

TECHNICAL DATA SHEET

OP-air®

Medical Face Mask with Earloops

Type IIR

Medical Device, Class I

EN 14683:2019 + AC:2019

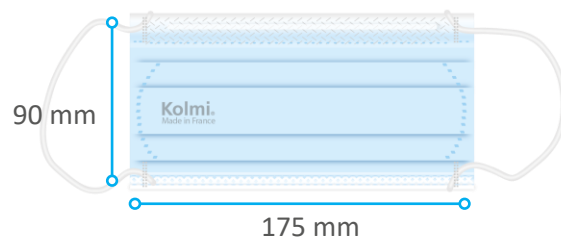


FEATURES & BENEFITS

- Protects the environment from droplets emitted by the wearer.
- Protects the healthcare professional from splashes of biological fluid.
- Kolmi medical face mask masks feature the exclusive Origami folding and Smile welding for better comfort and a perfect fit to the wearer's face.

RECOMMENDED USE

- Intended to be used by healthcare professionals.
- 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.



TECHNICAL DESCRIPTION

Product name: Kolmi® OP-air® Type IIR
 Product type: Single use, non-sterile
 Strap : Elastic earloops
 Nosepiece: Polypropylene and steel
 Unitary weight: 4,8 g (+/-10%)
 Quantity per box: 50
 Country of origin: FRANCE ■ ■

Article	Couleur
M35111-30	■ Blue
M35211-30	■ Green
M35311-30	■ Honey
M35511-30	■ Pink

PRODUCT PERFORMANCES EN 14683:2019+AC:2019

TEST	STANDARD	REQUIRED LEVEL	LABORATORY	REPORT N° & DATE	AVERAGE RESULTS
BFE	EN 14683:2019	≥ 98%	Nelson	1242388-S01 02/12/2019	98,8%
DELTA P	EN 14683:2019	< 60 Pa/cm ²	Centexbel	20.01944.01 24/04/2020	20,9 Pa/cm ²
SPLASH TEST	EN 14683:2019	≥ 16 kPa	Nelson	1249695-S01 18/12/2019	PASS
PFE	/	Not required	Nelson	1393998-S01 01/03/2021	99,8 %
VFE	/	Not Required	Nelson	1362437-S01 12/11/2020	98,4 %

BIOLOGICAL EVALUATION ACCORDING TO EN 14683:2019+AC:2019

- Absence of cytotoxicity – Namsa Report n°288178 of 11/01/2021.
- Non irritant – Namsa Report n°TI 262-800 of 13/04/2021.
- No-sensibilization – Namsa Report n°288181 of 22/02/2021.

MICROBIOLOGICAL INFORMATION

Assessment of initial microbial contamination according to standards EN 14683: 2019 + AC: 2019 & ISO 11737: 2018.
Additional microbiological controls: ASR, E.coli, Staphylococci, available upon request.

CERTIFICATIONS & STANDARDS

Meet the requirements of Regulation (EU) 2017/745 on medical devices.
Comply with the applicable standards EN 14683:2019 + AC: 2019.
Manufacturing site: ISO 9001 and ISO 13485 certification.

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 temperature between 5°C and 40°C.
Shelf life of the product: 5 years.

MARKING ON PACKAGING



* Do not use if package is damaged

LOGISTICAL INFORMATION

SPECIFICATIONS CARTON				SPECIFICATIONS BOITE			
ITEM	SIZE (mm)	WEIGHT (kg)	QTY/PALLET	OUTER CASE BARCODE	SIZE (mm)	QTE / OUTER CASE	INNER CASE BARCODE
M35111-30	400 x 400 x 220	3,9	48 cartons	3 662 036 0013 101	211 x 97 x 97	16 boites de 50 masques	3 662 036 013 118
M35211-30				3 662 036 013 149			3 662 036 013 156
M35311-30				3 662 036 013 125			3 662 036 013 132
M35511-30				3 662 036 020 185			3 662 036 020 192