

M14301-30 M14311-30-2000
M14311-30 Medical face mask with earloops - Type II - Kolmi[®] Softex
M14321-30 Medical Device Class I

FEATURES & BENEFITS

- Protects the environment against droplets emitted by the wearer.
- 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.
- Hypoallergenic.

Recommended use

- Use by medical staff.
- Medical masks may also be intended to be worn by patients and other individuals to reduce the risk of spreading infections, particularly in outbreak or pandemic situations.



PRODUCT DETAILS

Product name: Kolmi[®] Softex Type II
 Product type: Single use, non sterile
 Nose piece: Polypropylene and steel
 Size : 90 x 175 mm
 Unit weight : 2,8 g
 Origin : France

| Item | Color |
|----------------|---|
| M14301-30 | <input type="checkbox"/> White |
| M14311-30 | <input checked="" type="checkbox"/> Blue |
| M14311-30-2000 | <input checked="" type="checkbox"/> Blue |
| M14321-30 | <input checked="" type="checkbox"/> Green |

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.

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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 |
|----------------|-----------------|-------------------|------------|
| M14301-30 | | | |
| M14311-30 | 400 x 400 x 220 | 3,9 | 48 |
| M14321-30 | | | |
| M14311-30-2000 | 600 x 400 x 237 | 6,6 | 28 |

Inner box spec.

| Size (mm) | Gross weight (g) | Packaging |
|---------------------------------|------------------|---------------------|
| 211 x 97 x 97 | 215 | 16 boxes x 60 masks |
| Case of 2 000 pieces in one bag | | |

EAN Codes

| Item | Outer case | Inner box |
|----------------|-------------------|-------------------|
| M14301-30 | 3 662 036 012 173 | 3 662 036 012 180 |
| M14311-30 | 3 662 036 012 197 | 3 662 036 012 203 |
| M14311-30-2000 | 3 662 036 012 272 | / |
| M14321-30 | 3 662 036 012 210 | 3 662 036 012 227 |



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