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STC

医疗器械测试服务

Medical Devices Testing Service

www.stc.group

关于我们

STC总部设于香港，是一间独立、非牟利的测试、检验及认证机构。自1963年成立以来，STC为世界各地的客户提供专业的一站式符合性评估服务，助产品顺利进入全球市场。

STC作为跨国机构，除在中国上海、东莞、深圳、中山、北京、常州等多个主要城市设立实验室和办事处外，环球网络已延伸至德国、意大利、美国、越南及日本。STC拥有世界一流的实验室并受国际认可，可满足业内广泛需求。

我们一直不断致力于扩展服务范围，STC在设于东莞的枢纽中心斥资新建一栋大楼，提供化学和动物测试，配合电器和电子实验室，可以满足医疗设备制造商的全部测试需求，包括从化学表征、生物相容性评估、微生物评估、安全和性能验证到电磁兼容性测试等。STC医疗器械实验室已广泛受到国内和国际机构认可，包括IECEE、CNAS、DAkkS等。

About Us

Established in 1963, STC is an independent, not-for-profit testing, inspection and certification organization headquartered in Hong Kong, offering one-stop professional conformity assessment service for customers around the world to get access to the global markets.

As an organization with global network, not only has STC set up testing facilities and customer service offices in China's major cities such as Shanghai, Dongguan, Shenzhen, Zhongshan, Beijing and Changzhou, but also in countries like Germany, Italy, USA, Vietnam and Japan. Our world-class, internationally accredited testing facilities can meet the needs from a wide range of industries.

As part of our on-going efforts to expand our service portfolio, a testing block housing a chemical and animal laboratory has been added to our nerve centre in Dongguan, China, which, together with our electrical and electronic laboratory, can cater for all testing needs of medical device manufacturers – whether they be chemical characterization, biocompatibility evaluation, microbiological assessment, safety and performance verification, or electromagnetic compatibility testing. Our medical device testing facility has received accreditation from various national and international bodies, including IECEE, CNAS, DAkkS, etc.

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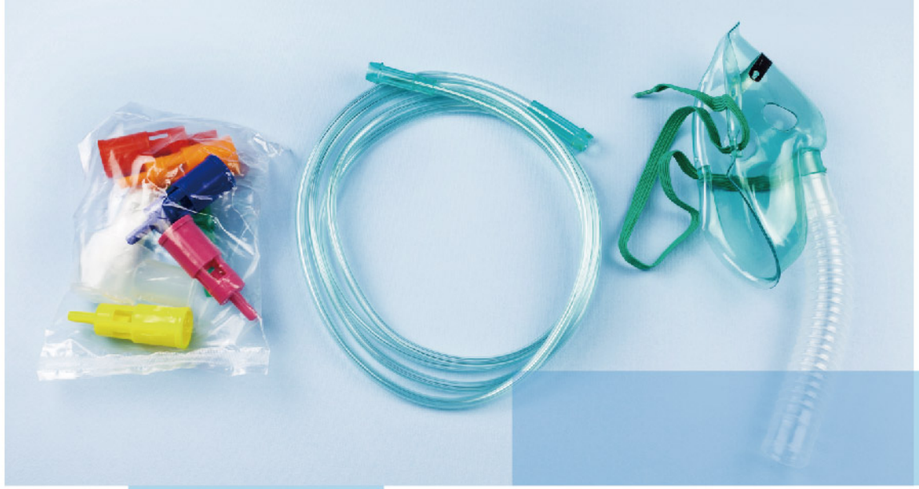
生物相容性测试

产品类别

- 失禁治疗吸收产品
- 粘合剂
- 采血及储血器械
- 骨空隙填料
- 中枢神经系统植入物
- 组合产品
- 隐形眼镜
- 牙种植体
- 包含抗菌剂的器械
- 设备原材料
- 血液透析一次性用品
- 植入式输药器械
- 输液/输血器械
- 人工晶状体
- 腹腔镜和内窥镜
- 义眼
- 畸齿矫正器械
- 骨科植入物
- 造瘘器械
- 可重复使用的器械
- 手术手套
- 手术缝合线
- 注射器
- 泌尿系统支架
- 泌尿系统导管
- 血管导管
- 人造血管
- 血管支架
- 心室辅助器械
- 伤口引流器械
- 伤口敷料



Biocompatibility Test

Product Categories

- Absorbent Incontinence Products
- Adhesives
- Blood Collection & Storage Devices
- Bone Void Fillers
- Central Nervous System Implants
- Combination Products
- Contact Lenses
- Dental Implants
- Devices Containing Antimicrobials
- Device Raw Materials
- Hemodialysis Disposables
- Implantable Drug Delivery Devices
- Infusion / transfusion Devices
- Intraocular Lenses
- Laparoscopes & Endoscopes
- Ocular Implants
- Orthodontic Devices
- Orthopedic Implants
- Ostomy Devices
- Reusable Devices
- Surgical Gloves
- Sutures
- Syringes
- Urinary Stents
- Urologic Catheters
- Vascular Catheters
- Vascular Grafts
- Vascular Stents
- Ventricular Assist Devices
- Wound Drainage Devices
- Wound Dressings

生物相容性测试

测试项目及标准

测试项目	标准	测试周期
细胞毒性测试		
细胞毒性测试（MTT法）	ISO 10993-5	3周
细胞毒性测试（琼脂法）	ISO 10993-5 / USP 87	3周
细胞毒性测试（滤膜法）	ISO 10993-5	3周
细胞毒性测试（直接接触法）	ISO 10993-5 / USP 87	3周
细胞毒性测试（洗脱法）	USP 87	3周
皮肤刺激和致敏测试		
致敏测试（最大剂量法 / 斑贴法）	ISO 10993-10	6~8周
皮肤刺激测试	ISO 10993-10	3周
皮内刺激测试	ISO 10993-10 / USP 88	3周
口腔刺激测试（需组织病理读片）	ISO 10993-10	8~10周
阴道刺激测试（需组织病理读片）	ISO 10993-10	8~10周
阴茎刺激测试（需组织病理读片）	ISO 10993-10	8~10周
直肠刺激测试（需组织病理读片）	ISO 10993-10	3个月
眼刺激测试	ISO 10993-10	3-4周
全身毒性测试		
急性全身毒性测试	ISO 10993-11 / USP 88	3周
亚急性全身毒性测试（14 / 28天）	ISO 10993-11	6周 / 8周
亚 / 慢性全身毒性测试（90 / 180天）	ISO 10993-11	5个月 / 8个月
热原测试	ISO 10993-11	3周
植入后局部反应测试		
皮下植入测试	ISO 10993-6	4周起
肌肉植入测试	ISO 10993-6	4周起
骨植入测试	ISO 10993-6	4周起
血液相容性测试		
溶血测试	ISO 10993-4 / GB	2周
溶血测试	ASTM F756	2周
凝血测试	ISO 10993-4 / GB	2周
血小板计数测试		2周
补体测试	ISO 10993-4 / GB	2周
血栓测试（体内、体外）	ISO 10993-4 / GB	2周
基因毒性 / 遗传毒性测试		
细菌回复性测试	ISO 10993-3	8周
小鼠淋巴瘤测试	ISO 10993-3	10周
染色体畸变测试	ISO 10993-3	10周
微核测试（小鼠）	ISO 10993-3	10周

Biocompatibility Test

Test Items and Standards

Test Item	Standard	Lead Time
Cytotoxicity Test		
Cytotoxicity Study (MTT Method)	ISO 10993-5	3 weeks
Cytotoxicity Study (Agarose Overlay Method)	ISO 10993-5 / USP 87	3 weeks
Cytotoxicity Study (Filter Diffusion Method)	ISO 10993-5	3 weeks
Cytotoxicity Study (Direct Contact Method)	ISO 10993-5 / USP 87	3 weeks
Cytotoxicity Study (MEM Method)	USP 87	3 weeks
Irritation and Skin Sensitization Test		
Skim Sensitization Study (GPMT / Closed-patch)	ISO 10993-10	6~8 weeks
Skin Irritation Test	ISO 10993-10	3 weeks
Intracutaneous (Intradermal) Reactivity Test	ISO 10993-10 / USP 88	3 weeks
Oral Mucosa Irritation Test	ISO 10993-10	8~10 weeks
Vaginal Irritation Test	ISO 10993-10	8~10 weeks
Penile Irritation Test	ISO 10993-10	8~10 weeks
Rectal Irritation Test	ISO 10993-10	3 months
Ocular Irritation Test	ISO 10993-10	3-4 weeks
Systemic Toxicity Test		
Acute Systemic Toxicity Test	ISO 10993-11 / USP 88	3 weeks
Subacute Systemic Toxicity Test (14 days / 28 days)	ISO 10993-11	6 or 8 weeks
Subchronic Systemic Toxicity Test (90 days / 180 days)	ISO 10993-11	5 or 8 months
Pyrogen Test	ISO 10993-11	3 weeks
Local Effects after Implantation Test		
Implantation in Subcutaneous Tissue Test	ISO 10993-6	4 weeks at least
Implantation in Muscle Test	ISO 10993-6	4 weeks at least
Implantation in Bone Test	ISO 10993-6	4 weeks at least
Interactions with Blood Test		
Hemolysis Test	ISO 10993-4 / GB	2 weeks
Hemolysis Test	ASTM F756	2 weeks
APTT、PT、TT、FIB	ISO 10993-4 / GB	2 weeks
Platelet Count Test		2 weeks
Complement Test	ISO 10993-4 / GB	2 weeks
Thrombosis Test (in Vivo / in Vitro)	ISO 10993-4 / GB	2 weeks
Genotoxicity Test		
Ames Test	ISO 10993-3	8 weeks
Mouse Lymphoma Assay Test	ISO 10993-3	10 weeks
Chromosome Aberration Test	ISO 10993-3	10 weeks
Mouse Micronucleus Test	ISO 10993-3	10 weeks

微生物测试

微生物测试是对成品设备、制造工艺以及制造环境的微生物特性进行评估，有助于减少微生物污染的风险，以降低患者、用户或第三方的感染风险。

STC提供全面的微生物测试，以协助医疗器械制造商符合微生物和灭菌安全法规的要求。

测试项目

- 生物负载测试
- 内毒素测定
- 无菌测试
- 包装的完整性测试
- 保质期/货架周期确认
- 微生物鉴定
- 药典测试
- 抗菌挑战
- 清洁验证
- 定制微生物评估
- 微生物限度测试
- 水抽样及无菌和微生物测试

Microbiological Test

Microbiological testing for assessing the microbiological characteristics of finished devices, manufacturing process and manufacturing environment can help eliminate or minimize the risk of microbial contamination, hence the risk of infection to patients, users or third parties.

STC offers a comprehensive scope of microbiological test to assist medical device manufacturers in meeting the microbiological and sterilization safety requirements for regulatory approval.

Testing Capabilities

- Bioburden test
- Endotoxin determination
- Sterility test
- Package integrity test
- Shelf life / Life cycle validation
- Microbial identification
- Compendial testing
- Antimicrobial challenge
- Cleaning validation
- Customized microbial assessments
- Microbiological limits test
- Water sampling and testing for Sterility and Microbiological safety

化学测试

材料表征是对用于医疗器械的材料的组成、纯度、均匀度、杀菌剂残留以及可萃取物进行分析，是验证医疗器械是否适用于接触人体的重要步骤，在产品的整个生命周期中不可或缺。

随着欧盟RoHS 2的实施（该指令限制电器及电子产品中指定的有害物质的含量），医疗器械也被添加到涵盖范围，必须符合RoHS要求。

STC化学实验室配备了最先进的检测仪器，我们的专家团队运用多种方法进行材料表征检测和RoHS分析。根据设备和材料的预期用途，以及其直接跟人体接触的预期属性，STC可协助制造商确定恰当的测试程序。

Chemical Test

Characterization for materials used in medical devices – an analysis of a material's composition, purity, uniformity, sterilant residuals and extractables – is an essential step to verify their suitability for human body contact, thus should not be missed out throughout the product life cycle.

Following the enforcement of RoHS 2 in the European Union, which restricts the use of specified hazardous substances in electrical and electronic equipment, medical devices are now added to the scope of the Directive and have to be verified as RoHS-compliant.

The chemical laboratory at STC is equipped with the most advanced testing equipment; our team of experts can perform material characterization and RoHS analysis with a wide range of testing methods. We can help manufacturers identify the appropriate testing program based on the intended use of a device and material, and its expected nature of contact with the human body.

化学测试

材料表征：评估指引和标准

- 美国食品与药品管理局蓝皮书备忘录 GP#95-1
- ISO 10993-1 标准：“医疗器械的生物学评估”
- ISO 10993-18 标准：“材料的化学表征”
- 美国食品与药品管理局指导文件：“人用药品和生物制品包装用容器密封系统”

材料表征测试能力

- 理化测试
- 傅里叶变换红外光谱(FTIR)
- 高性能液相色谱/质谱(HPLC-MS)
- 气相色谱 / 火焰离子化检测器(GC / FID)
- 气相色谱 / 质谱(GC / MS)
- 电感耦合等离子体光谱(ICP)
- 比重
- 凝胶渗透色谱法(GPC)
- 粘度
- 差示扫描量热法(DSC)

Chemical Test

Material Characterization: Guidelines and Standards

- U.S. FDA Blue Book Memorandum GP#95-1
- ISO 10993-1, “Biological Evaluation of Medical Devices”
- ISO 10993-18, “Chemical Characterization of Materials”
- FDA Guidance Document, “Container Closure Systems for Packaging Human Drugs and Biologics”

Material Characterization Testing capabilities

- Physiochemical test
- Fourier transform infrared spectroscopy (FTIR)
- High-performance liquid chromatography/mass spectrometry (HPLC-MS)
- Gas chromatography / flame ionization detector (GC / FID)
- Gas chromatography / mass spectrometry (GC / MS)
- Inductively coupled plasma spectrometry (ICP)
- Specific gravity
- Gel-permeation chromatography (GPC)
- Viscosity
- Differential scanning calorimetry (DSC)

安规及性能测试

产品类别

- 电子体温计
- 红外体温计
- 电子血压计
- 电子腹腔镜
- 电子内窥镜
- 心电图机
- 多参数监护仪
- 脉搏血氧仪
- 治疗灯
- 雾化器
- 神经肌肉刺激器
- 高压电位治疗仪
- 电疗仪器
- 磁疗仪器
- 助听器

测试项目及标准

测试项目	标准
通用标准	
通用要求	IEC / EN 60601-1
并行标准	
可用性	IEC / EN 60601-1-6; IEC / EN 62366
告警系统	IEC / EN 60601-1-8
家用医疗设备	IEC / EN 60601-1-11
专用要求	
神经和肌肉刺激器	IEC / EN 60601-2-10
心电相关设备	IEC / EN 60601-2-25; IEC / EN 60601-2-27; IEC / EN 60601-2-47
血压计	IEC / EN 80601-2-30; IEC / EN 60601-2-34; ISO / EN ISO 81060-1
多参监护仪	IEC / EN 60601-2-49
体温计	ISO / EN ISO 80601-2-56
光源设备	IEC / EN 60601-2-22; IEC / EN 60601-2-57
脉搏血氧仪	ISO / EN ISO 80601-2-61
助听器	IEC / EN 60601-2-66
更多专用要求	IEC / EN 60601-2-XX; IEC / EN 80601-2-XX, ISO / EN ISO 80601-2-XX; ISO / EN ISO XXXX

Safety and Performance Test

Product Categories

- Electronic Clinical Thermometers
- Infrared Thermometers
- Electronic Sphygmomanometers
- Electronic Laparoscopes
- Electronic Endoscopes
- Electrocardiographs
- Multi-parameter Monitors
- Pulse Oximeters
- Therapeutic Lamps
- Humidifiers
- Nerve and Muscle Stimulators
- High-potential Therapeutic Apparatus
- Electro-therapeutic Equipment
- Magnetic Therapy Equipment
- Hearing Aid

Test Items and Standards

Test Item	Standard
General Standard	
General Requirements	IEC / EN 60601-1
Collateral Standards	
Usability	IEC / EN 60601-1-6; IEC / EN 62366
Alarm System	IEC / EN 60601-1-8
Medical Electrical Equipment for Home Healthcare	IEC / EN 60601-1-11
Particular Requirements	
Nerve and Muscle Stimulators	IEC / EN 60601-2-10
ECG Related Equipment	IEC / EN 60601-2-25; IEC/EN 60601-2-27; IEC / EN 60601-2-47
Sphygmomanometers	IEC / EN 80601-2-30; IEC/EN 60601-2-34; ISO / EN ISO 81060-1
Multi-parameter Monitors	IEC / EN 60601-2-49
Thermometers	ISO / EN ISO 80601-2-56
Light Source Equipmen	IEC / EN 60601-2-22; IEC / EN 60601-2-57
Pulse Oximeters	ISO / EN ISO 80601-2-61
Hearing Aids	IEC / EN 60601-2-66
More Particular Requirements	IEC / EN 60601-2-XX; IEC / EN 80601-2-XX, ISO / EN ISO 80601-2-XX; ISO / EN ISO XXXX

电磁兼容性测试

产品类别

- 医用电气设备
- 体外诊断设备

测试项目及标准

测试项目	标准
电磁兼容性测试 (EMC)	IEC / EN 60601-1-2; CISPR 11 / EN 55011 IEC / EN 61326-1; IEC / EN 61326-2-6 FCC Part 15 / Part 18; ICES-001 / ICES-003
无线电频率测试 (RF)	EN 300330-1; EN 300330-2 (9 kHz to 30 MHz) EN 300220-1; EN 300220-2 (25 MHz to 1000 MHz) EN 300440-1; EN 300440-2 (1 GHz to 40 GHz) FCC Part 15 / Part 18; RSS-210 蓝牙： EN 300328 (2.4 GHz) FCC Part 15 / Part 18 RSS-247 Wi-Fi: EN 300328 (2.4 GHz TRx WiFi b / g / n) EN 301893 (5.8 GHz) FCC Part 15 / Part 18 RSS-247

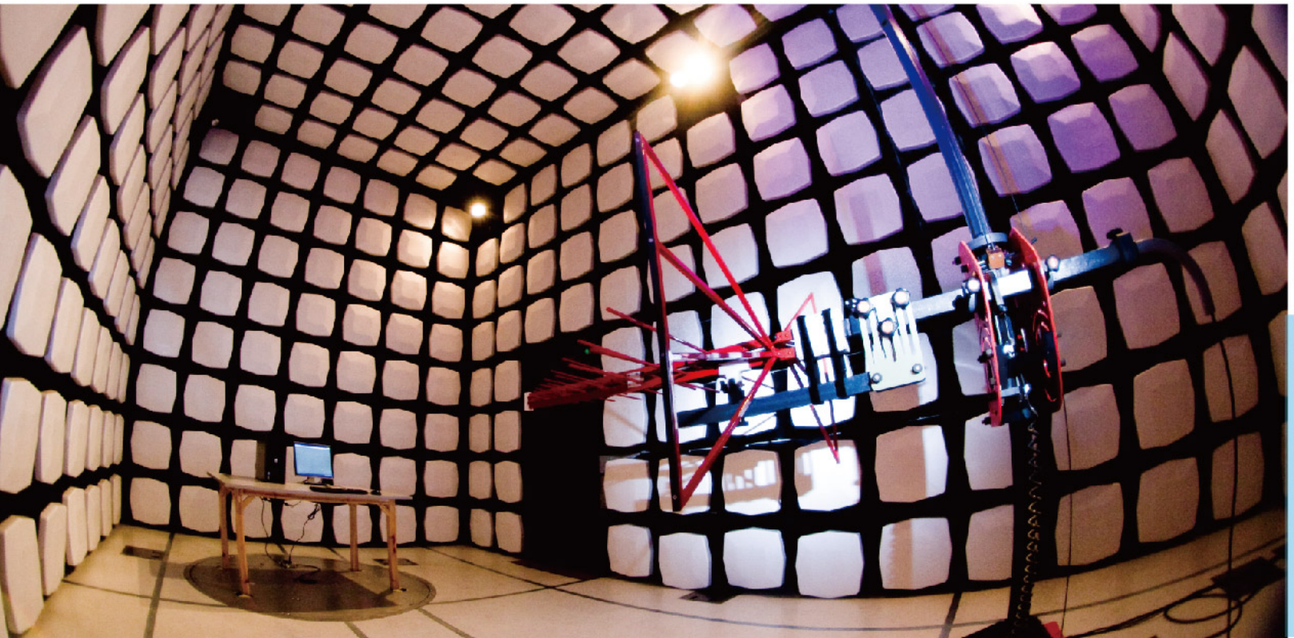
Electromagnetic Compatibility Test

Product Categories

- Medical Electrical Equipment
- In Vitro Diagnosis (IVD) Medical Equipment

Test Items and Standards

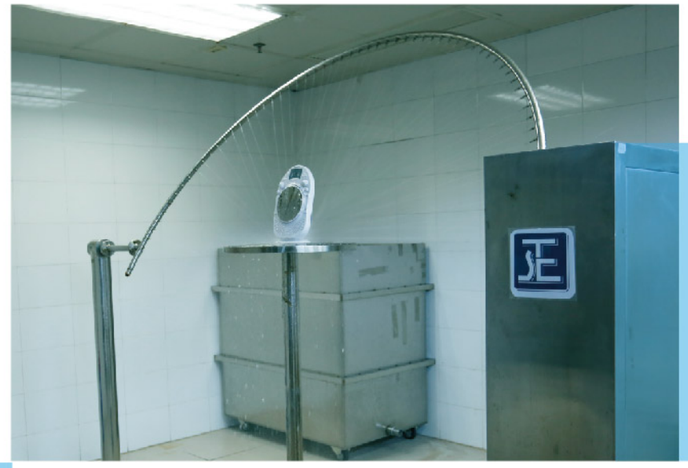
Test Item	Standard
Electromagnetic Compatibility Test (EMC)	IEC / EN 60601-1-2; CISPR 11 / EN 55011 IEC / EN 61326-1; IEC / EN 61326-2-6 FCC Part 15 / Part 18; ICES-001 / ICES-003
Radio Frequency Test (RF)	EN 300330-1; EN 300330-2 (9 kHz to 30 MHz) EN 300220-1; EN 300220-2 (25 MHz to 1000 MHz) EN 300440-1; EN 300440-2 (1 GHz to 40 GHz) FCC Part 15 / Part 18; RSS-210 Bluetooth: EN 300328 (2.4 GHz) FCC Part 15 / Part 18 RSS-247 Wi-Fi: EN 300328 (2.4 GHz TRx WiFi b / g / n) EN 301893 (5.8 GHz) FCC Part 15 / Part 18 RSS-247



光学测试、环境可靠度测试及其他测试

测试项目及标准

测试项目	标准
光辐射安全测试	IEC / EN 60825
光生物安全测试	IEC / EN 62471
美国IES标准	
固态照明光电测量	IES LM-79
国际照明委员会标准	
光强度分布测试	CIE 70
光度及分布光度测量	CIE 121
光通量测量	CIE 84
统一眩光指数	CIE 117
色温及演色性	CIE 15 & CIE 13.3
环境可靠度测试及其他测试	
易燃性测试	ISO 7176-16; EN 1021-1; EN 1021-2; EN 597-1; EN 597-2 BS 5852; BS 5852-2; BS 7177
防水防尘等级测试	IEC / EN 60529
环境模拟测试	IEC / EN 60721
环境测试	IEC / EN 60068-2 系列



Optics Test , Environmental Reliability Test and Other Tests

Test Items and Standards

Test Item	Standard
Safety of Laser Test	IEC / EN 60825
Photobiological Safety Test	IEC / EN 62471
US IES Standards	
Electrical and Photometric Measurements of Solid-State Lighting Products	IES LM-79
CIE Standards	
Luminous Intensity Distribution Test	CIE 70
Photometry and Goniophotometry	CIE 121
Measurement of Luminous Flux	CIE 84
UGR (Unified Glare Rating)	CIE 117
Colorimetry and Color Rendering	CIE 15 & CIE 13.3
Environmental Reliability Test and Other Tests	
Flammability Test	ISO 7176-16; EN 1021-1; EN 1021-2; EN 597-1; EN 597-2 BS 5852; BS 5852-2; BS 7177
IP Code Test	IEC / EN 60529
Environmental Simulation Test	IEC / EN 60721
Environmental Test	IEC / EN 60068-2 series