

Technical Data Sheet

OP-air®

Medical Face Mask with earloops

Type II

Medical Device Class I

EN14683:2019+AC:2019



FEATURES & BENEFITS

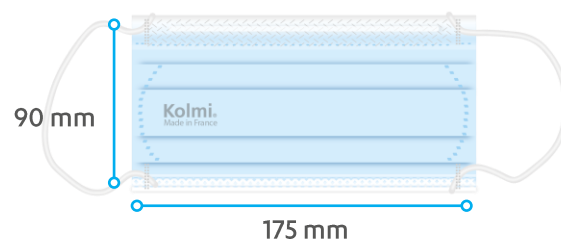
- Protects the environment against droplets emitted by the wearer
- Effective against bacteria, particles and viruses (BFE, PFE, & VFE)
- Kolmi masks feature the exclusive Omega folding and Smile welding for better comfort and a perfect fit on the wearer's face
- For maximum comfort, the inner layer is designed with a material that limits facial irritation and does not wear out over time, even in contact with the beard.
- Hypoallergenic

RECOMMENDED USE

- Use by medical staff
- Recommended for sensitive skin and beard wearers

PRODUCT DETAILS

Product name: Kolmi® OP-air®
Product type: Non sterile, single use
Fasteners : Earloops
Nose piece: Polypropylene & metal
Unit weight: 2,8 g (+/-10%)
Quantity per box: 60 masks
Manufacturing country: FRANCE 



Item	Color
M14301-30	White 
M14311-30	Blue 
M14321-30	Green 

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%	Centexebel	22.00525.02 29/02/2022	98,7 %
DELTA P	EN 14683:2019	< 40 Pa/cm²	Centexebel		25,1 Pa/cm²
Particles Filtration Efficiency 0,1µm : PFE	Not required by the standard	Not required	Nelson	1393997-S01 11/03/2021	99,3 %
Viral Filtration Efficiency: VFE	Not required by the standard	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

Complies with the requirements of Regulation (EU) 2017/745 relating to Medical Devices
Complies with applicable harmonized standards EN 14683:2019+AC:2019
Manufacturing site: ISO 9001 et ISO 13485

PRECAUTIONS

The device should only be used on intact skin only
Their re-use or prolonged use can produce infection or cross-contamination.
After use, comply with the national regulations in force for the disposal of the device.

STORAGE

Normal conditions of conservation and storage: must not be exposed to humidity and sun, must be stored at room temperature.
Product life: 5 years.

PACKAGING MARKING



LOGISTICS

Outer case specifications					Inner box specifications		
Item	Size (mm)	Weight (kg)	Qty/pallet	BARCODE	Size (mm)	QTY / outer case	BARCODE
M14301-30	400 x 400 x 220	3,9	48 Cases	3 662 036 012 173	211 x 97 x 97	16 boxes of 60 masks	3 662 036 012 180
M14311-30				3 662 036 012 197			3 662 036 012 203
M14321-30				3 662 036 012 210			3 662 036 012 227