



Reign Production Company
 17250 Parkway Office Center, Dallas, TX 75248
 NAICS Code: 423450 | SIC Codes: 5047
 FDA Owner Operator No: 10083394
 D&B D-U-N-S No.: 118568279



Highlights

- ❖ Complies with ASTM F2100 Level 2 Requirements.
- ❖ Specially designed inner facing for improved comfort.
- ❖ Composed of 3 integrated layers of protection working together with maximized breathability and optimum safety.
- ❖ Soft comfortable ear loops to provide easier donning.
- ❖ Features a contouring nose strip which can be adjusted for securing the mask to prevent gaps that increase the risk of inhalation exposure.

SAFETY DATA SHEET Medical Examination Masks



Complies with ASTM F2100

Fluid Resistance (mmHg):	120
BFE (%) @ 3.0 μm:	≥98
PFE (%) @ 0.1 μm:	≥98
ΔP (mm H ₂ O/cm ²):	<6.0
Flame Spread:	Class 1

Made in Vietnam

Box Packaging

Capacity Each Box contains 50 pieces
 Dimensions (L x W x H) | Weight (L x W x H) 18.5cm x 10.5cm x 9cm | 200g



Carton Packaging

Capacity Each Carton contains 50 Boxes | 605 Cartons per 40' Container
 Dimensions (L x W x H) | Weight 54.5cm x 38cm x 46.5cm | Net: 6.7kg; Gross: 11.7kg



Specifications

Product Description:	Disposable Medical (Level 2) Face Mask
Product Code:	Listed with FDA under the Product Code QKR: Product Classification (fda.gov)
Brand:	Reign Mask™
Colors:	Black and Blue
Features:	Adjustable plastic covered nose clip
Age Ranges:	Fits most children ages 2 to 8
Size of Mask:	17.5cm x 9.5cm (Length x Width)
Weight:	±2.7 Grams per mask
Targeted Area:	Nose and mouth
Technical Method:	Physical barrier to materials
Type:	3 – Layer Ear Loop Mask
Physical State:	Solid Materials
Material:	Layer 1 – Spunbond non-woven fabric (25 GSM) Layer 2 – Meltblown non-woven fabric (25 GSM) Level 3 – Spunbond non-woven fabric (25 GSM)
Composition:	Polypropylene, SMS non-woven fabrics & melt-blown paper
Ear-Loop:	Elastic band
Latex and Fiberglass Free:	Yes
Fluid Resistance:	120 mm Hg
Bacterial Filtration Efficiency @ 3.0 µm (BFE):	≥98.0 @ 3.0 micron
Particulate Filtration Efficiency @ 0.1 µm (PFE):	≥98.0 @ 0.1 micron
Differential Pressure (ΔP):	<5.0 mm H ₂ O/cm ²
Flame Spread:	Class 1
Mask Construction:	Sonic Welded
Quality Standards:	ASTM F2100-19 Level 2, ISO 13485:2016
Certificates:	FDA Registered

Safety Measures

Warnings:	California Proposition 65. Not suitable for harmful gases and steam, nor hypoxic environments, watersports, underwater operations or firefighting.
Immediate Health, Physical & Environmental Hazards:	This product, when used under reasonable conditions and in accordance with REIGN directions for use, should not present a health hazard. However, use or processing of the product in a manner not in accordance with the product's directions for use may affect the performance of the product and may present potential health and safety hazards.
Health Effects on Eye, Skin, Inhalation & Ingestion:	No potential health effects are expected.
Potential Environmental Effects:	Not determined.
First Aid Measures for Eye, Skin, Inhalation & Ingestion:	Based on the assumption that appropriate personal and industrial hygiene practices are followed, no need for first aid is anticipated
Specific Physical Form:	Non-woven Material
Odor:	Odorless
Respiratory Protection:	Not Applicable
Prevention of Swallowing:	Not an expected route of exposure
Exposure Guidelines:	None Established
Recommendations:	Do not use mask if it becomes wet, soiled, torn, or distorted in any way with reference to the above Warnings.

Frequently Asked Questions

Do Reign Mask™ contain Nanoform Graphene?

No. Nanoform Graphene is not added to Reign Mask™ raw materials, used as a coating or otherwise employed in any form nor has it ever been used by any of its manufacturers.

What is ASTM?

ASTM refers to the American Society of Testing and Materials; and it is an international standards organization that develops and publishes voluntary consensus technical standards for a wide range of materials, products, systems and services.

How long is Reign Mask™ effective?

The filtration efficiency and protective ability of a face mask is compromised when the mask becomes wet, torn or dislodged. Generally speaking, the higher protection value of a mask the longer it will maintain filtration; however, there is no set rule for how long a mask should be worn as it depends on humidity levels, respiration rate, nasal discharge, talking, etc. If a mask gets wet or soiled it should be replaced.

What are ASTM standards for medical face masks?

ASTM standards are referenced by the Food and Drug Administration (FDA), as the endorsed standard in the United States. ASTM F2100 specifies the performance requirements for Medical Face Masks with five basic criteria:

1. BFE (Bacterial Filtration Efficiency): BFE measures how well the medical face mask filters out bacteria when challenged with a bacteria-containing aerosol. ASTM specifies testing with a droplet size of 3.0 microns containing Staph. Aureus (average size 0.6-0.8 microns). In order to be called a medical/surgical mask, a minimum 95% filtration rate is required. Moderate and high protection masks must have bacterial filtration rates greater than 98%.
2. PFE (Particulate Filtration Efficiency): PFE measures how well a hospital mask filters sub-micron particles with the expectation that viruses will be filtered in a similar manner. The higher the percentage, the better the mask filtration. Although testing is available using a particle size from 0.1 to 5.0 microns, ASTM F2100 specifies that a particle size of 0.1 micron be used.
3. Fluid Resistance: Fluid resistance reflects the surgical mask's ability to minimize the amount of fluid that could transfer from the outer layers through to the inner layer as the result of a splash or spray. ASTM specifies testing with synthetic blood at pressures of 80, 120 or 160mm Hg to qualify for low, medium, or high fluid resistance. These pressures correlate to blood pressure: 80 mm Hg = venous pressure (Level 1), 120 mm Hg = arterial pressure (Level 2), and 160 mm Hg (Level 3) correlates to potential high pressures that may occur during trauma, or surgeries that include high pressure irrigation such as orthopedic procedures.
4. Delta P (Pressure Differential): Delta P measures the air flow resistance of the medical mask and is an objective measure of breathability. The Delta P is measured in units of mm H₂O/cm² and the lower the value the more breathable the mask feels. The ASTM standard requires that masks have a Delta P of less than 6.0 for moderate and high barrier masks, whereas low barrier masks must have a Delta P of less than 5.0.
5. Flame Spread: As hospitals contain sources of oxygen, heat, and fuel the ASTM standards include testing for flame resistance. Testing dictates that all hospital masks must withstand exposure to a burning flame (within a specified distance) for three seconds. All Reign Mask™ products meet this requirement.
6. ISO Certification: In addition to the above tests, all medical face masks must be tested to an international standard (ISO 10993-5, 10) for skin sensitivity and cytotoxic tests to ensure that no materials are harmful to the wearer. Tests are conducted on materials used in construction of the mask which come in contact with the user's skin.

Are there different levels of protection with ASTM-rated medical masks?

Yes, there are three unique levels of protection with ASTM-rated medical masks. Level 1 masks have the lowest barrier of protection, while Level 3 masks have the highest barrier of protection. For greater clarity on the differences, refer to the inform in the charts below:

ASTM PROTECTION VS. INTENDED USAGE		
Level 1 (Low) Barrier: 80 mm Hg	Level 2 (Moderate) Barrier: 120 mm Hg	Level 3 (High) Barrier: 160 mm Hg
Light/minimum BFE & PPE protection	High BFE & PFE Protection	High BFE & PFE Protection
Used for general procedures and respiratory etiquette	More breathable than high barrier mask	
Designed to resist a splash or spray at venous pressure	Designed to resist a splash or spray at arterial pressure	Highest fluid resistance – designed to resist a splash during tasks like orthopedic surgery or trauma

ASTM F2100 REQUIREMENTS FOR MEDICAL FACE MASKS			
Test	Level 1 (Low) Barrier: 80 mm Hg	Level 2 (Moderate) Barrier: 120 mm Hg	Level 3 (High) Barrier: 160 mm Hg
BFE (Bacterial Filtration Efficiency) at 3.0 micron ASTM F2101	≥95%	≥98%	≥98%
PFE (Particulate Filtration Efficiency) at 0.1 micron ASTM F2299	≥95%	≥98%	≥98%
Delta P (Differential Pressure) MIL-M-3654C, mm H ₂ O/cm ²	<4.0	<5.0	<6.0
Fluid Resistance to Synthetic Blood ASTM 1862, mm Hg	80	160	160
Flame Spread (16 CFR part 1610)	Class 1	Class 1	Class 1

How do I ensure a good fit?

A mask is only as effective as its fit. There should be no gaps along the side, around the nose or under the chin that would allow air and droplets to bypass the filter medium. The mask should be properly adjusted to fully cover both the mouth and nose. A well-fitting mask stays in place over the nose and cheeks. Mask should not be worn underneath the nose or dangling around the neck – they should be fully on, or disposed of.

How do I know if a mask is on correctly?

Generally, there are three things you should look for to ensure your masks fits correctly:

1. The nose clip is at the top.
2. The white (or smoothest side) is on the inside against the wearer's skin – the color always faces out.
3. The pleats fall down and away from the nose (called a "waterfall pleat").

Information For Use

General Uses

Reign Mask™ Face mask is intended to be worn by general public or healthcare personnel and excludes air purifying respirators. The mask covers the user's nose and mouth and may or may not meet fluid barrier or filtration efficiency levels. The device is either subject to the Enforcement Policy for Face Masks, Surgical Masks, Barrier Face Coverings, Face Shields, Surgical Masks, and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency, available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-face-masks-and-respirators-during-coronavirus-disease-covid-19-public-health>, provided that the device does not create undue risk by following the recommendations for this device type outlined in the guidance, or to the Face Mask Umbrella EUA, available at <https://www.fda.gov/media/137121/download>.

Donning Instructions

1. Draw the mask from the box with the color side of the mask facing out, and ensure the nosepiece is at the top.
2. Open the pleats and form the nosepiece lightly across the nose and cheekbones. Note that for dye-free mask (often white on both sides), the layer grasped to pull the mask from the box should be facing out once donned.
3. Once the nosepiece is formed, pull the ear loops behind your ears.
4. Ensure the mask pleats are opened enough to fully cover the nostrils and mouth.
5. Once the mask is on comfortably, press along the nosepiece to form a snug fit against the face.

Doffing Instructions

1. Remove masks by grasping the ear loops and pulling out to clear the ears.
2. After ear loops have been removed, discard the mask without touching the front of mask.
3. Masks should be regarded as contaminated after use and discarded.
4. When it is safe to do so, a mask should be replaced if it becomes wet, soiled, torn, or distorted in any way.

Disclaimer

REIGN believes that the information in this Safety Data Sheet is accurate and represents the best and most current information available at the Effective Date indicated below. As REIGN cannot control or anticipate the conditions under which the subject product may be used. Each user should review the information provided above in specific context of the planned use.

While REIGN considers the information in this Safety Data Sheet to be reliable it makes no representations or warranties either express or implied, concerning:

- (i) the safe use of its products.; and,
- (ii) the suitability of the product's material for any purpose, or
- (iii) the accuracy, completeness and correctness of the information contained within this document.

This Safety Data Sheet is intended for informational purposes only and should not be construed as legal advice for any particular facts or circumstances. The user of the subject product has the sole responsibility to determine the suitability of Reign Mask™ products and REIGN is not responsible for any damages or loss owing to its contract manufacturer(s) or any third-party acting based on the contents of this document; and REIGN reserves the right to change or amend this Safety Data Sheet at any time without notice.

Wherefore, to the maximum extent permitted at law and in equity, REIGN will not be responsible for damages of any nature resulting from use of or reliance upon the information contained in this Safety Data Sheet.

Effective Date: April 1, 2022