Half-mask Respirators Quality & Compliance

Respirator masks, also referred to as half-face masks, are Personal Protective Equipment, that protect the wearer against inhalation of potentially harmful droplets and particles suspended in the air. In healthcare environments they protect against airborne spread pathogens or infectious agents.

Product and regulatory scenario

Respirators are designed to cover the nose, mouth and chin and should be correctly adjusted to the face.

In Europe, respiratory masks are subject to Regulation EU 2016/425 (PPE), must meet the specifications of EN 149:2001+A1:2009 and bear a CE certification label. Depending on how well they protect the wearer from dust, liquid or solid particles and pathogens, they can be classified in levels FFP 1 to 3.

In the US, respirator masks, also known as N95 masks, are subject to the NIOSH-42C FR84 regulation.

Manufacturers are liable for these masks to comply with the safety and effectiveness requirements as displayed in the concerned regulations. Importers and brand owners bear the same responsibility if the product is manufactured abroad.

Eurofins can support you in ensuring the products' safety, functionality and compliance.

Service scope

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

All our laboratories are ISO 17025 accredited, delivering precise, reliable and accurate results to our customers.

Notified Body

CE-marking is a mandatory conformity mark required for PPEs in Europe. It reveals that products are safe and compliant with European Regulation (EU) 2016/425.

Eurofins Product Testing Italy, Notified Body n. 0477 for PPE Regulation on Respiratory Protective Equipment (Category III), provides certification and testing services to ensure compliance of your half-face masks to the concerned European regulation.

Test methods and requirements

Performance criteria	Europe (EN 149:2001+A1:2009)		
	FFP1	FFP2	FFP3
Filter performance – (must be ≥ X% efficient)	0,3 µm: ≥ 80%	0,3 µm: ≥ 94%	0,3 µm: ≥ 99%
Occupational Exposure Limit (OEL)	4X	12X	50X
Assumed Protection Factor (APF)	4X	10X	20X
PPE masks should bear the **CE-mark**, followed by the Notified Body identification number.			

Requirements I Comparative chart

The chart displays the regulatory requirements for US and Europe, the most stringent regions. If you need your products to reach both destination markets, we can help you saving costs, by testing to the most strict in each case.

Parameters	**US** N95 (NIOSH-42 CFR84)	**Europe** FFP2 (EN 149:2001+A1:2009)
Filter performance – (must be ≥ X% efficient)	≥ 95%	≥ 94%
Test agent	NaCl	NaCl and paraffin oil
Flow rate	85 L/min	95 L/min
Total inward leakage (TIL)* – tested on human subjects each performing exercises	N/A	≤ 8% leakage (arithmetic mean)
Inhalation resistance – max pressure drop	≤ 343 Pa	≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min) ≤ 500 Pa (clogging)
Flow rate	85 L/min	Varied – see above
Exhalation resistance - max pressure drop	≤ 245 Pa	≤ 300 Pa
Flow rate	85 L/min	160 L/min
Exhalation valve leakage requirement	Leak rate ≤ 30 mL/min	N/A
Force applied	-245 Pa	N/A
CO2 clearance requirement	N/A	≤ 1%

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.