

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 1 to 5) 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 : | 90 x 115 mm (+/- 5mm) |
| Unit weight : | 1,8 g |
| Origin : | France |

| Item | Color |
|-----------|--|
| M95241-30 |  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/cm ² | Centexbel | | 25,1 Pa/cm ² |
| 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 |
|-----------|-----------------|-------------------|------------|
| M95241-30 | 400 x 300 x 190 | 1,6 | 60 |

Inner box spec.

| Size (mm) | Gross weight (g) | Packaging |
|---------------|------------------|---------------------|
| 180 x 97 x 97 | 120 | 12 boxes x 50 masks |

 **EAN Codes**

| Item | Outer case | Inner box |
|-----------|-------------------|-------------------|
| M95241-30 | 3 662 036 012 760 | 3 662 036 012 777 |