



生命科学服务 — 医疗器械检测服务

LIFE SCIENCE SERVICES TESTING SERVICES FOR MEDICAL DEVICES

SGS

When you need to be sure



关于SGS

About SGS

SGS是国际公认的测试、检验和认证机构，是公认的品质与诚信的全球基准。SGS集团在全球各地共有99,600多名员工，分布在2,600多个分支机构和实验室，构成了全球性的服务网络。

通标标准技术服务有限公司是SGS集团和隶属于原国家质量技术监督局的中国标准技术开发公司共同建成于1991年的合资公司，在中国设立了90个分支机构和200多间实验室，拥有16,000多名训练有素的专业人员。

SGS生命科学实验室的运作遵循最高质量标准(cGMP、ISO 17025或者ISO 9001)，通过美国食品药品监督管理局(US FDA)及地方管理机构审核。SGS生命科学部的使命是提供专业和独立的临床研究和生物/制药和医疗器械的质量控制测试服务和测试研究，为我们的客户、员工、股东和世界各地的患者创造价值，以保证药品/医疗器械质量。

SGS is the world's leading testing, inspection and certification company. Recognized as the global benchmark for quality and integrity, with more than 99,600 employees and operates a network of over 2,600 offices and laboratories around the world.

SGS-CSTC Standards Technical Services Co., Ltd. was founded in 1991 as a joint venture between SGS Group and China Standard Technology Development Corp., under the State Administration of Quality Technical Supervision. SGS-CSTC boasts over 200 laboratories and 78 branches with over 16,000 professionals.

SGS's life sciences laboratories operate according to the highest quality standards (cGMP, ISO 17025 or ISO 9001) and passed audits from US FDA and local regulatory authorities. The life sciences mission at SGS is to safeguard the quality of medicines/medical devices by providing professional and independent services in clinical research, biologics characterization, analytical development, and quality control testing of pharmaceuticals, biopharmaceutical and medical devices creating value for our clients, employees, shareholders and patients worldwide.



遍布全球的分析实验室网络

Global network of contract analytical labs

SGS致力于为生物/制药和医疗器械行业提供检验和实验室服务，服务网络遍及欧洲，美国和亚洲12个国家，共有30个实验室，3,000多名员工，是全球最先进的临床研究检测机构，拥有最大的GMP/GLP合规实验室服务网络。

With 3,000 employees, a state-of-the-art clinical pharmacology unit and the world's largest network of GMP/GLP-compliance laboratories, SGS serves the pharmaceutical, biotechnology and medical device industries across Europe, the Americas and Asia with 30 labs located in 12 countries.

AMERICAS	EUROPE	ASIA
<p>CANADA</p> <ul style="list-style-type: none"> ● Toronto (Markham, ON) ● Toronto (Mississauga, ON) <p>USA</p> <ul style="list-style-type: none"> ● Chicago (Lincolnshire, IL) ● New Jersey (Fairfield, NJ) ● Philadelphia (West Chester, PA) ○ Boston (Hudson, NH) 	<p>BELGIUM</p> <ul style="list-style-type: none"> ● ● Brussels (Wavre, Zellik) <p>FRANCE</p> <ul style="list-style-type: none"> ● Paris (Villeneuve-La-Garenne) ● Poitiers <p>GERMANY</p> <ul style="list-style-type: none"> ● Aachen ● Berlin ● Berlin ● Frankfurt (Taunusstein) ● Munich ● Wiesbaden 	<p>AUSTRIA</p> <ul style="list-style-type: none"> ● Wörgl <p>IRELAND</p> <ul style="list-style-type: none"> ● Cork (Ringaskiddy) <p>SWITZERLAND</p> <ul style="list-style-type: none"> ● Geneva (Plan-les-Ouates) ● Basel (Birsfelden) <p>UNITED KINGDOM</p> <ul style="list-style-type: none"> ● Chester (Deeside) ● Glasgow <p>CZECH REPUBLIC</p> <ul style="list-style-type: none"> ● Prague
		<p>CHINA</p> <ul style="list-style-type: none"> ● Shanghai (Xuhui) ● Shanghai (Pudong) <p>INDIA</p> <ul style="list-style-type: none"> ● Navi-Mumbai
		<ul style="list-style-type: none"> ● QC / R&D ● Bioanalysis ○ Formulation & CDMO ● Medical / Clinical



基于cGMP/GLP的质量管理体系

Quality management system based on cGMP/GLP

SGS符合国际监管机构的准入要求

质量管理体系包含6个方面：

- 总部质量手册
- 总部政策
- 总部标准操作程序
- 本地质量手册
- 本地标准操作程序
- 本地质量文件

遵照GxP法规和本地其他的体系认证：

- ISO 17025
- ISO 9001
- WHO (资格预审方案)

SGS与国际监管机构合作：

- US FDA
- EMA/MHRA
- Health Canada

COUNTRY	LABORATORIES	QUALITY MANAGEMENT SYSTEM	ISO STANDARD	US-FDA REGISTERED	US-FDA INSPECTED
CANADA	Toronto (Markham)	GMP	-	•	•
CANADA	Toronto (Mississauga)	GMP	9001/13485	•	•
USA	Chicago (Lincolnshire)	GMP/GLP	9001	•	•
USA	New Jersey (Fairfield)	GMP	9001	•	•
USA	Philadelphia (West Chester)	GMP	-	•	•
BELGIUM	Brussels (Wavre)	GMP/GLP/GCP	17025	•	•
BELGIUM	Brussels (Zellik)	GMP	-	-	-
FRANCE	Paris (Villeneuve La Garenne)	GMP	-	•	•
FRANCE	Poitiers	GLP/GCP	-	•	•
GERMANY	Berlin	GMP	-	•	•
GERMANY	Frankfurt (Taunusstein)	GMP	17025	•	•
GERMANY	Wiesbaden	R&D	-	-	-
SWITZERLAND	Geneva	GMP/GLP/GCP	-	•	•
UK	Glasgow	GMP/GLP	-	•	•
CHINA	Shanghai	GMP/GLP	17025	•	•
CHINA	Qingdao	-	17025	-	-



我们的服务范围

Our service scope

测试服务

- 微生物检测
- 理化检测
- 生物学评价
- 材料分析
- 其他测试服务

项目服务

- 植入物产品清洗验证
- 可重复使用医疗器械再处理过程确认
- 容器/包装验证
- 稳定性研究
- 化学表征
- 呼吸气路的ISO 18562检测
- 含药器械的相容性研究

现场服务

- 空调系统验证
- 设备验证
- 水系统验证
- 洁净室环境验证

培训服务

- ISO 17025辅导
- ISO 13485:2016医疗器械质量管理体系内审员培训课程
- ISO 14971:2019医疗器械风险管理培训课程
- 美国医疗器械法规要求培训课程 (21 CFR 820, 510(K), QSIT)
- 欧盟医疗器械最新法规MDR培训课程
- IEC 62304医疗器械软件 软件生存周期过程培训课程
- 国内GMP法规要求综合解读培训课程
- 其他检测标准或法规培训

认证服务

- MDR欧盟认证

设备校准服务

TESTING SERVICES

- Microbiological Test
- Physical & Chemical Test
- Biocompatibility Evaluation
- Material Analysis
- Other Testing Services

PROJECT SERVICES

- Cleaning Validation of Orthopedic Products
- Reprocessing Verification of Reusable Medical Devices
- Container/Packaging Validation
- Stability Study
- Chemical Characterization
- ISO 18562 Biocompatibility Evaluation of Breathing Gas Pathway in Healthcare Application
- Compatibility Study of Device-drug Combination Products

ON-SITE SERVICES

- Air-conditioning System Validation
- Equipment Validation
- Water System Validation
- Cleanroom Environment Certification

TRAINING SERVICES

- ISO 17025 related training
- ISO 13485:2016 medical device quality management system internal auditor training course
- ISO 14971:2019 medical device risk management training course
- Training courses required by American Medical Device Regulations (21 CFR 820, 510(K), QSIT)
- Training course of the latest EU medical device regulations
- IEC 62304 medical device software; software life cycle process training course
- Training course for comprehensive interpretation of domestic GMP regulations
- Training on other testing standards or regulations

CERTIFICATION SERVICES

- Medical Device Regulation (MDR) Certification

CALIBRATION SERVICES





测试服务

Testing services

微生物检测

- 微生物检测
- 微生物限度测试
- 细菌内毒素检测(凝胶法、动态浊度法 / 显色法)
- 菌种鉴定(API, PCR)
- 抑菌性能
- 消毒剂有效性验证
- 环氧乙烷灭菌验证
 - 生物指示剂测试
 - 生物负载
 - 无菌验证/测试
- 辐照灭菌确认
 - 生物负载
 - 无菌验证/测试
- 不溶性微粒测试
- 环境监控
- 防腐效能测试及微生物挑战试验
- 过滤器细菌截留检测
- 抗病毒测试

理化检测

- 化学残留检测
 - 环氧乙烷
 - 2-氯乙烷
 - 总有机碳
 - 碳氢化合物
 - 重金属
- 材料成分分析
 - 光谱分析
 - 质谱分析
 - 能谱分析
- 材料物理性能测试
 - 外观表征
 - 力学测试
 - 热谱测试
- CMR (致癌、致突变及生育毒性物质)检测

MICROBIOLOGY TEST

- Microbiology Test
- Microbial Limits Test
- Bacterial Endotoxin Test (Gel / Dynamic Turbidity / Chromogenic Method)
- Strain Identification (API, PCR)
- Antimicrobial Properties
- Validation of Disinfectant Effectiveness
- Ethylene Oxide Sterilization Validation
 - Biological Indicator Test
 - Bioburden
 - Sterility Validation / Test
- Radiation Sterilization Confirmation
 - Bioburden
 - Sterility Validation / Test
- Insoluble Particle Test
- Environmental Monitoring
- Preservative & Microbial Challenges
- Bacterial Retention Test of Filter
- Antivirus Test



PHYSICAL & CHEMICAL TEST

- Chemical Residue Detection
 - Ethylene Oxide, EO
 - ECH
 - Total Organic Carbon, TOC
 - Hydrocarbon, THC
 - Heavy Metals
- Material Composition Analysis
 - Spectral Analysis
 - Mass Spectrometry
 - Energy Spectrum Analysis
- Physical Property Test of Material
 - Appearance Characterization
 - Mechanical Test
 - Thermal Spectrum Test
- CMR (Carcinogenic, Mutagenic, Reprotoxic) Test





测试服务

Testing services

生物学评价

- 体外细胞毒性试验
- 致敏试验
- 刺激试验
- 遗传毒性、致癌性和生殖毒性
- 急性 / 亚急性全身毒性试验
- 亚慢&慢性毒性试验
- 溶血试验
- 植入实验
- 热原试验

材料表征

- 成分分析
- 添加剂、助剂定性定量分析
- 元素分析
- 微观形态检测
- 热谱检测
- 核磁检测

其他测试服务

- 人因工程与可用性测试
- 核磁兼容
- 电磁兼容(EMC)测试
- 安规测试
- 无线测试
- 电池测试
- 寿命
- 环境可靠性
- 网络安全
- 功能安全
- 助行器性能测试

BIOCOMPATIBILITY EVALUATION

- Tests for in Vitro Cytotoxicity
- Sensitization Test
- Irritation Test
- Genotoxicity, Carcinogenicity and Reproductive Toxicity Test
- Acute / Subacute Systemic Toxicity Test
- Subchronic / Chronic Systemic Toxicity Test
- Hemolysis Test
- Implantation Test
- Pyrogen Test



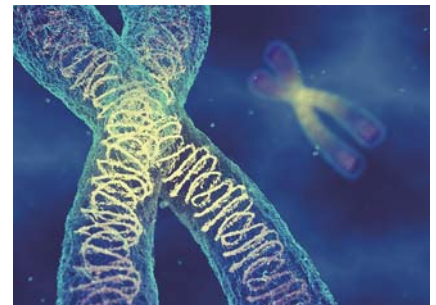
MATERIAL ANALYSIS

- Component Analysis
- Qualitative and Quantitative Analysis of Additives and Assistant Agents
- Elemental Analysis
- Micromorphology
- Thermal Spectrum Test
- NMR



OTHER TEST SERVICES

- Human Factors Engineering and Usability Test
- Magnetic Resonance Compatibility
- Electromagnetic Compatibility (EMC) Test
- Safety Test
- Wireless Test
- Battery Test
- Shelf-life Test
- Environment Reliability Test
- Network Security
- Functional Safety
- Walker Product Performance Test





项目服务

Project services

植入物产品清洗验证

- 表面污染
- 微生物污染(生物负载)
- 细菌内毒素
- 有机污染
- 总有机碳
- 碳氢化合物
- 脂溶性残留
- 水溶性残留
- 电导率
- 细胞毒性
- 颗粒物的评估

可重复使用医疗器械再处理过程确认

- 清洗验证
 - 手动清洗
 - 自动清洗
- 消毒验证
 - 化学消毒
 - 热力消毒
- 灭菌验证
 - 湿热灭菌
 - 过氧化氢低温等离子体灭菌
 - EO灭菌

容器/包装验证

- 包装研究
 - 材料成分分析
 - YBB符合性检测
 - 药典符合性检测 (CHP/USP/EP)
 - ISO 15378体系认证
- 货架寿命验证
 - 模拟运输试验 ISTA/ASTM D4169
 - 加速老化试验ASTM F1980
 - 密封强度测试
 - 鼓泡测试
 - 爆破测试
 - 染料渗透测试
 - 真空泄露测试
 - 微生物屏障测试

CLEANING VALIDATION OF ORTHOPEDIC PRODUCTS

- Surface Contamination
- Microbial Contamination (Bioburden)
- Bacterial Endotoxin
- Organic Pollution
- TOC
- THC
- Liposolubility Residual
- Water-soluble Residual
- Conductivity
- Cytotoxicity
- Particulate Associated Evaluation



REQUIREMENTS ON REPROCESSING OF REUSABLE MEDICAL DEVICES

- Cleaning Verification
 - Manual Cleaning
 - Automatic Cleaning
- Disinfection Verification
 - Chemical Disinfection
 - Thermal Disinfection
- Sterilization Validation
 - Steam Sterilization
 - Hydrogen Peroxide Hypothermic Plazms Sterilizing System
 - Ethylene Oxide Sterilization



CONTAINER/PACKAGE VALIDATION

- Packaging Research
 - Material Composition Analysis
 - YBB Conformance Test
 - Pharmacopeia (CHP / USP / EP) Conformance Test
 - ISO 15378 System Certification
- Shelf-life Validation
 - ISTA / ASTM D4169 Simulating Transportation Test
 - ASTM F1980 Accelerated Aging Testing
 - Seal Strength Test
 - Bubble Test
 - Burst Test
 - Dye Penetration Test
 - Leaks in Packages by Vacuum Decay Method
 - Microbial Barrier Ranking Test



项目服务

Project services

效期研究

- 实时老化
- 加速老化
- 光稳定性研究

化学表征

- 可浸提物研究
- 可沥滤物研究
- 毒理评估

含药器械的相容性研究

- 药械组合 - 药物吸附研究
- 药械组合 - 可沥滤物研究
- 毒理评估

呼吸气路检测

- 可吸入颗粒物(PM)释放测试
- 有机挥发物(VOCs)释放测试
- 凝析水中浸出物(Leachables)测试
- 医疗应用中呼吸管路的生物相容性评估

输注器械检测

- 还原物质 / 易氧化物
- 酸碱度
- 蒸发残渣
- 重金属
- 紫外吸收
- EO残留
- 细菌内毒素
- 无菌试验
- 细胞毒性试验
- 物理性能

眼科光学产品

- 软性角膜接触镜测试
- 硬性角膜接触镜测试
- 角膜接触镜护理产品测试
- 接触镜与接触镜护理产品的物理相容性测试

医美产品检测

- 透明质酸钠(玻尿酸)
- 胶原蛋白
- 微球类, 例聚左旋乳酸微球(童颜针)
- 等

防疫用品检测

- 防护服
- 口罩
- 熔喷布
- 医用手套

EXPIRY DATE

- Real Time Aging
- Accelerated Aging
- Photostability

CHEMICAL CHARACTERIZATION

- Extractable Study
- Leachable Study
- Toxicity Evaluation

COMPATIBILITY STUDY OF DEVICE-DRUG COMBINATION PRODUCTS

- Device-drug Combination-Drug Sorption
- Device-drug Combination Products-Leachables
- Toxicity Evaluation

BREATHING GAS PATHWAY TESTS

- Tests for Emissions of Particulate Matter
- Tests for Emissions of Volatile Organic Compounds
- Tests for Leachables in Condensate
- Biocompatibility Evaluation of Breathing Gas Pathway in Healthcare Application

INFUSION DEVICE TESTS

- Reducing Substances / Easily Oxidized Substances
- Acidity and Alkalinity
- Evaporation Residues
- Heavy Metals
- UV Absorption
- Ethylene Oxide Sterilization Residuals
- Bacterial Endotoxin
- Sterility
- Cytotoxicity
- Physical Properties

OPHTHALMIC OPTICS

- Soft Contact Lenses Test
- Rigid Contact Lenses Test
- Contact Lens Care Products
- Determination of Physical Compatibility of Contact Lens Care Products with Contact Lenses

MEDICAL AESTHETIC PRODUCT TESTING

- Sodium Hyaluronate
- Collagen
- Microspheres, e.g. poly-L-lactic acid microspheres
- Etc.

EPIDEMIC PREVENTION SUPPLIES

- Protective Clothing
- Mask
- Melt Blown
- Medical Glove



现场服务

On-site services

空调系统验证

AIR CONDITIONING SYSTEM VALIDATION

设备验证

EQUIPMENT VALIDATION

压缩气体

- 粒子
- 微生物
- 油分
- 水分

COMPRESSED GAS

- Particle
- Microbiological Organisms
- Oil Content
- Moisture Content

水系统验证

- 电导率
- 微生物限度
- 内毒素
- 总有机碳
- 其他理化测试

WATER SYSTEM VALIDATION

- Conductivity
- Microbial Limit
- Endotoxin
- TOC
- Other Physico-Chemical Tests

洁净室环境验证

- 高效过滤器完整性测试
- 风量/换气次数
- 静压差
- 自净时间
- 流型测试
- 温湿度
- 噪音和照度
- 悬浮粒子
- 浮游菌/沉降菌
- 生物安全柜测试

CLEANROOM ENVIRONMENT CERTIFICATION

- Integrity of High Efficiency Particulate Air Filter Tests
- Air Volume/Ventilation Rate
- Static Differential Pressure
- Clean-down Capability
- Airflow Pattern
- Temperature and Humidity
- Noise and Illumination
- Airborne Particle
- Settlement Bacteria/Planktonic Bacteria
- Biological Safety Cabinet Test





设备校准服务

Calibration services

SGS校准实验室是为社会提供仪器校准服务的机构，成立以来一贯致力于校准技术的开发和应用。在国内校准规范(JJF)、检定规程(JJG)的基础上，我们还着力研究ISO、ASTM、EN等国际通用的校准方法，不断提升实验室能力以满足国内外客户的要求。目前实验室已经取得中国合格评定国家认可委员会(CNAS)认可，出具的第三方校准证书可以在美国、英国、法国、意大利、德国、日本等众多国家和地区互认。

实验室在几何量、温度、电学、压力、质量、机械力学、化学等领域拥有世界先进的校准设备及专业的计量校准人员，能对相应专业的仪器设备进行校准、调试、维修的一站式服务。除此，SGS创建E-Calibration系统，致力于提供更好、更快、更简单的校准服务流程。长期以来，实验室严格按照ISO/IEC17025:2005《检测和校准实验室能力的通用要求》及国家相关法律法规的要求，建立完善的质量保证体系。为客户提供准确可靠的证书报告，赢得了众多国内外客户的赞赏和好评。

SGS Calibration laboratory is a technical third-party organisation which provides the calibration services to community with the dedication in the development and application of calibration technology .On the basis of local standards such as JJF and JJG standards, our calibration services are also extended to some international standards as ISO, ASTM, EN and other calibration methods to improve laboratory capacity. SGS Calibration lab has been accredited by China National Accreditation Service for Conformity Assessment (CNAS) , which is mutually recognized in USA, UK, France, Italy, Germany, Japan, etc.

Equipped by advanced calibration equipments and professional staff in the field of geometry, temperature, electrical,pressure, quality, mechanics and chemistry, we can provide one-stop service of calibration, commissioning and maintenance. Besides, SGS set up E-Calibration system to offer better, faster and simpler calibration service process. Over the years, the laboratory accords with ISO/IEC 17025:2005, national laws and regulations' requirements and has established a sound quality assurance system. We have won numerous appreciations and praises from clients through issuing accurate and reliable reports.

联系我们

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When you need to be sure

