

Technical Data Sheet

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 bacteria, 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.
- Hypoallergenic.



RECOMMENDED USE

- Use by medical staff.
- Use by operating room staff in surgeries where there is a risk of splashing of biological fluids.
- Medical face masks may also be intended to be worn by patients and others to reduce the risk of spreading infection, particularly in epidemic or pandemic situations.
- Wearing the mask should not exceed 4 hours

PRODUCT DETAILS

Product name :	Kolmi Vitals	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	

COMPLY WITH STANDARD EN 14683:2019+AC:2019

TEST	STANDARD	REQUIRED LEVEL	LABORATORY	REPORT N° & DATE	RESULTS
Bacterial Filtration Efficiency BFE	EN 14683:2019	≥ 98% (Type IIR)	Centexbel	21.06133.01 25/10/2021	99 %
DELTA P	EN 14683:2019	< 60 Pa/cm ²	Centexbel	22.00530.04 22/02/2022	28,1 Pa/cm ²
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 %

MICROBIOLOGICAL INFORMATION

Assessment of initial microbial contamination according to standards EN 14683: 2019+AC:2019 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.
- Complies with applicable standards EN 14683: 2019 + AC:2019.
- Manufacturing site : ISO 9001 – ISO 13485.

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.

Item	Size (mm)	Gross Weight (kg)	QTY/ Pallet
M33101-40	400 x 400 x 180	1,8	60 cases

Inner case spec

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