

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:

EN149 : 2021+A1 : 2009	EN14683 + AC : 2019
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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, 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

or by email: qualite@prism-medical-protect.fr

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

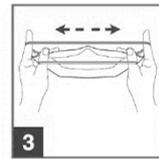
INSTRUCTIONS FOR USE:



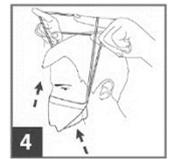
1 Separate the edges of the mask to fully open it.



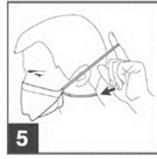
2 Fold the nasal barrette to hold the open respirator.



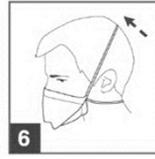
3 Separate each elastic link with index fingers and thumbs..



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
- SF, SI 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)