

# TECHNICAL DATA SHEET

## OP-air®

**Medical face mask with earloops**

**Type II Kids (5-12 years)**

Medical Device Class I

EN14683:2019+AC:2019



### FEATURES & BENEFITS

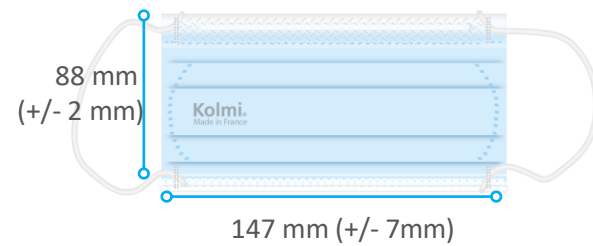
- Protects the environment from droplets emitted by the wearer
- Effective against bacteria, particles and viruses (BFE, PFE, & VFE).
- Kolmi masks feature the exclusive Origami folding and Smile welding for better comfort and a perfect fit to the wearer's face.
- For maximum comfort, the Softex inner layer is soft and non-irritating. It is appreciated by sensitive skin and does not wear out, even with prolonged use.
- Hypoallergenic.

### RECOMMENDED USE

- Use by contagious children patients (5 to 12 years old) when traveling within the hospital establishment.
- 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.
- Use in paediatric departments and infant surgery.
- The mask should be changed for each trip you make.
- A soiled mask must be changed.

### PRODUCT DETAILS

Product name : Kolmi® OP-air®  
 Product type : Single use, non sterile  
 Fasteners : Earloops  
 Nose piece : Polypropylene and metal  
 Unit weight : 1,5 g (+/-10%)  
 Qty per pack: 50 masks  
 Manufacturing country : FRANCE ■ ■



Item	Color
M95121-30	<span style="color: blue;">■</span> Blue

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

TEST	STANDARD	REQUIRED LEVEL	LABORATORY	REPORT N° & DATE	AVERAGE RESULT
Bacterial Filtration Efficiency : EFB	EN14683:2019	≥ 98%	Centexbel	22.00525.02 09/02/2022	98,7%
DELTA P	EN 14683:2019	< 40 Pa/cm <sup>2</sup>	Centexbel		25,1 Pa/cm <sup>2</sup>
Particles Filtration Efficiency 0,1 µm : EFP	Not required	Not required	Nelson	1393997-S01 11/03/2021	99,3 %
Viral Filtration Efficiency : EFV	Not required	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.

## MARKING ON PACKAGING



\* Do not use if packaged is damage.

## LOGISTICS INFORMATION

OUTER CASE SPECIFICATIONS					INNER CASE SPECIFICATIONS		
ITEM	SIZE (mm)	GROSS WEIGHT (kg)	QTY / PALLET	BARCODE	SIZE (mm)	QTY / CASE	BARCODE
M95121-30	400 x 300 x 200	1,6	72 cases (9 layer of 8 cases)	3 662 036 012 746	180 x 97 x 97	12 boxes of 50 masks	3 662 036 012 753