

M39001-30

Medical face mask with headloops - Type IIR - Kolmi[®] Softex
 Medical Device Class I

FEATURES & BENEFITS

- Protects the environment from droplets emitted by the wearer while ensuring protection against splashes of biological fluids.
- Effective against bacteria, particles, and viruses (tested for BFE, PFE, & VFE).
- Kolmi[®] masks feature the exclusive Origami fold and Smile welding for enhanced comfort and a perfect fit to the wearer's face.
- For maximum comfort, the inner layer is designed with Softex technology, which minimizes facial irritation and does not wear out during prolonged use, even in contact with a beard.
- The headloops combine the comfort of ties-on masks with the ease of use of earloops masks.
- Hypoallergenic.
- Individually wrapped masks guarantee perfect cleanliness.



RECOMMENDED USE

- Use by medical staff.
- Use by operating room personnel for surgeries with a risk of exposure to biological fluids.
- Medical masks may also be intended to be worn by patients and other individuals to reduce the risk of spreading infections, particularly in outbreak or pandemic situations.

PRODUCT DETAILS

Product name :	Kolmi [®] Softex Type IIR
Product type :	Single use, non sterile
Fasteners :	Headloops
Nose piece :	Polypropylene and steel
Size :	90 x 230 mm
Quantity / box :	50 units individually wrapped
Origin :	France

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

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.

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.

EN 14683:2019+AC:2019

TEST	STANDARD	REQUIRED LEVEL	LABORATORY	REPORT N° & DATE	AVERAGE RESULTS
Bacterial Filtration Efficiency : BFE	EN 14683:2019	≥ 98% (Type IIR)	Centexbel	21.06742.01 26/11/2021	99,5%
DELTA P	EN 14683:2019	< 60 Pa/cm ²	Centexbel	22.00530.06 22/02/2022	35,5 Pa/cm ²
SPLASH RESISTANCE	ISO 22609:2004	≥ 16 kPa	Centexbel	22.00530.07 22/02/2022	Conforme
Particles Filtration Efficiency 0,1 µm : PFE	ASTM F2299	No requirements	Nelson	1393998-S01 12/03/2021	99,8 %
Viral Filtration Efficiency : VFE	ASTM F2101	No requirements	Nelson	1362437-S01 22/12/2020	98,4 %

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 room temperature.

Shelf life of the product: 5 years.

PACKAGING MARKING



* Do not use if package is damaged

LOGISTICS

 **Outer case Spec.**

Item	Size (mm)	Gross weight (kg)	QTY/pallet
M39001-30	560 x 260 x 270	2,6	36

Inner box spec.

Size (mm)	Packaging
255 x 110 x 133	10 boxes x 50 masks

EAN Codes

Item	Outer case	Inner box
M39001-30	3 662 036 016 867	3 662 036 016 874