

# Product Specifications

Brand : Klinion<sup>®</sup> Protection  
Product : Medical Face mask type IIR, 3-ply

## Packaging & Product Reference

Product Reference	Description	Width in CM	Length in CM	Colour	Piece(s) per Inner carton	Carton dimension in MM	Pieces per Outer Carton	Carton dimension in MM
522720	KPP MEDICAL FACE MASK IIR EARLOOPS BLUE	17.5	9.5	Blue	50	185*100*80	2000	520*390*340

\* Sizes are approximate

## Product description

Klinion disposable non-sterile 3-ply medical face mask consists of PP nonwoven fabric, PP melt-blown fabric, adjustable nickel-free nose piece and elastic ear loops.

## Intended use

Klinion medical face mask is intended to be used by clinician to cover the nose and mouth to provide a physical barrier to prevent the direct penetration of pathogens, microorganisms, body fluids, etc. Single Use only.

## Classification

MDR (EU) 2017/745 Class I

## Features

- All seams are ultrasonically welded
- Soft, stretchy ear loops comfortably fit a wide variety of face
- Full-width, aluminium alloy nose piece will not kink and ensures a secure fit over the nose and across the cheeks.

## Performance and Limitation of Use

The mask must be selected properly for intended application. An individual risk assessment must be evaluated. Check the mask that it is undamaged with no visible defects. Do not use the mask if a defect is present or the end of shelf life has been exceeded.

- In compliance with: EN14683:2019+AC:2019

# Product Specifications

Product performance		
Test item	Test standard	Performance requirement
Bacterial Filtration Efficiency (BFE)	EN 14683:2019 + AC:2019 Appendix B	≥ 98%
Differential pressure (Delta-P)	EN 14683:2019 + AC:2019 Appendix C	< 60 Pa/cm <sup>2</sup>
Splash resistance pressure	ISO 22609 :2004	≥ 16 kPa
Microbial Cleanliness	EN 14683:2019 + AC:2019 Appendix CD	≤30 CFU/g

## Directions for use

1. Place the mask with blue layer outside and nose piece pointing upwards to the face.
2. Press the nose piece from the middle position and gradually move to the sides to make the nose piece fit the shape of the nose.
3. Spread the pleated creases and extend the mask to fully cover nose, mouth and jaw.

## Product components

Outer layer	Spunbond Polypropylene 25 g/m <sup>2</sup> (Blue)
Middle layer	Meltblown Polypropylene 25 g/m <sup>2</sup> (White)
Inner layer	Spunbond Polypropylene 20 g/m <sup>2</sup> (White)

- Products listed on this specification are:
  - Latex-free
  - Nose piece is nickel-free
  - Absent of human or animal tissue, blood or blood derivative

## Sterilization

Not applicable. This product is provided non-sterile

## Storage conditions

It is recommended to store protected from direct sunlight in a clean, dry space at ambient temperature.

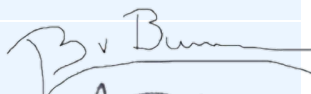
## Shelf life

3 years

# Product Specifications

Pictures



Approval	Name	Date	Signature
Product Manager	Levine van Buren	29-07-2022	
RA-Coordinator	Warsha Baboelal	01-08-2022	