

M21101-30 Medical mask with ties-on - Type II - 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.


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
M21101-30	 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 ²	Centexbel		25,1 Pa/cm ²
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
M21101-30	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
M21101-30	3 662 036 012 364	3 662 036 012 371