

TECHNICAL DATA SHEET

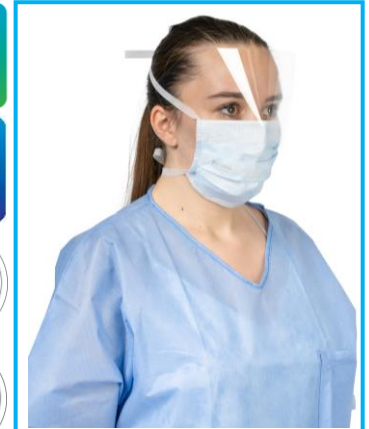
OP-air® ONE

Medical face mask with ties-on
With visor and anti-fog

Type IIR

Medical Device Class I

EN14683:2019+AC:2019



FEATURES & BENEFITS

- Protects the environment from droplets emitted by the wearer while providing protection from splashes of biological fluids.
- Effective against bacteria, particles and viruses (BFE, PFE, & VFE).
- Kolmi masks feature the exclusive Origami folding for greater comfort and a perfect fit on the wearer's face.
- For maximum comfort, the inner layer is designed with a material that limits irritation to the face.
- With Feeldry technology the inner layer has been specially designed to absorb perspiration and avoid the feeling of humidity inside the mask.
- Visor in transparent polyester with anti-fog treatment on both sides.
- The anti-fog strip prevents the glasses from fogging up.
- Hypoallergenic.

RECOMMENDED USED

- Use by medical staff for different types of care and other people to reduce the risk of spreading infections, especially in epidemic or pandemic situations.
- Use by operating room staff in surgeries where there is a risk of splashing of biological fluids.
- Use by medical staff wearing glasses or using binocular magnifiers.
- Recommended for sensitive skin.

PRODUCT DETAILS

Product name: Kolmi® OP-air® One Type IIR

Product type: Single use, non sterile

Fasteners: Ties-on

Nose piece: Polypropylene and metal

Unit weight: 8,6 g (+/-10%)

Qty per pack: 25

Manufacturing country: FRANCE ■ ■

Item	Color
M34101FV-30	■ Blue

PRODUCT PERFORMANCES EN 14683:2019+AC:2019

TEST	STANDARD	REQUIRED LEVEL	LABORATORY	REPORT N° & DATE	AVERAGE RESULT
Bacterial Filtration Efficiency: BFE	EN 14683:2019	≥ 98%	Centexbel	21.06133.02 25/10/2021	99,8 %
DELTA P	EN 14683:2019	< 60 Pa/cm²	Centexbel	22.00530.08 22/02/2022	25,9 Pa/cm²
SPLASH RESISTANCE (kPa)	EN 14683:2019	≥ 16	Centexbel	22.00530.09 22/02/2022	Conforme
Particles Filtration Efficiency 0,1µm : PFE	/	Not required	Nelson	1362445-S01 03/12/2020	99,5 %
Viral Filtration Efficiency: VFE	/	Not required	Nelson	1362444-S01 22/12/2020	99,4 %

MICROBIOLOGICAL INFORMATION

Assessment of initial microbial contamination according to standards EN 14683: 2019+AC:2019 and ISO 11737: 2018.
Additional microbiological controls: ASR, E.coli, Staphylococci, available upon request.

CERTIFICATIONS & STANDARDS

Meets the requirements of Regulation (EU) 2017/745 on medical devices.
Complies with applicable standards EN 14683: 2019 + AC:2019.
Manufacturing site: ISO 9001 and ISO 13485 certified.

PRECAUTIONS

The mask must be used on intact skin only.
The reuse or extended use may lead to infection or cross-contamination.
Please refer to your national legislation on the subject of disposal of this product once it has been used.

STORAGE CONDITIONS

Normal conditions of conservation & storage : not to be exposed to moisture and sunlight, must be stored in a cool environment or at room temperature.
Shelf life of the product: 5 years.

MARKING ON PACKAGING



* Do not use if packaged is damage.

LOGISTICS INFORMATION

INNER CASE SPECIFICATIONS					OUTER CASE SPECIFICATIONS		
ITEM	SIZE (mm)	GROSS WEIGHT (kg)	QTY / PALLET	BARCODE	SIZE (mm)	QTY / CASE	BARCODE
M34101FV-30	400 x 250 x 220	1,4	72 cases	3 662 036 013 439	222 x 190 x 96	4 boxes of 25 masks	3 662 036 013 422