Surgical / Medical Face Masks Accelerated Aging Tests

The increasing prevalence of infectious diseases in recent decades has posed a serious threat to public health, but their effects can be reduced by a simple face mask. Due to the ongoing COVID-19 pandemic, research has been accelerated towards improving the quality and performance of face masks following long periods of storage, for example through accelerated aging tests.

Eurofins offers a 3-step full testing protocol for surgical masks according to standard EN 14683:2019.

Product and regulatory scenario in Europe

Surgical/medical masks are designed to cover the mouth and nose providing a barrier that minimises the direct transmission of infectious agents between the wearer and a person close to them, or vice versa. Required in healthcare environments, these masks, subject to the EU 2017/745 Regulation on Medical Devices should be tested against the EN 14683 standard.

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 of a wide array of consumer product industries.

We have highlighted just some of these in this document:

Accelerated aging tests

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

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 test methods.

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Performance evaluated BEFORE aging tests
Bacterial filtration efficiency (BFE) EN 14683 (Annex B)
Breathability (Differential pressure) EN 14683 (Annex C)
Bioburden: Method Validation – ISO 11737- Microbiology – EN ISO 11737-1
Bioburden on 10 units - ISO 11737- aerobes – EN ISO 11737-1
Bioburden on 10 units – ISO 11737- yeast / mould – EN ISO 11737-1
Product general visual aspect – Visual examination
Strength of face masks for medical use

Performance evaluated DURING accelerated aging tests (1 year)
Simulation of a technical lifespan of 1 year through an aging of 26 days at 60°C with 40% of relative humidity
Simulation of a technical lifespan of 1 year through an aging of 51 days at 40°C with 75% of relative humidity

Performance evaluated AFTER accelerated aging tests
Bacterial filtration efficiency (BFE) EN 14683 (Annex B)
Breathability (Differential pressure) EN 14683 (Annex C)
Bioburden on 10 units - ISO 11737- aerobes – EN ISO 11737-1
Bioburden on 10 units – ISO 11737- yeast / mould – EN ISO 11737-1
Product general visual aspect – Visual examination
Strength of face masks for medical use

Quality Assurance and Control throughout the Supply Chain

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

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