

FOR IMMEDIATE RELEASE

HKQAA issues first “Medical Face Masks Product Certification”

(23 June 2020, Hong Kong) In order to support the community in the fight against the Coronavirus pandemic, Hong Kong Quality Assurance Agency (HKQAA) recently developed the "Medical Face Masks Product Certification Scheme", the first of its kind in Hong Kong. The Scheme aims to promote good practice in face mask manufacturing and enhance the overall performance of the industry, thereby helping to protect people's health.

Today, we are pleased to issue the first Scheme certificate to A.S. Watson Industries (a division of A.S. Watson Group (HK) Limited), which has also obtained ISO 13485 Medical Devices Quality Management Systems Certification. These certificates demonstrate that their medical face mask quality and production management have met international standards.

Comprehensive requirements covering product quality and production management

HKQAA's Scheme is the first medical face mask product certification scheme tailored to the local market. It specifies comprehensive requirements for the manufacture of face masks, emphasising both product quality and management systems. Key requirements include the following:

Areas covered by the Scheme	Key features and requirements
Production Environment	Attain ISO 14644-1 Class 8 clean room standard.
Face Mask Performance	Comply with face mask performance testing standard ASTM F2100, EN 14683 or GB 19083.
International and local requirements	The Scheme makes reference to international and national requirements, covering the above environmental and testing standards as well as ISO 9001, Quality Management Systems and ISO 13485, Medical Devices Quality Management Systems. It also refers to local laws and regulations, including but not limited to the Trade Descriptions Ordinance and the Consumer Goods Safety Ordinance.

<p>Impartiality in taking testing samples</p>	<p>HKQAA selects and obtains samples during the audit. The samples should be sealed and tested by a laboratory with accreditation in the field of microbiological testing.</p>
<p>Effective management</p>	<p>The certification emphasises both product quality and management systems, including special management requirements for medical face mask production and risk management requirements. The Scheme requires mask manufacturers to continuously and effectively manage production quality, not just pass a one-off testing exercise. During the three years of validity of the certification, HKQAA will conduct audits and evaluate whether the certified organisations continue to meet the requirements.</p>
<p>Emphasis on user's perspective</p>	<p>Manufacturers are required to gather user feedback on a regular basis in order to facilitate continuous improvement and increase user satisfaction.</p>

ISO 13485 Medical Devices — Quality Management Systems Certification

Medical face masks are one of most common items of protective equipments and medical devices. A.S. Watsons Industries also obtained ISO 13485, Medical Devices — Quality Management Systems Certification for the design and manufacture of medical face masks. ISO 13485 is based on ISO 9001 but it is specific to medical devices. The standard is recognised internationally and the stringent requirements cover product design, purchasing, manufacturing, storage and delivery. It emphasises personnel (men), equipment (machines), materials storage, procedures for manufacturing, control of the environment (4M1E), and product safety. In addition, ISO 13485 requires applicants to comply with related regulations, meet the expectations of users and fulfill the intended purpose of medical devices.



A.S. Watson Industries obtained the “Medical Face Masks Product Certification” and ISO 13485 Medical Devices Quality Management Systems Certification. Ir Peter K. W. Mok, Honorary Chairman (Right); Dr Michael P. H. Lam, Chief Executive Officer of HKQAA (Left), took a photo with Ms Michelle Chan, Managing Director of A.S. Watson Industries (Middle).



Ms Chan (Left) received the certification marks from Ir Mok (Right).

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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 industry. 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.

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", the "Hygiene Measures for CoV Prevention Certification Scheme" and "Community Health Ambassador" Personnel Registration.

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