

M95121-30

Medical face mask with earloops - Type II 5-12 years - Kolmi® Softex Kids
Medical Device Class I

FEATURES & BENEFITS

- Protects the environment against droplets emitted by the child.
- 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 child's face.
- For maximum comfort, the inner layer is designed with Softex technology, which minimizes facial irritation.
- Hypoallergenic.


Recommended use

- Use by contagious child patients (ages 5 to 12) during their movements within the hospital.
- Use in pediatric and pediatric surgery departments.



PRODUCT DETAILS

Product name:	Kolmi® Softex Kids Type II
Product type:	Single use, non sterile
Fasteners :	Earloops
Nose piece:	Polypropylene and steel
Size :	88 x 147 mm
Unit weight :	2,2 g
Origin :	France

Item	Color
M95121-30	 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 and 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 II)	Centexbel	22.00525.02 09/02/2022	98,7 %
DELTA P	EN 14683:2019	< 40 Pa/cm²	Centexbel		25,1 Pa/cm²
Particles Filtration Efficiency 0,1µm : PFE	ASTM F2299	No requirements	Nelson	1393997-S01 11/03/2021	99,3 %
Viral Filtration Efficiency: VFE	ASTM F2101	No requirements	Nelson	1362438-S01 18/12/2020	99,3 %

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
M95121-30	400 x 300 x 190	1,8	72

Inner box spec.

Size (mm)	Gross weight (g)	Packaging
180 x 97 x 97	140	12 boxes x 50 masks



EAN Codes

Item	Outer case	Inner box
M95121-30	3 662 036 012 746	3 662 036 012 753