

M13101-40 Medical mask with earloops - Type II Medical Device Class 1

FEATURES & BENEFITS

- Protects the environment from droplets emitted by the wearer.
- 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.

RECOMMENDED USE

- Use by medical staff.
- 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
Product type :	Single use, non sterile
Fasteners :	Earloops
Nose piece :	Polypropylene and metal
Color :	Blue
Quantity / box :	60 units
Size :	175 x 90 mm
Unit weight :	3 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 II)	Centexbel	22.00525.01 09/02/2022	98,8%
DELTA P	EN 14683:2019	< 40 Pa/cm ²	Centexbel	22.00525.01 09/02/2022	16 Pa/cm ²
Particles Filtration Efficiency 0,1µm : PFE	ASTM F2299	Not applicable	Nelson	1393994-S01 12/03/2021	99,7 %
Viral Filtration Efficiency: VFE	ASTM F2101	Not applicable	Nelson	1398380-S01 27/03/2021	99,2 %

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
M13101-40	400 x 400 x 220	3,9	48 cartons

Inner case spec

Size (mm)	Gross weight (g)	Packaging
211 x 97 x 97	215	16 x 60 units

EAN Codes

Item	Outer case	Inner box
M13101-40	3 662 036 022 684	3 662 036 022 691