



VELTEK ASSOCIATES, INC.

TECHNICAL DATA FILES

Face Masks

PF-2 Face Masks

Claims, product registrations, and regulatory requirements may vary based on local, regional, and/or national laws and regulations. Please contact your local sales representative for information specific to your region.

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PF-2 Face Mask

Product Description

The PF-2 face masks have been innovatively designed for use in the pharmaceutical, biotechnology, and medical device industries or in any cleanroom operation. VAI's PF-2 face masks are made of 100% rayon. The PF-2 face masks allows for excellent breathability, comfort, and protection, while maintaining filtration efficiency. The mask is designed to absorb moisture, therefore, it continually improves its own filtration efficiency. VAI's face masks are low in particulate and shedding characteristics and offer a barrier between the environment and the user.

PF-2 face masks come standard with a comfort fit nose piece that, along with the face mask's absorption efficiency, virtually eliminates fogging of one's own goggles. The comfort fit nose piece also protects the wearer from the lower edge of the goggle. This feature makes it unnecessary to continually adjust the goggles.

VAI's PF-2 sterile face mask has been redesigned to improve cleanliness by incorporating a new sewing method to eliminate any trailing thread ends. The masks are folded in a manner that allows them to be quickly, easily, and cleanly applied. It nearly eliminates the possibility of unintended contamination by touching the outside of the mask.

Sterile face masks are processed in an filled in an ISO 7 cleanroom (Grade B) manufacturing area. Sterility is assured through gamma irradiation and all sterile masks carry a ten-year validated closed packaged expiration date through high quality packaging for airtight seals. All sterile face masks are lot sterility tested according to current delivered with lot specific irradiation, conformance, and sterility data, tested to current USP compendium. PF-2 sterile face masks are individually labeled with lot number and expiration.



PF-2 face mask with two Elastic Ties

Features and Benefits

- Sterile masks are available individually packaged with bulk non-sterile packaging available
- Available in two different styles: either two elastic straps or 4 ties
- Tenyear validated closed packaged expiration date with sterility assured via gamma irradiation
- Delivered each time with lot specific documentation
- Soft, comfortable, and breathable
- Low particulate and shedding characteristics
- Mask continually improves its own filtration efficiency
- Goggle fogging is virtually eliminated due to absorption efficiency

Veltek Associates, Inc.

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Donning Procedure

1. Place mask over nose and mouth
2. Pull bottom of mask under chin
3. Mold nose piece around the nose

Testing Information

PF-2 Face Mask	
Grade:	B
Color:	White
Flammability:	Class 1
Breathability:	0.4 Delta P
Sterility testing with <i>B. Pumilis</i> Spore Strips:	Pass

Testing Specification

VAI Face Mask Test Data and Features								
Mark Type	Reorder Number	Sterility	Trade Name	Construction	Intended Use	BFE	PFE	ASTM Level
						Testing Method: ASTM F2101-19, EN 14683:2019	Testing Method: ASTM F2299	Reference ASTM: F2100-19/ EN 14683
Pharmaceutical Mask	PF-2SM-T-4-S-2021	Sterile	PF-2	Hand Sewn, Long Length, 4 Ties	Sterile Manufacturing	38.20%	38.40%	N/A
	PF-2SM-2-S-2026	Sterile	PF-2	Hand Sewn, Long Length, OP Band	Sterile Manufacturing	38.20%	38.40%	N/A
	PF-2SM-2-S-2027	Non-Sterile	PF-2	Hand Sewn, Long Length, OP Band	Non-Sterile Manufacturing	38.20%	38.40%	N/A

Reorder Information

Reorder Information		
Reorder Number	Description	Qty/Case
PF-2SM-T-4-S-2021	PF-2 Face Mask, 4 Ties, Individually Packaged, One Size, Sterile	500
PF-2SM-2-2027	PF-2 Face Mask, 2 Elastic Straps, One Size, Non-Sterile	500
PF-2SM-2-S-2026	PF-2 Face Mask, 2 Elastic Straps, Individually Packaged, Inner Bags of 50, One Size, Sterile	500



PF-2SM-T-4-S-2021



PF-2SM-2-S-2026

Additional Documentation Provided Upon Request

- Specific Testing Reports
- Sample Lot Documentation Packages
- Product Validation Reports
- VAI's Recommended Easy2Gown Gowning Procedure
- Cleanroom Apparel Technical Data Cut Sheets



DPMD

Veltek Associates, Inc. Disposable Products Manufacturing Division's capabilities include sterile disposable garments, sterile disposable face masks, dry wipers, sterile wipers, custom cleanroom documentation, sterile synthetic writing substrate, and a HEPA filtered cleanroom printer. DPMD has responded and met demands of professionals in the industry since 1985. Our manufacturing capabilities assure that we will be able to meet all requests and fulfill all of our customer's needs. All sterile DPMD products are processed and packaged in cleanroom facilities from beginning to end and subsequently gamma irradiated or aseptically filled in order to assure sterility. Visit www.sterile.com or call 610-644-8335 for more information regarding these products.

Patents: www.sterile.com/patents