Surgical/Medical, Hygienic Masks Quality & Compliance

Surgical or medical masks and hygienic masks intended to be distributed to a specific market should meet the safety and performance benchmarks outlined in the standards of the country in which the products are sold.

Product and regulatory scenario

Hygienic Masks

Hygienic masks intended to be distributed to the general public should meet the safety and performance benchmarks outlined in the standards of the country in which they are sold. Hygienic masks are not subject to specific regulation in Europe, but certain countries have recommended use of such masks in light of the coronavirus outbreak. As a result, Spain, France and Mexico have published some relevant standards with certain basic requirements (UNE 0065, UNE 0064-1, UNE 0064-2, AFNOR-SPEC-S76, breathability, particle filtration, etc.).

Surgical/Medical Masks

Surgical/medical masks are designed to cover the mouth and nose providing a barrier to minimise the direct transmission of infective agents between the wearer and a person close to them, or vice versa. There are different kinds of surgical masks: Type I, Type II and Type IIR (in Europe according to Directive 93/42/EEC to be replaced by Regulation (EU) 2017/745); Level 1, Level 2, Level 3 and Level 4 (in US according to FDA requirements) and class 1, class 2 and class 3 (splash/fluid resistant) in India according to IS 16289. Surgical and medical masks are classified as medical devices.

Eurofins can support manufacturers in ensuring the functionality and safety of these products.

Service scope

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

Tests Methods and Requirements

Manufacturers are responsible for ensuring that masks which are put on the market and supplied to healthcare workers comply with safety and effectiveness requirements and the standards which are required in the country in which they are sold.

Eurofins provides high standard quality assurance and control services throughout the supply chain. Our laboratories are ISO/IEC17025:2017 accredited for Bacterial Filtration Efficiency testing (BFE), differential pressure (breathability) and resistance to synthetic blood splashes, delivering precise, reliable and accurate testing results to our customers for ISO and ASTM test methods.

www.eurofins.com/covid-19-product-testing

Regulatory frameworks for masks in Europe and US

		EN 14683:2019			ASTM F2100-19			New requirements by FDA under the current emergency situation		
		Type I	Type II	Type IIR	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Barrier testing	Bacterial filtration efficiency (BFE) EN 14683 (Annex B)/ ASTM F2101	≥95 %	≥98 %		≥95 %	≥98 %		Not required		
	Particle filtration efficiency (PFE) ASTM F2299	Not required			≥95 %	≥98 %		Not required		
	Splash resistance pressure (or Synthetic Blood) ISO 22609/ ASTM F1862	Not required		≥16,0 kPa	80 mmHg	120 mmHg	160 mmHg	80 mmHg	120 mmHg	160 mmHg
Physical testing	Differential pressure EN 14683 (Annex C)	<40 Pa/cm2		<60 Pa/cm2	<5 mmH2O/cm2	<6 mmH2O/cm2		Not required		
Safety testing	Microbial cleanliness (bioburden, ref. ISO 11737-1)	≤ 30 cfu/g			Not required			Not required		
	Biocompatibility (ISO 10993 series)	Manufacturer to complete evaluation of medical face mask according to standard. Determination of applicable toxicology testing regime. Results to be documented			Not required / recomended			Not required (manufacturer simply need to list all materials)		
	Flammability 16 CFR Part 1610	Not required			Class I	Class I	Class I	Class I	Class I	Class I

On-site inspections and audits

Assessing the manufacturing site before launching mass production and checking the products' quality prior to shipment are key parts of the quality control process, to ensure that the production was carried out according to the quality standards and expectations of destination markets.

Quality assurance and control throughout the supply chain

Whichever your role in the supply chain you need to safeguard the reputation of your brand and/or that of your client.

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