

## NELSON Labs

REGION SUPPLIERS PTE LTD

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### Bacterial Filtration Efficiency (BFE) Final Report

Test Article: MoharMed 010620

Study Number: 1309736-S01

Study Received Date: 12 Jun 2020

Testing Facility: Nelson Laboratories, LLC

6280 S. Redwood Rd.

Salt Lake City, UT 84123 U.S.A.

Test Procedure(s): Standard Test Protocol (STP) Number: STP0004 Rev 18

**Summary:** The BFE test is performed to determine the filtration efficiency of test articles by comparing the bacterial control counts upstream of the test article to the bacterial counts downstream. A suspension of *Staphylococcus aureus* was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and fixed air pressure. The challenge delivery was maintained at  $1.7 - 3.0 \times 10^3$  colony forming units (CFU) with a mean particle size (MPS) of  $3.0 \pm 0.3 \mu\text{m}$ . The aerosols were drawn through a six stage, viable particle, Andersen sampler for collection. This test method complies with ASTM F2101-19 and EN 14683:2019, Annex B.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Side: Inside

BFE Test Area:  $\sim 40 \text{ cm}^2$

BFE Flow Rate: 28.3 Liters per minute (L/min)

Conditioning Parameters:  $85 \pm 5\%$  relative humidity (RH) and  $21 \pm 5^\circ\text{C}$  for a minimum of 4 hours

Test Article Dimensions:  $\sim 175 \text{ mm} \times \sim 162 \text{ mm}$

Positive Control Average:  $1.8 \times 10^3$  CFU

Negative Monitor Count:  $< 1$  CFU

MPS:  $2.9 \mu\text{m}$

### Results:

Test Article Number Average Percent BFE 99.7 (%)

Note: The plate count total is available upon request

### PRODUCT DESCRIPTION

MoharMedical 3PLY Surgical Mask is comfort to fit over the nose and the mouth so that body fluid expelled by wearer is not released to the environment. The mask consists of three layers, namely an inner absorbent layer, a middle filtration layer and an outer repellent layer.

The mask functions similarly to commercially available disposable 3-ply medical masks.

### INTENDED PURPOSE

The intended purpose of MoharMedical 3PLY Surgical Mask is used as medical device to protect the patient, conformity to MDR 2017/745 and PPE Regulation (EU) 2016/425.

The mask is intended in particular to limit the transmission of infectious germs from healthcare professionals to patients during surgical operations and other medical procedures with similar requirements.

## TECHNICAL SPECIFICATION

### Mohar Medical 3PLY Surgical Mask

- 3-ply Disposable Medical Face Mask with Ear-Loop
- 3-ply with middle filter
- Bacterial Filtration Efficiency BFE% > 99%
- ASTM F2100-19, Level 3 / EN14683 : 2019



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