

M34001-40

M34101-40

M34201-40

**Medical mask with ties-on - Type IIR - Kolmi® Feeldry**

Medical Device Class I

### FEATURES & BENEFITS

- Protects the environment from droplets emitted by the wearer while providing protection from splashes of biological fluids.
- Effective against bacteria, particles and viruses (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 a material that limits irritation to the face.
- With Feeldry technology the inner layer has been specially designed to absorb perspiration and avoid the feeling of humidity inside the mask.
- 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® Feeldry Type IIR
Product type :	Single use, non sterile
Fasteners :	Ties-on
Nose piece :	Polypropylene and steel
Size :	95 x 175 mm
Unit weight :	4,7 g
Quantity / box :	50 masks
Origin :	France

Item	Color
M34001-40	 White
M34101-40	 Blue
M34201-40	 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	21.06133.02 25/10/2021	99,8 %
DELTA P	EN 14683:2025*	≤ 300 Pa	Centexbel	22.00530.08 22/02/2022	127 Pa
SPLASH RESISTANCE	ISO 22609:2004	≥ 16 kPa	Centexbel	22.00530.09 22/02/2022	Conform
Particles Filtration Efficiency 0,1 µm : PFE	ASTM F2299	No requirements	Nelson	1362445-S01 03/12/2020	99,5 %
Viral Filtration Efficiency : VFE	ASTM F2101	No requirements	Nelson	1362444-S01 22/12/2020	99,4 %

\* 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
M34001-40			
M34101-40	400 x 400 x 178	2,1	54
M34201-40			

**Inner box spec.**

Size (mm)	Gross weight (g)	Packaging
192 x 125 x 165	291	6 boxes x 50 masks

## EAN Codes

Item	Outer case	Inner box
M34001-40	3 701 407 400 239	3 701 407 400 222
M34101-40	3 701 407 400 215	3 701 407 400 208
M34201-40	3 701 407 400 178	3 701 407 400 161