## S Medicom

# **Technical Data Sheet**

M36101-40 Medical mask with earloops - Type IIR 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 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.

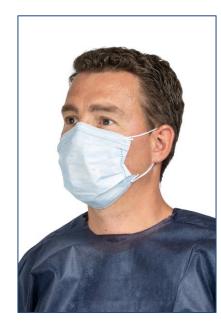
Kolmi®

Vitals

• 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: Outer layer: Splash barrier: Filter media: Nose piece: Elastics: spunbond polypropylene spunbond polypropylene spunbond polypropylene meltblown polypropylene polypropylene + metal 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 %

#### **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



#### LOGISTICS

Outer cas spec.	se				Inner case Spec.	
Item	Size (mm)	Gross Weight (kg)	QTY/ Pallet	Size mm	Gross weight (g)	Packaging
M36101-40	400 x 400 x 220	3,8	42 cartons	211 x 97 x 97	220	16 x 50 units

#### EAN Codes

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



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