

### M33101-40 Medical mask with ties-on - Type IIR Medical Device Class 1

#### FEATURES & BENEFITS

- Protects the environment from droplets emitted by the wearer while providing protection from splashes of biological fluids.
- Effective against bacterias, particles and viruses (BFE, PFE, & VFE tested).
- 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.
- Hypoallergenic.



#### RECOMMENDED USE

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

#### PRODUCT DETAILS

Product name :	<b>Kolmi Vitals</b>	Number of layers: 4
Product type :	Single use, non sterile	Inner layer: spunbond polypropylene
Fasteners :	Ties-on	Outer layer: spunbond polypropylene
Nose piece :	Polypropylene and metal	Splash barrier: spunbond polypropylene
Color :	Blue	Filter media: meltblown polypropylene
Quantity / box :	50 units	Nose piece: polypropylene + metal
Size :	175 x 95 mm	Ties-on: spunbond polypropylene
Unit weight :	4,4 g	
Origin :	France	

#### EN 14683:2025\*

TEST	STANDARD	REQUIRED LEVEL	LABORATORY	REPORT N° & DATE	RESULTS
Bacterial Filtration Efficiency BFE	EN 14683:2025*	≥ 98% (Type IIR)	Centexbel	21.06133.01 25/10/2021	99 %
DELTA P	EN 14683:2025*	≤ 300 Pa	Centexbel	22.00530.04 22/02/2022	138 Pa
RESISTANCE SPLASH	ISO 22609:2004	≥ 16 kPa	Centexbel	22.00530.05 22/02/2022	Compliant
Particles Filtration Efficiency 0,1µm : PFE	ASTM F2299	Not applicable	Nelson	1393995-S01 12/03/2021	99,5 %
Viral Filtration Efficiency: VFE	ASTM F2101	Not applicable	Nelson	1398379-S01 27/03/2021	98,4 %

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

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### MICROBIOLOGICAL INFORMATION

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

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

### 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.

### 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

Normal storage conditions : should not be exposed to moisture and sunlight, must be stored at room temperature.

Product shelf life: 5 years.

### PACKAGING MARKING



### LOGISTICS



Outer case spec.

Inner case spec

Item	Size (mm)	Gross Weight (kg)	QTY/ Pallet
M33101-40	400 x 400 x 180	1,8	54 cases

Size (mm)	Gross weight (g)	Packaging
211 x 97 x 97	265	6 x 50 units

### EAN Codes

Item	Outer case	Inner box
M33101-40	3 662 036 022 721	3 662 036 022 738