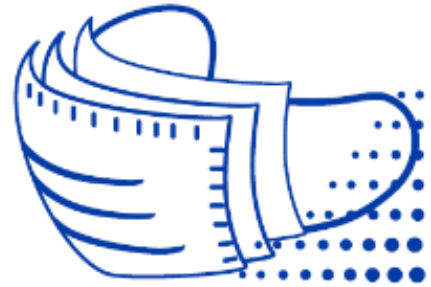


# PPE COVID-19

## PRODUCT LEAFLET

PRODUCT CODE 8913-TY3-01  
DESCRIPTION Medical face mask disposable Type IIR (surgical)  
UNIT OF MEASURE 100 pieces



DIMENSIONS 17.5 x 9.5 cm

PRODUCT DESIGN Surgical face mask Type IIR with flat pleats and ear loop strings, disposable, non-sterile

Characteristic	Result
Flame retardation	5 sec
Bacterial Filtration Efficiency (BFE)	98 - 99%
Differential pressure	NMT 40 Pa/cm <sup>2</sup>
Microbial cleanliness	NMT 30 CFU/g
Splash resistance pressure (kPa)	16 kPa

**INTENDED USE** It 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. The mask has an additional splash resistance feature.  
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

**DISPOSAL** Dispose as medical waste in accordance with hospital, administrative and/or local government regulations and policies.

**REGULATORY APPROVAL** Approved in EU (CE) as per EU Medical Device Directive (declaration of conformity as per MDD 93/42/EEC, risk class I), including manufacturer quality management system as per ISO 13485:2016 for medical device industry.

**APPLICABLE STANDARDS** Product is complying with the following standard as declaration of conformity

- EN14683:2019, (medical face masks - requirements and test methods)
- ISO 10993 (biocompatibility)
- ISO22609 (protection against penetrations fluid)
- EN ISO 11737 (test method microorganisms)

**STORAGE** Store in a cool and dry place

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SHELF LIFE 36 months

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PACK SIZE 10 pieces per pouch  
100 pieces (10 pouches) per bag  
2000 pieces (20 bags) per shipper carton