Technical Data Sheet

OP-air® ONE

Medical face mask with ties-on

Type IIR

Medical Device Class 1

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.
- 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.
- 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 & metal
Unit weight :	4,8 g (+/-10%)
Qty per box :	40 masks
Manufacturing country :	FRANCE

Item	Color
M34001-30	White
M34101-30	Blue
M34201-30	Green
M34301-30	Honeycomb
M34511-30	Pink

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	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	EN 14683:2019	≥ 16 kPa	Centexbel	22.00530.09 22/02/2022	Compliant
Particles Filtration Efficiency 0,1µm : PFE	/	Not required by the standard	Nelson	1362445-S01 03/12/2020	99,5 %
Viral Filtration Efficiency: VFE	/	Not required by the standard	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 conversation & storage: not to be exposed to moisture and sunlight, must be stored at a room temperature.
Shelf life of the product: 5 years.

PACKAGING MARKING

CE MD Medical Device 

* Do not use if package is damaged

LOGISTICS INFORMATION

OUTER CASE SPECIFICATIONS					INNER BOX SPECIFICATIONS		
Item	Size (mm)	Gross wieght (kg)	Qty / pallet	BARCODE	Size (mm)	Qty/case	BARCODE
M34001-30	333 x 300 x 230	1,6	72 cases	3662036013378	210 x 104 x 140	6 boxes of 40 masks	3662036013361
M34101-30			68 cases	3662036013392			3662036013385
M34201-30			72 cases	3662036012951			3662036012944
M34301-30			72 cases	3662036013590			3662036013583
M34511-30			72 cases	3662036021199			3662036021205