

**M35001SB-30** Medical face mask with earloops - Type IIR - Without nose piece - 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.
- Without nose piece.
- Hypoallergenic.

## RECOMMENDED USE

- Recommended for use by patients undergoing MRI, CT scan or X-ray.
- May also be suitable for use in prison or psychiatric settings where the metal nose piece may be considered dangerous.



## PRODUCT DETAILS

Product name :	Kolmi® Softex Type IIR
Product type :	Single use, non sterile
Fasteners :	Earloops
Size :	90 x 175 mm
Unit weight :	3,6 g
Quantity / box :	50 units
Origin :	France

Item	Color
M35001SB-30	<input type="checkbox"/> White

## 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/cm²	Centexbel	22.00530.06 22/02/2022	35,5 Pa/cm²
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
M35001SB-30	400 x 400 x 220	3,4	48

**Inner box spec.**

Size (mm)	Gross weight (g)	Packaging
211 x 97 x 97	200	16 x 50 masks

**EAN Codes**

Item	Outer case	Inner box
M35001SB-30	3 662 036 013 743	3 662 036 013 750