



2092
2092S

Safe+Oxygen

RESPIRATORY PROTECTION MASK WITH HEADLOOPS

Personal Protective Equipment, Category III and Medical Device, Class I

FEATURES & BENEFITS

- Filtering half mask, efficiency class FFP2 NR D developed to protect
- against solid and liquid aerosols
- Ultrasonic welding

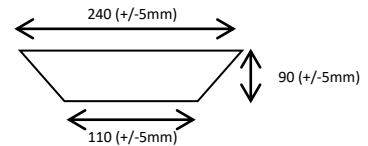
Recommended use:

- Use in dusty environment
- To prevent against risky infectious diseases (According to national recommendations)
- Using time: 8 H



PRODUCT DETAILS

| | |
|--------------------|-------------------------|
| Product name: | Mask FFP2 NR D |
| Product type: | Single use, non-sterile |
| Outer/Inner layer: | Spunbond polypropylene |
| Filter: | Meltblown polypropylene |
| Link: | Synthetic elastic |
| Nosepiece: | Polypropylene and iron |
| Colour: | Blue / White |
| Unit weight: | 6,2 g (± 10%) |
| Origin: | France |



EN 149:2001+A1:2009

| Test | Required level | Laboratory | Report number | Date of Report | Average value |
|---------------------------------------|---|------------|---------------|----------------|---------------|
| Paraffin Oil penetration | < 6 % after 120mg exposure | APAVE | 20.0073 | 15/05/2020 | Compliant |
| NaCl penetration | < 6 % after 120mg exposure | | | | Compliant |
| Facial leakage | 46 results ≤ 11 % 8 averages in 10 ≤ 8% | | | | Compliant |
| Air permeability inhalation 30 l/min | ≤ 0,7 mbars | | | | Compliant |
| Air permeability inhalation 95 l/min | ≤ 2,4 mbars | | | | Compliant |
| Air permeability exhalation 160 l/min | ≤ 3 mbars | | | | Compliant |
| Carbon dioxide content | < 1,0 % | | | | Compliant |
| Flammability | Must not burn or continue to burn for more than 5 seconds after the withdrawal of the flame | | | | Compliant |

Protection (D) : protection against solid and liquid aerosols, combined with resistance higher to clogging tested with dolomite dust

Annual observation according to module C2 - Reg (UE) 2016/425 done by APAVE

NF EN 14683:2019

| Test | Standard | Required level | Laboratory | Report number | Date of Report | Value |
|--------------------------------------|----------------|---|------------|---------------|----------------|---|
| Bacterial Filtration Efficiency: BFE | EN 14683:2019 | ≥ 98% (Type IIR) | CENTEXBEL | 20.00718.02 | 20/03/2020 | 99.9% min |
| DELTA P | EN 14683:2019 | < 60 Pa/cm ² | CENTEXBEL | 20.00718.02 | 20/03/2020 | 46,3 Pa/cm ² max |
| SPLASH | ISO 22609:2004 | ≥ 16 kPa | CENTEXBEL | 20.00718.02 | 20/03/2020 | Compliant |
| Intracutaneous irritation test | ISO 10993-10 | no irritation | NAMSA | 231037 | 21/06/2017 | no irritation |
| Cytotoxicity | ISO 10993-5 | no cytotoxicity | NELSON | 1030830-S01 | 20/03/2018 | no cytotoxicity |
| Sensitization | ISO 10993-10 | no sensitization | NAMSA | 231038 | 19/06/2017 | no sensitization |
| Microbial cleanliness CFU/g | NF 11737:2018 | ≤30 cfu/g | MICROSEPT | 1812011-15 | 14/04/2020 | Compliant |
| Using time : BFE + Delta P | EN 14683:2014 | ≥ 98% (Type IIR) < 49 Pa/cm ² | NELSON | 961620-S01 | 10/05/2017 | 8h : > 99.9% 8h : < 37,00 Pa/cm ² |

PRECAUTIONS FOR USE

The device should only be used on healthy skin.

Their re-use or prolonged use can produce infection or cross-contamination.

After use, comply with the national regulations in force for the disposal of the device.

CERTIFICATION & STANDARDS

Meets the requirements of Regulation (EU) 2017/745 and Regulation (EU) 2016/425.

Complies with the applicable harmonized standards EN 14683 and EN 149.

Manufactured under an ISO 13485 and ISO 9001 certified system.

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 | Packaging | QTY |
|-------|-----------------|-----------------|---------------------------------------|-----------------|----------------|-----------------------|
| 2092 | 560 x 260 x 270 | 4,3 | 36 cartons (6 layers of 6 cartons) | 255 x 110 x 133 | Bulk | 10 boxes of 50 pieces |
| 2092S | 560 x 260 x 270 | 4,8 | 36 cartons (6 layers of 6 cartons) | 255 x 110 x 133 | Individual bag | 10 boxes of 50 pieces |