DISPOSABLE FILTER MASK 3 PLY EARLOOP FACE MASKS

This single-use disposable face mask covers the nose and mouth, providing a physical barrier to protect the wearer from harmful viruses in the environment. The mask is made with a built-in adjustable wire nose piece and a elastic band ear loops for a secure fit.

It features 3 layers of protection: made out of non-woven fabric, a material that is gentle and breathable.

- These masks should be disposed of after each use.
- Protective coverings are intended for general use.
- This mask is not intended for medical use, and not proven to reduce the transmission of disease.

WARNING: Not recommended in settings where exposure to liquid, bodily, or other hazardous fluids is expected, or where infection risk through inhalation is high, or in the presence of a high-intensity heat source or flammable gas.

Live Image per customer reqest

2020

CERTIFICATE OF REGISTRATION

This certifies that:

ZHANGJIAGANG SUNRISE KNITTING & APPAREL CO LTD.
No. 63 North Road
Fenghuan Town
Zhangjiagang Jiangsu, CN

is registered with the U.S. Food and Drug Administration for FY 2020 pursuant to Title 21, 807 et seq. of the United States Code of Federal Regulations:

Establishment Owner/Operator Number:	**10067094**
Device Classification Name:	**RESPIRATOR, SURGICAL**
Product Code:	**MSH**
Regulation Number:	**878.4040**
Official Correspondent and U.S. Agent:	**Registrar Corp** 144 Research Drive, Hampton, Virginia, 23666, USA Telephone: +1-757-224-0177 • Fax: +1-757-224-0179

Registrar Corp will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year stated above, unless said registration is terminated after issuance of this certificate. Registrar Corp makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. Registrar Corp assumes no liability to any person or entity in connection with the foregoing.

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Dated: April 6, 2020

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A Sotera Health company

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Bacterial Filtration Efficiency (BFE) Final Report

Test Article:	BFE101C/LOTE1
Study Number:	1365096-S01
Study Received Date:	19 Nov 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
Deviation(s):	None

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 x 10^3 colony forming units (CFU) with a mean particle size (MPS) of 3.0 ± 0.3 µm. 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:	~40 cm^2
BFE Flow Rate:	28.3 Liters per minute (L/min)
Conditioning Parameters:	85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours
Test Article Dimensions:	~174 mm x ~162 mm
Positive Control Average:	1.7 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	2.8 µm

ilac-MRA ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

Mikell Goldsberry electronically approved	22 Jan 2021 03:58 (+00:00)
Study Director Mikell Goldsberry	Study Completion Date and Time

Results:

Test Article Number	Percent BFE (%)
1	99.8
2	99.5
3	99.4
4	99.7
5	99.7

The filtration efficiency percentages were calculated using the following equation:

$$\% BFE = \frac{C - T}{C} x\ 100$$

C = Positive control average

T = Plate count total recovered downstream of the test article

Note: The plate count total is available upon request