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To meet global demand for testing services, not only has STC set up testing laboratories and / or offices in Shanghai, Dongguan, Shenzhen and Zhongshan, but also has it landed in Germany, USA, Vietnam and Japan.

STC (香港標準及檢定中心) 是香港首間獨立、非牟利的測試、檢驗及認證機構。自1963年成立以來，一直緊貼工業及貿易發展，致力為業界提供專業、可靠及全面的檢測服務，並發出不偏不倚的檢測報告，確保產品符合相關的技術及安全標準。

STC作為跨國機構，除了於中國上海、東莞、深圳、常州等多個主要城市設立實驗室及辦事處，我們的環球網絡已伸延至德國、美國、越南及日本。

# **Type-Approval Or Type-Acceptance of Industrial, Scientific and Medical (ISM) equipment emitting radio frequency energy intentionally**

**Kenneth Cheung, Senior Manager**

# HONG KONG TELECOMMUNICATIONS EQUIPMENT EVALUATION AND CERTIFICATION (HKTEC) SCHEME

香港電訊設備鑑定及驗證計劃

# Hong Kong Telecommunications Equipment Evaluation and Certification (HKTEC) Scheme



- HKTEC is a scheme for the evaluation and certification of Telecommunications Equipment (TE) and Industrial, Scientific and Medical (ISM) equipment [emitting radio frequency energy intentionally](#)
- 香港電訊設備鑑定及驗證計劃旨在規管電訊設備以及蓄意發出射頻能量的工業、科學及醫學設備的鑑定和驗證事宜
- Certification requirement of TE and ISM equipment consists of two parts, namely “Voluntary Certification Scheme (VCS)” and “[Compulsory Certification Scheme \(CCS\)](#)”
- 電訊設備和工業、科學及醫學設備的驗證要求包括兩部分，即「自願驗證計劃」與「[強制驗證計劃](#)」

# Hong Kong Telecommunications Equipment Evaluation and Certification (HKTEC) Scheme



- Certification of the TE and ISM equipment (including the assignment of certificate numbers) will be granted by a **Local Certification Body** (accredited by Office of the Communications Authority, OFCA) or a Foreign Certification Body (via APEC Tel MRA)
- **本地認證機構** (由通訊事務管理局辦公室認可) 或 **海外認證機構** (經亞太經濟合作組織有關電訊設備合格評定的互認安排) 會為電訊設備和工業、科學及醫學設備驗證 (包括指配證書編號)
- List of Certification Bodies **認證機構名單**

[http://www.ofca.gov.hk/en/industry\\_focus/telecommunications/standards/telecom/list\\_of\\_certification\\_bodies/index.html](http://www.ofca.gov.hk/en/industry_focus/telecommunications/standards/telecom/list_of_certification_bodies/index.html)

LCB Code LCB 編號	Name of Local Certification Body (LCB) 本地認證機構 ( LCB ) 名稱	Scope of Service 服務範圍
HK001	Hong Kong Standards and Testing Centre Ltd. 香港標準及檢定中心有限公司	Full 全項
HK002	Intertek Testing Services Hong Kong Ltd.	Full
HK003	SGS Hong Kong Ltd.	Full

FCB Code FCB 編號	Name of Foreign Certification Body (FCB) 海外認證機構 ( FCB ) 名稱	Scope of Service 服務範圍
CA001	Nemko North America, Inc.	Limited
US001	Bay Area Compliance Laboratories Corp.	Limited
US002	SIEMIC, Inc.	Limited
US003	Curtis-Straus LLC	Limited
US004	American Certification Body, Inc. (ACB, Inc.)	Limited

# Hong Kong Telecommunications Equipment Evaluation and Certification (HKTEC) Scheme



- **Radio Equipment Specifications (HKCA 10XX)**

- **無線電設備規格 (HKCA 10XX)**

[http://www.ofca.gov.hk/en/industry\\_focus/telecommunications/standards/hkca/radio\\_equipment\\_specifications/index.html](http://www.ofca.gov.hk/en/industry_focus/telecommunications/standards/hkca/radio_equipment_specifications/index.html)

- **GMDSS Marine Radio Equipment Specifications (HKCA 12XX)**

- **用於全球海上遇險和安全系統GMDSS的海上無線電設備規格(HKCA 12XX)**

[http://www.ofca.gov.hk/en/industry\\_focus/telecommunications/standards/hkca/gmdss\\_specifications/index.html](http://www.ofca.gov.hk/en/industry_focus/telecommunications/standards/hkca/gmdss_specifications/index.html)

- **Network Equipment Specifications (HKCA 2XXX)**

- **網絡設備規格 (HKCA 2XXX)**

[http://www.ofca.gov.hk/en/industry\\_focus/telecommunications/standards/hkca/fixed\\_network\\_equipment\\_specifications/index.html](http://www.ofca.gov.hk/en/industry_focus/telecommunications/standards/hkca/fixed_network_equipment_specifications/index.html)

## 第106章 《電訊條例》

### Cap. 106 Telecommunications Ordinance

#### ▶ Timeline

Search:

Point in Time:

- 8. 除根據牌照進行外，禁止設置與維持電訊設施等**
- (1) 除根據與按照總督會同行政局批給的牌照或以管理局批給或設立的適當牌照行事外，任何人不得在香港或在於香港註冊或領牌的任何船舶、航空器或空間物體上——(由1990年第39號第3條修訂；由1990年第74號第104(3)條修訂；由2000年第36號第5條修訂；由2011年第17號第28條修訂)
- (a) 設置或維持任何電訊設施；或
- (aa) 在業務運作中，要約提供電訊服務；或 (由2000年第36號第5條增補)
- (b) 管有或使用任何作無線電通訊之用的器具或產生並發射無線電波的任何種類器具，即使這些器具並非預定作無線電通訊之用；或
- (c) 在營商過程或業務運作中，經營作無線電通訊之用的器具或材料，或該等器具的元件，或經營產生並發射無線電波的任何種類器具，不論該等器具是否預定作或是否能夠作無線電通訊之用的；或
- (d) 為在營商過程或業務運作中予以售賣而示範任何作無線電通訊之用的器具或材料。
- (1A) 就第(1)(aa)款而言，如某人——
- (a) 作出要約，而該要約若被接納則會構成由該人提供電訊服務的協議、安排或協定，或會構成由另一名已與

**8. Prohibition of establishment and maintenance of means of telecommunications, etc., except under licence**

- (1) Save under and in accordance with a licence granted by the Governor in Council or with the appropriate licence granted or created by the Authority, no person shall in Hong Kong or on board any ship, aircraft or space object that is registered or licensed in Hong Kong— (Amended 39 of 1990 s. 3; 74 of 1990 s. 104(3); 36 of 2000 s. 5)
- (a) establish or maintain any means of telecommunications; or
- (aa) offer in the course of business a telecommunications service; or (Added 36 of 2000 s. 5)
- (b) possess or use any apparatus for radiocommunications or any apparatus of any kind that generates and emits radio waves notwithstanding that the apparatus is not intended for radiocommunications; or
- (c) deal in the course of trade or business in apparatus or material for radiocommunications or in any component part of any such apparatus or in apparatus of any kind that generates and emits radio waves whether or not the apparatus is intended, or capable of being used, for radiocommunications; or

[https://www.elegislation.gov.hk/hk/cap106/en-zh-Hant-HK?xid=ID\\_1438402544590\\_002&INDEX\\_CS=N](https://www.elegislation.gov.hk/hk/cap106/en-zh-Hant-HK?xid=ID_1438402544590_002&INDEX_CS=N)



# Classification of Radiocommunications Equipment



Type of Radio Equipment 無線電設備類別	Relevant Technical Specification 有關的HKCA規格	Classification 分類
<ul style="list-style-type: none"> <li>Wireless microphone equipment not exempted from licensing</li> <li>沒有豁免領牌的無線電麥克風設備</li> </ul>	HKCA 1008	<u>Compulsory Certification Scheme (CCS)</u> 強制驗證計劃
<ul style="list-style-type: none"> <li>Citizen Band (CB) radio equipment</li> <li>使用市民波段(CB)的無線電收發設備</li> </ul>	HKCA 1022 HKCA 1050	
<ul style="list-style-type: none"> <li>Equipment for use in Maritime GMDSS radio services</li> <li>用於全球海上遇險和安全系統(GMDSS)無線電服務的設備</li> </ul>	HKCA 12xx	
<ul style="list-style-type: none"> <li>Land Mobile Radio Equipment</li> <li>陸地流動無線電設備</li> </ul>	HKCA 1002 HKCA 1004	
	HKCA 1010 HKCA 1016	
	HKCA 1047 HKCA 1020	
	HKCA 1043 HKCA 1053	
	HKCA 1056 HKCA 1064	
<ul style="list-style-type: none"> <li>Aeronautical Mobile Radio Equipment</li> <li>航空流動無線電設備</li> </ul>	HKCA 1065 HKCA 1069	
	HKCA 1072 HKCA 1077	
<ul style="list-style-type: none"> <li>Fixed Link Equipment</li> <li>固定鏈路設備</li> </ul>	HKCA 1066	
	HKCA 1067	
	HKCA 1003 HKCA 1036	
	HKCA 1037 HKCA 1042	
<ul style="list-style-type: none"> <li>2.3GHz digital multipoint radio equipment</li> <li>在2.3吉赫頻帶操作的數碼多點無線電設備</li> </ul>	HKCA 1063 HKCA 1068	
	HKCA 1070 HKCA 1071	
	HKCA 1076	
<ul style="list-style-type: none"> <li>Industrial, scientific &amp; medical (ISM) equipment</li> <li>工業、科學與醫療(ISM)射頻設備</li> </ul>	HKCA 1007	

- <http://www.ofca.gov.hk/filemanager/ofca/common/Industry/telecom/standard/i401e.pdf> [last 2 pages]

# Classification of Radiocommunications Equipment



Type of Radio Equipment 無線電設備類別	Relevant Technical Specification 有關的HKCA規格	Classification 分類
• GSM, PCS and GSM/PCS dual-mode	HKCA 1033	Voluntary Certification Scheme (VCS) 自願驗證計劃
• 3G mobile CDMA Direct Spread (UTRA FDD)	HKCA 1048	
• 3G mobile cdma2000 Spread Spectrum	HKCA 1054	
• LTE (E-UTRA FDD)	HKCA 1057	
• LTE (E-UTRA TDD)	HKCA 1073	
• TV antenna amplifier	HKCA 1019	
• Radio Equipment Exempted From Licensing (Low Power Device)	HKCA 1035	
• Short Range Devices operating in the 433 MHz band	HKCA 1061	
• Model control and radio equipment operating in the 27 MHz band	HKCA 1041	
• RFID equipment operating in the 865 – 868 / 920 – 925 MHz bands (射頻識別設備)	HKCA 1049	
• 1.7/47 MHz cordless telephone	HKCA 1006	
• 864.1/868 MHz cordless telephone	HKCA 1015	
• 46/49 MHz cordless telephone	HKCA 1026	
• Digital Enhanced Cordless Telecommunications (DECT) equipment for private use	HKCA 1034	
• Bluetooth (藍芽)	HKCA 1039	
• 2.4 / 5.8 GHz cordless telephone	HKCA 1039	
• 2.4 / 5 GHz wireless LAN equipment (無線區域網絡設備)	HKCA 1039	
• 254/380 MHz cordless telephone	HKCA 1045	
• 60 GHz radiocommunications equipment	HKCA 1074	
• 409 MHz short-range portable radio	HKCA 1044	
• Medical implant communication system (醫療植入通訊系統)	HKCA 1052	
• Public paging receiver	HKCA 1004	
• 79 GHz short-range radar equipment	HKCA 1075	
• Radio equipment operating in the 920 - 925 MHz Band for the provision of Public Telecommunications Services	HKCA 1078	
• Short range devices operating in 4.2 – 4.8 GHz and/or 6.0 – 8.5 GHz bands employing UWB technology	HKCA 1080	
• Equipment for use in Maritime GMDSS radio services	HKCA 12xx	

- <http://www.ofca.gov.hk/filemanager/ofca/common/Industry/telecom/standard/i401e.pdf> [last 2 pages]

# Voluntary Certification Scheme (VCS)



- Radio equipment classified under the VCS can be used or marketed in Hong Kong without obtaining type-approval
- 在自願驗證計劃（VCS）下的無線電設備，不須獲得類型檢定便可在香港使用或銷售
  
- It is incumbent on manufacturers, suppliers or dealers to ensure that their radio equipment meet the prescribed technical requirements
- 製造商、供應商或經銷商有責任確保本身的無線電設備符合訂明的技術要求
  
- The manufacturers, suppliers or dealers may apply to a Certification Body (CB) for type-approval of radio equipment against the relevant HKCA specifications on a voluntary basis
- 製造商、供應商或經銷商可以自願性形式，向認證機構申請根據有關HKCA規格對無線電設備進行類型檢定
  
- In general, voluntary type-approval applies to radio equipment which is exempted from licensing under the Telecommunications Ordinance
- 自願性類型檢定一般適用於獲《電訊條例》豁免領牌的無線電設備

- Radio equipment classified under the CCS must be granted a type-approval before it can be used or offered for sale in Hong Kong
- 在強制驗證計劃(CCS)下的無線電設備，必須獲批類型檢定才可在使用或推出銷售
- The use of which is generally subject to licensing control, e.g. Industrial Scientific and Medical Electronic Machine (ISMEM) Licence
- 使用這類設備一般須受發牌監管，例如 工業，科學及醫學電子器材(ISMEM) 牌照

申請工業，科學及醫學電子器材(ISMEM) 牌照

## APPLICATION FOR INDUSTRIAL SCIENTIFIC AND MEDICAL ELECTRONIC MACHINE (ISMEM) LICENCE

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填寫本表格前，請你閱讀以下資料。牌照申請指引刊載於通訊事務管理局網站 (<http://www.coms-auth.hk>)。

1. 任何人士欲管有或使用無線電發射及／或接收裝置作無線電通訊、遠距指令、控制或其他用途，必須申請適當的電訊牌照。
2. 工業，科學及醫學電子器材 (ISMEM) 牌照的牌費為每年港幣八十元。交回申請表時，請勿附上任何牌照費用，一俟申請獲得批准，通訊事務管理局辦公室會通知申請人繳付牌照費用。
3. 申請人可授權代理人（以下稱為“代理人”）代為填寫及遞交申請表，代理人必須為有效的無線電商牌照〔放寬限制〕的持牌人。同時，一份由申請人簽發委託代理人代為申請牌照的有效授權書必須連同申請表一併遞交。該授權書須有簽發日期，申請人的簽署及公司的蓋印（如適用）。授權書有效期限是簽發後十八個月，除非申請人另有書面說明，過期授權書不會被接受。
4. 所選用的無線電器材，必須已獲通訊事務管理局類型檢定。如須索取更多資料，請致電2961 6321本辦公室電訊標準組，或於本辦公室的網站 (<http://www.ofca.gov.hk>) 查閱經驗証的電訊設備名單。

[https://www.ofca.gov.hk/filemanager/ofca/common/electronic\\_services/licenses\\_application/A116.pdf](https://www.ofca.gov.hk/filemanager/ofca/common/electronic_services/licenses_application/A116.pdf)

# What is Type Approval / Acceptance of ISM equipment



- Industrial, scientific & medical (ISM) equipment emitting radio frequency energy intentionally, shall meet technical requirements prescribed by the Communications Authority, e.g. [HKCA 1007](#), [HKCA 1052](#) etc.
  - 蓄意發出射頻能量的工業、科學及醫學設備必須符合通訊事務管理局訂明的技術要求，如[HKCA 1007](#)、[HKCA 1052](#) 等
  - ISM equipment has been evaluated against and meets the relevant HKCA specification may be granted a [Type-Approval](#)
  - 根據有關HKCA規格鑑定和符合規格的工業、科學及醫學設備，可獲批予類型檢定
- 
- For ISM equipment without relevant HKCA specification for type-approval evaluation, a [Type-Acceptance](#) procedure is available
  - 對於那些沒有相關HKCA規格可作類型檢定的工業、科學及醫學設備，則可進行類型認可程序
  - Manufacturers, suppliers or dealers can submit the technical specifications of the equipment to LCB for consideration.
  - 製造商、供應商或經銷商可提交無線電設備的技術規格供本地認證機構考慮

- 1. SCOPE OF SPECIFICATION

Minimum performance requirements for industrial, scientific and medical (ISM) radio-frequency equipment and domestic and similar appliances designed to generate and/or use locally radio-frequency energy.

- 2. OPERATING FREQUENCIES

The equipment shall operate within the following frequency ranges:-

Frequency Range (MHz)	Frequency Range (GHz)
6.765-6.795	5.725-5.875
13.553-13.567	24.00-24.25
26.957-27.283	61.0-61.5
40.66-40.70	122.0-123.0
2400.0-2483.5	244.0-246.0

- 3. TECHNICAL REQUIREMENTS

The limits and methods of measurement of the equipment shall comply with the latest edition of:-

- CISPR 11 “Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics – Limits and methods of measurement”

- 1. SCOPE OF SPECIFICATION  
Minimum performance requirements for Medical Implant Communication Systems (MICS).
  
- 2. SAFETY AND ELECTRICAL PROTECTION
  - (a) The equipment connecting to public telecommunication network shall comply with HKCA 2001
  - (b) For equipment not connecting to the public telecommunications network, it shall comply with EN/IEC 60601-1 “Medical electrical equipment - Part 1: General requirements for basic safety and essential performance”
  
- 3. OPERATING FREQUENCIES  
The equipment shall operate in the 402 – 405 MHz band.
  
- 4. TECHNICAL REQUIREMENTS
  - (a) Maximum power: 25  $\mu$ W eirp  
Maximum channel bandwidth: 300 kHz
  
  - (b) The equipment shall meet the technical requirements of ETSI EN 301 839-1 “Ultra Low Power Active Medical Implants and Peripherals operating in the frequency range 402 MHz to 405 MHz; Part 1: Technical characteristics and test methods”

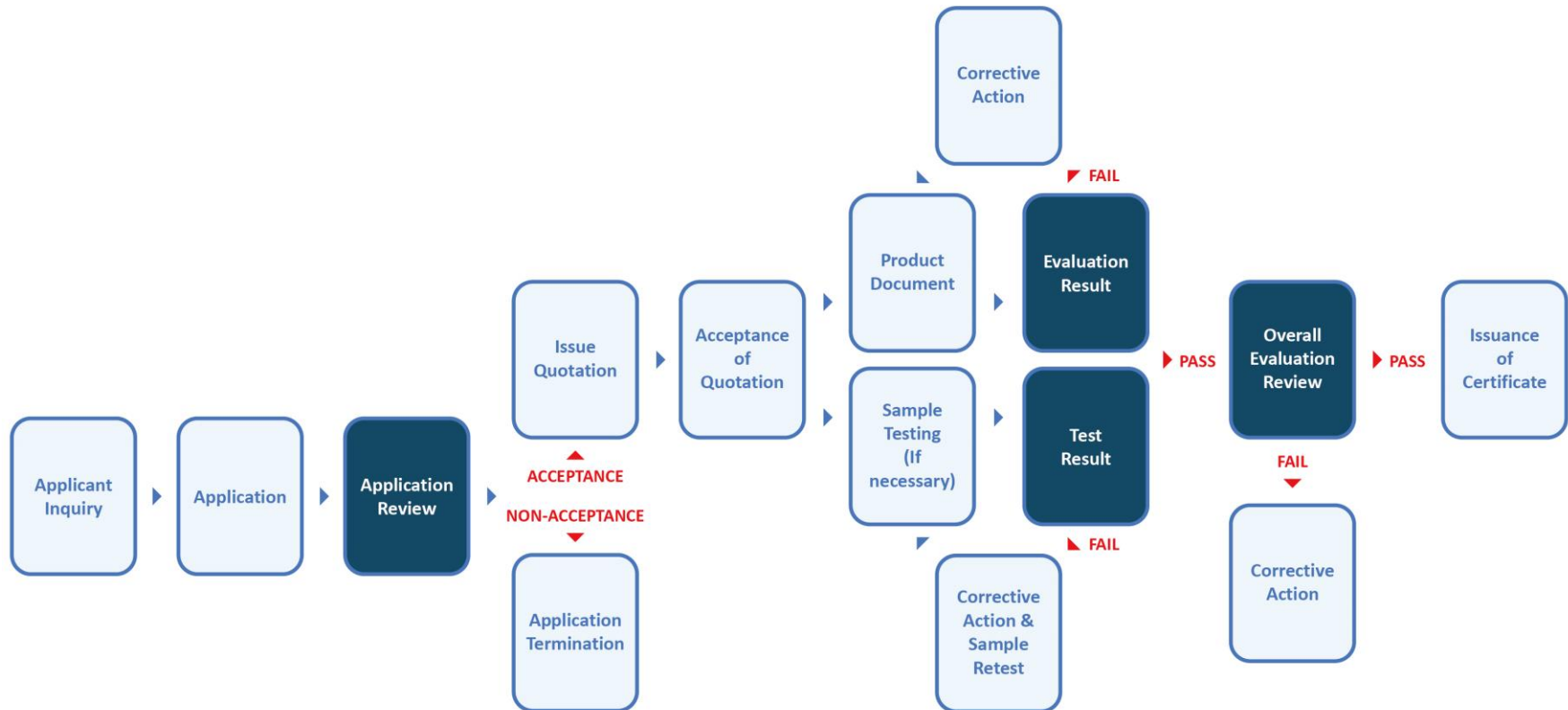
# Application Requirements under HKTEC Scheme



- Application form
- 申請表格
  
- Equipment description, e.g. advertising material, schematic diagrams and block diagrams of circuitry, technical and user manuals
- 設備說明 (包括宣傳資料、原理圖及電路方塊圖、技術及用戶手冊)
  
- ISO/IEC 17025 [accredited test reports](#) and associated conformity assurance documents
- ISO/IEC 17025 [認可的測試報告](#)及相關符合性評審文檔
  
- Photographs of the internal circuit boards and external views
- 內部線路版和設備外形的照片，以供準確識別該設備
  
- Declaration letter of equipment identity (if the applying product has type variant or model number changes)
- 設備一致性聲明的文件 (如有變體或型號變更)
  
- Authorization letter (if the applicant himself is not the brand owner)
- 授權函 (如申請人不是品牌的擁有着)
  
- Business registration documents of the certificate holder
- 證書持有人的商業登記文件



# Certification Flow Chart



Service type	Lead time
Document evaluation and certification for Type-Approval / Acceptance	18 Working Days
Sample Testing document evaluation and certification for Type-Approval / Acceptance	40 Working Days

Under the HKTEC Scheme, manufacturers, suppliers or dealers may affix on a **voluntary basis** a label prescribed by the Communications Authority to a certified TE or ISM equipment 在香港電訊設備鑑定及驗證計劃下，製造商、供應商或經銷商可以**自願形式**在已獲驗證的電訊設備或工業、科學及醫學設備上貼上通訊局指定的標籤



## Format of Certificate No.:

- ◆ ZZZZZ : Certification Body code assigned by OFCA, e.g **HK001 (Hong Kong Standards and Testing Centre)**
- ◆ YY : Year of issue
- ◆ XXXXX : Serial number of certificate issued during that calendar year

# Publication of Certified Equipment



Certified equipment together with the certification number assigned by a CB to the equipment will be posted under the [List of Certified Equipment](#) in OFCA's website  
經驗證的設備和認證機構指配的證書編號，都會刊登在通訊辦網站的[經驗證設備清單](#)上  
<http://app1.ofca.gov.hk/apps/cte/content/listEquip.asp>



[English](#) | [繁體版](#) | [簡體版](#)

## List of Certified Telecommunications Equipment for Use in Hong Kong

### Search Certified Telecommunications Equipment

Equipment Category

-- All --

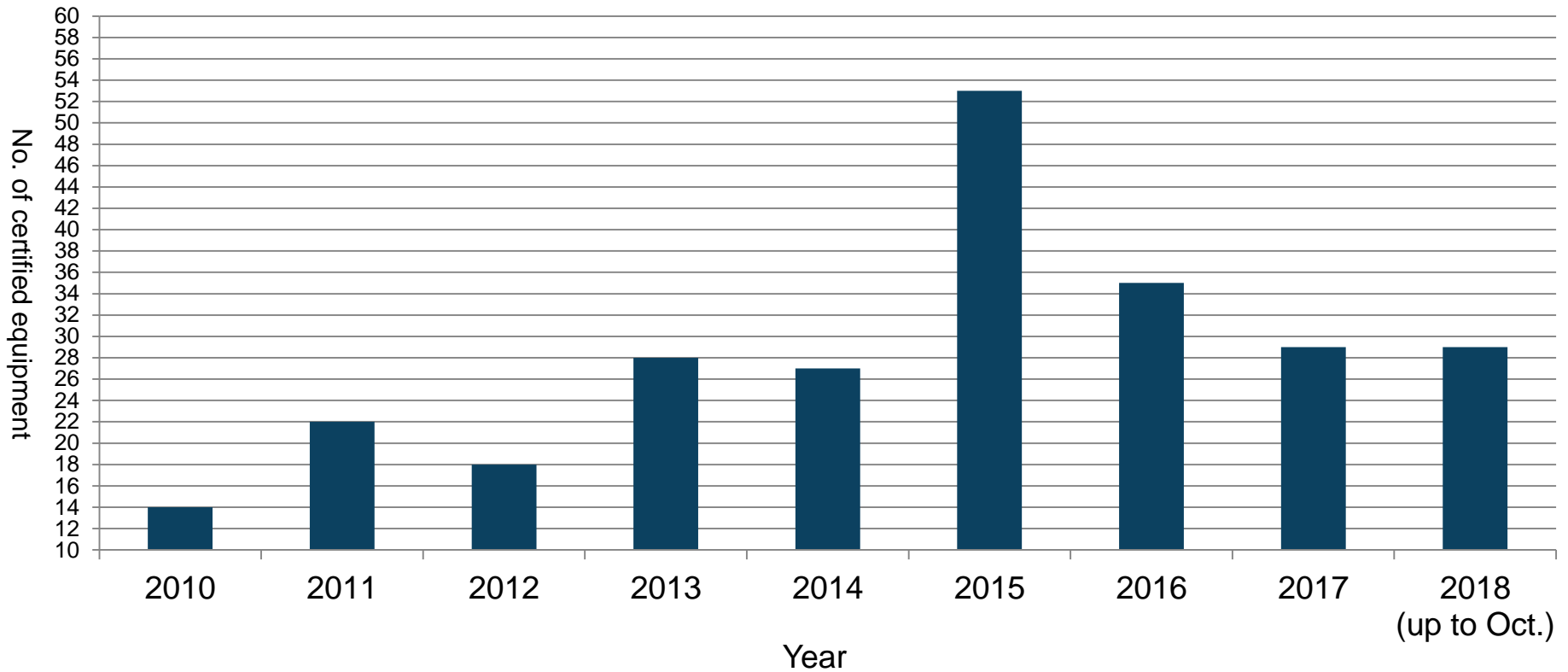
Marketing Name / Designation

Certificate Number

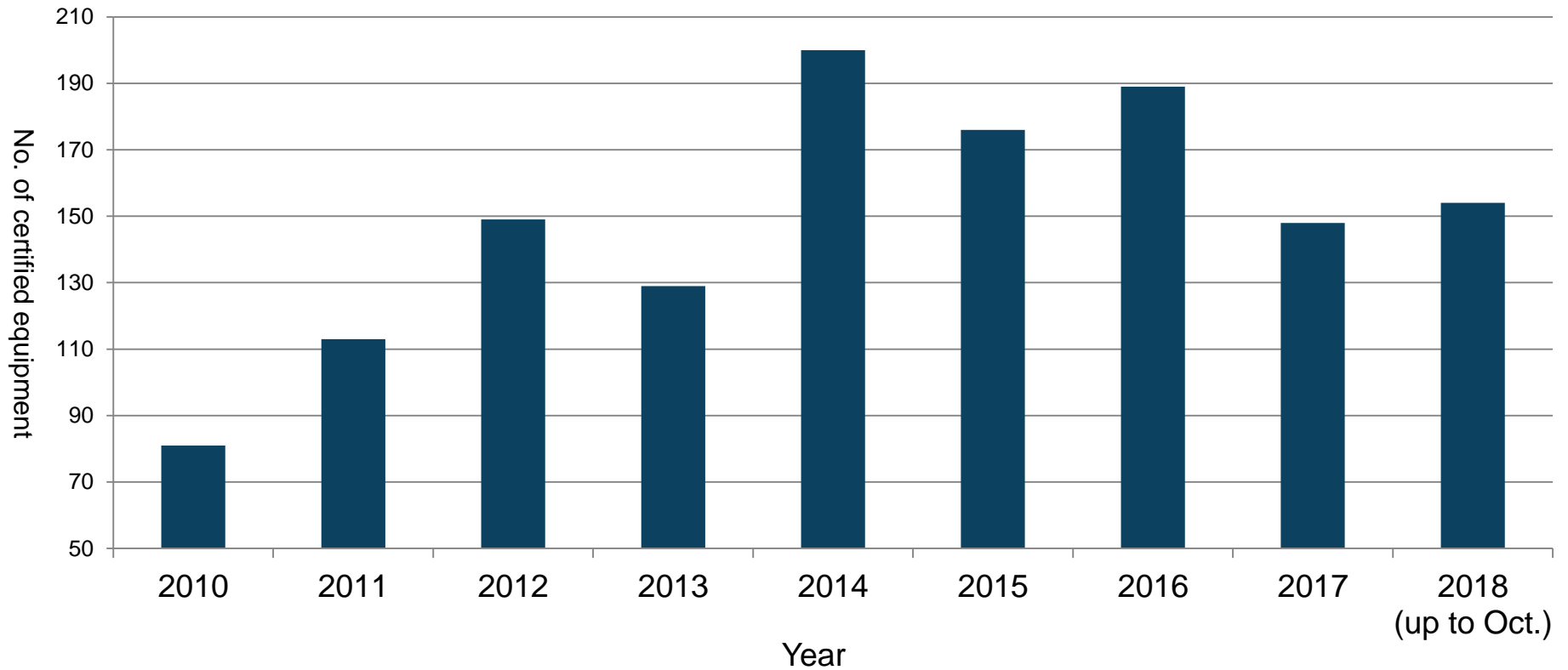
Search ▶

Reset ▶

# No. of Certified ISM RF Equipment under Licences (Year 2010 to Year 2018)



# No. of Certified 2.4 / 5 GHz Wireless LAN Equipment (Year 2010 to Year 2018, for reference only)



# THE END

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**Email: [kennethcheung@stc.group](mailto:kennethcheung@stc.group)**

\*\* 医疗器械生物安全评价实验室（配有屏障级动物实验室和普通级动物实验室），占地面积1000平方米，动物房面积约二分之一，按照国际GLP质量管理标准运营，提供ISO10993以及GB16886/USP美国药典等标准的生物相容性检测服务。

\*\* 配套电子电器实验室提供医疗器械安规及EMC测试（IEC/EN 60601），全球互认CB认证。



公司实景图

# 实验动物使用许可证

许可证号 SYXK(粤)2016-0159

单位名称：东莞标检产品检测有限公司

法定代表人：黄桂友

设施地址：东莞市大朗镇富民南路 68 号一栋

适用范围：普通环境（豚鼠、兔，一栋-A 一楼 240 m<sup>2</sup>）  
屏障环境（大鼠、小鼠，一栋-C 二楼 203 m<sup>2</sup>）

有效期：2016 年 9 月 2 日至 2021 年 9 月 1 日

发证机关：广东省科学技术厅  
二〇一七年二月九日







内容	标准	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

内容	标准	周期
<b>植入测试</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
<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		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