ViriMASK™

April 8, 2020

Regulatory Status for the ViriMASK™, Mask & FIlter

Oneg HaKarmel Ltd., the manufacturer of ViriMASK™ has a long and solid history of manufacturing medical devices for the operating theatre and emergency medicine. Our Quality Management system is certified according to ISO13485:2016, and the company's products are certified according to MDD and FDA requirements.

There are several standards and directives for Personal Protective Equipment (PPE) including: CE (EU), FDA, and NIOSH (USA). Those agencies recently issued guidance to allow non CE-marked/FDA cleared/OSHA approved PPE, which comply with necessary health & safety standards, to enter the EU/USA/GB markets during the Coronavirus pandemic.

Testing to those standards for PPE masks will start as soon as production-line ViriMASK components are available, in 7-14 days for air-lifting to Nelson Laboratory (www.nelsonlabs.com). Nelson Labs is a leading global provider of laboratory testing and expert advisory services for medical technology and pharmaceuticals. A roster of tests is included with this letter, and the results will become available on our website (www.virimask.com), shortly thereafter.

Best of Health,

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CEO and CMO

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Tests in Progress for ViriMASK - Results will be posted to our website.

BFE110 Bacterial Filtration Efficiency (BFE) w/ Diff. Pressure	**NRC110 NIOSH Respirator Certification: Sodium Chloride (NaCl)**
These tests comply with ASTM F2100 (ASTM F2101 and Mil-M-36954C) and EN14683. A flow rate of 28.3 L/min is required for BFE testing. Results are reported up to 99.9%. The differential pressure test evaluates the breathability of masks or airflow resistance of other products at a flow rate of 8 L/min.	For filtration efficiency, twenty respirators are conditioned for 25 hours at 85% RH and C. After conditioning, filters are put into a test system that passes a neutralized NaCl aerosol through the sample at 85 L/min. This aerosol has a particle size distribution with a count median diameter of 0.0750.020ȝm, a mass median diameter of 0.26ȝm, and a geometric standard deviation not exceeding 1.86ȝm. Masks are loaded with the NaCl until maximum penetration or until filter exceeds the designated particle limit. The maximum filter penetration that can occur to maintain a N95 rating is ≤5% (≥95% efficiency). For a N99 rating maximum filter penetration is ≤1% (≥99% efficiency).
BFE125 Bacterial Filtration Efficiency (BFE) at an increased challenge	**NRC115 NIOSH Respirator Certification: Dioctyl Phthalate (DOP)**
The Increased Bacterial Filtration Efficiency test determines the filtration efficiency by comparing the bacterial control counts to test article effluent counts. The test is conducted using Staphylococcus aureus as the challenge organism. A liquid suspension of S. aureus is aerosolized and delivered to the filtration media at a constant flow rate of 30 liters per minute (LPM).	For DOP tests on R- and P-rating filtration efficiency, twenty respirators are tested. Filters are put into a test system that passes a DOP aerosol through the sample at 85 L/min. This aerosol has a particle size distribution with a count median diameter of 0.1850.020ȝm, and a geometric standard deviation not exceeding 1.60ȝm. Masks are loaded with the DOP until maximum penetration occurs, or until filter exceeds the designated particle limit. The maximum filter penetration that can occur to maintain a R95 or P95 rating is ≤5% (≥95 % efficiency). For a R99 or P99 rating maximum filter penetration is ≤1% (≥99 % efficiency).
VFE110 Virus Filtration Efficiency (VFE): Bacteriophage	**NRC120 NIOSH Respirator Certification: Inhalation and Exhalation**
The VFE test is adapted from the BFE testing (ASTM F2101). Results for VFE testing are reported up to 99.9%. This test is normally performed on face masks and flat sheet materials.	For airflow resistance two tests are performed: exhalation resistance and inhalation resistance. We determine the initial breathability of three masks, in both directions of exhalation and inhalation (42 CFR Part 84.180). Measurements are made with a 6 inch slant manometer. Initial Inhalation resistance cannot exceed 35 mm water and initial exhalation resistance cannot exceed 25 mm water.
VFE125 Virus Filtration Efficiency (VFE): Bacteriophage	**NRC125 NIOSH Respirator Certification: Valve Leak Test**
The Increased VFE test follows the same procedure as BFE, except the challenge organism used is the bacteriophage phiX174. Challenge controls are maintained at ≥1×106 plaque-forming units (PFU) with a mean particle size (MPS) of 3.0 ± 0.3 µm. This allows filtration efficiencies to be reported up to >99.9999%	For exhalation valve leak, three valves are removed from respirators and the leakage across the valve determined according to 42 CFR Part 84.182. Measurements are made with a digital soap film flowmeter and leakage cannot exceed 30 mL/min. Valve leakage is only necessary if the product contains an exhalation valve. NOTE: ViriMask does not incorporate any valves, thus this test is unnecessary.

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SBP210 Synthetic Blood Penetration for Face Masks (sets of 32), per set	**CTX110 Cytotoxicity: MEM elution, 48 hr inc., L929, 24 hr ext (non-implant)**
This test complies with ASTM F1862 and EN14683 (ISO 22609). (Horizontal projection of fixed volume at a known velocity) The test can be conducted at pressures of 80, 120, or 160mmHg. The ASTM F1862 method is preferred to AATCC 22 as it is a more severe challenge and relies less on technician bias for test results and rating. ASTM F1862 meets the requirements of ASTM F2100. For general use masks generally 80 or 120 mmHg should be tested. Surgical masks are tested at 120mmHg or 160mmHg.	The cytotoxicity test is designed to evaluate the general toxicity of medical devices and materials. Testing involves extracting devices in a cell culture media and then exposing the extract fluid to mouse fibroblast cells (L929). The cells are allowed to grow in the extract fluid for a specified amount of time before the cells are evaluated using either qualitative or quantitative methods. The test is performed on all medical devices with patient contact, raw materials, and devices undergoing a cleaning validation or residual manufacturing.
PFE115 Particle Filtration Efficiency: Latex Particle Challenge	**SCX240 Sensitization: Buehler Method, Patch Test**
The procedure employs the basic test method described in ASTM F2299 (formerly ASTM F1215), but incorporates a non- neutralized challenge.	The Irritation test(s) can be used to determine if a material or chemical will cause local irritation in the skin, mucosal, or ocular tissues. The test article extracts are dosed or the test article is directly applied to the animal. The dosed sites will be examined and scored at 24 ± 2, 48 ± 2, and 72 ± 2 hours after treatment. The scoring will measure the irritation reaction (erythema and edema) to a single, repeated, or continual exposure from device materials or chemicals
FTS101 Flammability Test, 16 CFR part 1610	
The Flammability test determines the time of flame spread for the given material. All fabrics of natural or regenerated cellulose, as well as certain types of finished and unfinished fabrics made from other natural or synthetic fibers, are combustible. Some combustible fabrics are potentially dangerous to the wearer because of the speed and intensity of flame with which these fabrics burn and their ease of ignition, hence this is a critical test.	

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