



VELTEK ASSOCIATES, INC.

TECHNICAL DATA FILES



Face Masks

PF-4 Face Masks

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PF-4 Face Masks



VELTEK ASSOCIATES, INC.

PF-4 Face Mask

Product Description

The PF-4 face mask is made up of 3 layers of non-woven material. This material has a soft layer which helps prevent skin irritation or allergy problems. A coated metal strip acts as a nose piece to keep the mask secure when worn. This mask is electro-mechanically sealed, completely machine made in a clean environment.

All sterile masks are delivered with lot specific irradiation, conformance, and sterility data, tested to current USP compendium. Sterility is assured through gamma irradiation at 10.0-20.0 kGy and all sterile masks carry a ten-year closed package expiration date through high quality packaging for air tight seals.

Mask Composition

- Outer layer – 25g Spunbound Polypropylene (SBPP)
- Middle layer – 25g Meltblown Polypropylene (MBPP)
- Inner layer – 68g Rayon material

Features and Benefits

- Sterile face masks are available individually packaged
- Sterile masks are gamma irradiated at 10.0 – 20.0 kGy
- Hypoallergenic-soft surface layers that prevents skin irritation and allergy problems
- Silicon free headloop OP bands
- Loop bands are ultrasonic bonded ensuring a cleaner mask by reducing contamination and outgassing

Donning Procedure

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



PF-4SM-2-S-2029

Veltek Associates, Inc.

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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-4SM-2-S-2029, PF-4SM-T-4-S-2032	Sterile	PF-4	Machine Made Ultrasonic welded, OP Band, 3 layer, 25g SBPP, 25g MBPP, 68g Rayon Inner layer	Sterile Manufacturing, prevention of small particle inhalation	94.74%	85.60%	N/A

Reorder Information

Reorder Information		
Reorder Number	Description	Qty/Case
PF-4SM-2-S-2029	PF-4 Face Mask, Elastic Straps, One Size, Individually Packaged, Sterile	500
PF-4SM-T-4-S-2032	PF-4 Face Mask, 4 Ties, One Size, Individually Packaged, Sterile	500



PF-4SM-2-S-2029

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 assure sterility. Visit www.sterile.com or call 610-644-8335 for more information regarding these products. Patents: www.sterile.com/patents