



Paris, February 19th 2021

Letter to users of the Filtering half mask to protect against particles (FFP2 PPE category III)

Product reference: 1016-07003-US

In the context of emergency use authorization June 6th, 2020 due to the COVID-19 health crisis, you will find on this letter the information on the Filtering half mask to protect against COVID-19.

This filtering half-mask is made for filtering particles.

This mask meets the requirements set forth by regulation (EU) 2015/425 and standard EN149:2001+ A1 2009. It was examined by APAVE (notified body number 0082), APAVE SUDEUROPE SAS - CS60193 - 13322 MARSEILLE CEDEX 16 – France.

Single-use BioSerenity protective masks do not contain latex.

The EU declaration of conformity is available at www.bioserenity.com

You can find in the URL website <https://www.bioserenity.com/en/quality-and-regulatory/>, certificates and information on our masks.

INDICATION

These filtering masks are recommended for any person seeking protection against liquid and solid particles.

DISPOSAL

Depending on its use, this mask should be considered an infected device once it has been used. In this case, the mask must be disposed in an Infectious Medical Waste (IMW) receptacle. If the mask is to be used outside of a medical centre without an IMW system, it is recommended that, at a minimum, the mask must be enclosed inside a sealed leak tight plastic bag and discarded in the trash.

**PROCEDURE FOR
PUTTING ON THE MASK**

General recommendation: adjust the position of the mask and shape the nose bar to minimize air leakage. Reducing air leakage is essential to ensure proper mask performance. If the mask does not have a sufficient seal, the mask must be replaced.

1. **Separate the edges of the mask** to open it completely.
2. **Unfold and flatten the nose bar** to keep the breathing portion of the mask open.
3. Hold the mask by the elastic straps and **place it on your face with the elastic straps around your ears.**
4. **Adjust the position of the mask** for the best possible contact between the mask, chin and cheeks.
5. **Adjust the nosepiece as much as possible** by pressing and pinching both sides of the nose.

6. Inhale and exhale several times. When exhaling **assess whether air leaks appear** between the mask, chin, cheeks and nose. Adjust if necessary in accordance with general recommendations.

STORAGE

Store according to the recommendations on the packaging.

PRECAUTIONS FOR USE

- Remove the mask from its packaging at the time of intended use.
- Before using the mask, make sure that the mask and the elastic loops are intact.

WARNING

Discard and replace the mask if it:

- is damaged;
- seems to obstruct breathing;
- seems wet or moist;
- does not have a tight seal;
- is contaminated by one or more bodily fluids or any other infectious materials.

This mask is not flame resistant and should not be used in areas with open flames.

LIMITS OF USE

This mask does not protect against gas or vapours :

- This half-mask does not supply oxygen.
- Do not use in environments not containing at least 17% oxygen.
- Do not use in an explosive environment.
- This mask does not need maintenance.

It is designed to be used for a maximum of 8 hours and worn once.

- Not following instructions and precautions concerning the use of this protective respiratory mask during the exposure period may reduce its protective efficacy.
- This product does not eliminate the risk of contracting diseases or infections.
- It is unlikely that the requirements relating to leak tightness and fit will be met if there is facial hair around the face seal .

CONTACT

To contact support, use the following address: support@bioserenity.com

MANUFACTURER

BioSerenity
ICM-iPEPS
47, bd de l'hôpital
75013 Paris - France

Julien Dupont, Quality and Regulatory Affairs Director

