

**MAFF2 – FFP2 NR**  
**Instructions for use for respirators without FFP2 NR single-use expiratory valve:**

**RESPIRATORY MASK FFP2 NR**

FFP2 NR Efficiency Class Half Mask Filter

Make: F-MASK – Model: MAFF2

Reference:

- MAFF2-2020-4P (size 245mm SME, SF, SI)
- MAFF2-2021- 4P (size 225 mmSME, SF, SI)

**Notified body: APAVE SUDEUROPE SAS**

Notified body involved in the EU module type examination (B) and the annual quality assurance check of the module type production mode (C2) according to Regulation 2016/425/EU.

**APAVE SUDEUROPE SAS**  
CS60193 – 13332 Marseille Cedex 16 – France

**0082**

This mask complies with the requirements defined by :

- European Regulation: 2016/425 and 2017/745

This mask has been evaluated according to the following standards:

<b>EN149 : 2021+A1 : 2009</b>	<b>EN14683 + AC : 2019</b>
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**Date of first affixing of the CE marking: 05/01/2021**

Note: The standards and results of our tests can be downloaded from our website, [www.prism-medical-protect.fr](http://www.prism-medical-protect.fr), by registering by clicking on the "login" tab.

Based on compliance and assessment indications, the FFP2 NR mask is PPE (Personal Protective Equipment) for use in industry.

The mask is also a Class I medical device (DM), suitable for use in hospitals, health professionals, patients and visitors to hospitals.

**TYPOLOGY:**

FFP2 NR Efficiency Class Half Mask Filter, Duck Beak Type, Single Use Mask, Non-sterile, Non-reusable.

**PRECONIZATIONS:**

It is intended to protect the wearer from inhaling both droplets and airborne particles.

This mask is used to protect its wearer from dust, and aerosols (fine droplets suspended in the air).

**TIPS FOR USE:**

- Single-use, non-reusable mask for up to 8 hours.
- Close the box after use.
- Mask to be discarded after use in a garbage can provided for this purpose and not in nature.
- In case of respiratory pathology, dermatological and allergic problem, in case of psychiatric disorder, person suffering from autism disorder and any other adverse effects, please consult a health professional



**BEFORE USE:**

- Check the box before opening.
- Check for moisture or mould.
- Check the box for crushing.
- If in doubt, change units or boxes.
- Read instructions and seek advice from a health professional

**WARNINGS:**

- The half-mask is not designed to protect its wearer from gases.
- The mask cannot be used in an explosive atmosphere.
- It is unlikely that the sealing requirements of the mask will be met if facial hair passes under the face seal.
- Keep out of reach of children.
- Do not use after expiry date.
- Product containing non-woven components, to be used with caution for allergic persons.
- In intensive work situations, wearing a mask is recommended for 15 minutes.
- The half-mask must not be used in atmospheres where there is a risk of oxygen deficiency.
- If the mask is damaged or breathing resistance is more difficult change the mask.



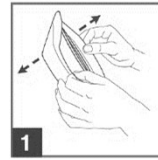
The EU declaration of EC conformity and the data sheet can be downloaded from

[www.prism-medical-protect.fr](http://www.prism-medical-protect.fr)

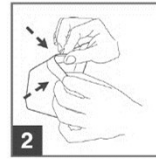
or by email: [qualite@prism-medical-protect.fr](mailto:qualite@prism-medical-protect.fr)

**Any complaint must be addressed by post, specifying the batch number and the mask number:**

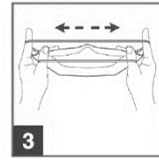
**INSTRUCTIONS FOR USE:**



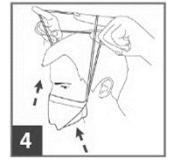
1 Separate the edges of the mask to fully open it.



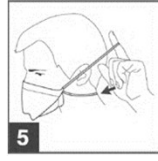
2 Fold the nasal barrette to hold the open respirator.



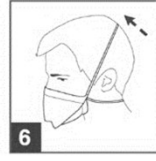
3 Separate each elastic link with indexes and thumbs..



4 Wedge the hollow formed mask under the chin and pass the elastics above the head holding them with the thumb and forefinger



5 Release the inner elastic and place it at the bottom of the neck



6 Position the 2nd elastic at the top of the skull



7 Adjust the nasal bar by pressing well at the wings of the nose with the fingers



8 Position the mask until it adheres perfectly to the face

**ADJUSTMENT AND CONTROL OF WATER RESISTANCE::**

The seal of the mask must be checked before any use:

To check the seal of the mask :

- Put on your mask,
- Adjust the wire pinch nose,
- Blow with your mouth for the mask to swell,
- If air comes out of the nose, adjust the thread pinch nose,
- If air still comes out after adjusting the nose clip, change the mask.

**NORMAL STORAGE AND STORAGE CONDITIONS:**

- Do not store in the sun
- Store UV-free
- Store in a protected location
- Store between 5°C and 40°C
- Do not store in a damp place and protected from the weather
- Store in a dry room where humidity is less than 60%
- Do not wet the mask before use

Storage conditions should be checked regularly

**MORE INFORMATIONS :**

- Non-reusable
- No latex
- Non-sterile product
- Date of manufacture
- Expiration date
- lot number
- Mask Reference Number
- medical device
- Unique identification of devices
- Name of material compositions

They support us, and are members of the following organizations,



European product made in France



Protect the environment by throwing the used mask into a trash can

In the event of a serious incident related to this device, please notify the manufacturer and the ANSM ([www.ansm.santé.fr](http://www.ansm.santé.fr))