

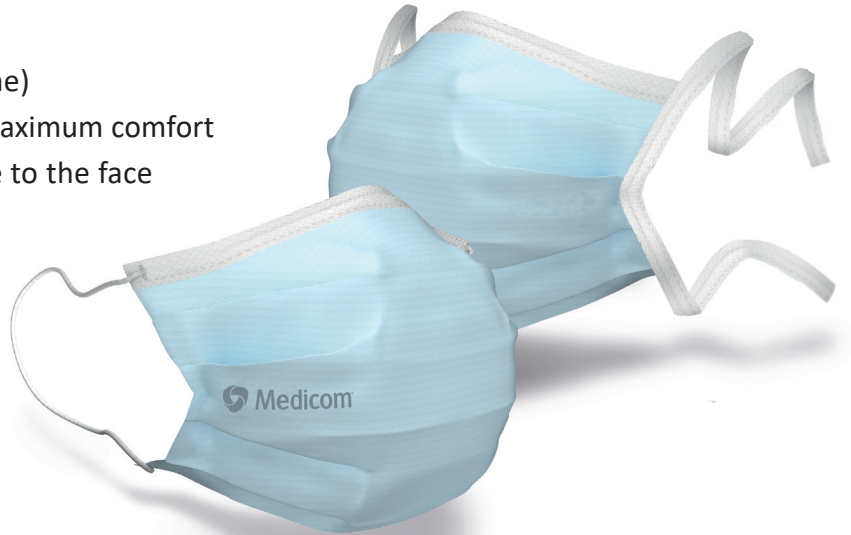
MEDICOM® SAFEMASK®

MEDICAL MASK TYPE IIR (TIE-ON / WITH EARLOOPS)

Medical Device, Class I

FEATURES & BENEFITS

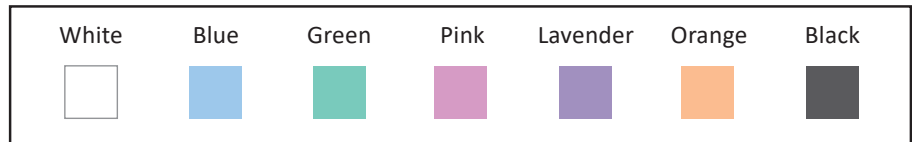
- High filtration media (polypropylene)
- 4 tie straps / 2 wide ear loops for maximum comfort
- Anatomical folding limiting leakage to the face
- Integrated nose piece
- Fiber glass free filter



PRODUCT DESCRIPTION

Product name: Medicom® SafeMask®
 Product type: Single use, non sterile
 Material: Interior layer: Spunbonded polypropylene
 Filter: Melt blown polypropylene
 Exterior layer: Spunbonded polypropylene
 Dimensions: 90 mm (±5 mm) x 175 mm (±7 mm)

Available colours:



Performance requirements for medical face masks

Test	Type I ^a	Type II	Type IIR
Bacterial filtration efficiency (BFE), (%)	≥ 95	≥ 98	≥ 98
Differential pressure (Pa/cm ²)	< 40	< 40	< 60
Splash resistance pressure (kPa)	Not required	Not required	≥ 60
Microbial cleanliness (cfu/g)	≤ 30	≤ 30	≤ 30

^a Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.

Product is in compliance to Standard EN 14683: 2019.

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PRECAUTIONS

Should be used on clean, healthy skin only.
Their re-use or prolonged use can lead to infection and/or cross contamination.
After use, comply with the national regulations set in place for the disposal of the device.

CERTIFICATION & STANDARDS

Complies with the requirements of European Regulation 2017 745 relating to Medical Devices.
Manufactured under an ISO 9001 and ISO 13485 certified system.
Complies with applicable harmonized standards EN 14683.

STORAGE CONDITIONS

Normal conditions of conservation & storage: not to be exposed to moisture and sun, must be stored at a temperature between 5°C and 40°C.



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