eurofins | Medical Device Testing



Surgical Mask Testing

Whether you are manufacturing personal protective equipment (PPE), such as surgical masks, face shields and respirators, under the FDA's emergency use authorization (EUA) policy or you need support for a complete 510K submission, Eurofins Medical Device Testing provides manufacturers with comprehensive testing support for all levels of approval.

Choose Eurofins Medical Device Testing to help you:

- Understand new testing requirements related to the COVID-19 crisis
- Meet requirements for FDA Enforcement Policy for Face Masks and Respirators
- Meet requirements for a 501k submission
- Select the most appropriate method for your specific product
- Ensure the safety of every lot released

Comprehensive Testing Services:

- **Penetration of Synthetic Blood Testing (ASTM F1862):** The test is used to evaluate the resistance of medical face masks to penetration of a high-velocity stream of synthetic blood. A visual assessment of blood penetration is used to determine product acceptability.

- **Flammability Testing (16 CFR 1610):** The test is used to evaluate the flammability of materials commonly used to manufacture medical textiles such as face masks. Specimens are cut to a prescribed shape and subjected to a standardized flame for one second. The time required for the flame to spread and resistance to ignition are used to determine material acceptability.

- **Bacterial Filtration Efficiency (BFE):** Eurofins Medical Device Testing provides BFE testing services following the ASTM F2100, ASTM F2101 and EN 14683.

- **Particle Filtration Efficiency (PFE):** Used to determine a material's ability to retain specific particle levels of sub-microns from up-or downstream at a filtration rate of 1 CFM. This is performed per ASTM F2100 and follows basic principles described in ASTM F2299.

- **Differential Pressure:** Used to measure differential pressure of air coming through a mask at a consistent flow rate. Testing performed per EN 14683:2019 Annex C.

- **ISO 10993-1: 2018 Biocompatibility:** Used to determine need for further toxicological studies per ISO 10993. A medical face mask is a surface device with prolonged contact (> 24 hours, <30 days), considering the cumulative application. Recommended tests include ISO 10993-5 (Cytotoxicity), ISO 10993-10 (Irritation & Sensitization) and ISO 10993-23 (Irritation).

Reference Methods

Our testing methods follow the most current requirements outlined in:

- ASTM F2100
- EN 14683
- ASTM F1862
- 16 CFR 1610
- ASTM F2101
- ISO 10993

Request A Quote for your surgical mask or face shield product.