

FOR IMMEDIATE RELEASE

HKQAA kicks off the first “Medical Face Masks Product Certification Scheme” in Hong Kong

(25 March 2020, Hong Kong) The Hong Kong Quality Assurance Agency (HKQAA) announced today the kickoff of its "Medical Face Masks Product Certification Scheme", which is the first of its kind in Hong Kong to support the community in the fight against Coronavirus disease. Through professional and impartial certification, the Scheme assists local manufacturers to demonstrate their ability to produce medical face masks at international standard level, so as to help protect people's health.

COVID-19 has spread across the globe, and the supply and quality of medical face masks has become an issue of great importance. The HKSAR Government has launched a series of measures to combat the virus and support the local manufacture of face masks. Some private enterprises, civic groups and organisations have been preparing to set up local production lines for this product.

In order to support the government and meet the needs of the industry and society, HKQAA has developed the "Medical Face Masks Product Certification Scheme". Through professional and impartial third-party certification, the Scheme assists local manufacturers to demonstrate that their mask products meet specified product quality and production process management requirements of international standards, thereby helping to protect people's health.

Quick response to meet the needs of our society

As a non-profit organisation established by the Hong Kong Government in 1989, HKQAA consistently upholds the spirit of professionalism and impartiality. We strive to introduce advanced international management systems and developed innovative services, such as certification services for hygiene control, green finance and wine storage management, so as to create value for enterprises and bring benefits to the community.

After the outbreak of "SARS" more than a decade ago, society was encouraged to pay more attention to public health. HKQAA took the lead in developing the HKQAA - Hygiene Control System Certification Scheme to promote a new culture of hygiene practices. In 2006, HKQAA provided the ISO 13485 Medical Devices Quality Management System certification service to support the medical device industry in its efforts to improve professional standards.

Since the beginning of the spread of COVID-19, at the end of December 2019, HKQAA has paid close attention to the situation. To support the community in the fight against this virus, we have made good use of our expertise to quickly develop the "Medical Face Masks Product Certification Scheme" kicked off today.

International Standards and local regulatory requirements

The Scheme is the first medical face mask product certification scheme tailored to the local market. It is applicable to all face mask manufacturing companies and organisations. In order to ensure that the certification requirements are comprehensive, HKQAA has developed the

Scheme with reference to international and national requirements, including the ISO 13485 medical devices quality management system standard, the ISO 14644-1 clean room standard, national GB19083 technical requirements for protective face masks, American ASTM F2100 medical face masks standards, and European EN 14683 standards, as well as related local regulatory requirements.

To obtain certification for their mask product, manufacturers need to meet the requirements listed in the "Medical Face Masks Product Certification Scheme" handbook. The requirements are based on the ISO 13485 standard, with additional risk management requirements and special management requirements for medical face mask production. Additionally, the mask product needs to comply with the testing standard of GB 19083, ASTM F2100 or EN 14683, while its production environment is required to meet the ISO 14644-1 standard.

Enhance public confidence with continuous quality management

The Scheme requires mask manufacturers to continuously and effectively manage production quality, not just pass a one-off testing exercise. This requirement helps manufacturers boost their reputation and improves the overall performance of the industry, enhancing public confidence. Upon successful certification, manufacturers are entitled to display the certification mark on the packaging of their certified face mask products, which will help consumers to make a wise purchasing choice.

Some experts predict that the virus outbreak will continue for a period of time locally and globally. The huge demand for face mask products in Hong Kong may continue to grow, and there will be more products on the market. It is believed that the "Medical Face Masks Product Certification Scheme" will play an important role in upholding product quality and support Hong Kong citizens' fight against the virus.

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For enquiries, please contact:

Hong Kong Quality Assurance Agency – Corporate Communications Unit

Ms. Tammy Tsang / Ms. Vivian Li

Tel: 2202 9372 / 2202 9303

E-mail: tammy.tsang@hkqaa.org / vivian.li@hkqaa.org

HKQAA Background

HKQAA is a non-profit organisation established by the Hong Kong Government in 1989. As one of the leading conformity organisations in the Asia-Pacific region, HKQAA is committed to providing certification and assessment services for the industries. Through knowledge sharing and technology transfer, HKQAA helps enterprises enhance management performance and competitiveness. In addition to introducing world-class management systems, HKQAA has launched a wide range of innovative services to cope with increasingly diversified market demands, bringing benefits to the community.

Please visit <http://www.hkqaa.org> for further information.