STC

医疗器械测试服务

Medical Devices Testing Services

OECD GLP医疗器械实验室

GLP Medical Devices Laboratory Accredited by OECD

www.stc.group

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、上海、常州、广西等多个城市或地区成立分公司外，环球网络已延伸至越南、日本、美国及德国。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、大动物实验、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、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 services 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, Shanghai, Changzhou, Guangxi, but also in countries like Vietnam, Japan, the USA and Germany. 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 set up a series of full-featured laboratories such as passive medical device laboratories and active medical device laboratories. We can meet the pre-clinical R&D testing needs of medical device manufacturers as well as providing one-stop services, including chemical characterization, biocompatibility testing, large animal testing, microbiological testing, safety and performance verification, electromagnetic compatibility testing and more. STC's Medical Device Laboratory has been recognized by a wide range of local and international organizations, including IECEE, CE, FDA, NEMKO, INMETRO, CNAS, CMA, etc., and became the first Chinese OECD member of the GLP regulatory agency EMA (Entidad Mexicana de Acreditacion, ac) accredited medical device GLP laboratory.

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
ACCREDITATIONS

01

02

03

04

- 检验检测机构资质认定 (CMA)
- 中国合格评定国家认可委员会 (CNAS)
- OECD成员国墨西哥 GLP 监管署
- 国际电工委员会（IEC）
- China Inspection Body and Laboratory Mandatory Approval (CMA)
- China National Accreditation Service for Conformity Assessment (CNAS)
- ema-Mexican Accreditation Body (OECD GLP)
- International Electrotechnical Commission (IEC)

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生物相容性测试
BIOCOMPATIBILITY TEST

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- 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
- 眼植入物
- 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

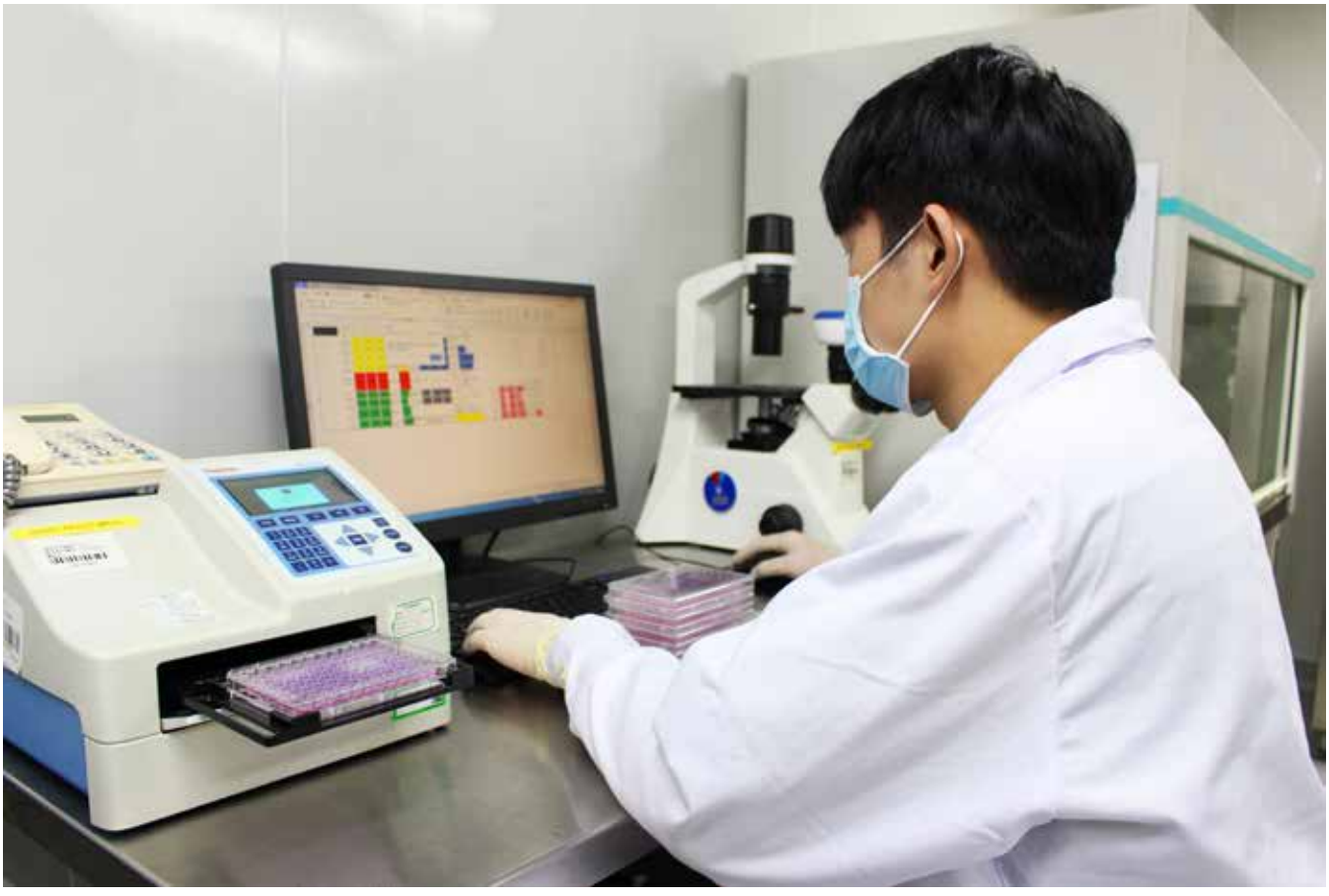
Product Categories

- 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

体外刺激测试 / In Vitro Irritation Test

生物学试验基于体外试验及体内试验。基于动物福利要求，越来越多体外试验方法被开发及应用。其中，体外刺激测试利用RhE模型检测医疗器械对皮肤的刺激作用，RhE模型是一种重建的人表皮模型，该方法对刺激性的检测，具有与传统的动物皮肤测试相同的敏感性，因此，可以替代皮肤暴露和皮内给药刺激的活体兔试验。

Biological testing is mainly divided into in vitro and in vivo test methods. To cope with animal welfare requirements, more in vitro test methods are developed and applied. Among them, the In Vitro Irritation Test uses the RhE model to detect the irritant effect of medical devices on the skin. The RhE model is a reconstructed human epidermis model, and this method has the same sensitivity for the detection of irritation as traditional animal skin tests. Therefore, the In Vivo Rabbit Test for skin exposure and intradermal administration stimulation can be substituted.



生物相容性测试
BIOCOMPATIBILITY TEST

测试项目 / Test Items	标准 / Standards
细胞毒性测试 **Cytotoxicity Test**	
细胞毒性测试（MTT法） Cytotoxicity Study (MTT Method)	ISO 10993-5; GB / T 16886.5
细胞毒性测试（琼脂法） Cytotoxicity Study (Agarose Overlay Method)	ISO 10993-5; GB / T 16886.5; USP 87; ISO 7405
细胞毒性测试（滤膜法） Cytotoxicity Study (Filter Diffusion Method)	ISO 10993-5; GB / T 16886.5; ISO 7405
细胞毒性测试（直接接触法） Cytotoxicity Study (Direct Contact Method)	ISO 10993-5; GB / T 16886.5; USP 87
细胞毒性测试（洗脱法） Cytotoxicity Study (MEM Method)	ISO 10993-5; GB / T 16886.5; USP 87
皮肤刺激和致敏测试 **Irritation and Skin Sensitization Test**	
致敏测试（最大剂量法 / 斑贴法） Skim Sensitization Test (GPMT / Closed-patch)	ISO 10993-10; GB / T 16886.10
皮肤刺激测试 Skin Irritation Test	ISO 10993-10; GB / T 16886.10; ISO 10993-23
皮内刺激测试 Intracutaneous (Intradermal) Reactivity Test	ISO 10993-10; GB / T 16886.10; USP 88
口腔刺激测试（需组织病理读片） Oral Mucosa Irritation Test	ISO 10993-10; GB / T 16886.10
阴道刺激测试（需组织病理读片） Vaginal Irritation Test	ISO 10993-10; GB / T 16886.10
阴茎刺激测试（需组织病理读片） Penile Irritation Test	ISO 10993-10; GB / T 16886.10
直肠刺激测试（需组织病理读片） Rectal Irritation Test	ISO 10993-10; GB / T 16886.10
眼刺激测试 Ocular Irritation Test	ISO 10993-10; GB / T 16886.10
全身毒性测试 **Systemic Toxicity Test**	
急性全身毒性测试 Acute Systemic Toxicity Test	ISO 10993-11; GB / T 16886.11; USP 88
亚急性全身毒性测试（14 / 28天） Subacute Systemic Toxicity Test (14 days / 28 days)	ISO 10993-11; GB / T 16886.11
亚慢 / 慢性全身毒性测试（90 / 180天） Subchronic / Chronic Systemic Toxicity Test (90 days / 180 days)	ISO 10993-11; GB / T 16886.11
热原测试 Pyrogen Test	ISO 10993-11; GB / T 16886.11; USP 151

测试项目 / Test Items	标准 / Standards
植入后局部反应测试 **Local Effects after Implantation Test**	
皮下植入测试 Implantation in Subcutaneous Tissue Test	ISO 10993-6; GB / T 16886.6
肌肉植入测试 Implantation in Muscle Test	ISO 10993-6; GB / T 16886.6; USP 88
骨植入测试 Implantation in Bone Test	ISO 10993-6; GB / T 16886.6
脑植入测试 Implantation in Brain Test	ISO 10993-6; GB / T 16886.6
血液相容性测试 **Interactions with Blood Test**	
溶血测试 Hemolysis Test	ISO 10993-4; GB / T 16886.4
溶血测试 Hemolysis Test	ASTM F756
凝血测试 Coagulation Test	ISO 10993-4; GB / T 16886.4
血小板计数测试 Platelet Count Test	ASTM F2888
补体测试 Complement Test	ISO 10993-4; GB / T 16886.4
血栓测试（体内、体外） Thrombosis Test（in Vivo / in Vitro)	ISO 10993-4; GB / T 16886.4
基因毒性 / 遗传毒性测试 **Genotoxicity Test**	
细菌回复性测试 Ames Test	ISO 10993-3; GB / T 16886.3
小鼠淋巴瘤测试 Mouse Lymphoma Assay Test	ISO 10993-3; GB / T 16886.3
染色体畸变测试 Chromosome Aberration Test	ISO 10993-3; GB / T 16886.3
微核测试（小鼠） Mouse Micronucleus Test	ISO 10993-3; GB / T 16886.3
生殖辅助相关测试 **Reproductive Assisted Test**	
体外鼠胚测试 In Vitro Mouse Embryo Test	YY / T 1434-2016

大动物实验
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's 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/灌流装置
- 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

大动物实验
LARGE ANIMAL TEST

STC配备介入导管室，其医用血管造影X射线系统（简称DSA）以及介入手术所需配套设备，满足各类心血管类动物实验手术的要求，可开展冠脉支架植入术、冠脉药物球囊介入治疗、PTCA球囊导管介入术、外周血管类支架植入术、主动脉瓣置换术、颅内取栓等。

STC heavily invested in an interventional room, which equipped with Digital Subtraction Angiographic System (DSA) and other ancillary equipment for interventional surgery, meets the requirements of various cardiovascular animal experimental operations, including Intracoronary Stent Implantation, Coronary Drug Balloon Interventional Therapy, PTCA Balloon Catheter Intervention, Peripheral Vascular Stent Implantation, Aortic Valve Replacement, and Intracranial Thrombus Extraction.

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

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

测试项目	Test Items
• 内毒素测定 • 无菌测试 • 微生物鉴定 • 药典测试 • 抗菌挑战 • 定制微生物评估 • 微生物限度测试 • 水样微生物测试	• Endotoxin Determination • Sterility Test • Microbial Identification • Compendial Testing • Antimicrobial Challenge • Customized Microbial Assessments • Microbiological Limits Test • Microbiological Testing of Water Samples

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 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 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.

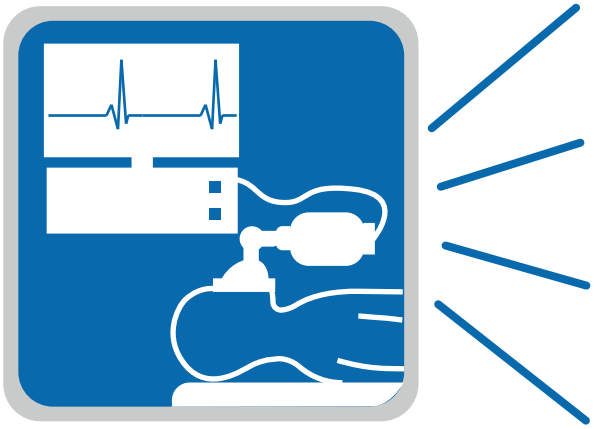
材料表征： 评估指引和标准
Material Characterization: Guidelines and Standards

- ISO 10993-1 标准："医疗器械的生物学评估"
  ISO 10993-1: "Biological Evaluation of Medical Devices"
- ISO 10993-18 标准："材料的化学表征"
  ISO 10993-18: "Chemical Characterization of Materials"
- FDA ISO 10993-1标准的使用指南
  FDA Guidance for Using of International Standard ISO 10993-1
- 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"
  FDA Guidance Document: "Container Closure Systems for Packaging Human Drugs and Biologics"

呼吸气路测试
BREATHING GAS PATHWAYS TEST

针对呼吸气路,如呼吸器、麻醉工作站(包括气体混合器)、呼吸系统、氧气保护设备、氧气浓缩器、雾化器、低压软管、医用加湿器、湿热交换器(人工鼻)、呼吸气体监控器、呼吸监护器、呼吸面罩、人工呼吸器、呼吸管、呼吸系统过滤器和三通管，STC提供生物学评价及测试等一系列完整的支持服务。

STC provides the full set of evaluation and testing services for breathing gas pathways, such as ventilators, anesthesia workstations (including gas mixers), breathing systems, oxygen conserving equipment, oxygen concentrators, nebulizers, low-pressure hose assemblies, humidifiers, heat and moisture exchangers, respiratory gas monitors, respiration monitors, masks, mouth pieces, resuscitators, breathing tubes, breathing system filters and Y-pieces.

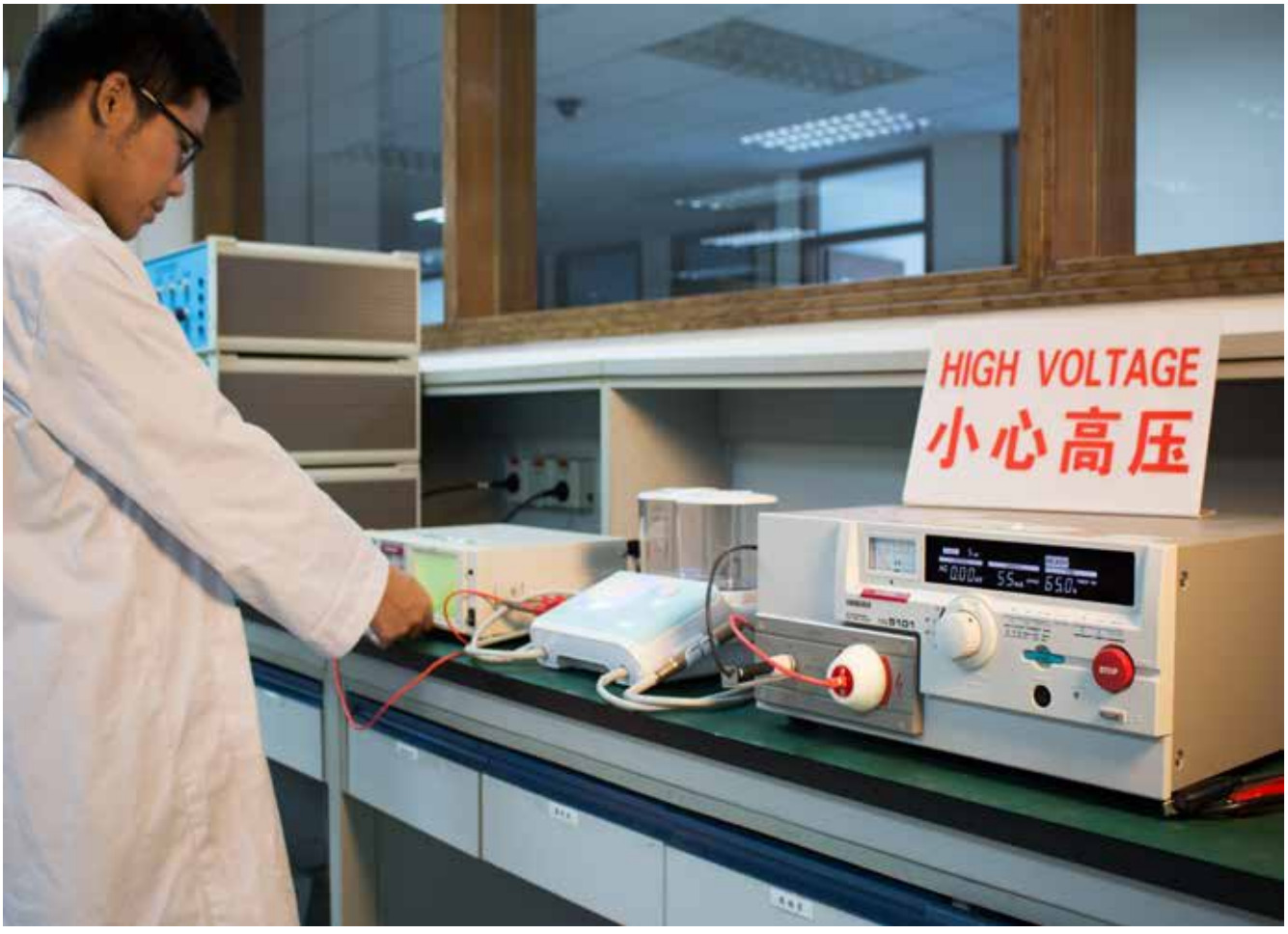


- ISO 18562-1 风险管理过程中的评估和测试
  Evaluation and Testing within a Risk Management Process
- ISO 18562-2 颗粒物释放测试
  Tests for Emissions of Particulate Matter
- ISO 18562-3 有机挥发物释放测试
  Tests for Emissions of Volatile Organic Compounds (VOCs)
- ISO 18562-4 冷凝水中析出物的测试
  Tests for Leachables in Condensate

安规及性能测试
SAFETY AND PERFORMANCE TEST

产品类别 / Product Categories

- 加热垫、加热毯
- 内窥镜
- 医用病床
- 牙科设备
- 刺激器
- 肌电及诱发反应设备
- 心电类设备
- 脑电图机
- 多参监护仪
- 体温计
- 光源设备
- 脉搏血氧仪
- 助听器
- 血压计
- 呼吸类设备
- 制氧机设备
- Heating Pad, Heating Blanket
- Endoscope
- Hospital Bed
- Dental Equipment
- Stimulators
- Electromyographs and Evoked Response Equipment
- ECG Related Equipment
- Electroencephalograph
- Multi-parameter Monitors
- Thermometers
- Light Source Equipment
- Pulse Oximeters
- Hearing Aids
- Sphygmomanometers
- Breathing Related Equipment
- Medical Electrical Equipment



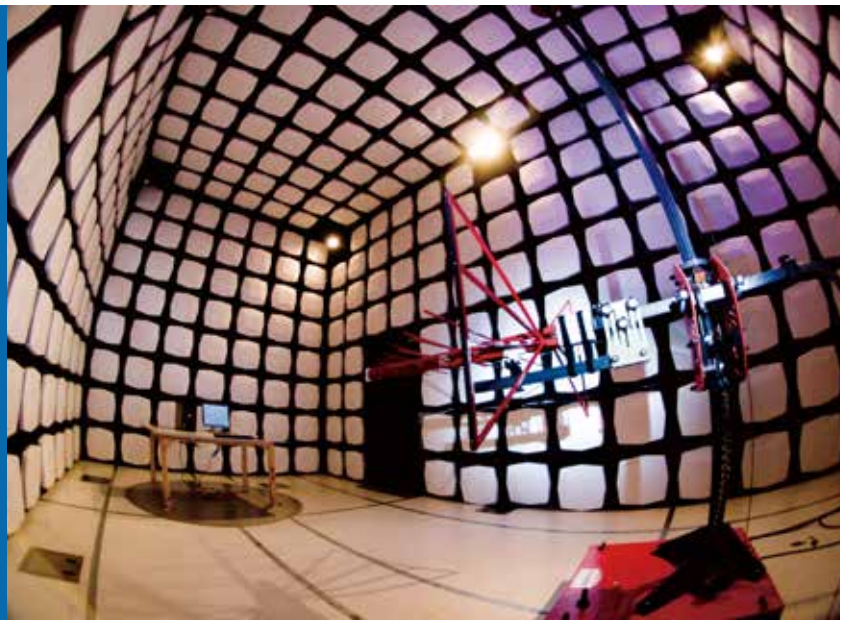
测试项目 / Test Items	标准 / Standards
医用电气设备 / Requirements for Medical Electrical Equipment	
通用要求 / **General Requirements**	IEC / EN 60601-1; GB 9706.1
并列要求 / **Collateral Standards**	
报警系统 Alarm Systems	IEC / EN 60601-1-8; YY 0709; YY 9706.108
家用环境 Home Healthcare Environment	IEC / EN 60601-1-11; YY 9706.111
紧急医疗服务环境 Emergency Medical Services Environment	IEC / EN 60601-1-12; YY 9706.112
专用要求 / **Particular Requirements**	
加热垫、加热毯 Heating Pad, Heating Blanket	IEC / EN 80601-2-35; YY 0834; YY 9706.235
内窥镜 Endoscope	IEC / EN 60601-2-18; GB 9706.19
医用病床 Hospital Bed	IEC / EN 60601-2-52; YY 0571
牙科设备 Dental Equipment	ISO / EN IEC 80601-2-60; GB 9706.260
刺激器 Stimulators	IEC / EN 60601-2-10; YY 0607; YY 9706.210
肌电及诱发反应设备 Electromyographs and Evoked Response Equipment	IEC / EN 60601-2-40; YY 0896; YY 9706.240
心电类设备 ECG Related Equipment	IEC / EN 60601-2-25; IEC / EN 60601-2-27; IEC / EN 60601-2-47; GB 10793; GB 9706.25; YY 0885
脑电图机 Electroencephalograph	IEC / EN 60601-2-26; GB 9706.26
多参监护仪 Multi-parameter Monitors	IEC / EN IEC 80601-2-49; YY 0668
体温计 Thermometers	ISO / EN ISO 80601-2-56; ASTM E1965; ASTM E1112; GB / T 21416; GB / T 21417.1
光源设备 Light Source Equipment	IEC / EN 60601-2-22; IEC / EN 60601-2-57; IEC / EN IEC 60601-2-83; YY 9706.257; GB 9706.20
脉搏血氧仪 Pulse Oximeters	ISO / EN ISO 80601-2-61; YY 0784
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 81060-1; YY 0667; YY 0670; YY 0783
呼吸类设备 Breathing Related Equipment	ISO / EN ISO 80601-2-12; ISO / EN ISO 80601-2-70; ISO / EN ISO 80601-2-72; ISO / EN ISO 80601-2-74; GB 9706.212
制氧机设备 Medical Electrical Equipment	ISO / EN 80601-2-29；YY 9706.269
体外诊断设备 / Requirements for in Vitro Diagnostic (IVD) Medical Equipment	
通用要求 / **General Requirements**	IEC / EN 61010-1; GB 4793.1
专用要求 / **Particular Requirements**	IEC / EN 61010-2-101; YY 0648

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; YY 0505; YY 9706.102 IEC / EN 61326-1; IEC / EN 61326-2-6; GB / T 18268.1; GB / T 18268.26 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; GB / T 14710

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