

MACH2R – CHIRURGICAL

Instructions for use for single-use surgical respiratory masks:

SURGICAL RESPIRATORY PROTECTION MASK

TYPE II R

Brand: F-MASK – Model: MACH2R

References:

- MACH2R-2020-3P (blue)
- MACH2R-2020-3PB (white)
- MACH2R-2020-3PN (black)

Notified body: National Laboratory of Metrology and Testing (LNE)

All the regulatory tests of EN 14683 were carried out by the LNE..

Laboratoire National de métrologie et d'essais (LNE)
1, rue Gaston Boissier – 75724 Paris Cedex 15 – France



This mask complies with the recommendations defined by:

- Standard: EN 14683 + AC 2019

This mask has been evaluated according to the standard:

EN14683 : 2019+AC : 2009

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.

Given the indications of conformity and evaluation the surgical mask is a DM (medical device) of class I usable in hospital, health professionals, patients and visitors of hospital environments

Date of first affixing of the CE marking: 16/08/2021

TYPOLGY:

Type II R surgical mask, single-use, non-sterile, non-reusable

PRECONIZATIONS:

It is intended to prevent, during the exhalation of the wearer, the projection of upper airway secretions or saliva that may contain infectious agents transmissible by "droplets" or "aerial".

Worn by the caregiver, it prevents contamination of the patient and his environment (air, surface, products, etc.).

Carried by the contagious patient, it prevents contamination of his environment and surroundings.

This mask protects the wearer from "droplet" transmissible infectious agents, but in no way protects against "airborne" transmissible infectious agents

TIPS FOR USE:

- Single-use, non-reusable mask for up to 4 hours.
- Close the box after use.
- Mask to be discarded after use in a designated garbage can and not in the wild.
- 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 thoroughly 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

WARNING:

- The mask is not designed to protect the 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 allergy sufferers.
- 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

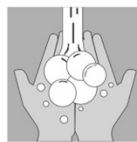
or by email: qualite@prism-medical-protect.fr

Any complaint must be sent by post, specifying the batch number:

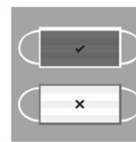
SAS PRISM, ZI du Barnier, 51 rue des paluds- 34110 FRONTIGNAN – France

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

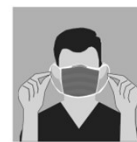
INSTRUCTIONS FOR USE:



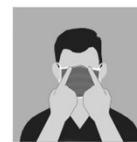
Wash one's hands



Place the mask in the direction shown



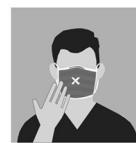
Place the elastic bands of the mask behind the ears.



Pinch the rigid edge to fit the shape of the nose.



Adjust the position of the mask so that it covers the face and its contour is as close as possible to the skin.



Avoid touching the mask while wearing. Do not place the mask on the forehead or chin in a ready position



Remove the mask by touching only the elastics.



Throw the mask in the trash and wash your hands.

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 thread pinch nose,
- Blow with your mouth to inflate the mask,
- If air comes out of the nose, adjust the thread pinch nose,
- If air is still coming 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, weatherproof location
- Store in a dry room where humidity is less than 80%
- Do not wet the mask before use

Storage conditions should be checked regularly.

VARIOUS INFORMATIONS



Not reusable



Sin 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 a member of the following organizations



European product made in France



Protect the environment by throwing the used mask in the trash