



# 医疗器械测试服务

MEDICAL DEVICE TESTING SERVICE

首批OECD GLP医疗器械实验室  
the First GLP Medical Device  
Laboratory Authorized by OECD



# 公司简介

## COMPANY PROFILE

STC是一间独立、非牟利的测试、检验及认证机构，总部设于香港。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，除在中国东莞、深圳、中山、上海、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，并广受国际认可，可满足业内广泛需求。

我们一直不断致力于扩展服务范围，经过多年的发展，STC创建了符合国际标准的临床前医疗器械研发测试平台，建立了无源医疗器械实验室、有源医疗器械实验室等系列全功能实验室，可满足医疗器械制造商的临床前全部研发测试需求，提供一站式服务，包括从化学表征、生物相容性测试、大动物试验、微生物测试、安全和性能验证到电磁兼容性测试等。STC医疗器械实验室已受到广泛的国内和国际机构认可，包括IECEE、CE、DAkks、FDA、NEMKO、INMETRO、CNAS、CMA等，并成为中国首家由OECD成员国墨西哥GLP监管署EMA (Entidad Mexicana de Acreditacion, a.c.) 审核认证的医疗器械GLP实验室。

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 Dongguan, Shenzhen, Zhongshan, Shanghai 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.

We have been continuously expanding our service scope. After years of development, STC has established a pre-clinical medical device R&D test platform that meets international standards, and established a series of full-featured laboratories such as passive medical device laboratories and active medical device laboratories. To meet the pre-clinical R&D testing needs of medical device manufacturers, providing one-stop services, including chemical characterization, biocompatibility testing, large animal testing, microbiological testing, safety and performance verification, and electromagnetic compatibility testing. STC Medical Device Laboratories has been recognized by a wide range of domestic and international organizations, including IECEE, CE, DAkks, FDA, NEMKO, INMETRO, CNAS, CMA, etc., and became the first Chinese OECD member of the GLP regulatory agency EMA (Entidad Mexicana de Acreditacion, ac) Review of certified medical device GLP laboratories.







愿景  
Vision

成为全球首屈一指, 备受尊崇及认可的检测机构。

To become a leading conformity assessment service provider  
that is recognized and respected worldwide.





# 资质证书 CERTIFICATIONS



- 德国认可委员会(DAKKS)
- Deutsche Akkreditierungsstelle GmbH (DAKKS)
- 中国合格评定国家认可委员会(CNAS)
- China National Accreditation Service for Conformity Assessment (CNAS)
- 中国计量认证(CMA)
- China Metrology Accreditation (CMA)
- OECD成员国墨西哥GLP监管署
- ema-Mexican Accreditation Body (OECD GLP)
- 国际电工委员会 (IEC)
- International Electrotechnical Commission (IEC)



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# 生物相容性测试

## BIOCOMPATIBILITY TEST



产品类别		Product Categories	
• 失禁治疗吸收产品	• 畸齿矫正器械	• Absorbent Incontinence Products	• Orthodontic Devices
• 粘合剂	• 骨科植入物	• Adhesives	• Orthopedic Implants
• 采血及储血器械	• 造瘘器械	• Blood Collection & Storage Devices	• Ostomy Devices
• 骨空隙填料	• 可重复使用的器械	• Bone Void Fillers	• Reusable Devices
• 中枢神经系统植入物	• 手术手套	• Central Nervous System Implants	• Surgical Gloves
• 组合产品	• 手术缝合线	• Combination Products	• Sutures
• 隐形眼镜	• 注射器	• Contact Lenses	• Syringes
• 牙种植体	• 泌尿系统支架	• Dental Implants	• Urinary Stents
• 包含抗菌剂的器械	• 泌尿系统导管	• Devices Containing Antimicrobials	• Urologic Catheters
• 设备原材料	• 血管导管	• Device Raw Materials	• Vascular Catheters
• 血液透析一次性用品	• 人造血管	• Hemodialysis Disposables	• Vascular Grafts
• 植入式输药器械	• 血管支架	• Implantable Drug Delivery Devices	• Vascular Stents
• 输液/输血器械	• 心室辅助器械	• Infusion / Transfusion Devices	• Ventricular Assist Devices
• 人工晶状体	• 伤口引流器械	• Intraocular Lenses	• Wound Drainage Devices
• 腹腔镜和内窥镜	• 伤口敷料	• Laparoscopes & Endoscopes	• Wound Dressings
• 义眼		• Ocular Implants	







# 生物相容性测试

测试项目	标准	测试周期
<b>细胞毒性测试</b>		
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
<b>皮肤刺激和致敏测试</b>		
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
<b>全身毒性测试</b>		
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
<b>植入后局部反应测试</b>		
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
脑植入测试	ISO 10993-6	4周起
<b>血液相容性测试</b>		
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	ASTM F2888	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
<b>基因毒性 / 遗传毒性测试</b>		
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
<b>生殖辅助相关测试</b>		
体外鼠胚测试	YYT 1434-2016	10周
人精子存活测试	YYT 1535-2017	10周



# BIOCOMPATIBILITY TEST

Test Items	Standards	Lead Time
<b>Cytotoxicity Test</b>		
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
<b>Irritation and Skin Sensitization Test</b>		
Skin 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
<b>Systemic Toxicity Test</b>		
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
<b>Local Effects after Implantation Test</b>		
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
Implantation in Brain Test	ISO 10993-6	4 weeks at least
<b>Interactions with Blood Test</b>		
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	ASTM F2888	2 weeks
Complement Test	ISO 10993-4 / GB	2 weeks
Thrombosis Test (in Vivo / in Vitro)	ISO 10993-4 / GB	2 weeks
<b>Genotoxicity Test</b>		
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	YSO 10993-3	10 weeks
<b>Reproductive Assisted Test</b>		
In vitro mouse embryo test	YYT 1434-2016	10 weeks
Human sperm survival test	YYT 1535-2017	10 weeks



# 大动物试验

## LARGE ANIMAL TEST

STC大动物实验室是按照美国FDA良好实验室规范 (GLP) 和AAALAC建立的临床前大动物实验平台, 可进行心血管、骨科 (含脊柱)、脑部、呼吸科等高风险医疗器械的安全性和有效性评价。

STC large animal laboratory is a pre-clinical large animal study platform that is established in accordance with the FDA good laboratory practice standards (GLP) and AAALAC, which can evaluate the safety and effectiveness of cardiovascular, orthopedics (including spine), brain, respiratory and other high risk medical devices

01

动物实验方案制定和实施  
Animal Study Plan Generation and Implementation

02

多种病理模型和分析手段  
Broad Range of in Vivo Models and Analysis Tools

03

科研实验合作  
Scientific Research Study Cooperation



04

科研课题联合申报  
Joint Application for Scientific Research Funding Projects

05

医师手术操作练习  
Physician Surgery Training

06

实验环境和设施的租用  
Rental of Experimental Environment and Facilities





## 产品类型 Products Categories

- 植入式心脏起搏器类
- 植入式心脏电极导线类
- 植入式神经刺激类
- 植入式心室辅助装置类
- 超声软组织切割止血系统
- 双极高频电外科血管闭合设备
- 人工心脏瓣膜
- 取栓器械
- 血管重建装置
- 主动脉支架
- 人工血管
- 瓣膜成形环
- 血管吻合器
- 组织吻合器
- 体外循环/灌注装置
- 完全可吸收神经修复材料
- 完全可吸收组织修复补片
- 腹腔内置疝修补补片
- 含BMP等成骨因子的骨填充物
- 可吸收外科锚钉
- 带有新型涂层的关节产品
- 新型颈椎间盘
- 软骨修复产品
- 钙磷硅类骨填充材料
- 可吸收结扎夹
- 可吸收吻合钉
- 可吸收外科止血材料
- 可吸收外科防粘连材料
- 新型氧合器
- Implantable Cardiac Pacemakers
- Implantable Cardiac Electrode Leads Class
- Implantable Neural Stimulation
- Implantable Ventricular Assist Device Class
- Ultrasonic Soft Tissue Cutting Hemostasis System
- Bipolar High Frequency Electrosurgical Vessel Closure Equipment
- Artificial Heart Valve
- Thrombectomy Instrument
- Revascularization Device
- Aortic Stent
- Artificial Blood Vessels
- Valvuloplasty Ring
- Vascular Anastomat
- Tissue Anastomat
- Extracorporeal Circulation / Perfusion Device
- Fully Absorbable Nerve Repair Material
- Fully Absorbable Tissue Repair Patch
- Internal Abdominal Hernia Repair Mesh
- Bone Fillers Containing BMP and Other Osteogen Factors
- Absorbable Surgical Anchors
- Joint Products with New Coating
- New Type Cervical Disc
- Cartilage Repair Products
- Calcium Phosphorus Silicon Bone Filling Material
- Absorbable Ligature Clip
- Absorbable Anastomotic Nail
- Absorbable Surgical Hemostatic Material
- Absorbable Surgical Anti-adhesion Materials
- New Type Oxygenator



# 微生物测试

## MICROBIOLOGICAL TEST

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。

Microbiological testing for assessing the microbiological characteristics of finished device, 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.



测试项目	Testing Items
<ul style="list-style-type: none"><li>• 生物负载测试</li><li>• 内毒素测定</li><li>• 无菌测试</li><li>• 包装的完整性测试</li><li>• 保质期/货架周期确认</li><li>• 微生物鉴定</li><li>• 药典测试</li><li>• 抗菌挑战</li><li>• 清洁验证</li><li>• 定制微生物评估</li><li>• 微生物限度测试</li><li>• 水抽样及无菌和微生物测试</li></ul>	<ul style="list-style-type: none"><li>• Bioburden Test</li><li>• Endotoxin Determination</li><li>• Sterility Test</li><li>• Package Integrity Test</li><li>• Shelf Life / Life Cycle Validation</li><li>• Microbial Identification</li><li>• Compendial Testing</li><li>• Antimicrobial Challenge</li><li>• Cleaning Validation</li><li>• Customized Microbial Assessments</li><li>• Microbiological Limits Test</li><li>• Water Sampling and Testing for Sterility and Microbiological Safety</li></ul>





## 灭菌验证 / Sterilization Validations

STC向客户提供全方位技术领域的产品灭菌验证的卓越专家意见。STC拥有一个资源和专业整合的全球团队。我们对材料相容性、灭菌技术、验证理论和灭菌循环优化有深刻理解，确保我们拥有可靠的验证策略。

STC provides clients with excellent expertise in product sterilization validations across a broad range of technologies. There is a combined resources and expertise in the globe team of STC, we have deep insight of material compatibility, sterilization technology, validation approaches and cycle optimization to make sure clients get a reliable validation strategy.

灭菌验证

Sterilization Validations

- 环氧乙烷灭菌验证  
Ethylene Oxide Sterilization Validation
- 辐照灭菌验证  
Radiation Sterilization Validation
- 清洗验证  
Cleaning Validation
- 高温蒸汽验证  
Autoclave Validation
- 包装验证  
Packaging Validation
- 临床再处理灭菌验证和功能性研究  
Clinical Reprocessing Sterilization Validations and Functionality Studies



# 化学测试

## CHEMICAL TEST

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。

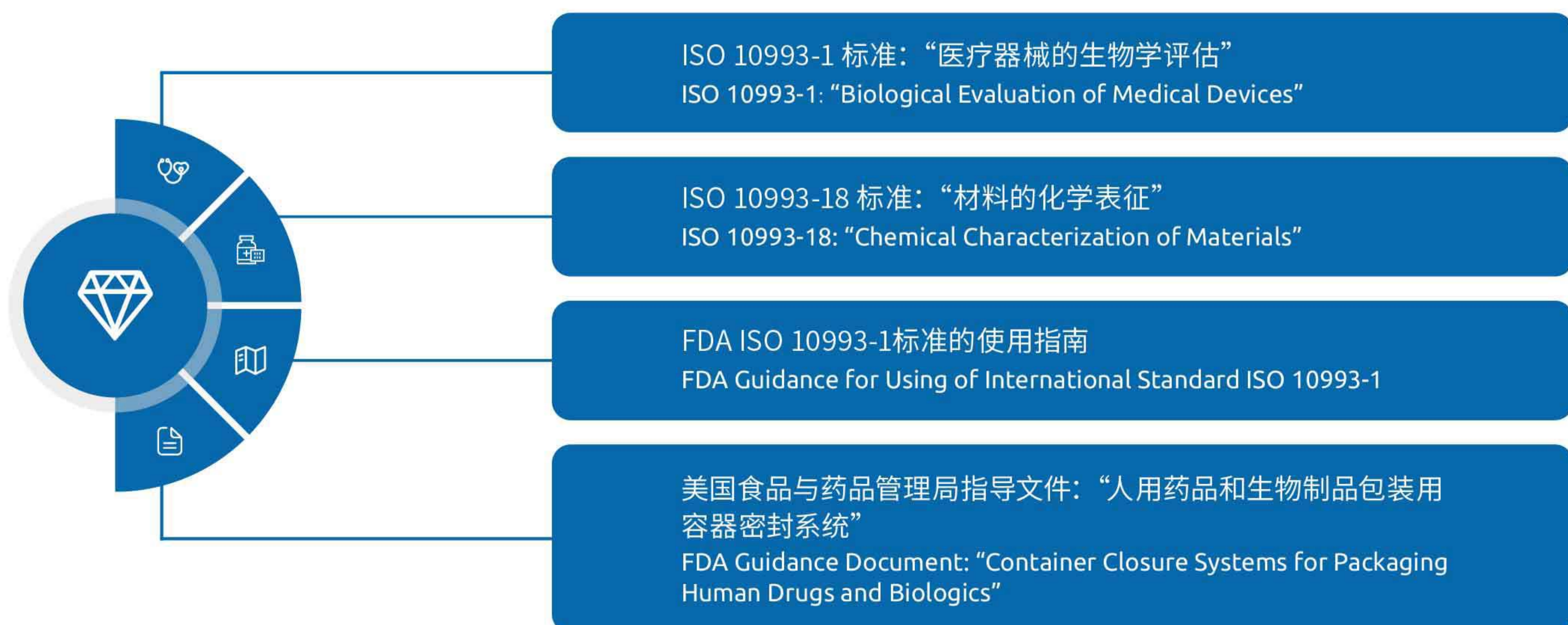
Characterization for materials used in medical device – an analysis of a material’s composition, purity, uniformity, sterilant residuals and extractables – is an essential step to verify their suitability for human body contact, thus should not be missed out throughout the product life cycle.

Following the enforcement of RoHS 2 in the European Union, which restricts the use of specified hazardous substances in electrical and electronic equipment, medical device 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.



### 材料表征：评估指引和标准 Material Characterization: Guidelines and Standards







## 材料表征测试能力 Material Characterization Testing Capabilities

- 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)
- 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

## SAFETY AND PERFORMANCE TEST



### 产品类别 / Product Categories

- 体温计
- 血压计
- 心电图机
- 多参数监护仪
- 脉搏血氧仪
- 内窥镜
- 高频手术设备
- 牙科产品
- 神经肌肉刺激器
- 雾化器
- 光疗设备
- 助听器
- 体外诊断设备
- Thermometers
- Sphygmomanometers
- Electrocardiographs
- Multi-parameter Monitors
- Pulse Oximeters
- Endoscopes
- HF Surgical Equipment
- Dental Equipment
- Nerve and Muscle Stimulators
- Humidifiers
- Light Source Equipment
- Hearing Aid
- In Vitro Diagnostic (IVD) Medical Equipment





## 测试项目 / Test Items

## 标准 / Standards

### 医用电气设备/ Requirements for Medical Electrical Equipment

#### 通用要求 / General Requirements

IEC/EN 60601-1

#### 并列要求 / Collateral Standards

报警系统

Alarm Systems

IEC/EN 60601-1-8

家用环境

Home Healthcare Environment

IEC/EN 60601-1-11

紧急医疗服务环境

Emergency Medical Services Environment

IEC/EN 60601-1-12

#### 专用要求 / Particular Requirements

高频电刀及其附件

High Frequency Electric Knife and Its Accessories

IEC/EN IEC 60601-2-2

加热垫、加热毯

Heating Pad, Heating Blanket

IEC/EN 80601-2-35

超声设备

Ultrasonic Equipment

IEC/EN 60601-2-37

内窥镜

Endoscope

IEC/EN 60601-2-18

医用病床

Hospital Bed

IEC/EN 60601-2-52

牙科设备

Dental Equipment

ISO/EN 80601-2-60

刺激器

Stimulators

IEC/EN 60601-2-10

心电类设备

ECG Related Equipment

IEC/EN 60601-2-25, IEC/EN 60601-2-27,  
IEC/EN 60601-2-47

多参监护仪

Multi-parameter Monitors

IEC/EN 60601-2-49, IEC 80601-2-49

体温计

Thermometers

ISO/EN ISO 80601-2-56

光源设备

Light Source Equipment

IEC/EN 60601-2-22, IEC/EN 60601-2-57

脉搏血氧仪

Pulse Oximeters

ISO/EN ISO 80601-2-61

助听器

Hearing Aids

IEC/EN 60601-2-66

血压计

Sphygmomanometers

IEC/EN IEC 80601-2-30, IEC/EN 60601-2-34,  
ISO/EN ISO 81060-1, EN 1060-3

### 体外诊断设备 / Requirements for in Vitro Diagnostic (IVD) Medical Equipment

#### 通用要求 / General Requirements

IEC/EN 61010-1

#### 专用要求 / Particular Requirements

IEC/EN 61010-2-10 1



# 电磁兼容性测试

## ELECTROMAGNETIC COMPATIBILITY TEST



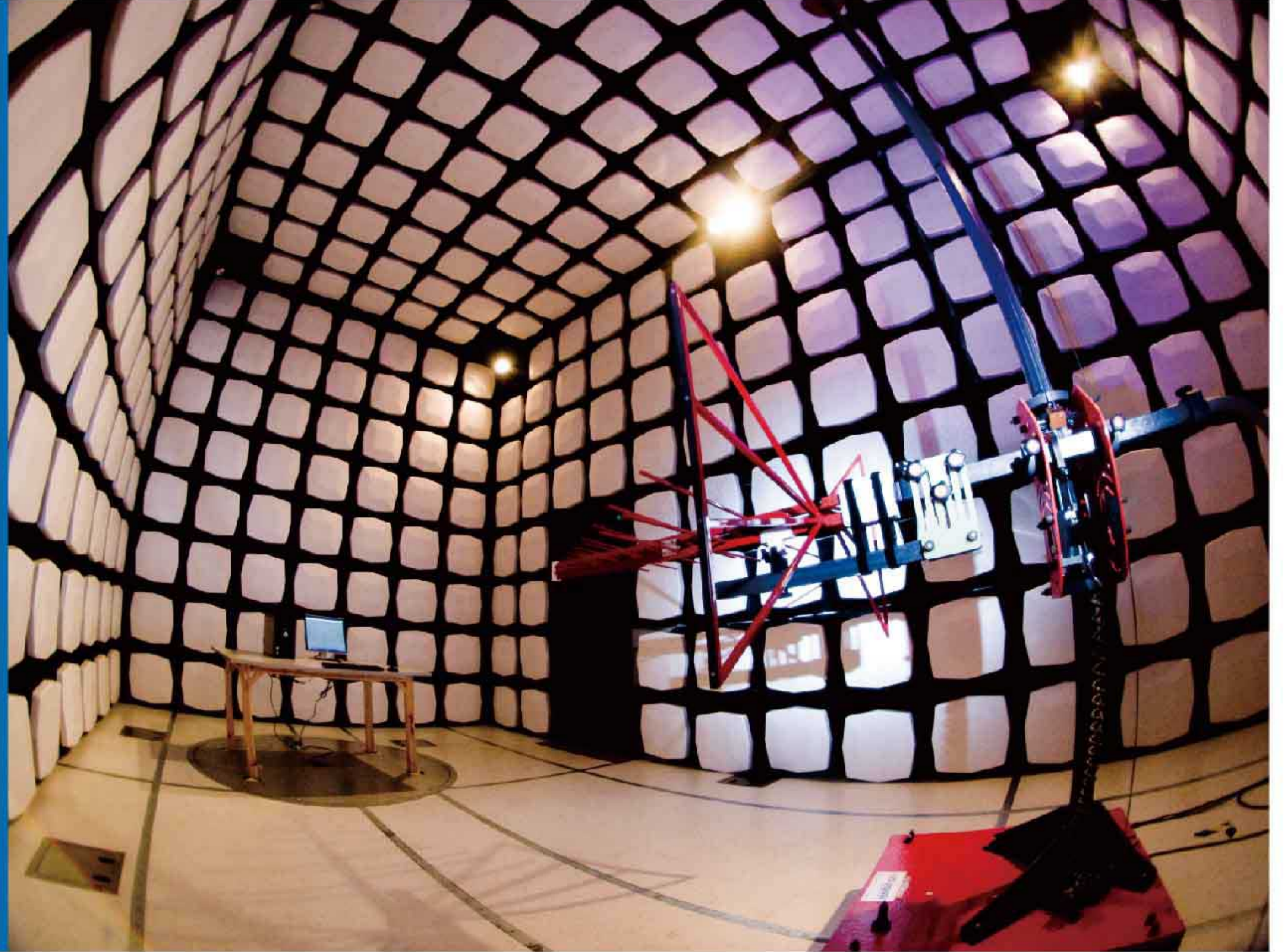
产品类型 / Product Categories

医用电气设备

Medical Electrical Equipment

体外诊断设备

In Vitro Diagnosis (IVD) Medical Equipment



测试项目 / Test Items

标准 / Standards



电磁兼容性测试

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



无线电频率测试

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

蓝牙 / 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

## OPTICS TEST, ENVIRONMENTAL RELIABILITY TEST AND OTHER TESTS

测试项目 / Test Items	标准 / Standards
光辐射安全测试 Safety of Laser Test	IEC / EN 60825
光生物安全测试 Photobiological Safety Test	IEC / EN 62471
美国IES标准 / US IES Standards	
固态照明光电测量 Electrical and Photometric Measurements of Solid-State Lighting Products	IES LM-79
国际照明委员会标准 / CIE Standards	
光强度分布测试 Luminous Intensity Distribution Test	CIE 70
光度及分布光度测量 Photometry and Goniophotometry	CIE 121
光通量测量 Measurement of Luminous Flux	CIE 84
统一眩光指数 UGR (Unified Glare Rating)	CIE 117
色温及演色性 Colorimetry and Color Rendering	CIE 15 & CIE 13.3
环境可靠度测试及其他测试 / Environmental Reliability Test and Other Tests	
易燃性测试 Flammability Test	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 IP Code Test	IEC / EN 60529
环境模拟测试 Environmental Simulation Test	IEC / EN 60721
环境测试 Environmental Test	IEC / EN 60068-2 系列 / series



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