

M31101-40 Medical mask with ties-on - Type IIR - Kolmi® Softex
M31201-40 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 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.
- **NEW PACKAGING** : Each tie-on is folded under each mask for convenient and tidy single removal.





RECOMMENDED USE

- Use by medical staff.
- Use by operating room staff for surgeries with a risk of biological fluid splashes.

PRODUCT DETAILS

Product name :	Kolmi® Softex Type IIR
Product type :	Single use, non sterile
Fasteners :	Ties-on
Nose piece :	Polypropylene and steel
Size :	95 x 175 mm
Unit weight :	4,6 g
Quantity / box :	50 masks
Origin :	France

Item	Color
M31101-40	 Blue
M31201-40	 Green

CERTIFICATIONS & STANDARDS

Meet the requirements of Regulation (EU) 2017/745 on medical devices.
 Meets applicable requirements of EN 14683:2025 *based on testing to EN14683:2019 + 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 14683:2025						
TEST	STANDARD	REQUIRED LEVEL		LABORATORY	REPORT N° & DATE	AVERAGE RESULTS
Bacterial Filtration Efficiency : BFE	*EN 14683:2025	≥ 98% (Type IIR)		Centexbel	21.06742.01 26/11/2021	99,5%
DELTA P	*EN 14683:2025	EN 14683:2019 < 60 Pa/cm²	EN 14683:2025 300 Pa	Centexbel	22.00530.06 22/02/2022	EN 14683:2019 35,5 Pa/cm² EN 14683:2025 174 Pa
SPLASH RESISTANCE	*EN 14683:2025	≥ 16 kPa		Centexbel	22.00530.07 22/02/2022	Compliant
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 %

*The 2019 version of the EN 14683 standard measured the differential pressure (delta P) in Pa/cm². The 2025 version now measures it in Pa. The values remain the same; only the unit of measurement has changed.

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

CE

MD Medical Device

no latex

no flame

no water

no sharp

no heat

*

* Do not use if package is damaged

LOGISTICS

Outer case Spec.				Inner box spec.		
Item	Size (mm)	Gross weight (kg)	QTY/pallet	Size (mm)	Gross weight (g)	Packaging
M31101-40	400 x 400 x 178	2	54	192 x 125 x 165	285	6 boxes x 50 masks
M31201-40						

EAN Codes

Item	Outer case	Inner box
M31101-40	3 701 407 400 277	3 701 407 400 260
M31201-40	3 701 407 400 253	3 701 407 400 246