

FFP2 MASK DATA SHEET
100% FRENCH

RESPIRATORY MASK FFP2 NR FFP2 NR

FFP2 NR efficiency class half-mask filter

(NR: non-reusable^②)

Class III PPE and Class I Medical Device



Distributor Manufacturer

PRISM

**ZI du Barnier, 51 rue des paluds
34110 FRONTIGNAN (FRANCE)**

Model : MAFF2

Make : F-MASK

Reference : MAFF2-2020-4P

TECHNICAL CHARACTERISTICS

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).

DESCRIPTION OF THE MASK:

The mask is made up of several elements that have a very specific function:

A “duckbill” mask organized in several layers (called folds), whose exteriors are made of non-woven polypropylene, called “SPUNBOND”, of 2 layers intermediaries (filter media) provides filtration, called “MELTBLOWN”.

A nose clip with a double steel wire, called nose clip which allows to adjust the mask to the shape of the nose, also to avoid leaks and to reduce fogging of the glasses.

Occipital fasteners, which allow the mask to be fixed to the face by a double flat elastic (Manual separation).

EXTERIOR COLOR 1: white

ASSEMBLY : By ultrasonic welding

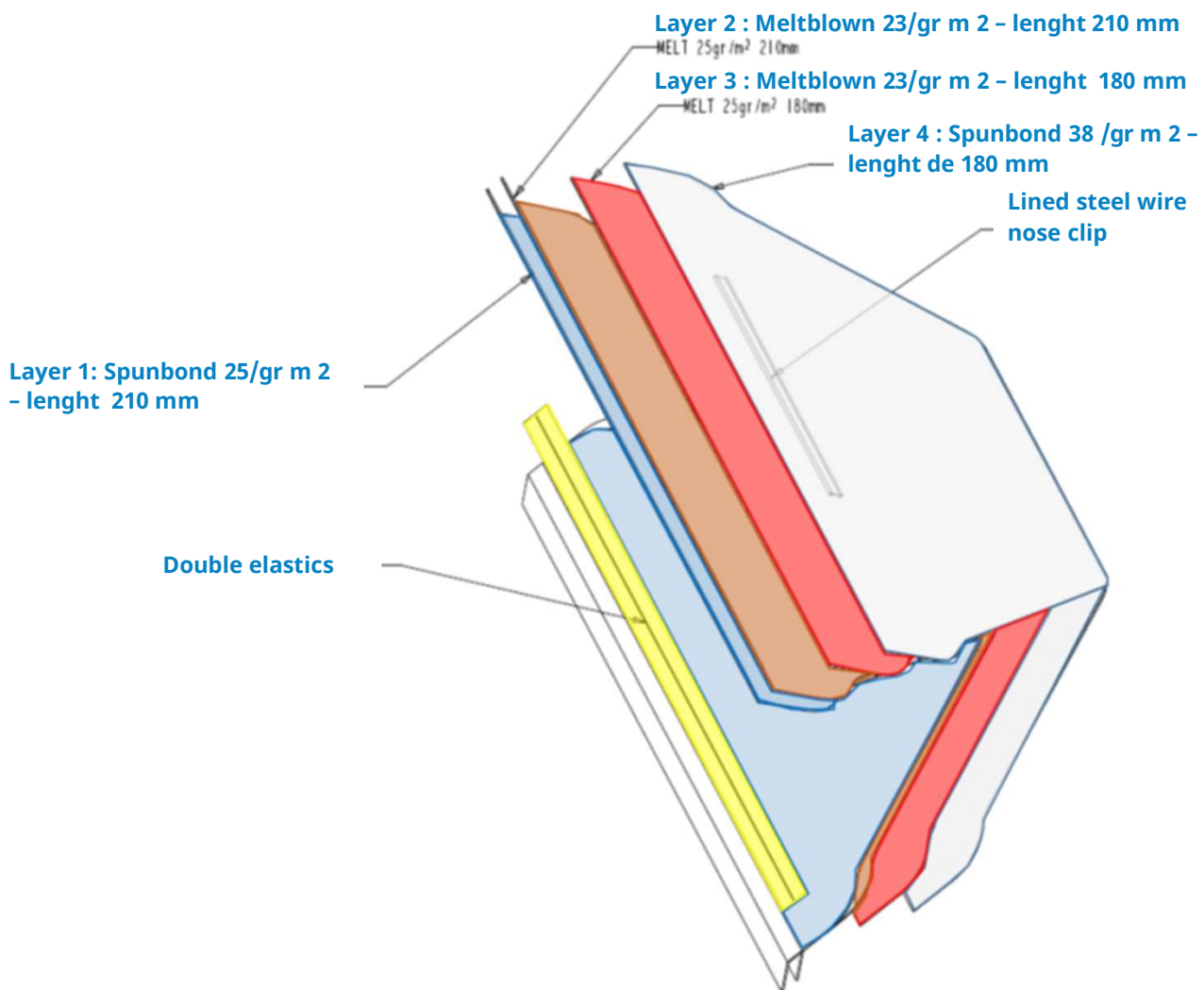
STERILITY : Non-sterile product



MASK COMPONENTS:

Soft and hypoallergenic, its shape in «duck's beak» makes it ergonomic by adapting closely to the face, covering the nose, mouth and chin.

The 2 filter layers are assembled by a revolutionary process called «Assembly by expansion». An air slide comes between the two filter layers. Thus the material is not crushed like most conventional manufacturing processes and allows to breathe better while keeping the best filtration.



All mask components are latex free

Elastics:

Benefits – Features

No latex non irritant.

Contains no silicone – PVC and no azo dye.

Specific surface treatment for bonding.

Excellent tear resistance.

Packaging in continuous strips without knot of connections allowing an optimization of the product.

Formula established in compliance with REACH regulations.

Mechanical and dimensional properties

Elastomer Synthetic rubber

Nominal Thickness +/- 10%

Width Nominal +/- 5%

100% module extension 90g/mm² +/- 15%
(1st cycle)

200% module extension 130g/mm² +/- 15%
(2nd cycle)

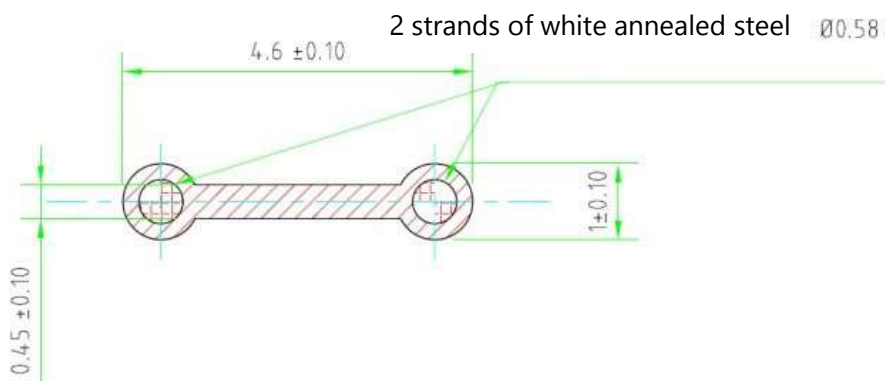
Elongation at break > 500%

DRA 8%

Nose clip:

Lined metal wire (steel) and polypropylene.

The nasal bar is adjustable and suitable for all types of morphology.



Layer 1 external : Spunbond

- 100% polypropylene
- Weight 25 gr
- Melting point (°C) > 140
- Water-insoluble
- Odorless

PARAMETERS	UNIT	TYPICAL AVERAGE	TEST METHOD
Basis weight	gr/m ²	25 +/-2	WSP 130.1 (1)
Tensile strength MD	N/5 cm	60	WSP 110.4 (2)
Tensile strength CD	N/5 cm	19	WSP 110.4 (2)
Top Stretch MD	%	90	WSP 110.4 (2)
Tensile rotation deformation CD	%	90	WSP 110.4 (2)
Air permeability	l/m ² /s	5000	WSP 70.1 (3)

Note:

-(1) Sample area: 2500 cm²

-(2) Distance between clamps: 200 mm, speed

Test: 200 mm/min

-(3) Test area: 20 cm², dP: 200 Pa

Layers 2 et 3 intermédiaires filtrantes : Meltblown

- 100% polypropylene
- Weight 25 gr
- Melting point (°C) > 140
- Water-insoluble
- Odorless

PROPERTIES	UNIT	TYPICAL AVERAGE	TEST METHOD
Basis weight	gr/m ²	23 +/- 5%	ISO 9073-1 (1)
Thickness	mm	0.28 +/- 5 %	ISO 9073-2 (1)
Penetration au NaCl (95 l/min)	%	not measured	EN 149
Penetration with parrafin oil (95 l/min)	%	< 3.5	EN 149
Breathing resistance (Insp 30l /min)	%	< 0,35	EN 149
Breathing resistance (Insp 95 l/min)	%	< 1.10	EN 149
Breathing resistance (Exp 160 l/min)	%	< 1.70	EN 149
Long force	N/5cm	>13	ISO 9073-3(2)
Force sense across	N/5cm	>13	ISO 9073-3(2)
Elongation at rupture in long direction	%	<85	ISO 9073-4(2)
Elongation at the rupture across direction	%	<85	ISO 9073-4(2)

Outer Layer 4 (face to face): Spunbond

- 100% polypropylene
- Weight 25 gr
- Melting point (°C) > 140
- Water-insoluble
- Odorless

Note:

-(1) Sample area: 2500 cm²

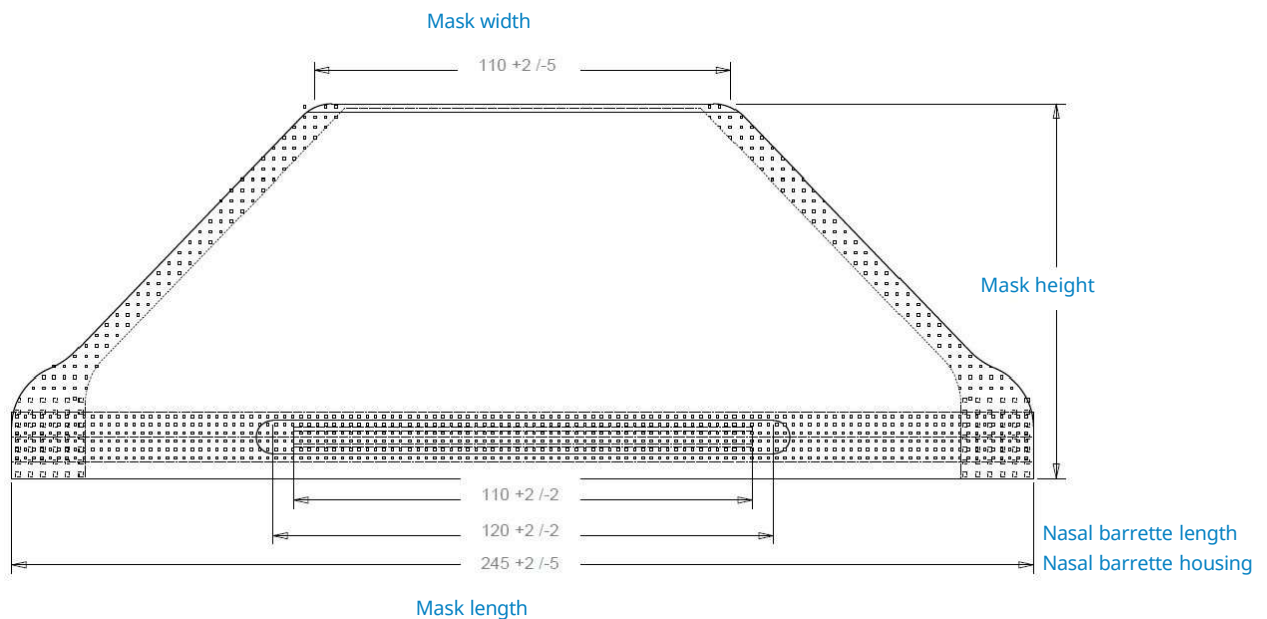
-(2) Distance between clamps: 200 mm, speed

Test: 200 mm/min

-(3) Test area: 20 cm², dP: 200 Pa

PARAMETERS	UNIT	TYPICAL AVERAGE	TEST METHOD
Basis weight	gr/m ²	38 +/-2	WSP 130.1 (1)
Tensile strength MD	N/5 cm	93	WSP 110.4 (2)
Tensile strength CD	N/5 cm	35	WSP 110.4 (2)
Top Stretch MD	%	100	WSP 110.4 (2)
Tensile rotation deformation CD	%	100	WSP 110.4 (2)
Air permeability	l/m ² /s	3100	WSP 70.1 (3)

Size



CHARACTERISTIC QUALITIES

The mask is manufactured according to the recommendations of the standards:

NF EN 149+A1 2009 and in reference to EPI Regulation 2016/425

Currently being accredited for EN 14683 + AC 2019

PRISM carries out self-checkings quality as and when its productions

0082  compliant product

Testing	Requirement	Results(maximum measured value)	Conformity
Simulated port processing	No mechanical failure of the face part or straps, no crushing	-	YES
Temperature conditioning	no crushing	-	YES
Mechanical strength	--		YES
Practical Performance Test	No imperfection as regards its acceptance by the bearer	-	YES
Total leakage inward	46 of 50 individual results 11%	50 Number	YES
	8 of 10 averages 8%	10 Number	YES
Flammability	The materials used must not be hazardous to the wearer or highly flammable in nature. Does not continue to burn more than 5s after removal of flame	-	Unrealized
Carbon dioxide content of inhaled air	Carbon dioxide content of inhaled air $\leq 1.0\%$	0.86 %	YES
Expiratory resistance 160 l/min	Expiratory resistance 160 l/min $\leq 3,0$ mbar	1,48 mbar	YES
Inspiratory resistance 30 l/min	Inspiratory resistance 30 l/min $\leq 0,7$ mbar	0,28 mbar	YES
Inspiratory resistance 95 l/min	Inspiratory resistance 95 l/min $\leq 2,4$ mbar	1,04 mbar	YES
Filter Material Penetration - Liquid Particulate Testing (Paraffin Oil)	Penetration test(3 min, 95 l/min) $\leq 6,0$ %	0,86 %	YES
Filter Material Penetration - Liquid Particulate Testing (Paraffin Oil)	Penetration test (120 mg, 95 l/min) $\leq 6,0$ %	5,22 %	YES
Filter Material Penetration - Solid Particulate Testing (Sodium Chloride)	Exposure test(3 min, 95 l/min) $\leq 6,0$ %	0,35 %	YES
Filter Material Penetration - Solid Particulate Testing (Sodium Chloride)	Exposure test (120 mg, 95 l/min) $\leq 6,0$ %	0,63 %	YES

* Leak inward below:

Exercise	Test subject reference									
		1	2	3	4	5	6	7	8	9
Slow walking	0,19	0,78	0,28	0,91	0,56	0,07	0,54	0,71	0,13	0,24
Left-Right	0,60	2,51	0,75	1,67	0,67	0,07	0,50	1,36	2,60	0,44
Up-down	1,05	3,15	6,13	2,41	0,89	0,09	0,71	1,10	4,14	0,50
Speak out	1,41	6,86	2,63	1,46	1,15	0,14	1,06	1,38	2,66	0,33
Fast Walking	0,59	5,84	1,01	1,60	0,80	0,05	0,66	3,87	3,25	0,36
Medium	0,77	3,83	2,16	1,61	0,81	0,08	0,69	1,68	2,56	0,37

PRISM has entrusted the control mission of module B to APAVE SUDEUROPE SAS

All the tests carried out to check our masks according to EN 149 have been entrusted to L'APAVE SUDEUROPE, CS60193 - 13322 MARSEILLE CEDEX 16 - France.

PRISM has entrusted the regulatory control task of type C2, as defined in Annex VII of EPI Regulation 2016/425

Module selected:	Module C2 Module D
Number of the Notified Body:	0082
Name of the Notified Body:	APAVE SUDEUROPE SAS
Address of the Notified Body:	CS60193 – 13322 MARSEILLE CEDEX 16 – France

PACKAGING FEATURES

The masks are placed in a recycled and autoclaved cardboard box that prevents moisture and the growth of bacteria or mould.

On request to **PRISM** the masks can be inserted in polypropylene pouches, either individually or by several.

Single box of: 40 pieces, without pouches - 20 pieces, in pouches

Box size: 250 mm x 100 mm x 95 mm Net weight: 285 gr (+/- 10 gr)

Packaging boxes in cartons: 600 mm x 400 mm x 400 mm

Carboard quantity: 37 boxes, or 1480 masks **weight cardboard:** 11.5 kg (+/- 300 gr)

Possibility of packaging in cartons of 1000 pieces, 25 boxes (on request), packaging in carton 500 mm x 500 mm x 260 mm.

STANDARD LABELLING

Model reference

Product Reference

LOT NO.

Quantity

Date of manufacture

Expiry date

Barcode (optional QR code)

CUSTOM PRINT FEATURES

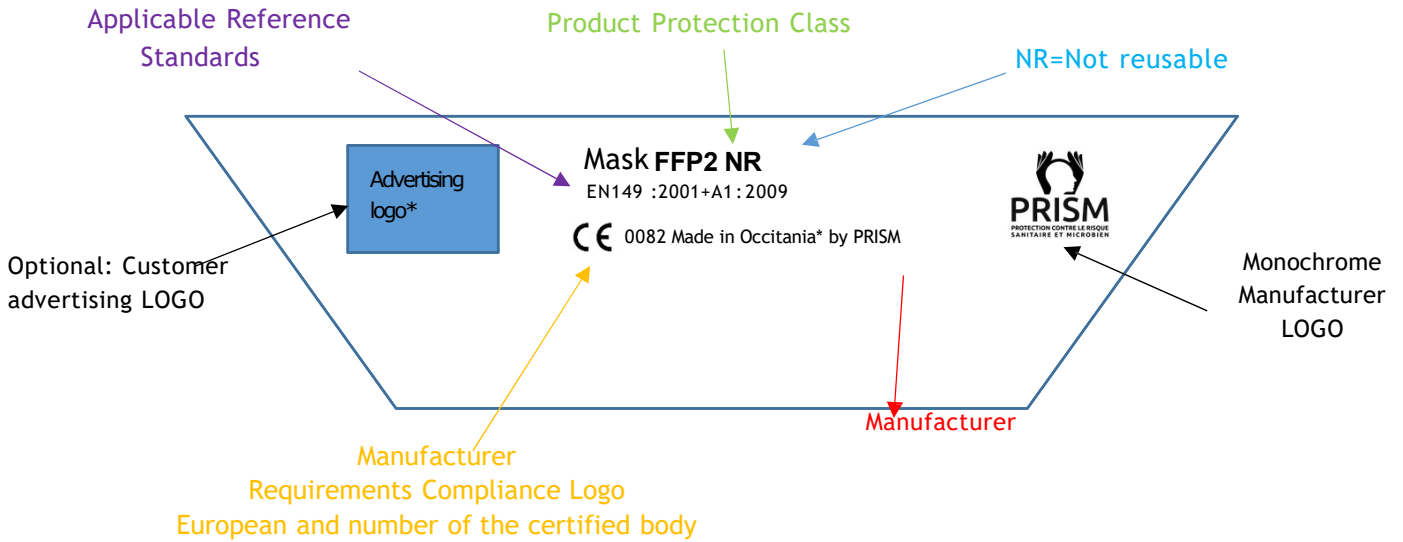
MASK PRINTING

Composition of inks:

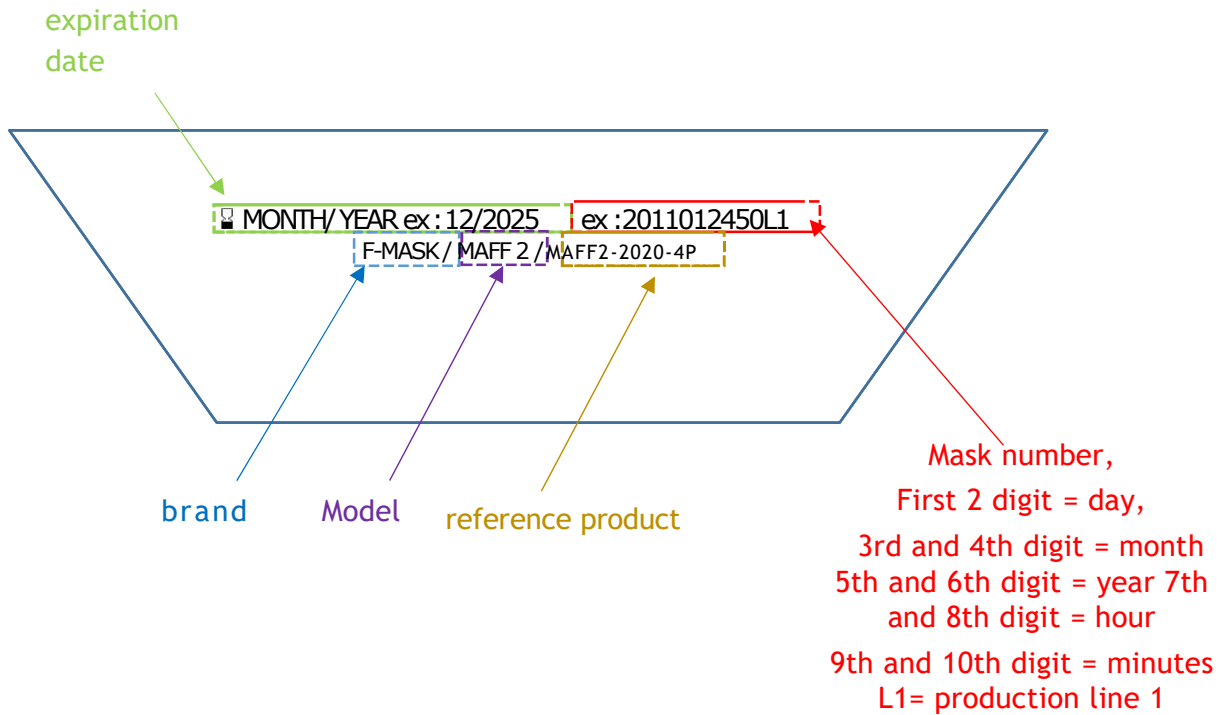
Color Black

Chemical name	Common name and synonyms	CAS number	%
Water		7732-18-5	70-95
2-pyrrolidone		616-45-5	<5
Carbon black		1333-86-4	<5

MARKING MASK FRONT



BACK



STORAGE CONDITIONS

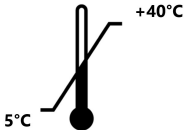
Normal storage and storage conditions:



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.

Instructions 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



WARNING

- 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

Instructions for use

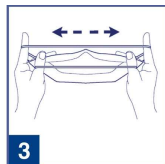
To put on his mask,



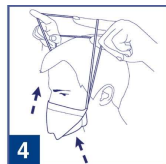
1
Separate the edges of the mask to fully open it.



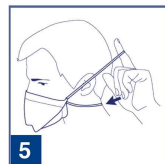
2
Fold the nasal barrette to hold the open respirator.



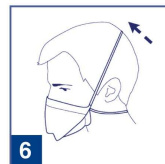
3
Separate each elastic link with indexes and thumbs.



4
Wedge the hollow formed mask under the chin and pass the elastics above of 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

Fit and leak check:

Mask seal must be checked prior to use

To check the seal of the mask:

- Put on your mask
- Adjust the wire pinch nose

- Blow with your mouth to make the mask 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

BEFORE USE

- Check the box before opening
- Check for moisture or mould
- Check for crushing of the box
- If in doubt change units or boxes

FURTHER INFORMATION

Masque FFP2 NR


L1


Modèle : MAFF2 Blanc

Référence : MAFF2-2020-4P

N° LOT: F20ABLX1-4P-100921

40 Pièces/Boites

 **09/2021**

 **09/2026**



1000011


Mask FFP2 NR (Brand in Production) L1 (Production Line)


Model: MAFF2 (Mask Model)

Reference: MAFF2-2020-4P (Mask Reference)

40 pieces (Number of pieces in box)

BATCH : ex : F20ABLX1-4P-100921 (Batch Number in Production)

 **Month / Year, ex: 09/2021 (Date of Manufacture)**

 **Month/year, ex: 09/2026 (Expiry date)**

CERTIFICATE OF CONFORMITY

Downloadable on www.prism-medical-protect.fr
or on request by email: qualite@prism-medical-protect.fr



DECLARATION DE CONFORMITE UE EU DECLARATION OF CONFORMITY

CE 0082

Nous déclarons sous notre seule responsabilité,
We declare, under our own responsibility, that the following product :

MASQUE DE PROTECTION RESPIRATOIRE FFP2 NR
Demi-masque filtrant de classe d'efficacité FFP2 NR
Marque : F-MASK – Modèle : MAFF2 (245 mm)

FFP2 NR RESPIRATORY PROTECTION MASK
FFP2 NR efficiency class filtering half-mask
Brand: F-MASK - Model: MAFF2 (245 mm)

Est conforme aux dispositions du règlement (UE) 2016/425 du Parlement européen et du Conseil, du 9 mars 2016, relatif aux équipements de protection individuelle et abrogeant la directive 89/686/CEE du Conseil.

Complies with the provisions of Regulation (EU) 2016/425 of the European Parliament and of the Council, of 9 March 2016, on personal protective equipment and repealing Council Directive 89/686 / EEC.

- Est classé comme EPI de catégorie III selon l'article 8.2
Have been classified as Category III according to article 8.2
- Répond aux exigences de l'annexe II
Fulfills to requirements of Annex II
- Est conforme à la norme EN 149:2001+A1:2009
Complies with EN149 :2001+A1:2009
- Est conforme à la norme EN14683+AC:2019
Complies with EN14683+AC:2019
- Est conforme à la Directive 93/42/CEE du Parlement européen et du Conseil
Complies with the provisions of Directive 93/42/EEC of the European Parliament and Council
- L'organisme notifié laboratoire Apave SudEurope SAS, N°0082, sis 17 Boulevard Paul Langevin, 38600 Fontaine-France, a effectué l'examen UE de type (module B) et a établi l'attestation d'examen UE de type numéro : 0082/3840/079/12/20/0887.
The notified body laboratory Apave SudEurope SAS, N°0082, located at 17 Boulevard Paul Langevin, 38600 Fontaine-France, has carried out the EU type examination (module B) and has issued the EU type examination certificate number : 0082/3840/079/12/20/0887.
- L'EPI a été soumis à l'évaluation de la conformité du module C2 sous la surveillance de l'organisme notifié laboratoire Apave SudEurope SAS, N°0082, sis 17 Boulevard Paul Langevin, 38600 Fontaine-France.
The PPE has undergone conformity assessment of the C2 module under the supervision of the notified body laboratory Apave SudEurope SAS, N°0082, located at 17 Boulevard Paul Langevin, 38600 Fontaine-France.

Nom et titre du signataire : Christian Curel, Directeur Général
Name and title of signatory : Christian Curel, Managing Director



PRISM
51, rue des Paluds
34110 FRONTIGNAN
Tél : 06 08 73 90 96
Siret : 888 059 532 00026

Lieu, date et signature : Frontignan, le 09 septembre 2021
Place, date and signature : Frontignan, september 09 2021

PRISM – 51 rue des Paluds, 34110 FRONTIGNAN
SAS au capital de 200 000 euros – VAT FR 82 888 059 532 – SIRET 888 059 532 00026-
DEC-005-QUA V1 – 09/09/2021

CERTIFICAT DE CONFORMITE

Downloadable on : ww.prism-medical-protect.fr





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

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

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

100% French confection mask by PRISM



CREATEUR	DATE	SIGNATURE
M.Krencker	09/09/2021	
APPROBATEUR	DATE	SIGNATURE
C.Curel	09/09/2021	

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

