

DISPOSABLE RESPIRATORS FFP2

TECHNICAL DATA SHEET



PRODUCT INFORMATION

This disposable respirator is a robust protective solution designed for use in medical, surgical and laboratory environments, providing effective defense against hazardous airborne contaminants. Certified as both FFP2, EN 14683 Type IIR and NIOSH grade, it also offers fluid resistance for enhanced safety.

This respirator achieves over 95% filtration efficiency for particles between 0.1 and 0.3 microns. Equipped with dual headbands that do not require tying and an adjustable nose clip, it ensures a secure fit across various face shapes and sizes, effectively preventing air leakage. Its 3-panel design supports breathability and prevents collapse during use, offering reliable comfort. The respirator is latex-free, valve-free, and individually packaged for maximum safety and practicality, making it an excellent choice for healthcare and lab professionals.



DESCRIPTION

This product is double certified and has been tested to meet both the USA NIOSH standard of Surgical N95 and EU standard for FFP2 and EN14683 Type IIR. This mask has demonstrated conformance to FDA specified requirements and is intended for use in all healthcare settings and for all medical purposes where respiratory protection is needed to protect the wearer. This product is extremely durable with a soft and comfortable inner surface, with an adjustable nose piece and secured headstraps to provide a proper fit.



The advanced mask design combines innovation and comfort for optimal performance. The high-density nose foam ensures a better and more secure seal, backed by intensive research on leakage rates. To enhance user comfort, the masks feature newly designed TPE head straps, which reduce pressure on the nose bridge and provide an anti-slip function when positioned behind the head.

The foldable 3-panel design makes the mask easy to carry and use, while also offering a larger filtering area for improved efficiency. Additionally, the low breathing resistance enhances breathability, ensuring a comfortable experience even during prolonged use.

PRODUCT DATA

Sizes	One size fits all
Compliance	Medical device class I (MDR 2017/745)
	NIOSH
	FDA
	FFP2
	EN 14683 Type IIR (CE)
NIOSH TC-number	TC-84A-9460
Filtering Efficiency	≥ 98%
Synthetic Blood Penetration (ASTM F1862)	Pass at 160mmHg
Flammability (16 CFR Part 1610)	Class 1 (≥3.5 seconds)
Splash Resistance	Pass at ≥ 16.0 kPa
Differential Pressure	< 60 Pa/cm ²
Microbial Cleanliness	≤ 30 cfu/g
Biocompatibility (ISO 10993)	Pass
Color	Blue
Sterility	Non-sterile
Latex status	Not made with natural rubber latex
Shelf life	5 years
Manufacturer QMS	ISO 13485, ISO 9001

ABOUT OUR MANUFACTURER

Established in 1984, Makrite is a leading global manufacturer of disposable face masks, serving medical, industrial, automotive, and consumer markets worldwide. With over 75 NIOSH-approved products, Makrite's masks also meet international standards such as EN149/CE, UKCA, AS/NZS, MHLW, KOSHA, and others, ensuring compliance with safety regulations across various countries.

Makrite's commitment to quality is evident in their use of high-speed automated machinery, which maintains stringent quality controls and production consistency. This dedication results in premium masks offered at competitive prices, with prompt delivery and exceptional customer service.

Headquartered in Taiwan, Makrite supports its global clientele through satellite offices in Korea, Japan, the U.S., and Singapore, reinforcing its position as a trusted provider of high-quality respiratory protection products worldwide.

FITTING INSTRUCTIONS

-  Hold the mask in your hand as shown, with the nosepiece at your fingertips and the headbands hanging freely below your hand.
-  Place mask under your chin with the nosepiece up. Pull the top headband over your head and above the ears.
-  Pull the bottom headband over your head and place around neck below the ears.
-  Adjust headbands for comfortable fit. Push the nosepiece inward with your fingertips to conform to the shape of your nose.
-  Cup both hands over the mask, checking for tightness. Inhale sharply, negative pressure should be felt in the mask. Re-adjust as necessary.

PACKAGING METHOD: 20PCS/BOX 20BOXES/CARTON

Carton size (cm)			Box (cm)			Total
Length	Width	Height	Length	Width	Height	
51.0	49.5	36.0	24.5	9.5	17.0	400 pcs

REORDERING

Item	Product number
FFP2 Disposable Respirator	FIT+4803

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