

# SAFE COMFORT

## 5 LAYERS SANITARY RESPIRATORY MASK

# FP5

Face mask for COVID-19 protection that can be used by operative healthcare personnel even in the presence of aerosols.

### DUAL CERTIFICATION:

- "MASK AGAINST COVID-19" PPE-R/02.075-V2
- "SURGICAL MASK" M.D. EN 14683 TYPE IIR

CE  
0161



Filtration level 1.12% (FFP3 1% - FFP2 6%)

(Filter Penetration Test with Sodium Chloride standard EN 149:2001+A1:2009 point 8.11)

### SAFE COMFORT FEATURES

- Professional bacterial protection face mask entirely made in Italy by AXELMED S.r.l.
- Five-layer hypoallergenic material made in Germany
- Maximum biological filtration at surgical level in accordance with CE ISO 14683
- Effective barrier against viruses, bacteria and spores in air dispersion and aerosols
- Excellent nose-mouth breathability with spongy intermediate layer for dissipation of heat exhaled
- Surgical / hospital / medical area: sterilization in heat-sealed pouch with standard fractionated vacuum cycle (121°C - 8 min) in Class B autoclave.
- First aid / ambulance / medical guard area: can be sprayed with non-detergent alcohol-based disinfectant spray (as example: isopropanol) and left to dry completely without touching it, open and at room temperature.
- Reusable and machine washable (40 ° C - 35 minutes)
- One minute disinfection with a domestic microwave oven
- The innovative Safe Comfort design adheres perfectly and does not cause irritation
- Elastic tubular with easily adjustable self-adaptive sliding system
- Absence of valve to avoid transmission of the virus also if worn by positive people
- The special shape of the nose piece allows you to position the protective glasses over the mask to prevent lens fogging.



### SAFE COMFORT DESCRIPTION

The FP5 SafeComfort mask consists of five layers of non-woven polypropylene sandwich laminates. Each layer (outer facing, double meltblown, sponge, inner facing) is structured differently for the specific function for which it is intended: anti-splash protective, filtering, dissipating, hypoallergenic. It does not cause blisters or irritation. Latex-free. It does not contain phthalates. Absolute biocompatibility and biological safety of the materials used (extensive scientific documentation to support).

### SAFE COMFORT PROPERTIES AND ADVANTAGES

The FP5 SafeComfort mask is sewn in three steps: it does not contain adhesives often associated with skin irritation. The hypoallergenic inner layer (facing inwards) in contact with the soft nose-mouth system managed comfort, while the fibers of which it is included avoids both maceration and irritation. The 2 coupled filters (double meltblown) are made up of high-filtration micro brews. The intermediate layer (sponge) covers the circulation of the hot air emitted by cooling it and extending the life of the mask. The nose pad in soft anatomical material is adaptable to the face and makes the FP5 comfortable and without the need to "push" continuously the metal band. The extra-long and hypoallergenic adjustable tubular laces ensure a perfect seal both with and without headgear or protective mask.

### Technical Data

- Certified "Mask against COVID-19" PPE-R/02.075.V2
- Conform to normative UNI EN 14683:2019 Tipo IIR
- Conform to normative ISO EN ISO 10993-1-5-10-12-18
- Conform to normative ISO EN 11737-1:2018
- Conform to normative ISO 22609:2005
- Penetration Test with nebulized Sodium Chloride 1.12% according to EN149:2001+A1:2009 (FFP3 max 1% - FFP2 max 6%)
- Bacterial Filtration Efficiency BFE ≥ 98% exceed ISO Standard Annex B (Test BFE 99,9%)
- Differential Pressure / Breathability exceed <60 Pa/cm<sup>2</sup> / Tipo IIR Annex C (Test 53,9 Pa/cm<sup>2</sup>)
- Microbic Cleanless ≤ 30 ufc/g - Bioburden exceed ISO EN 11737-1:2018 Annex D (Test 12 cfu/g)
- Blood/Saliva Splash Resistant ≥ 16,0 (kPa) Type II R EN 14683 Annex C (tested 32 masks)

This filtering half mask is manufactured for COVID-19 protection only. As requested by World Health Organization recommendations, for this specific use, the nominal protection factor given by this filtering half mask is the same as the FFP2 nominal protection factor defined in EN 149: 2001 + A1: 2009. This filtering half mask is not a filtering half mask for general use and shall not be used for purposes other than protection against COVID-19.



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