

TECHNICAL DATA SHEET

OP-air®

Medical Face Mask with headloops

Type IIR

Medical Device, Class I

EN 14683:2019 + AC:2019



FEATURES & BENEFITS

- Protects the environment against droplets emitted by the wearer, while providing protection against splashes of biological fluids.
- Effective against bacteria, particles and viruses (BFE, PFE, & VFE tested).
- For maximum comfort, the inner layer is designed with Softex technology. It limits irritation to the face and won't wear out with prolonged use, even when in contact with beards.
- Its headloops combine the comfort of masks with links with the ease of use of masks with ear elastics.
- Its large size allows to cover a large part of the face and can be worn over a hood.
- Hypoallergenic
- Individually wrapped masks guarantee perfect cleanliness.

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
Fasteners: Headloops
Nosepiece: Polypropylene and steel
Size: 90 x 230 mm (+/-10%)
Quantity per box: 50 masks individually wrapped
Country of origin: FRANCE

Item	Color
M39001-30	<input type="checkbox"/> White

PRODUCT PERFORMANCES EN 14683:2019+AC:2019

TEST	STANDARD	REQUIRED LEVEL	LABORATORY	REPORT N° & DATE	AVERAGE RESULTS
BFE	EN 14683:2019	≥ 98%	Centexbel	21.06742.01 29/11/2021	99,5%
DELTA P	EN 14683:2019	< 60 Pa/cm²	Centexbel	22.00530.06 22/02/2022	35,5 Pa/cm²
SPLASH TEST	EN 14683:2019	≥ 16 kPa	Centexbel	22.00530.07 22/02/2022	Compliant
PFE	/	Not required	Nelson	1393998-S01 01/03/2021	99,8 %
VFE	/	Not Required	Nelson	1362437-S01 12/11/2020	98,4 %

MICROBIOLOGICAL INFORMATION

Assessment of initial microbial contamination according to standards EN 14683: 2019 + AC: 2019 & ISO 11737: 2018+A1:2021.
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 conservation & storage: not to be exposed to moisture and sunlight, must be stored at room temperature.
Shelf life of the product: 5 years.

MARKING ON PACKAGING



* Do not use if package is damaged

LOGISTICS

SPECIFICATIONS CARTON					SPECIFICATIONS BOITE		
ITEM	SIZE (mm)	WEIGHT (kg)	QTY/PALLET	OUTER CASE BARCODE	SIZE (mm)	QTE / OUTER CASE	INNER CASE BARCODE
M39001-30	560 x 260 x 270	2,6	36 cases	3 662 036 016 867	255 x 110 x 133	10 boxes of 50 masks	3 662 036 016 874