

**M24101-30**

**Medical mask with ties-on - Type II - 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.


### RECOMMENDED USE

- For use by medical staff
- 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  |
|-----------|--|
| M24101-30 |  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<br>09/02/2022 | 98,7 %                  |
| DELTA P   | EN 14683:2019 | < 40 Pa/cm <sup>2</sup> | Centexbel  |                           | 22,1 Pa/cm <sup>2</sup> |
| Particles Filtration Efficiency<br>0,1 µm : PFE | ASTM F2299    | No requirements         | Nelson     | 1393992-S01<br>12/03/2021 | 99,6 %                  |
| Viral Filtration Efficiency : VFE               | ASTM F2101    | No requirements         | Nelson     | 1362439-S01<br>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 |
|-----------|-----------------|-------------------|------------|
| M24101-30 | 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         |
|-----------|-------------------|-------------------|
| M24101-30 | 3 662 036 012 487 | 3 662 036 012 494 |