





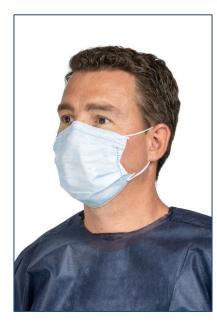
M36101-40 Medical mask with earloops - Type IIR Medical Device Class I

## **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.
- 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 Number of layers: 4

Product type: Single use, non sterile Inner layer: sp

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	Not applicable Nelson		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









## **LOGISTICS**



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	48 cartons		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	

