

# Technical Data Sheet

# OP-R®

## Earloops medical face mask

### Type II

Medical Device Class I

EN14683:2019+AC:2019

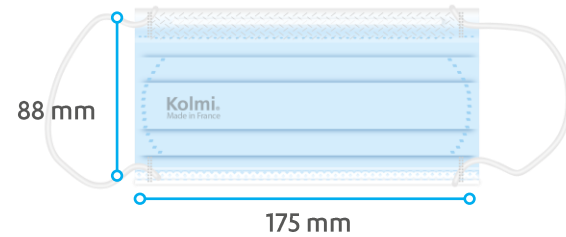


### FEATURES & BENEFITS

- Protects the environment from droplets emitted by the wearer.
- Effective against bacterias, particles and viruses (BFE, PFE, & VFE tested).
- Kolmi masks feature the exclusive Origami folding and Smile welding for greater comfort and a perfect fit on the wearer's face.
- Hypoallergenic.

### RECOMMENDED USE

- Use by medical staff.
- 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.



### PRODUCT DETAILS

Product name : Kolmi® OP'R®  
 Product type : Single use, non sterile  
 Fasteners : Earloops  
 Nose piece : Polypropylene and metal  
 Unit weight : 2,8 g (+/-10%)  
 Qty per pack : 60  
 Manufacturing country : FRANCE ■ ■

Item	Colors
M13001-30	<span style="color: white;">■</span> White
M13101-30	<span style="color: blue;">■</span> Blue
M13201-30	<span style="color: green;">■</span> 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%	Centexbel	22.00525.01 09/02/2022	98,8%
DELTA P	EN 14683:2019	< 40 Pa/cm²	Centexbel	22.00525.01 09/02/2022	16 Pa/cm²
Particles Filtration Efficiency 0,1µm : PFE	/	Not required	Nelson	1393994-S01 12/03/2021	99,7%
Viral Filtration Efficiency: VFE	/	Not required	Nelson	1398380-S01 27/03/2021	99,2%

## 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

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

## 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

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.

## PACKAGING MARKING



\* Do not use if package is damaged

## LOGISTICS INFORMATION

OUTER CASE SPECIFICATIONS				INNER CASE SPECIFICATIONS			
ITEM	SIZE (mm)	GROSS WEIGHT (kg)	QTY / PALLET	BARCODE	SIZE (mm)	QTY / CASE	BARCODE
M13001-30	400 x 400 x 220	3,9	48 cases	3662036012692	211 x 97 x 97	16 boxes of 60 masks	3662036012685
M13101-30				3662036012715			3662036012708
M13201-30				3662036012739			3662036012722