

M35111V-30

Medical face mask with earloops - Type IIR - Visor - Kolmi[®] Softex
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 bacteria, particles and viruses (tested for BFE, PFE, & VFE).
- Kolmi[®] masks feature the exclusive Origami fold and Smile welding for enhanced comfort and a perfect fit to the wearer's face.
- For maximum comfort, the inner layer is designed with Softex technology, which minimizes facial irritation and does not wear out during prolonged use, even in contact with a beard.
- Transparent polyester visor with anti-fog treatment on both sides. To ensure its protection, the outer face is protected by a film to be removed before use. This helps to ensure perfect vision for the user.
- Hypoallergenic




RECOMMENDED USE

- Use by medical staff.
- Use by operating room staff in surgeries where there is a risk of splashing of biological fluids.

PRODUCT DETAILS

Product name :	Kolmi [®] Softex Type IIR
Product type :	Single use, non sterile
Fasteners :	Earloops
Nose piece :	Polypropylene and steel
Visor :	Polyester
Size :	90 x 175 mm
Unit weight :	8 g
Quantity / box :	25 units
Origin :	France

Item	Color
M35111V-30	 Blue

CERTIFICATIONS & STANDARDS

Meet the requirements of Regulation (EU) 2017/745 on medical devices.
 Comply with the applicable standards EN 14683:2019 + AC: 2019.
 Manufacturing site: ISO 9001 and ISO 13485 certification.

MICROBIOLOGICAL INFORMATION

Assessment of initial microbial contamination according to standards EN 14683: 2019 + AC: 2019 & ISO 11737: 2018+A1:2021.
 Additional microbiological controls: ASR, E.coli, Staphylococci, available upon request.

EN 14683:2019+AC:2019

TEST	STANDARD	REQUIRED LEVEL	LABORATORY	REPORT N° & DATE	AVERAGE RESULTS
Bacterial Filtration Efficiency : BFE	EN 14683:2019	≥ 98% (Type IIR)	Centexbel	21.06742.01 26/11/2021	99,5%
DELTA P	EN 14683:2019	< 60 Pa/cm ²	Centexbel	22.00530.06 22/02/2022	35,5 Pa/cm ²
SPLASH RESISTANCE	ISO 22609:2004	≥ 16 kPa	Centexbel	22.00530.07 22/02/2022	Conforme
Particles Filtration Efficiency 0,1 µm : PFE	ASTM F2299	No requirements	Nelson	1393998-S01 12/03/2021	99,8 %
Viral Filtration Efficiency : VFE	ASTM F2101	No requirements	Nelson	1362437-S01 22/12/2020	98,4 %

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 CONDITIONS

Normal conditions of conversation & storage: not to be exposed to moisture and sunlight, must be stored at room temperature.

Shelf life of the product: 5 years.

PACKAGING MARKING


* Do not use if package is damaged

LOGISTICS

 **Outer case Spec.**

Item	Size (mm)	Gross weight (kg)	QTY/pallet
M35111V-30	400 x 250 x 220	1,3	72

Inner box spec.

Size (mm)	Packaging
222 x 190 x 96	4 boxes x 25 masks

EAN Codes

Item	Outer case	Inner box
M35111V-30	3 662 036 013 767	3 662 036 013 774