

# SCOOP

THE LATEST TRENDS, SERVICES & PROMOTIONS

CONSUMER & RETAIL SERVICES, SGS HONG KONG

DEC 2020

## SGS IS RECOGNIZED BY FDA FOR 510(K) 3<sup>RD</sup> PARTY REVIEWER FOR SURGICAL MASKS

As the shortage in medical use personal protective equipment continues amid the coronavirus disease (COVID-19) pandemic, the US Food and Drug Administration (FDA) is lifting requirements for certain masks and respirators to increase their availability.

For face masks intended for medical purposes, FDA says it is lifting major regulatory requirements to increase availability of the devices, including 510(k) submission, so long as the devices do not create an undue risk for users.

FDA says it will allow the distribution and use of surgical masks, which are Class II devices, without 510(k) clearance, given that the masks meet certain standards for fluid resistance and flammability and include accurate labelling.

Typically, re-processors must obtain 510(k) clearance to reprocess single use devices. However, given the urgent need for respirators, FDA says it will work with companies to expedite the EUA process and provides a detailed list of information for companies to provide to support an EUA request.

In early Dec 2020, SGS had been nominated by FDA to be a official 510(k) Third-Party Review Organization (see [here](#) for the announcement).

SGS provides a Comprehensive Solution for Mask Quality, including ISO 14644 cleanroom certification, EN 14683 / ASTM F2100 product testing, pre-shipment inspection, ISO 13485 medical device quality management system certification and overall project management.

For more information on FDA's clarification on Medical Mask Sample Size Requirements for 510(K), please see [here](#).

*SGS's medical device testing, certification, audit and training services can help you navigate the complexities of international medical device regulations to bring your products to market while ensuring compliance with the required regulations and standards and providing a high level of safety to patients and healthcare professionals.*



### FOR ENQUIRIES

#### HONG KONG

Mr. Joe Choy (Customer Service Team)  
e [HK.Hardlines.Enquiry@sgs.com](mailto:HK.Hardlines.Enquiry@sgs.com)

©2020 SGS. All rights reserved. Information contained herein is provided "as is" and SGS does not warrant that it will be error-free or meet any particular criteria of performance or quality. Do not quote or refer any information herein without SGS' prior written consent. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.

