





Community masks | Tested quality

Community masks intended for distribution in a specific market must meet the safety and performance benchmarks outlined in the standards of the country in which the products are sold.

Product and regulatory scenario

Community masks, also called **hygienic mask**, are those used by the general public. These are intended to protect others from the wearer, thereby helping to mitigate the spread of the virus.

In the middle of the coronavirus crisis, many governments have made the use of masks recommended or even mandatory in public places where social distancing can't be guaranteed.

In parallel, international, regional and local authorities are trying to ultimately funnel efforts into a standardised minimum quality benchmarks, such as the recommendations by the World Health Organization, the <u>EU CEN</u> guideline document CWA 17533, or the local initiatives being implemented in numerous countries, as displayed further on the tables in this document.

Community masks are not considered medical devices, nor are they personal protective equipment. They are consumer products which also fall under the General Product Safety Directive (GPSD) and other legislations such as international chemical regulations (e.g. REACH) or country-specific ones, of the country where the products are sold.

Service scope

Eurofins provides high-standard quality assurance and control services throughout the supply chain.

Manufacturers are responsible for ensuring that the masks they supply and put on the market comply with safety and effectiveness requirements and the standards required in the country in which they are sold. Our laboratories are ISO/IEC17025:2017 accredited for Particulate Filtration Efficiency testing (PFE), Bacterial Filtration Efficiency testing (BFE) and differential pressure (breathability), delivering precise, reliable and accurate testing results to our customers for EN, ISO and ASTM test methods.

Another important consideration is the information made available to consumers at the point of purchase. Well-designed product specifications and claims helps to ensure that the user can easily and correctly access, understand and use the mask. Eurofins offers check service for marking, labelling and instructions of use, according to the recommendations by the national Authorities.

International regulatory frameworks for community masks

Summarised below are the barrier performance regulations, standards and/or guidelines defined by countries, some of which have implemented them as a mandatory conditions, whereas other have simply set them up as recommendable measures.





Europe

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		CWA 17553	
Specifications	Specifications		Requirements
		ISO 13274-7	Level 70%: > 70%
	Filtration	Bacterial Filtration Efficiency (BFE) - EN14683	Level 90%: >90%
Performance and protection	Breathability	Air permeability - ISO 9237	> 96 l/m²/s, depression at 100 Pa
		Differential pressure - EN14683	< 70 Pa/cm²
	Visual inspection, Fit & sizing	As per the guidelines	
Design	Ties and ear loop attachment strength		10N
Washability	Washes and air drying		60°C (at least 5)

Belgium				
Specifications		NBN/DTD S65-001:2020		
		Test method	Requirements	
Performance and protection	Filtration	EN 13274-7	Particle size 3 µm > 70%	
		Bacterial Filtration Efficiency (BFE) - EN14683		
	Breathability	Air permeability - ISO 9237	> 100 l/s/m², depression at 100 Pa	
		Differential pressure - EN14683	< 70 Pa/cm²	
Design (Visual inspection, fit & sizing, ties and ear loop attachment strength)		As per the guidelines		
Washability	Washes and air drying		60°C (at least 25)	

France				
Specifications		AFNOR \$76-001		
		Test method	Requirements	
Filtration		ISO 13274-7	Particle size 3 µm ≥ 70% (category 2) ≥ 90% (category 1)	
Performance and protection	Breathability	Air permeability - ISO 9237	> 96 l/m²/s, depression at 100 Pa	
		Differential pressure - EN14683	< 60 Pa/cm²	
Design	Fit & sizing, Visual inspection	As per the guidelines		
Washability claims substantiation	Washes	60°C		



Ireland				
Specifications		SWIFT 19:2020		
		Test method	Requirements	
	Filtration		> 70%	
Performance and protection	Breathability	Air permeability - ISO 9237	> 96 l/m²/s, depression at 100 Pa	
		Differential pressure - EN14683	< 60 Pa/cm²	
Design (Visual inspection, fit & sizing, etc.)		As per the guidelines		
Washability	Washes and air drying		60°C	

Netherlands			
Charifications		NEN Spec 1-2	
Specifications		Test method	Requirements
	Filtration	Bacterial Filtration Efficiency (BFE) - EN14683	> 70% (level 1) > 90% (level 2)
	rillation	ISO 13274-7	> 70% (level 1) > 90% (level 2)
Performance and protection	Breathability	Air permeability - ISO 9237	> 96 l/m²/s, depression at 100 Pa
		Differential pressure - EN14683	< 70 Pa/cm²
	Biocompatibility	Within a risk assessment process	
Design (Visual inspection, fit & s	sizing, etc.)	As per the guidelines	
	Chemical testing	As per the guidelines	
Safe Materials	Flammability	ASTM D1230 Flame 1 second	Spread over 127 mm should be lower than 4 s
Washability	Washes and air drying	ISO 6330	60°C 5, at least

Portugal				
Mandatory for retailers		Yes		
		DNP TS C004202007		
Specifications		Test method	Requirements	
Performance and protection	Filtration	Bacterial Filtration Efficiency (BFE) - EN14683	≥ 70% (level 3) ≥ 90% (level 2)	
		ISO 13274-7	≥ 70% (level 3) ≥ 80% (level 2)	
	Breathability	Differential pressure - EN14683	≤ 40 Pa/cm²	
Design (Visual inspection, fit & sizing, etc.)		As per the guidelines		
Washability	Washes and air drying	EN ISO 6330 60°C		



Spain				
Specifications		UNE 0064 – Single use / UNE 0065 – Reuse		
		Test method	Requirements	
Performance and protection	Filtration e and protection	Bacterial Filtration Efficiency (BFE) - EN14683	Reusable for adults and children ≥ 90% Single use for adult and children ≥ 95%	
	Breathability	Differential pressure - EN14683	< 60 Pa/cm²	
Design (Visual inspection, fit & sizing, etc.)		As per the guidelines		
Washability	Washes and air drying	EN ISO 6330	60°C	

Switzerland				
Specifications		Swiss National COVID-19 Science Task Force		
		Test method	Requirements	
Filtration		Particulate Filtration Efficiency (PFE)	> 70% (for 1 micron)	
Performance and protection	Breathability	Differential pressure - EN14683	< 60 Pa/cm²	
	Blood Splash resistance	ISO 22609	No penetration in 10 specimens	
	Biocompatibility	ISO 10993	Within a risk assessment process	
Design (Fit & sizing)		As per the guidelines		
Washability	Washes and air drying	ISO 6330	60°C (at least 5)	

Turkey				
		TSEK 599		
Specifications		Test method	Requirements	
Deufenmenne and musto etian	Filtration	Bacterial Filtration Efficiency (BFE) - EN14683	≥ 90%	
Performance and protection	Breathability	Differential pressure - EN14683	< 60 Pa/cm²	
Microbial Cleanliness		ISO 11737-1	≤ 30 CFU/g	
Electrostatic feature (only for Polyester Fabric)		EN 1149-2	A maximum of 5% deviation from the declared value	
Electrostatic feature (only for Polyester Fabric)		As per the guidelines		
Washability	Washes and air drying	EN ISO 6330	60°C (at least 5)	



US and Canada

US/Canada				
Considerations		AATCC M014		
Specifications		Test method	Requirements	
	Particulate Filtration Efficiency (PFE)	ASTM F2299	> 70% (3 micron)	
Performance and protection	Breathability	ISO 9237, depression at 100 Pa	> 0.91l/min/cm ²	
	2. Status my	Differential pressure	< 36.7 Pa/cm ²	
	Visual inspection, fit & sizing	As per the guidelines		
Design	Ties and ear loop attachment strength	ASTM D5034	44.5 N	
	Elastic recovery	ASTM D4964	90% after 60 s	
Safe Materials	Flammability		US 16CFR1610 CA SOR/2016-194	
Washability	Washes and air drying	AATCC LP1	Care instructions	

Marking checks on labels, packaging and instructions for use

Marking on the product, whether directly or on a label, and/or on its packaging and instruction manual, is mandatory and must be displayed in the applicable official domestic language(s) and observe the wording as defined in the country-specific legislation.

Eurofins' label and marking check service includes:

- Completion of name, trademark, address and contact details of the responsible actor (producer or importer)
- Product batch ID (whenever applicable)
- If tested against the CWA document: "Community face coverings CWA", followed by the version of the CWA document concerned
- The filtration efficiency level, method used and standard
- Durability i.e. reusable or disposable
- Targeted user age e.g. child or adult
- Restriction warning e.g. "Not suitable for children under 3 years of age"





Tested Quality seal

In an effort to provide our clients with proof of compliance for hygienic masks, our experts have developed the Tested Quality seal for Community masks, which will be granted to masks meeting the thoroughly designed testing protocols.

Eurofins Quality Seal				
Specifications		Test method	Requirements	
	Filtration	Bacterial Filtration Efficiency (BFE) - EN14683	> 80% before and after washing	
Performance and protection	Breathability	Differential pressure - EN14683	< 70 Pa/cm² before and after washing	
	Visual inspection, fit & sizing	As per the guidelines		
Design	Ties and ear loop attachment strength	As per the guidelines		
	Elastic recovery	10N		
	Colourfastness	In-house method	As per Eurofins requirements	
Safe materials	Chemical testing	ISO 14184-1 (Textile) / ISO 17226-1 and ISO 17226-2 (Leather)	Formaldehyde free -	
	Ph -	ISO 3071 (Textile) / ISO 4045 (Leather)	As per Eurofins requirements	
Washability	Washes and air drying	EN ISO 6330	60°C (at least 5)	

Quality Assurance and Control throughout the Supply Chain

Whatever your role in the supply chain, it's important to safeguard the reputation of your brand and/or that of your client.

From suppliers' assessments and R&D support to regulatory guidance and supply chain mapping, all the way through to compliance and bespoke testing, QC inspections, failure analysis and market surveillance, we cover every stage of your product's quality journey.



