

M24101N-30 Medical mask with ties-on - Type II - Anti-glare strip - Kolmi[®] Feeldry Medical Device Class I

FEATURES & BENEFITS

- Protects the environment from droplets emitted by the wearer
- Effective against bacteria, particles and viruses (BFE, PFE, & VFE)
- Kolmi[®] masks feature the exclusive Origami folding for greater comfort and a perfect fit on the wearer's face.
- For maximum comfort, the inner layer is designed with a material that limits irritation to the face.
- With Feeldry technology the inner layer has been specially designed to absorb perspiration and avoid the feeling of humidity inside the mask.
- Hypoallergenic.
- The anti-glare strip reduces the risk of glare in operating theatres.




RECOMMENDED USE

- For use by medical staff in operating theatres or in areas of high light intensity.
- Medical masks can also be worn by patients and others to reduce the risk of spreading infection, particularly in epidemic or pandemic situations.

PRODUCT DETAILS

Product name :	Kolmi [®] Feeldry Type II
Product type :	Single use, non sterile
Fasteners :	Ties-on
Nose piece :	Polypropylene and steel
Size :	95 x 175 mm
Unit weight :	3,2 g
Quantity / box :	50 masks
Origin :	France

Item	Color
M24101N-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 II)	Centexbel	22.00553.01 09/02/2022	98,7 %
DELTA P	EN 14683:2019	< 40 Pa/cm ²	Centexbel		22,1 Pa/cm ²
Particles Filtration Efficiency 0,1 µm : PFE	ASTM F2299	No requirements	Nelson	1393992-S01 12/03/2021	99,6 %
Viral Filtration Efficiency : VFE	ASTM F2101	No requirements	Nelson	1362439-S01 22/12/2020	98,7 %

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
M24101N-30	300 x 300 x 230	3,6	72

Inner box spec.

Size (mm)	Gross weight (g)	Packaging
210 x 104 x 140	210	6 boxes x 50 masks

 EAN Codes

Item	Outer case	Inner Box
M24101N-30	3 662 036 013 828	3 662 036 013 835