



2965-10

2968-10

2969-10

SAFE+MASK® PREMIUM NORMASKIN / Type II with earloops Medical Device, Class I

FEATURES & BENEFITS

- High filtration with filter media (polypropylene)
- 2 comfortable large earloops
- Very soft polypropylene nonwoven edge
- Anatomic folding limiting inward leakage
- Integrated anti-fog nose piece
- Filter without micro glass
- Production in ISO 8 clean room (particle and microbiological control)

Recommended use :

- Use by caregiver for different types of care
- If mask is dirty during operation, therefore change it
- Suitable for the movement of contagious patients (adults) within the hospital

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PRODUCT DETAILS

| | |
|---------------|---|
| Product name: | Safe+Mask® Premium NormaSkin – Type II with earloops |
| Product type: | Single use, non-sterile |
| Inner layer: | White Hypoallergenic Thermobond polypropylene |
| Filter: | PP Complex (Meltblown + Spunbond) |
| Link: | Earloops |
| Size: | 90 x 175 mm (± 5 mm) |
| Unit weight: | 2,8 g (± 10%) |
| Packaging: | Box of 60 units |
| Origin : | France |

| Item | Colour |
|---------|--------|
| 2965-10 | Blue |
| 2968-10 | Green |
| 2969-10 | White |



Filtration and Comfort Information - NF EN 14683:2014 Type II

Measurements done by NELSON Laboratory (report available on request)

| TEST | Required level | Laboratory | Report number | Date of Report | Average | Minimum value | Maximum value |
|--|----------------|------------|---------------|----------------|------------------|---------------|---------------|
| Bacterial Filtration Efficiency: BFE (%) | 98 | NELSON | 1033927-S01 | 16/04/2018 | 98,66 | 98,2 | 99,0 |
| DELTA P (Pa/cm²) | 29,4 | NELSON | 1033927-S01 | 16/04/2018 | 16,34 | 15,6 | 17,5 |
| PFE PARTICULE 0,1µm (%) | | NELSON | 614275 | 16/01/2012 | 98,96 | 98,9 | 99,0 |
| Using time efficiency: BFE | | NELSON | 1033927-S01 | 16/04/2018 | 4H: BFE = 98,20% | | |

Manufacturing Microbiological Information (by MICROSEPT Laboratory)

Bioburden evaluation meets the requirements of EN 14683: 2014 and NF EN 11737: 2006
 Additional microbiological controls: ASR, E.Coli, Staphylococcus, on request

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Biological Evaluation - NF EN 14683:2014

| | Standard | Required level | Laboratory | Report number | Date of Report | Results |
|--------------------------------|-----------------------|---|------------|---------------|----------------|---|
| Intracutaneous irritation test | ISO 10993-10 | non irritation | NAMSA | 231037 | 21/06/2017 | non irritation |
| Cytotoxicity | ISO 10993-5 | no cytotoxicity | NELSON | 1030858-S01 | 22/03/2018 | no cytotoxicity |
| Sensitization | ISO 10993-10 and -10A | topical application: no sensitization | NAMSA | 231038 | 19/07/2017 | topical application: no sensitization |
| | | intradermal injection: no sensitization | | | | intradermal injection: no sensitization |

CERTIFICATION & STANDARDS

In accordance with requirements of medical devices Dir.93/42/EEC modified by Dir.2007/47/EC
 Manufactured under ISO 13485 certified quality system.
 In conformity with the relevant harmonized standard EN 14683 and EN ISO 14971

STORAGE CONDITIONS

Normal conditions of conservation & storage: not to be exposed to moisture and sun, must be stored at a temperature between 5°C and 40°C
 Shelf life of the product: 5 years

LOGISTICAL INFORMATION



Outer case specifications

Inner case specifications

| Item | Size mm | Gross weight kg | QTY/pallet | Size mm | QTY |
|-------------------------------|-----------------|-----------------|--|---------------|-----------------------|
| 2965-10 2968-10 2969-10 | 400 x 400 x 220 | 3,9 | 60 cartons (10 layers of 6 cartons) | 211 x 97 x 97 | 16 boxes of 60 pieces |



EAN Codes

| Item | Outer case | Inner case |
|---------|-------------------|-------------------|
| 2965-10 | 8 718 007 908 374 | 8 718 007 908 381 |
| 2968-10 | 8 718 007 908 398 | 8 718 007 908 404 |
| 2969-10 | 8 718 007 908 411 | 8 718 007 908 428 |



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