Kolmi® Vitals

Medicom

Technical Data Sheet

M36101-40 Medical mask with earloops - Type IIR

Medical Device Class I

DOMINIQUE DUTSCHER SAS

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 and Smile welding for greater comfort and a perfect fit on the wearer's face.
- Hypoallergenic.
- Wearing the mask should not exceed 4 hours



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.

PRODUCT DETAILS

Product name :	**Kolmi Vitals**
Product type :	Single use, non sterile
Fasteners :	Earloops
Nose piece :	Polypropylene and metal
Color :	Blue
Quantity / box :	50 units
Size :	175 x 90 mm
Unit weight :	3,7 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
Elastics:	polypropylene + elastane

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/cm²	Centexbel	22.00530.04 22/02/2022	28,1 Pa/cm²
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 %

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MICROBIOLOGICAL INFORMATION

Assessment of initial microbial contamination according to standards EN 14683: 2019+AC:2019 and ISO 11737: 2018 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



*Do not use if package is damaged

LOGISTICS

Outer case spec.

Item	Size (mm)	Gross Weight (kg)	QTY/ Pallet
M36101-40	400 x 400 x 220	3,8	42 cartons

Inner case Spec.

Size mm	Gross weight (g)	Packaging
211 x 97 x 97	220	16 x 50 units

EAN Codes

Item	Outer case	Inner box
M36101-40	3 662 036 022 707	3 662 036 022 714

DOMINIQUE DUTSCHER SAS

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