

**M21101M-40**

**Medical mask with ties-on - Type II - Foam strip - Kolmi<sup>®</sup> 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<sup>®</sup> masks feature the exclusive Origami folding for greater comfort and a perfect fit on the wearer's face.
- Featuring a wide and ultra-flexible nose strip, they ensure an excellent fit to the face and effectively limit leakage around the nose, thereby significantly reducing fogging.
- 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 foam strip improves comfort for the user and reduces the appearance of fogging on the glasses.
- **NEW PACKAGING** : Each tie-on is folded under each mask for convenient and tidy single removal.




## 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 <sup>®</sup> Softex Type II
Product type :	Single use, non sterile
Fasteners :	Ties-on
Nose piece :	Polypropylene and steel
Size :	95 x 175 mm
Unit weight :	3,9 g
Quantity / box :	60 masks
Origin :	France

Item	Color
M21101M-40	 Blue

## CERTIFICATIONS & STANDARDS

Meet the requirements of Regulation (EU) 2017/745 on medical devices.

Meets applicable requirements of EN 14683:2025\*.

Manufacturing site: ISO 9001 and ISO 13485 certification.

## MICROBIOLOGICAL INFORMATION

Assessment of initial microbial contamination according to standards EN 14683:2025\* & ISO 11737:2018+A1:2021.

Additional microbiological controls: ASR, E.coli, Staphylococci, available upon request.

**EN 14683:2025\***

TEST	STANDARD	REQUIRED LEVEL	LABORATORY	REPORT N° & DATE	AVERAGE RESULTS
Bacterial Filtration Efficiency : BFE	EN 14683:2025*	≥ 98% (Type II)	Centexbel	22.00525.02 09/02/2022	98,7%
DELTA P	EN 14683:2025*	≤ 200 Pa	Centexbel		123 Pa
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 %

\* based on testing to EN14683:2019 + AC:2019

## 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
M21101M-40	400 x 400 x 178	2	54

**Inner box spec.**

Size (mm)	Gross weight (g)	Packaging
192 x 125 x 165	287	6 boxes x 60 masks

## EAN Codes

Item	Outer case	Inner Box
M21101M-40	3 701 407 400 352	3 701 407 400 345