

American Surgical Mask LLC
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USA
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FDA Registration Number: 3017153452
Product Code: FXX



PRODUCT SPECIFICATIONS

This product is manufactured in compliance with the FDA Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised). This product may be used in settings where exposure to liquid or bodily fluids may be expected. The following tests have been conducted at standards that meet the highest levels of testing to be labeled as Surgical Masks. Test results are also attached as separate documents:

Bacterial Filtration Efficiency (BFE) per ASTM F2101-19 Standard > 99%.

Meets Level 3 Fluid Resistance Testing (liquid barrier performance) consistent with ASTM F1862-17 at 160mm Hg.

Meets ASTM F2100-19 Class 1 Flammability Test per 16 CFR 1610.

It is important to note that what sets ASM apart from ordinary non-surgical masks is surgical-grade fluid resistance. Fluid resistance is what makes a mask so important for COVID because in general use it is what makes the mask block respiratory droplets. In addition to CDC recommended public uses, surgical masks with the highest levels of fluid resistance are also more suited to medical procedures.

Fluid resistance is measured at 80mmHg, 120mmHg, and 160mmHg. After looking at comparable products, many of them were tested at 80 or 120, while ours were tested at 160. Our fluid resistance passed ASTM fluid resistance testing (ASTM 1862) at the highest level, which is measured at 160mmHg. Fluid resistance is so important that testing was specifically mandated by the FDA in order to distribute surgical masks under the Emergency Guidance.

In addition, our Bacterial Filtration Efficiency (BFE) is greater than 99%, which also meets or exceeds the highest level of ASTM testing.

Please feel free to contact me if you have any further questions.

Thank You.

Kalu Watanabe
Chief Strategic Officer

**AMERICAN SURGICAL MASK
ASM 101**

Components

EARLOOPS NON-LATEX
FLEXIBLE NOSE BRIDGE



175 mm./ 6 and 7/8 Inches

Mask Dimensions

