Specification – Data Sheet
www.pleatmaskusa.com

PleatMask™

Proudly made in the U.S.A.

PleatMask™ is a single use disposable Surgical Mask, proudly made using all American parts, materials and labor at our factory in South Carolina.

PleatMask is a **Medical Device Class 2, Level 3 PPE - *ASTM, F1862, ISO 22609, passing at 160 mmHg (Highest Level of Fluid Resistance).** PleatMask material is impermeable to air, bacteria and particles. *Ideal for procedures where heavy to moderate amounts of fluid, spray and/or aerosols are produced.*

***ASTM:** ASTM F1862 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity). **https://www.astm.org/Standards/F1862.htm** Per Nelson Labs test results, PleatMask is a Medical/Surgical Face Mask

Per **FDA** updated guidelines and **PleatMask** testing conducted by Nelson Labs in April 2020 (see test results below; **https://www.nelsonlabs.com/**), the polyethylene barrier on the PleatMask reduces the risk of oral secretion based COVID transfer.

PleatMask is intended to be used (along with other PPE) in an environment where people are in close proximity to others, including workspaces (office and manufacturing), restaurants (kitchen and service crews), retail and grocery environments, and other situations requiring Level 3 Fluid Resistance.

SPECIFICATIONS & INSTRUCTIONS

The PleatMask is made of lightweight paper (13lbs/22 gm) extruded with a thin coat of low-density polyethylene (LDPE 8 lbs/5 gm) with latex free elastics for ear-loops (1-150/34 SD POLY).

PleatMask is available in several sizes to fit a wide range of faces.: Large has a 7.5" wide mask with 8" ear loops and Medium has a 7" wide mask with 8.5" ear loops.

Pack sizes can be configured to the customer's specific needs.

PleatMask is constructed with 15 pleats and is intended to be worn loosely with pleats directed downward.

PleatMask can be printed with clients' desired Logo/Artwork.

For optimal use, when wearing the PleatMask it is recommended to expand the pleats by pulling gently to achieve full coverage of the face, from nose bridge to throat.

For improved breathability, it is recommended to ensure that the pleats in front of the mouth and nose are well expanded.

FDA "Recommendation against use in the presence of high intensity heat source or flammable gas."

*Current **FDA** guidelines are listed below along with Nelson Labs' certified **PleatMask test results.***

"Surgical Masks Intended to Provide Liquid Barrier Protection"
Per updated FDA guidelines (excerpts)

"A surgical mask is a loose-fitting, disposable device that creates a physical barrier between the mouth and nose of the wearer and potential contaminants in the immediate environment. Surgical masks are not to be shared and may be labeled as surgical, isolation, dental, or medical procedure masks. They may come with or without a face shield. These are often referred to as face masks, although not all face masks are regulated as surgical masks."

"Surgical Masks Intended to Provide Liquid Barrier Protection Surgical masks are class II devices that cover the user's nose and mouth and provide a physical barrier to fluids and particulate materials. Surgical masks are made in different thicknesses and with different ability to protect you from contact with liquids. These properties may also affect how easily you can breathe through the face mask and how well the surgical mask protects you".

"If worn properly, a surgical mask is meant to help block large-particle droplets, splashes, sprays, or splatter that may contain germs (viruses and bacteria), keeping it from reaching your mouth and nose. Surgical masks may also help reduce exposure of your saliva and respiratory secretions to others".

"Surgical masks are not intended to be used more than once. If your mask is damaged or soiled, or if breathing through the mask becomes difficult, you should remove the face mask, discard it safely, and replace it with a new one. To safely discard your mask, place it in a plastic bag and put it in the trash. Wash your hands after handling the used mask."

*Sources: https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/n95-respirators-and-surgical-masks-face-masks and https://www.fda.gov/media/136449/download)

info@pleatmaskusa.com

Medical Face Mask Tests and Requirements

U.S.A.: ASTM F2100-19 STANDARD SPECIFICATION FOR PERFORMANCE OF MATERIALS USED IN MEDICAL FACE MASKS
EUROPE: EN 14683:2019 MEDICAL FACE MASKS – REQUIREMENTS AND TEST METHODS

		ASTM F2100-19			EN 14683:2019 Barrier Levels		
		Level 1	Level 2	Level 3	Type I	Type II	Type IIR
Barrier Testing	BFE % ASTM F2101, EN 14683	≥95	≥98		≥95	≥98	
	PFE % ASTM F2299	≥95	≥98		Not required		
	Synthetic Blood ASTM F1862, ISO22609	Pass at 80 mmHg	Pass at 120 mmHg	Pass at 160 mmHg	Not required		Pass at ≥ 16.0 kPa (>120 mmHg)
Physical Testing	Differential Pressure EN 14683	<5.0 mmH_2O/cm^2	<6.0 mmH_2O/cm^2		<40 Pa/cm^2		<60 Pa/cm^2
Safety Testing	Flammability 16 CFR Part 1610	Class 1 (≥ 3.5 seconds)			See European Medical Directive (2007/47/EC, MDD 93/42/EEC)		
	Microbial Cleanliness ISO 11737-1	Not required			≤30 cfu/g		
	Biocompatibility ISO 10993	510 K Guidance recommends testing to ISO 10993			Complete an evaluation according to ISO 10993		
Sampling ANSI/ASQC Z1.4 ISO 2859-1		• AQL 4% for BFE, PFE, Delta P • 32 masks for Synthetic Blood (Pass = ≥29 passing, Fail = ≤28 passing) • 14 masks for Flammability			• Minimum of 5 masks up to an AQL of 4% for BFE, Delta P and Microbial Cleanliness • 32 masks for Synthetic Blood (Pass = ≥29 passing, Fail = ≤28 passing)		

Nelson Labs.
A Sotera Health company

Sponsor:
Akiva Buchberg
GreenDustries Corporation
7875 NE 191 St.
Ste. 601
Aventura, FL 33180

Synthetic Blood Penetration Resistance Final Report

Test Article:	Pleated masks
Purchase Order:	100013
Study Number:	1285247-S01
Study Received Date:	06 Apr 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: STP0012 Rev 09
Deviation(s):	None

Summary: This procedure was performed to evaluate surgical facemasks and other types of protective clothing materials designed to protect against fluid penetration. The purpose of this procedure is to simulate an arterial spray and evaluate the effectiveness of the test article in protecting the user from possible exposure to blood and other body fluids. The distance from the target area surface to the tip of the cannula is 30.5 cm. A test volume of 2 mL of synthetic blood was employed using the targeting plate method.

This test method was designed to comply with ASTM F1862 and ISO 22609 (as referenced in EN 14683:2019 and AS4381:2015) with the following exception: ISO 22609 requires testing to be performed in an environment with a temperature of 21 ± 5°C and a relative humidity of 85 ± 10%. Instead, testing was performed at ambient conditions within one minute of removal from the environmental chamber held at those parameters.

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.

Number of Test Articles Tested:	32
Number of Test Articles Passed:	32
Test Side:	Outside
Pre-Conditioning:	Minimum of 4 hours at 21 ± 5°C and 85 ± 5% relative humidity (RH)
Test Conditions:	20.0°C and 22% RH

Results: Per ASTM F1862 and ISO 22609, an acceptable quality limit of 4.0% is met for a normal single sampling plan when ≥29 of 32 test articles show passing results.

Test Pressure: 160 mmHg (21.3 kPa)

Test Article Number	Synthetic Blood Penetration
1-32	None Seen

Study Director James W. Luskin For

13 Apr 2020
Study Completion Date

1285247-S01