

# DISPOSABLE TYPE IIR MASK

## TECHNICAL DATA SHEET



### PRODUCT INFORMATION

This disposable protection mask is specifically designed for patients in ward areas, providing reliable and comfortable protection. It is also certified as a surgical mask according to EN 14683 Type IIR, and it offers high-quality filtration with an efficiency level of at least 98%.

The mask features an adjustable nose clip for a secure fit and two earloops for easy application without the need for tying. It ensures a snug fit across a variety of face shapes and sizes while maintaining excellent breathability for prolonged use. The internal and external faces are clearly identified for proper wear (blue/white). Additionally, the mask is latex-free, making it suitable for individuals with latex sensitivities, and is crafted to meet both safety and comfort standards.



## DESCRIPTION

Makrites CE certified surgical pleated face masks are compliance with EN 14683:2019+AC:2019 type IIR and are manufactured using high quality materials.

- 3-ply soft fiber construction and adjustable nosepiece for superb comfort and fit
- Low profile design allows for perfect vision with glasses or safety goggles
- Allows for easy breathing and normal speaking
- Disposable and maintenance free
- Ultrasonically welded latex free ear loop
- One size fit most
- Materials are latex-free and do not contain any nature rubbers.

## PRODUCT DATA

Sizes	One size fits all
Compliance	Medical device class I (MDR 2017/745) EN 14683 Type IIR (CE)
Filtering Efficiency	≥ 98%
Splash Resistance	Pass at ≥ 16.0 kPa
Differential Pressure	< 60 Pa/cm <sup>2</sup>
Microbial Cleanliness	≤ 30 cfu/g
Biocompatibility (ISO 10993)	Pass
Color	Blue
Sterility	Non-sterile
Latex status	Not made with natural rubber latex
Shelf life	2 years
Manufacturer QMS	ISO 13485, ISO 9001

## INTENDED USE

This Medical Face Mask is intended to be worn to protect both the patient and healthcare personnel from spreading of pathogenic microorganism and particulate material. This is a single use, disposable device(s), provided non-sterile.

## REORDERING

Item	Product number
Disposable 3-Layer Procedure Ear loop Face mask.	M633BE



## FITTING INSTRUCTION



**Step 1:** Position the mask with the nose piece on top. Blue layer (Hydrophobic) side out.



**Step 2:** Gentle stretch the straps and loop behind both ears.



**Step 3:** Pull pleats down to cover the chin.



**Step 4:** Press the nose piece towards the nose to ensure a proper seal.

## PACKAGING METOD: 50PCS/BOX 40BOXES/CARTON

Carton size (cm)			Box (cm)			Total
Length	Width	Height	Length	Width	Height	
52.0	38.0	34.0	18.0	10.0	8.0	2,000 pcs

## 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.

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