

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*.
 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.

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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*	≤ 300 Pa	Centexbel	22.00530.06 22/02/2022	174 Pa
SPLASH RESISTANCE	ISO 22609:2004	≥ 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 %

* 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
M31101-40	400 x 400 x 178	2	54
M31201-40			

**Inner box
spec.**

Size (mm)	Gross weight (g)	Packaging
192 x 125 x 165	285	6 boxes x 50 masks

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