TECHNICAL DATA SHEET

OP-air®

Medical face mask with ties-on
With anti-fog 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).
- Kolmi masks feature the exclusive Origami folding for better comfort and a perfect fit to the wearer's face.
- For maximum comfort, the inner layer is designed with Softex technology. It limits irritation to the face and does not wear out with prolonged use, even in contact with the beard.
- Hypoallergenic.
- The anti-fog strip prevents the glasses from fogging up.

RECOMMENDED USE

- Use by medical personnel wearing glasses.
- Medical 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 beard wearers.

PRODUCT DETAILS

Product name : Kolmi® OP-air® Type II
Product type : Single use, non sterile
Fasteners : Ties-on
Nose piece : Polypropylene and metal
Unit weight : 3,2 g (+/-10%)
Qty per pack : 50
Manufacturing country : FRANCE

Item	Color
M21101F-30	Blue

PRODUCT PERFORMANCES EN 14683:2019+AC:2019

TEST	STANDARD	REQUIRED LEVEL	LABORATORY	REPORT N° & DATE	AVERAGE RESULTS
Bacterial Filtration Efficiency : BFE	EN 14683:2019	≥ 98%	Centexbel	22.00525.02 09/02/2022	98,7%
DELTA P	EN 14683:2019	< 40 Pa/cm²	Centexbel		25,1 Pa/cm²
Particles Filtration Efficiency 0,1µm : PFE	Not required	/	Nelson	1393997-S01 11/03/2021	99,3 %
Viral Filtration Efficiency: VFE	Not required	/	Nelson	1362438-S01 18/12/2020	99,3 %

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
M21101F-30	330 x 300 x 230	3,6	72 cases	3 662 036 012 388	211 x 103 x 140	6 boxes of 50 masks	3 662 036 012 395