

ACI launches ISO 13485 Medical Protective Face Mask Product Certification

As the coronavirus disease 2019 (COVID-19) pandemic progresses all over the world, the supply and quality of protective face masks have received much attention. The Hong Kong SAR Government (HKSAR) has launched series of anti-epidemic measures supporting new factories and private organizations in setting up production lines for face mask.

In support of this, and to meet the needs of the industry and society, ACI has developed the "ISO 13485 Medical Protective Face Mask Product Certification", which aims to help local manufacturers demonstrate their commitment to the safety and quality of their product by providing professional and fair third-party certification services. This certification ensures that the manufacturer has reached International Standards in terms of production process management, delivering compliant products to protect the health of citizens and support the community fight against this pandemic.



ACI's "ISO 13485 Medical Protective Face Mask Product Certification" assists the medical industry in upgrading and be on par with international standards. This certification is applicable to all mask manufacturers and institutions. In the process, ISO 13485 Medical Devices Quality Management System standard must be complied with. Besides this, production environment will be checked against ISO 14644-1 Cleanrooms standard. The product must also pass the requirements required by American Standard ASTM F2100 Medical Mask standard or European Union EN 14683 Bacterial Filtration Efficiency standard, as well as international, national and local requirements (e.g. local laws and regulations).





All of these are incorporated by ACI to provide a more intensive and comprehensive certification. This certification provides the consumers a confidence that the mask manufacturer continuously and effectively implements production quality control to ensure the safety and quality of their products. Mask products that have successfully obtained this certification may use the certification logo on their product packaging, allowing consumers to easily identify products marked with quality over the others.

Experts expect that this virus will continue for a year or two locally and globally, making the demand for protective masks in Hong Kong persist. Hence, "**ISO 13485 Medical Protective Face Mask Product Certification**" will continue to play a vital role in ensuring quality control of these masks, allowing Hong Kong citizens face this pandemic with more confidence.

Manifesting integrity and professionalism, **ACI** is committed to introducing advanced international management systems, and actively developing leading, high-quality management methods and related standards. With extensive professional service experience, **ACI** is committed to promote excellence and value-added services that will benefit our society.