

TECHNICAL DATA SHEET

OP-air® ONE

Medical face mask with ties-on
With foam strip

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.
- The foam strip improves comfort for the user and reduces fogging of the glasses.
- Hypoallergenic.

RECOMMENDED USE

- 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.
- For 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 et metal

Unit weight : 4,5 g (+/-10%)

Qty per pack : 40 masks

Manufacturing country : FRANCE

Item	Color
M34101M-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/cm ²	Centexbel	22.00530.08 22/02/2022	25,9 Pa/cm ²
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

OUTER CASE SPECIFICATIONS					INNER CASE SPECIFICATIONS		
ITEM	SIZE (mm)	GROSS WEIGHT (kg)	QTY / PALLET	BARCODE	SIZE (mm)	QTY / CASE	BARCODE
M34101M-30	333 x 300 x 230	1,6	72 cases	3 662 036 013 453	210 x 104 x 140	6 boxes of 40 masks	3 662 036 013 446