

## M21101F-30 Medical mask with ties-on - Type II - Anti-fog strip - Kolmi® Softex Medical Device Class I

### FEATURES & BENEFITS

- Protects the environment from droplets emitted by the wearer.
- Effective against bacteria, particles and viruses (tested for BFE, PFE, & VFE)
- Kolmi® masks feature the exclusive Origami folding for greater comfort and a perfect fit on 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.
- Hypoallergenic.
- The anti-fog strip prevents the glasses from fogging up.


### RECOMMENDED USE

- Use by medical staff.
- 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 II
Product type :	Single use, non sterile
Fasteners :	Ties-on
Nose piece :	Polypropylene and steel
Size :	95 x 175 mm
Unit weight :	3,2 g
Quantity / box :	50 masks
Origin :	France

Item	Color
M21101F-30	 Blue

### 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 II)	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 : PFE	ASTM F2299	No requirements	Nelson	1393997-S01 11/03/2021	99,3 %
Viral Filtration Efficiency : VFE	ASTM F2101	No requirements	Nelson	1362438-S01 18/12/2020	99,3 %

**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
M21101F-30	300 x 300 x 230	3,6	72

**Inner box spec.**

Size (mm)	Gross weight (g)	Packaging
210 x 104 x 140	210	6 boxes x 50 masks

 **EAN Codes**

Item	Outer case	Inner Box
M21101F-30	3 662 036 012 388	3 662 036 012 395