作场所外使用的产品制定相应认证要求，但大部分的零售商仍会要求产品通过NRTL的测试。SGS美国是OSHA认可的NRTL。产品贴有SGS Ω MARK列名标识表明该产品已经符合指定的安全标准的要求。

OSHA/NRTL (Nationally Recognized Testing Laboratory) Recognition is a governmental program designed to satisfy the need for approval of products to be used in the workplace (that is, subject to OSHA regulations). Product Certification in the US is not required for products used outside the workplace, but most retailers will not sell unlisted products. SGS NA is OSHA approved NRTL. The SGS Ω MARK indicates the product meets the safety requirement in US.

非洲　AFRICA

非洲市场中，以下国家已经把医疗器械列入了规制产品中，医疗器械出口至这些国家清关时必须提供"产品符合性"证书。

- 尼日利亚
- 肯尼亚
- 阿尔及利亚
- 布隆迪

SGS作为上述各国政府授权的评定机构，对出口产品及生产过程进行鉴定工作，通过产品测试、验货及认证等过程确认产品是否符合进口国相关法律指定的要求，并发放产品符合性证书。

Medical devices are under regulatory approval in certain countries in Africa, therefore COC(Certificate of Conformity) should be obtained and provided for custom clearance in case shipments to these countries.

- Nigeria
- Kenya
- Algeria
- Burundi

Authorized as the rating agency by the above governments, SGS verifies export and produce process of products, identifies related law requirements of the export country by in-lab testing, inspection and certification, and finally issues the COC.

ISO 13485认证 ISO 13485

作为全球协调的法规符合性要求，ISO 13485适用于所有医疗器械制造商及其零件提供商、分包服务商及经销商。SGS提供全球认可的ISO 13485认证，帮助您获得法规许可、医疗器械销售资格、控制风险并减少执法审查及供应商审核的次数。

Now the global basis for regulatory compliance, ISO 13485 is applicable to all manufacturers and providers of medical devices, components, contract services and distributors of medical devices. We offer certification against this standard with our global recognition. ISO 13485 will help you achieve regulatory approval, sell your devices, manage your risks, and reduce the number of regulatory and supplier audits you undergo.

加拿大CMDCAS ISO 13485认证

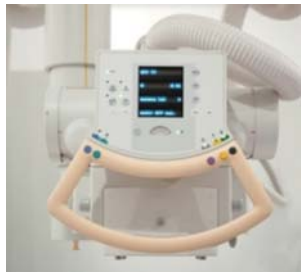
加拿大医疗器械法规要求所有II类、III类及IV类医疗器械在申请许可证及投放加拿大市场前，都需要获得CMDCAS认可登记机构签发的ISO 13485证书。SGS UK是加拿大标准委员会(SCC)认可的CMDCAS认可登记机构。我们的现场审核包含针对ISO 13485及部分必须的加拿大医疗器械法规要求的审核。

The Canadian medical devices regulations require all manufacturers of Class II, III and IV devices to obtain ISO 13485 certification from a CMDCAS Recognised Registrar before applying for a licence and selling products in Canada. SGS UK is Standards Council of Canada accredited as a CMDCAS Recognised Registrar and our site audits will assess compliance to ISO 13485 and parts of the Canadian regulations as necessary.

JPAL日本药事法 JPAL
JAPANESE PHARMACEUTICAL AFFAIRS LAW

日本医疗器械法规允许其认可的机构，如SGS日本公司，为意欲进入日本市场的II类医疗器械及体外诊断试剂制造商提供技术文件评审和制造现场审核。我们在日本及全球都提供此项服务,现场审核频次是每两年半进行一次。

The Japanese medical devices regulation allows approved bodies, such as SGS Japan Inc. to review the technical documentation and audit the manufacturing site of certain Class II medical devices and IVD reagents to give access to the Japanese market. We offer this service in Japan and globally and audit every 2½ years.



其他医疗器械认证服务
OTHER MEDICAL DEVICES CERTIFICATION SERVICES

- ISO 14971风险管理认证
- 台湾认可的TCP法规符合性审核
- 澳大利亚、香港CAB认可的法规符合性审核
- CAS客户定制审核, Gap Analysis差距分析
- 美国食品药品管理局现场检查 (US FDA)

- ISO 14971 Risk management
- Taiwan Technical Co operation Program
- Australia/HongKong CAB (Conformity Assessment Body) accredited body
- CAS customer-made audit service, Gap Analysis
- U.S. Food & Drug Administration (FDA) site inspection

培训 TRAINING

医疗器械行业培训课程及服务
MEDICAL DEVICE VOCATION TRAINING AND SERVICES

在医疗器械最终使用者越来越关注医疗器械及其相关设备的安全性和有效性的同时，销售国主管当局也通过一系列法律法规进行干预，以确保医疗器械产品的安全性和有效性，更好的满足使用者的期望。以下培训课程和服务是为企业提供更深入的知识及技能，以持续改善业务运作，及更有效地实施企业内部质量管理体系。

When End-users of medical devices are increasingly concerned about the safety and effectiveness of medical devices and related equipment, the competent authorities of the sales countries also intervene through a series of laws and regulations to ensure the safety and effectiveness of medical device products and hence to better meet users' expectation. The training courses and services below are to provide the enterprises with more in-depth knowledge and skills so that the business operation can be continuously improved and internal quality management system can be more effectively implemented.

序号	课程名称
1	医疗器械指令(Directive 93/42/EEC)法规培训
2	医疗器械指令(Directive 93/42/EEC) MDD内审员培训
3	体外诊断器械欧盟指令(Directive 98/79/EC) IVD法规培训
4	体外诊断器械欧盟指令(Directive 98/79/EC) IVDD内审员培训
5	医疗器械风险管理(ISO 14971)培训
6	医疗器械(MD或IVD)技术文档准备(NB-MED/2.5.1)培训
7	医疗电气设备安全测试(IEC 60601, Safety, EMC Testing)培训
8	供应商控制及自主品牌要求(Supplier Control/Own Branding)培训
9	医疗器械体系整合培训及产品上市解决方案
10	灭菌确认及过程监控、包装确认(ISO 11135或ISO 11137)培训
11	医疗器械软件确认(IEC 62304)培训
12	临床评估(MEDDEV 2.7.1,ISO 14155)培训
13	微生物(无菌）测试/洁净室(Clean Room)测试培训
14	ISO 13485标准讲解培训
15	ISO 13485内审员培训

序号	课程名称
16	基于ISO 9001体系建立ISO 13485医疗器械管理体系培训
17	美国医疗器械FDA法规培训(21CFR820, 510(K), QSIT)
18	加拿大医疗器械法规(CMDCAS)培训
19	澳大利亚医疗器械法规(TGA)培训
20	HK医疗器械规管制度(MDACS)培训
21	洁净室建立及管理监控(Clean Room, ISO 14644)培训
22	医疗器械生物学评价(ISO 10993)培训
23	过程确认(Process Validation)培训

更多服务 MUCH MORE SERVICES

- 检验 —— 生产初期产品检验，生产中期产品检验，生产终期产品检验，装箱/卸货监管
- 社会责任 —— BSIC, ETI-SMETA, WRAP, ICS, EICC, C-TPAT
- INSPECTION – Initial Production Check (IPC), During Production Check (DUPRO), Final Random Inspection (FRI), Loading/Unloading Supervision (LSUS)
- SOCIAL RESPONSIBILITY – Associated with BSIC, ETI-SMETA, WRAP, ICS, EICC, C-TPAT

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