

# Providing Options and Opportunities

Hong Kong's testing and certification industry provides essential services to ensure the safety and quality of medical and healthcare products, while supporting further development and innovation of those products in the city. By Leon Lee



Devices such as tai chi machines are subject to a number of tests including electromagnetic compatibility (EMC)

Testing and certification are crucial services that ensure the safety and quality of products as well as services to consumers. With the world's ageing population and their medical needs growing, there has been a surge of demand for more accessible, accurate and advanced medical and healthcare devices, and thus highlighting the importance of testing and certification in the growing market of such products.

## Tests for safety and efficacy

According to Jonathan Tang, Study Director of the Medical Device Department at Hong Kong Standards and Testing Centre (STC), a conformity assessment body based in Hong Kong, testing and certification organisations that handle medical device testing, in particular, act as gatekeepers for product quality which protect the rights of patients and users. "Medical devices are like medicine. They are closely related to people's lives, so their importance is understandable," he says. "The testing of medical devices is not just a test, but

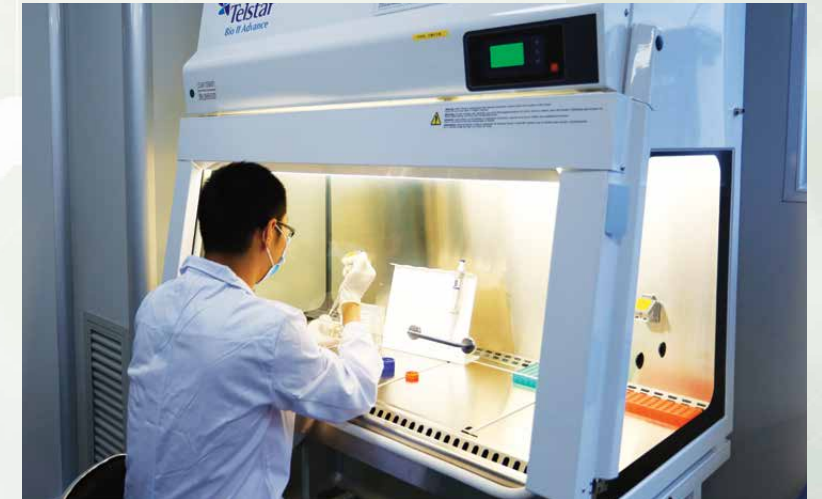
also part of the biological safety evaluation and risk management process. We need to pay extra attention to risk assessment."

Medical devices can be categorised into invasive, non-invasive, and active ones. The most widely adopted international testing standard for biocompatibility and medical electrical safety is the ISO 10993 series and IEC 60601-1 respectively, whereas that for the safety particular requirements for in vitro diagnostic (IVD) medical equipment is IEC 61010-2-101. Other widely used standards are ISO 13485 for medical devices quality management system, and ISO 14971 for medical devices risk management.

"Since medical devices and products are multidisciplinary, there are a multitude of tests required for their manufacturers to demonstrate product safety and efficacy," says Bryan So, Principal Consultant of Smart Healthcare, MedTech and Optics of the Automotive and Electronics Division at the Hong Kong Productivity Council (HKPC). "Mechanical testing will help determine the strength and durability of medical devices like surgical needles. There are tests on product materials such as medical plastic to help manufacturers understand the material properties, thus ensuring their optimal performance. Medical electrical safety testing is used to ensure the relevant devices comply with general requirements in terms of basic safety and electromagnetic disturbances. The latter is particularly important for medical devices since many different types of electronic devices will be operating in a hospital at the same time."

## Responsive to market needs

With different standards and regulations in place, there are many areas that companies and manufacturers should be mindful of to prevent



Laboratories act as gatekeepers to protect the rights of patients and users by ensuring the quality and safety of products and services

testing failures. Testing and certification organisations can provide guidance to businesses to avoid potential pitfalls from the very beginning. They can provide evaluation on the safety of a device's design, materials being used, manufacturing process and manufacturing environment. All these can help businesses verify product safety, and contribute to research and development as well as product improvement. Some testing and certification organisations can even assist businesses in obtaining market approval and/or permits by writing technical documents and preparing registration filings.

"Medical device testing and certification organisations help companies to better understand and become more familiar with

the global testing and regulatory requirements, accelerate product improvement to meet the global market requirements and overcome trade barriers," says STC's Tang. He adds that Hong Kong can become a medical device hub as some of Asia's top medical resources and R&D institutions have set up their offices here.

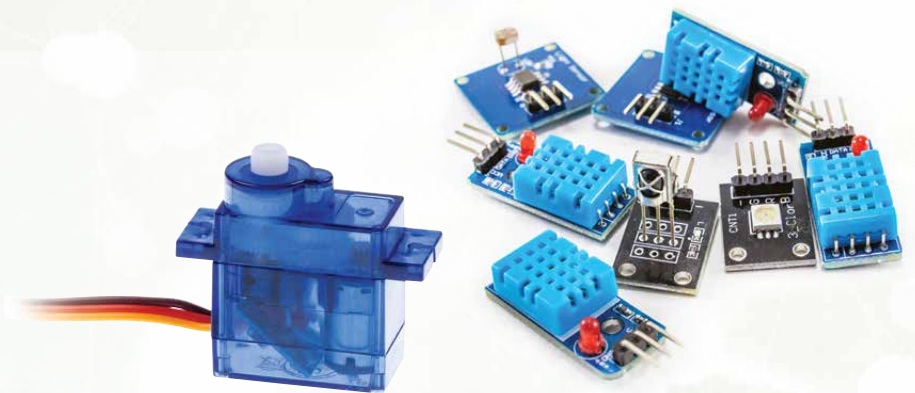
HKPC's So agrees that testing and certification services will greatly benefit from a booming medical and healthcare sector. "As medical devices are subject to stringent regulations, there are essential requirements for pre-market approval in all major markets, which are fulfilled through compliance tests and certifications. Hong Kong's testing and certification bodies are well-prepared to assist the medical and healthcare sector in this regard," says So.

#### A win-win situation

As the market of medical and healthcare electronic products grows, it has created business opportunities in other sectors such as electronic components. This is one of the areas that Hong Kong manufacturers are equipped for with years of experience and quality products. But before they attempt to enter the thriving industry, manufacturers need to understand the stringent requirements and regulations on medical and healthcare electronic devices. As such, the Hong Kong Electronic Industries Association (HKEIA) has launched a project to enhance and upgrade the ability of the local electronics industry for entering the smart medical and healthcare device market.

"This project aims to enhance the capability of local electronics players through improving their understanding of related international

*With good understanding of international regulatory requirements and appropriate manufacturing practices, Hong Kong electronic component suppliers can enter and contribute to the growing smart medical and healthcare device market*



*EMC tests ensure electrical devices will not interfere with the operation of other devices in its vicinity*

regulatory requirements and appropriate manufacturing practices," says Basil Wai, CEO of HKEIA. "Consumers will have more confidence in products with recognised medical grade certifications. In order to obtain those certifications, manufacturers would need to understand and meet the requirements of ISO standards."

Funded by the SME Development Fund, the project targets five specific electronic components: sensors, microprocessors, integrated circuits, actuators and LCD displays. The Industry Competence Assessment Scheme, as part of the project, aims to help certain Hong Kong electronics companies to upgrade their process flow and quality management system according to ISO 13485. Also included in the project are seminars and training workshops for information and technology updates.

Wai explains that the project aims at helping

SMEs so that they could also benefit from Hong Kong's testing and certification services, just as the large corporations.

"We hope to offer more choices to the medical and healthcare industry with this project. As we target to enhance local electronics companies' understanding of international regulatory requirements and appropriate manufacturing practices for medical devices, they are more likely to be able to demonstrate compliance to the required quality standard to their business partners. This will give more confidence to medical and healthcare companies to procure reliable components from Hong Kong SMEs, which will be a win-win situation for both industries," Wai says.

For more information about Hong Kong's testing and certification industry, please visit the website of the Hong Kong Council for Testing and Certification at [www.hkctc.gov.hk](http://www.hkctc.gov.hk).