



Document

AMDS.0024.v01
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Item code

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Key features

Protection: BFE >98%, 2IR
Replaceable filters
CE Certified as medical device
Designed and made in Italy



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Data sheet

SafeBreath Medical grade protection Mask



SafeBreath medical grade face protection mask in soft copolymer, with replaceable filters, BFE >98%, CE certified as a medical device

Materials

- Mask: high performance elastic copolymer certified as a medical device
- Filter and valve seal rings: certified elastic copolymer, safe colors
- Filter: synthetic fiber, water-repellent, 3 layers, thermobonded
 - (1) Spunbond polypropylene hydrophobic non-woven fabric, 20gsm
 - (2) Melt blown PBT polypropylene inner filter 30 gsm
 - (3) Spunbond polypropylene hydrophobic non-woven fabric, 20gsm
- Nose bridge: metal, embedded in mask body
- Mask and ring nuts are suitable for sterilisation with water and detergents
- Replaceable, disposable, 2-way filters

Technical specifications, filter

- BFE rating: >98% as per EN 14683: 2019 normative (Staphylococcus aureus aerosol 28.3 ± 0.2 L/min 50.3 cm²)
- Thickness measured as per ISO3034 normative
- Compliant to splash resistance test at >16 kPa on ISO22609 as per EN 14683:2019
- Compliant to air permeability test at 280 L/m²/s as per ISO 9237 norm
- Compliant to breathability test at >40 Pa/cm² as per EN 24683: 2019 norm
- Efficiency: 70%@0.3m /90%@0.6m as per PALAS MFP-1000 norm

Certifications

- Mask material elastic copolymer meets USP class VI, ISO 10993-10, ISO 10993-11, ISO 10993-4 (Hemolysis) and ISO 10993-5 (Cytotoxicity)**.
- CE Certification as per MD Directive 2007/47/EC
- CE certification as per Annexes I and VII of EU Directive 93/42/EC
- ISO 9001:2005 certification for QMS manufacturing

Packaging

- One kit comprises 1 mask body, 20 filters, one seal ring, white color
- Valve seal protection ring available in six colors
- Spare filters: sachet of 10 pieces, sterilised