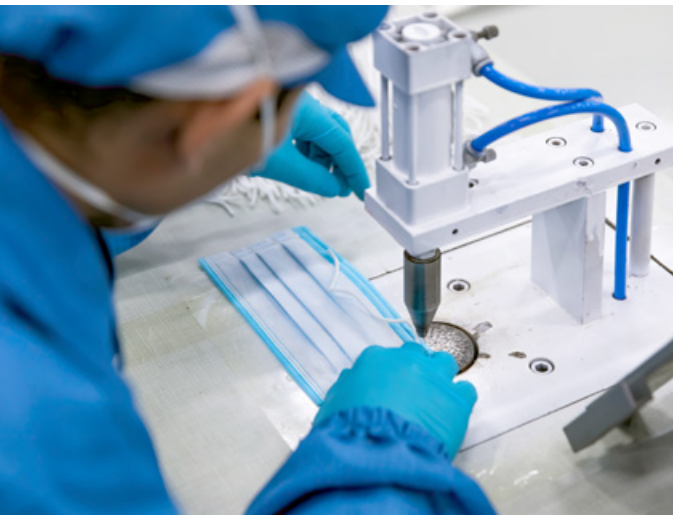




# FACE MASK PRODUCT LIFECYCLE QUALITY MANAGEMENT



## Testing, Inspection, Audit and Certification for Surgical Face Masks

### BUSINESS CHALLENGE

Manufacturers worldwide are transforming production lines to meet the growing needs of people worldwide for surgical face masks. As a buyer or seller, how confident are you in your process and product controls in meeting regulatory as well as brand specifications in these most challenging times.

For two of the largest markets, the testing and certification requirements for USA (ASTM) and Europe (EN) are detailed in the table below:

		ASTM F 2100-2019			EN 14683:2019		
		Level 1	Level 2	Level 3	Type I <sup>a</sup>	Type II	Type IIR
Barrier Tests	BFE % ASTM 2101/EN14683	≥95	≥98		≥95	≥98	
	PFE% ASTM F2299	≥95	≥98		Not required		
	Splash resistance pressure ASTM F1862/ISO 22609	80 mmHg	120 mmHg	160 mmHg	Not required	≥16.0 (kPa)	
Safety Tests	Microbial Cleanliness ISO 11737-1	Not required			≤30 (cfu/g)		
	Flammability 16 CFR part 1610	Class 1			Not required		
Physical Tests	Differential Pressure EN 14683 (Pa/cm <sup>2</sup> )	<5.0 H <sub>2</sub> O/cm <sup>2</sup>	<6.0 H <sub>2</sub> O/cm <sup>2</sup>		< 40	< 60	
Certification Requirements		Premarket Notification [510(k)] Submissions - FDA-2003-D-0305 *			CE marking - Regulation (EU) 2017/745 ** Temporary exemption - Recommendation (EU) 2020/403 ***		

\* Premarket Notification [510(k)] Submissions - FDA-2003-D-0305

\*\* CE marking - Regulation (EU) 2017/745

\*\*\* Temporary CE marking exemption - Recommendation (EU) 2020/403

### Temporary CE marking Exemption

RECOMMENDATION (EU) 2020/403 of 13 March 2020 was released within the context of the COVID-19 threat to address the shortage of surgical face masks.

Where non-CE marked surgical face masks are intended to enter the EU market, the relevant market surveillance authorities will evaluate the products and, if found to be compliant with the essential health and safety requirements, will take measures to allow the placing on the Union market for a limited period of time, or while the conformity assessment procedure with the notified body is being carried out.

## KEY BENEFITS



### Supplier Selection

Assessment and benchmarking of the capability and capacity of your chosen factory



### Product Selection

Verification that your product meets microbiological and quality thresholds



### Customer Confidence

By affixing a CE marking for Europe, you provide confidence to the end user and buyer that the mask meets regulatory requirements



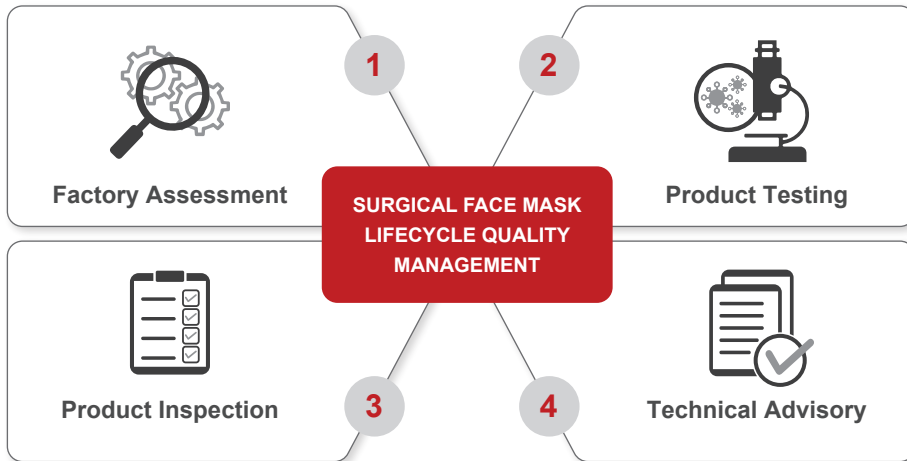
### Document Review

Third party technical assessment check of all surgical face mask technical documentation against requirements for your intended market(s)



## OUR SOLUTION

### PRODUCT LIFECYCLE QUALITY MANAGEMENT



#### Factory Assessment

Supports with assessment of conformity with the special arrangements given to address the COVID-19 outbreak. Specific requirements for surgical face masks include: sterilization facilities; disinfection areas; clean rooms; proper protective clothing & storage; ...

#### Product Testing

Microbiological hub in Sri Lanka provides Bacterial Filtration Efficiency (BFE) and associated testing for surgical face masks against EN 14683 and its counterpart committee requirements in the U.S. (ASTM F2101).

#### Product Inspection

Bureau Veritas has trained inspectors in major surgical face mask production countries worldwide. The inspection protocol addresses quantity, labeling and specification review as well as a variety of on-site testing including: product dimension measurement; nose clip reliability; tensile test to the mask connection points; claimed function as well as actual wear test.

#### Technical Advisory

**Level 1: Document Review:** Adequacy check of documentation including the applicable test requirements, third party lab accreditation, vendor information and overall rating;

**Level 2: CE marking Access.** Our specialists can help you achieve formal CE marking from an appointed Notified Body or surveillance authority exemption acceptance.

## WHY CHOOSE BUREAU VERITAS SERVICES?



#### NETWORK

Committed to World Class Service Delivery, Driving Optimal Performance & Reliability



#### KNOWLEDGE

Trained Surgical Face Mask Engineers, Inspectors and Auditors Worldwide



#### LEADERSHIP

A Recognized Global Leader in Testing, Inspection & Certification (TIC)



#### MARK OF GLOBAL RECOGNITION

Improve Reputation. Fast access to Existing & New Markets

## CONTACT US

🌐 [www.cps.bureauveritas.com](http://www.cps.bureauveritas.com)

✉️ [cps.global@bureauveritas.com](mailto:cps.global@bureauveritas.com)