

# PPE COVID-19

## PRODUCT LEAFLET

PRODUCT CODE 8913-TY1-17  
DESCRIPTION Medical face mask disposable Type II (surgical)  
UNIT OF MEASURE 50 pieces



DIMENSIONS 17.5 x 9.5 cm

PRODUCT DESIGN AND SPECIFICATION The product consists of mask body, mask band, and nose clip. Mask is non-sterile and disposable.

Characteristic	Result
Size	
<ul style="list-style-type: none"><li>Length</li><li>Width</li></ul>	<ul style="list-style-type: none"><li>17.5 cm</li><li>9.5 cm</li></ul>
Fabric weight	
<ul style="list-style-type: none"><li>Outer layer non-woven</li><li>Middle layer melt blown</li><li>Inner layer non-woven</li><li>Ear loop polyester</li></ul>	<ul style="list-style-type: none"><li>Min 25 g/m<sup>2</sup></li><li>Min 25 g/m<sup>2</sup></li><li>Min 25 g/m<sup>2</sup></li><li>Min 35 g/m<sup>2</sup></li></ul>
Differential pressure	NMT 40 Pa/cm <sup>2</sup>
Microbial cleanliness	NMT 30 CFU/g
Splash resistance pressure (kPa)	16 kPa
Nose wire length	10.5-10.6 cm
Strength of connecting point of tie or elastic to body	Min 11N
Flame retardation	3-4 sec
Bacterial Filtration Efficiency (BFE)	98-99%
Differential pressure	NMT 33 Pa/cm <sup>2</sup>
Microbial cleanliness	5~11CFU/g

INTENDED USE The mask is intended to be worn by health professionals during surgery and during nursing to catch the bacteria shed in liquid droplets and aerosols from the wearer's mouth and nose. It is not designed to protect the wearer from inhaling airborne bacteria or virus particles, and is less effective than a respirator, such as a N95 or FFP mask, which provides better protection due to its material, shape and tight seal.

INSTRUCTION FOR USE

- Hold the mask by both ear loops and place a loop around each ear
- Mould the bendable metallic upper strip to the shape of the nose by pinching and pressing it down with your fingers
- Pull the bottom of the mask over the mouth and chin
- Be sure the mask fits snugly
- Do not touch the mask once in position

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DISPOSAL	Dispose as medical waste in accordance with hospital, administrative and/or local government regulations and policies.
REGULATORY APPROVAL	EU medical Device directive (Declaration of Conformity as Per MDD 93/42/EEC Risk class I)
APPLICABLE STANDARDS	Product is complying with the following standards: <ul style="list-style-type: none"><li>• EN14683:2019 (medical face masks - Requirements and test methods)</li><li>• ISO 10993 (biocompatibility)</li><li>• EN ISO 11737 (test method microorganisms)</li></ul>
STORAGE	Store in a well ventilated and clean indoor storage, without corrosive gases. It is strictly forbidden to store the products in a warehouse where chemical and wet items are stored as well.
SHELF LIFE	36 months
PACK SIZE	50 pieces per box

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PRODUCT PHOTO

