Surgical Face Masks
Compliance & Quality Control
Frequently Asked Questions (FAQ)

COMPLIANCE – TEST & CERTIFICATION	
Q1	**What are the testing requirements for surgical (medical) face masks?**
A1	There are 2 major standards for face masks, ASTM F 2100-19 which addresses the USA and EN 14683 which addresses EU.

		ASTM F 2100-2019			EN 14683:2019		
		Level 1	Level 2	Level 3	Type I[a]	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/cm²)	<5.0 H_20/cm^2	<6.0 H_20/cm^2		< 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 ***		

Q2	**As a supplier (manufacturer), what are the certification requirements that I need to follow to supply masks to EU / US market?**
A2	**USA**: Surgical Masks - Premarket Notification [510(k)] Submissions | FDA-2003-D-0305 **EU**: Surgical (medical) mask – CE marking required | Regulation (EU) 2017/745
Q3	**I do not have CE marking registration, can I still supply to EU market?**
A3	Yes, the COMMISSION RECOMMENDATION (EU) 2020/403 of 13 March 2020 on conformity assessment and market surveillance procedures within the context of the COVID-19 threat to address the shortage of PPE (necessary in the context of the COVID-19 outbreak), provides necessary provisions where non-CE marked masks are intended to enter the EU market. Bureau Veritas can support and assess whether these provisions are fulfilled as part of our Advisory service portfolio

Q4	**What is BFE %?**
A4	Bacterial filtration efficiency (BFE) of medical face mask materials is a test (assessment), employing a ratio of the upstream bacterial challenge to downstream residual concentration to determine filtration efficiency of medical face mask materials. The test method has been specifically designed for measuring bacterial filtration efficiency of medical face masks, using Staphylococcus aureus as the challenge organism. The use of S. aureus is based on its clinical relevance as a leading cause of nosocomial infections. This test method is a quantitative method that allows filtration efficiency for medical face mask materials to be determined. The maximum filtration efficiency that can be determined by this method is 99.9 %.
Q5	**Which side of the mask should be tested?**
A5	Unless otherwise specified, the testing shall be performed with the outside of the medical face mask in contact with the bacterial challenge. Testing may be performed with the aerosol challenge directed through either the face side or liner side of the test specimen, thereby, allowing evaluation of filtration efficiencies which relate to both patient-generated aerosols and wearer-generated aerosols.
Q6	**Can external factors, such as physical deterioration due to handling and exposure to any chemical, impact performance of the mask?**
A6	Degradation by physical, chemical, and thermal stresses could negatively impact the performance of the medical face mask material. The integrity of the material can also be compromised during use by such effects as flexing and abrasion, or by wetting with contaminants such as alcohol and perspiration.
Q7	**Are there any disclaimers?**
A7	This test method evaluates medical face mask materials as an item of protective clothing but does not evaluate materials for regulatory approval as respirators. If respiratory protection for the wearer is needed, a NIOSH-certified respirator should be used. Relatively high bacterial filtration efficiency measurements for a particular medical face mask material does not ensure that the wearer will be protected from biological aerosols, since this test method primarily evaluates the performance of the composite materials used in the construction of the medical face mask and not its design, fit, or facial-sealing properties. This test method does not address breathability of the medical face mask materials or any other properties affecting the ease of breathing through the medical face mask material.

QUALITY CONTROL - INSPECTIONS	
Q1	**What kinds of inspection service can Bureau Veritas provide for face masks?**
A1	As a professional and comprehensive 3rd inspection party, Bureau Veritas Consumer Products Services has full capability and capacity to provide inspection services as follows across most major surgical face mask production countries: ▪ Factory Assessment to face mask factory; ▪ Production In-line Inspection for face mask manufacturing; ▪ Final Random Inspection for face mask; ▪ Sample Collection for lab testing purpose; ▪ Loading Check for container loading supervision; ▪ Witness Destruction to unwanted articles; ▪ Customized Inspection Service per client specific requirement.
Q2	**Does Bureau Veritas provides a CoC (i.e. Certificate of Confirmation) after an inspection to prove that the face mask to be inspected will meet EU safety requirements?**
A2	No. After inspection completed, Bureau Veritas will issue an inspection report that interprets all findings among the bulk products correctly, impartially and completely. The reporting will reflect the product quality and the measured deviation against the inspection requirement, rather than to focus on product character conformance with EU safety related standard. As such, no CoC will be officially distributed.
Q3	**What are the key points that BV will check during the Final Random Inspection (pre-shipment inspection)?**
A3	The inspection covers: ▪ Conformity of product style, marking, printing, labeling information. ▪ Workmanship quality ▪ Basic function, like nose clip, head (ear) strip. ▪ Measurement, like face mask size, nose clip length, strip length. ▪ Actual wearing quality test ▪ Product internal structure ▪ Strength check, like tensile test to if head (ear) strip can meet normal waring requirement. ▪ Durability of nose clip The Final Random Inspection follows ANSI/ASQC Z1.4/ISO 2859-1, Single, Normal, Level II, and AQL 2.5/4.0.

Q4	**What will the Bureau Veritas inspector NOT check during an inspection?**
A4	The inspection does not cover: ▪ Filter efficiency ▪ Bacterial filtration efficiency (BFE) ▪ If the product is conformed to medical standard, like EN14683 ** To test filter efficiency, BFE requires specific experiment facility and testing environment, which cannot be tested on site during an inspection. During Final Random Inspection, Bureau Veritas inspectors can collect samples for lab testing purpose (Bureau Veritas labs can provide this service).
Q5	**Will the Bureau Veritas inspector check CE marking during inspection?**
A5	Yes, because to apply CE marking on face mask is the primary requirement to EU market so BV inspector will inspect the requirement during inspection, e.g. to apply CE on mask (FFP1, FFP2 or FFP3), or on package (Type I, Type II, Type IIR), etc.
Q6	**Can Bureau Veritas send an inspector to be situated onsite for a 'factory resident inspection'?**
A6	Yes. This is a normal service type in Bureau Veritas. We usually provide such services for client on a full week, month or per season / year. In Bureau Veritas we call the service "Production In-line Inspection".
Q7	**What are the advantages of an Inline Inspection versus Pre- Shipment inspection for masks?** **What are the checkpoints of the Production In-line Inspection?**
A7	A production inline inspection provides visibility of the production status and production quality at an early stage, to give more buffer for client to manager the potential quality and on-time delivery risk. Production In-line Inspection is usually customized inspection service by fully meeting client expectation of the monitoring of the factory manufacturing process. The checkpoint of the service will include but not limited to: 1. Production progress monitoring; 2. Manufacturing process monitoring; 3. Factory quality control practice; 4. Potential risk detection and analysis; 5. Deviation CAPA issuing; 6. Finished products inspection, etc.

Q8	**Why choose BV as face mask inspection 3rd party, especially with goods being shipped to EU?**
A8	Bureau Veritas is a world leading testing, inspection, audit and certification group. Bureau Veritas originated in Europe almost 200-years ago in 1828, and now Bureau Veritas has many branches across Europe and indeed worldwide. We know European demands and expectations. We also have also carried our intensive research upon the quality requirements for face masks being used on the Europe market, especially to support at the period of COVID-19 breakout.
Q9	**Can the Bureau Veritas inspector test for Bacterial Filtration Efficiency (BFE)?**
A9	No. BFE test requires special facility and testing environment. Bureau Veritas does have facilities that can perform the test and our inspectors can help collect samples from factory for testing.