

TECHNICAL DATA SHEET

OP-air® K*i*D

Medical face mask with earloops

Type II Kids (1-5 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 (1-5 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® (Range Kids)

Product type : Single use, non sterile

Fasteners : Earloops

Nose piece : Polypropylene and metal

Unit weight : 1,8 g (+/-10%)

Qty per pack: 50 masks

Manufacturing country : FRANCE

Item	Color
M95241-30	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 ²	Centexbel		25,1 Pa/cm ²
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
M95241-30	400 x 300 x 190	1,6	72 cases	3 662 036 012 760	211 x 97 x 97	12 boxes of 50 masks	3 662 036 012 777

