Kolmi® Vitals

Medicom

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 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 :	**Kolmi Vitals**
Product type :	Single use, non sterile
Fasteners :	Ties-on
Nose piece :	Polypropylene and metal
Color :	Blue
Quantity / box :	50 units
Size :	175 x 95 mm
Unit weight :	4,4 g
Origin :	France

Number of layers: 4

Inner layer:	spunbond polypropylene
Outer layer:	spunbond polypropylene
Splash barrier:	spunbond polypropylene
Filter media:	meltblown polypropylene
Nose piece:	polypropylene + metal
Ties-on:	spunbond polypropylene

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.

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

DOMINIQUE DUTSCHER SAS

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