

# Technical Data Sheet

## OP-air<sup>®</sup> ONE

Medical face mask with ties-on  
With foam strip + anti-glare strip

Type II

Medical Device Class I

EN14683:2019+AC:2019



### FEATURES & BENEFITS

- Protects the environment from droplets emitted by the wearer.
- Effective against bacteria, particles and viruses (BFE, PFE, & VFE tested).
- Kolmi masks feature the exclusive Origami folding and Smile welding 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.
- Hypoallergenic.
- The foam band improves user comfort and reduces fogging of the glasses.
- The anti-reflective strip reduces the risk of glare in operating theatres.

### RECOMMENDED USE

- Use by medical personnel wearing glasses or using binocular magnifiers.
- For use by medical staff in operating theatres or in areas of high light intensity.
- Medical face masks may also be intended to be worn by patients and others to reduce the risk of spreading infection, particularly in epidemic or pandemic situations.
- Recommended for sensitive skin and long-term operations.

### PRODUCT DETAILS

Product name : Kolmi<sup>®</sup> OP-air<sup>®</sup> One  
Product type : Single use, non sterile  
Fasteners : Ties-on  
Nose piece : Polypropylene and metal  
Size : 95 x 175 mm  
Unit weight : 3,8 g (+/-10%)  
Qty per pack : 50  
Manufacturing country : FRANCE

Item	Color
M24101MN-30	Blue

### PRODUCT PERFORMANCES NF EN 14683:2019 + AC: 2019 Type II

TEST	STANDARD	REQUIRED LEVEL	LABORATORY	REPORT N° & DATE	AVERAGE RESULTS
Bacterial Filtration Efficiency: BFE	EN 14683:2019	≥ 98%	Centexbel	22.00553.01 09/02/2022	98,7%
DELTA P	EN 14683:2019	< 40 Pa/cm <sup>2</sup>	Centexbel		22,1 Pa/cm <sup>2</sup>
Particles Filtration Efficiency 0,1µm : PFE	Not required	Not required	Nelson	1393992-S01 12/03/2021	99,6 %
Viral Filtration Efficiency: VFE	Not required	Not required	Nelson	1362439-S01 22/12/2020	98,7 %

## 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.

## PACKAGING MARKING



\* Do not use if packaged is damage.

## LOGISTICS INFORMATIONS

OUTER CASE SPECIFICATIONS					INNER CASE SPECIFICATIONS		
ITEM	SIZE (mm)	GROSS WEIGHT (kg)	QTY/ PALLET	BARCODE	SIZE (mm)	QTY/ CASE	BARCODE
M24101MN-30	300 x 300 x 230	3,6	72 cases	3 662 036 013 804	211 x 103 x 140	6 boxes of 50 masks	3 662 036 013 811