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THOUGHT LEADERSHIP

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Are You Purchasing Low-Quality Face Masks?

Tips for Importing Face Masks During COVID-19

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Face masks are a critical resource in the prevention of COVID-19 transmission. While China has historically contributed to 50% of global face mask production, its manufacturers are currently struggling to meet global demand. Producers of textiles, outdoor gear, and mobile phones are rapidly building production lines to help address this shortage. As some emerging manufacturers have little experience with high-quality mask production and lack cleanroom facilities, experts question whether their products can meet American and European safety standards. To protect the safety of healthcare professionals and other occupational mask wearers, importers should perform comparative assessments of commercial masks before purchase. If possible, importers should also evaluate mask options to ensure they meet quality requirements for occupational use.

Mask Certification Processes in the U.S. and the EU

Face mask certification in the United States is conducted by the National Institute of Occupational Safety and Health (NIOSH). Manufacturers seeking NIOSH approval must submit technical documents and mask samples to NIOSH. The organization and its subsidiaries conduct tests based on 42 CFR Part 84 that generally include evaluating filtration efficiency, breathing resistance, and total inward leakage. For surgical N95 masks, additional tests for bacteria filtration efficiency, differential pressure, sub-micro particulate filtration, and resistance to penetration by synthetic blood are required as defined by ASTM F2100. It is important to note that the FDA has established Emergency Use Authorizations (EUAs) due to COVID-19 and is currently exercising enforcement discretion for certain device regulations. For example, a recently released EUA claimed that filtering facepiece respirators from certain countries would be eligible for authorization under FDA if they could meet the performance standards.

For European certification, the face mask approval process can only be conducted by certified facilities authorized by Module B and Module C2/Module D according to CE directive R 2016/425 (Personal Protective Equipment). Masks must meet the standards listed in Table 1 to complete the certification process, especially EN 149: 2001 + A1:2009 for filter respirators and EN 14683 for medical face masks. There are over 2,000 notified bodies in Europe, but only about 50 of them are the appropriate bodies for mask certification.

Table 1. European Standards Related to Face Masks

Standard	Type of Face Mask
EN 149: 2001+A1:2009	Filtering Half Masks to protect against particles
EN14683	Medical Face Masks
EN 136: 1998	Full Face Masks – Class 1, 2, or 3
EN 140: 1999	Half/Quarter Masks
EN 14387: 2006	Gas Filters & Combined Filters
EN 143: 2000	Particle Filters

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Current Challenges to Certification and Mask Quality

Applications for certifications in the United States and Europe have increased exponentially since the outbreak of COVID-19. The certification process can take several months, as labs are flooded with requests, and response times are generally longer than normal. In an attempt to shorten this process, some certification agents are seeking certification from notified bodies that are not suitable for mask certification. Exporters of improperly certified masks face an increased risk of customs refusal, fines, and potential product destruction. EU importers can check the European Commission website to ensure their exporters have the correct CE certification.

Unfortunately, even with proper certification or registration, the quality of masks cannot be guaranteed since there are many unexperienced manufacturers in this industry. Hundreds of production lines have been set up since January. While most manufacturers have good intent, successful mask production requires complicated systems, access to a specialty melt-blown fabric currently in short supply, and high-quality metal strips and ear loops that can support an effective facial seal. Recent tests of face masks imported into Singapore and the Netherlands showed drastic variation in melt-blown fabric weight and filter efficiency and fitting, respectively. The masks imported to the Netherlands could not meet minimum standards and were determined to be unsafe for healthcare professional use.

Importance of Comparative Testing Before Purchase

To protect the safety of healthcare professionals and other occupational mask wearers, importers should perform comparative assessments of commercial masks before purchase. If possible, importers should also evaluate mask options to ensure they meet quality requirements for occupational use. To ensure consistent testing results, importers should use labs certified by the China National Accreditation Service (CNAS).

Exponent's Expertise

Exponent's multi-disciplinary team of engineers and health scientists can help importers monitor manufacturers' production capabilities, perform comparative assessments of mask options, and interpret testing results. With on-the-ground technical experts in the United States, Europe, the UK, Shanghai, Hong Kong, and Singapore, we can guide organizations in all parts of the world during this difficult time.

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