

Stopgap Face Mask (SFM) - Test report

Risk Element: Inadequate fluid resistance

Guidance document suggests the following: ASTM F1862/F1862M-17

Test Results:

We conducted a test approximating ASTM F1862. Synthetic blood was mixed in the ratios specified by the standard. 2 ml of blood in a 3 ml syringe with a ½” long 18 gauge tapered needle was dispensed over 0.5 seconds at a distance of 12” from the mask. No blood passed to the clean side of the mask within 10 seconds. The device passed the challenge condition.

Risk Element: Inadequate barrier for bacteria

Guidance document suggests the following: ASTM F1215-89

Test Results:

Verified that the portions of the mask that we believed to be non-conducting and therefore not available for gas exchange are non-conducting. Have not tested coupons from the surgical mask used as those materials have already undergone the 510(k) review process.

Risk Element: Inadequate air exchange (differential pressure)

Guidance document suggests the following: MIL-M-36945C 4.4.1.1.1

Test Results:

Validated the adequacy of air exchange in our design using two individuals: one male, one female each performing continuous CPR chest compressions on a mannequin for a period of 2 minutes.

Additionally, surgeons and nurses have worn the masks for their shifts and rated the breathability as adequate.

Risk Element: Flammability

Guidance document suggests using one of the following:

CPSC CS-191-53 Flammability Test Method (16 CFR 1610) Standard for Flammability of Clothing Textiles

Test Results:

Flame did not climb to the top of the test coupon in 3.5 seconds. Device met the requirements of the standard.

Risk Element: Evaluation of Bio-Compatibility

Listing skin contacting components as described in plan.