



# PRISM

PROTECTION CONTRE LE RISQUE  
SANITAIRE ET MICROBIEN

## SURGICAL MASK DATA SHEET

**100% FRANCAIS**

### **TYPE IIR SURGICAL MASK**



**Model:** MACH2R

**Brand :** F-MASK

**Reference :** MACH2R-2020-3P (Blue)

MACH2R-2020-3PB (White)

MACH2R-2020-3PN (Black)

**Distributor manufacturer:**

**PRISM**

**ZI du Barnier, 51 rue des paluds**

**34110 FRONTIGNAN**

## **TECHNICAL FEATURES**

### **TPOLOGY:**

Single-use, non-sterile type II R surgical mask

### **PRECONIZATIONS:**

The purpose of the surgical mask is to prevent, when the wearer exhales, 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 the contamination of the patient's environment and its environment.

In addition, the medical mask protects the wearer from infectious agents Transmissible by droplet.

Under no circumstances does it protect against infectious agents that can be transmitted by air.

### **DESCRIPTION OF THE MASK:**

The mask is composed of several elements that have a specific function:

A screen arranged in several layers (called folds), the exteriors of which are not Polypropylene woven, called "SPUNBOND", an intermediate layer (media filter) provides filtration, called "MELTBLOWN".

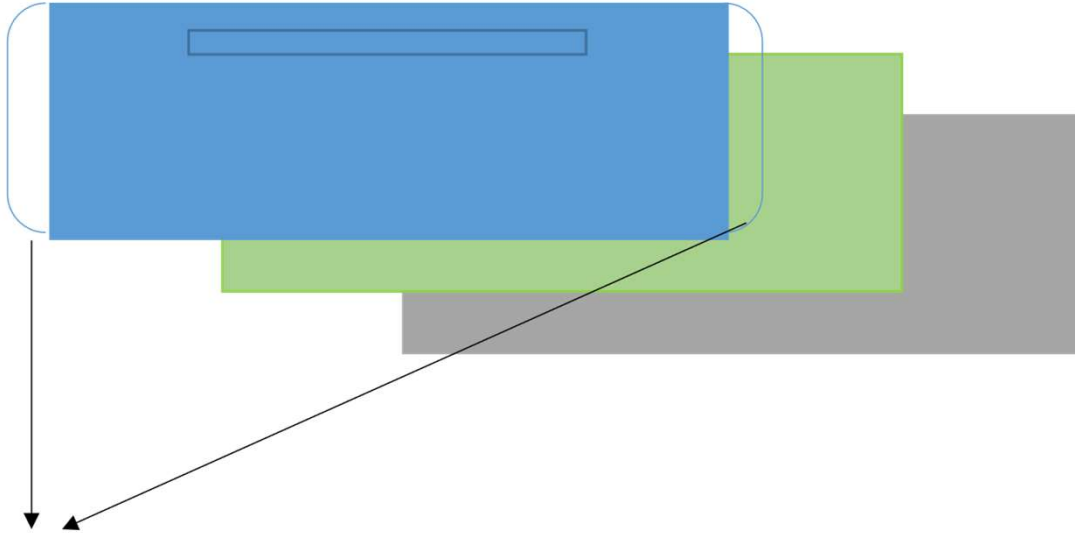
A nasal barrette, called a nose clip that adjusts the mask to the shape of the Nose, also avoid leaks and reduce fogging on the glasses.

Ear bindings (elastic), which allow the mask to be fixed to the face.

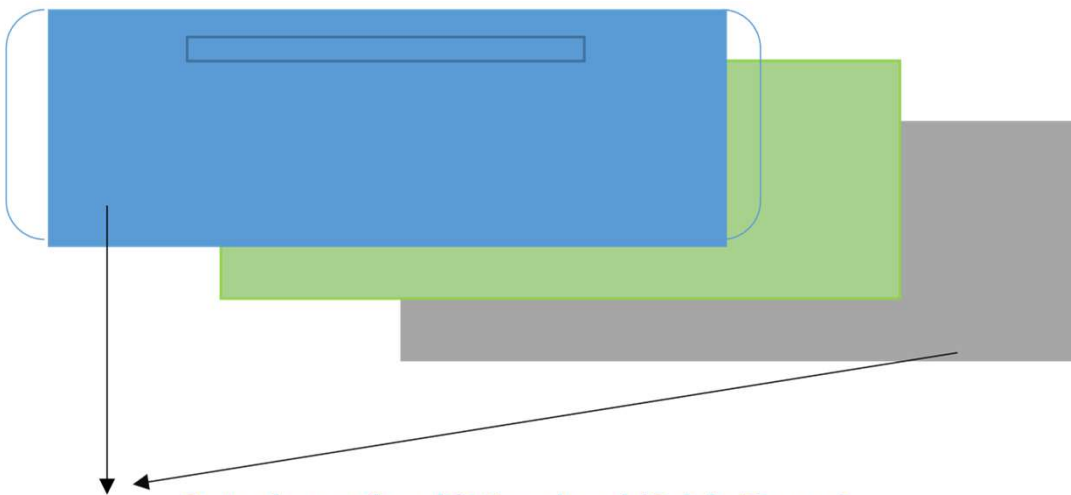
**EXTERIOR COLOR 1:** Possibility blue, white and black

**ASSEMBLY:** By ultrasonic welding

## Mask components:



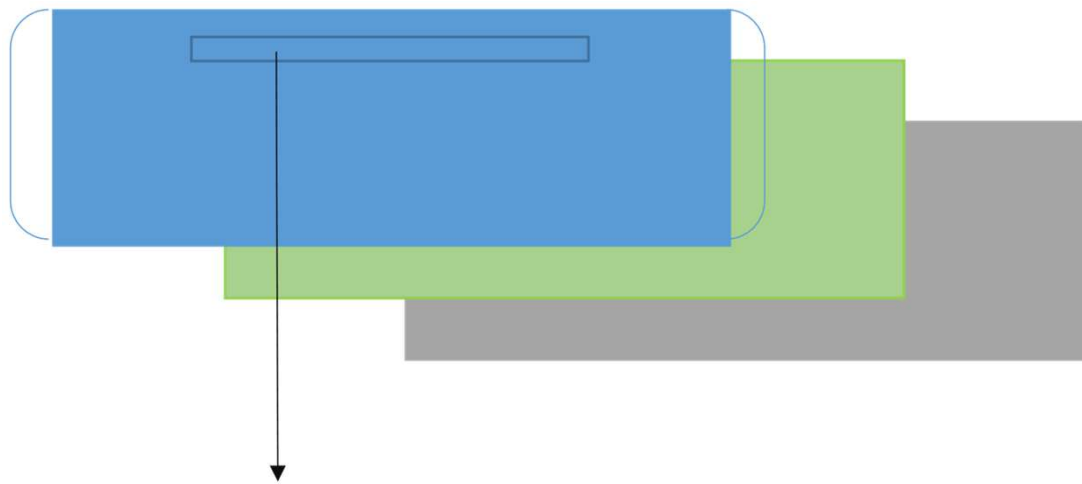
**Elastics:** (Non-EU origin), round tricotine type  $\varnothing$  0.25 in polypropylene and 13-15% elastane for 200% elongation, or flat tubular elastic 3-4 mm in polyester and spandex lycra for 240% elongation.



### Outer layers 1 and 2: Spunbond (Origin France)

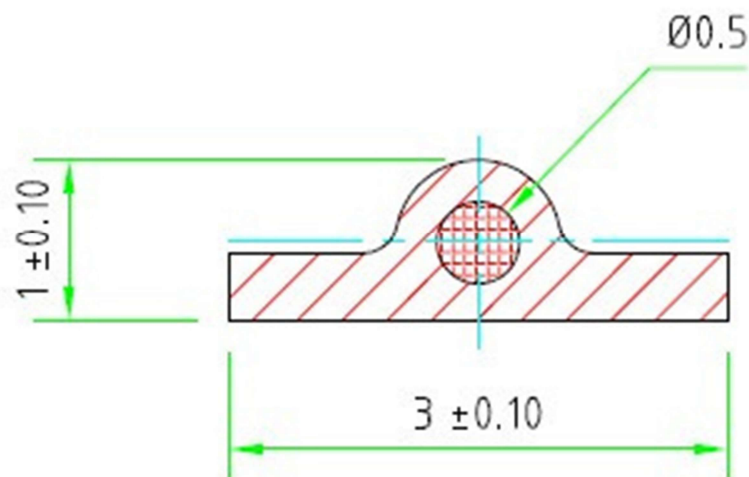
- 100 % polypropylene
- Weight 25 gr
- Melting point (°C) > 140
- Water insoluble
- Odorless

PARAMETRE	UNITE	MOYENNE TYPIQUE	METHODE TEST
Surface mass	gr/m <sup>2</sup>	26 ≥ 25 ≥ 24	WSP 130.1
Tensile strength in long direction (TM)	N/5 cm	60	WSP 110.4
Resistance to rupture in the cross direction (CD)	N/5 cm	19	WSP 110.4
Elongation at long-direction rupture (TM)	%	90	WSP 110.4
Elongation at break-through direction (CD)	%	90	WSP 110.4
Air permeability	l/m <sup>2</sup> /s	5000	WSP 70.1



Nasal barrette: (origin France)

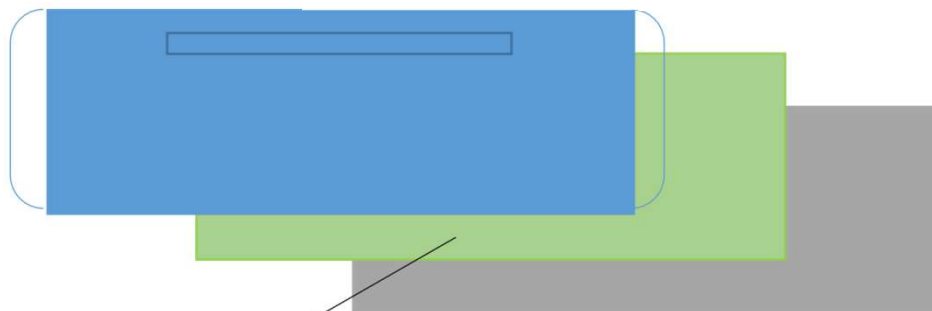
- Wire (steel) caught in polypropylene sheath





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**Filter layer: Meltblown**, filter material (Origin France)

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

	UNIT	SPECIFICATION	METHOD	TEST PARAMETER
Masse surfacique	gr/m <sup>2</sup>	25 +/-5 %		ISO 9073-1 ISO
Epaisseur	mm	0.29 +/-10%		9073-2 EN
Pression différentielle	Pa/cm <sup>2</sup>	<30		14683
Efficacité de filtration bactérienne	%	>98		EN14683 ISO
Résistance à la rupture sens long (MD)	N/5cm	>9		9073-18 ISO
Résistance à la rupture sens travers (CD)	N/5cm	>9		9073-18 ISO
Elongation à la rupture sens long (MD)	%	<60		9073-18 ISO
Elongation à la rupture sens travers (CD)	%	<85		9073-18

## SIZE:

95 mm +/- 5 mm



175 mm +/- 5 mm

## QUALITY CHARACTERISTICS

The mask is manufactured according to the recommendations of the standard: EN 14683 + AC 2019, type IIR, resistant to projections.

PRISM carries out quality checks as and when its productions.

PRISM has entrusted the control mission to the National Laboratory of Metrology and Testing (LNE).

All the tests carried out to check our masks according to EN 14683  
Were entrusted to the National Laboratory of Metrology and Testing (LNE).

**LNE**  
1, rue Gaston Boissier  
75724 PARIS Cedex 15

**All compliance reports 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)

## PACKAGING FEATURES

The masks are pre-packaged in a polyethylene film, transparent (only on request individual or multiple pouches on request) and/or boxed without film (standard) in recycled cardboard and autoclave to prevent moisture and the proliferation of bacteria or fungi.



**Single box of:** 50 pieces, possibility of individual or multiple pockets on request

**Box size:** 200 mm x 110 mm x 75 mm Net weight: 210 gr (+/- 10 gr)

### Packaging of boxes in cartons:

- 40 boxes in American box 600 mm x 400 mm x 400 mm or 2000 pieces, 9.4 kg/carton
- 50 boxes in American case 600 mm x 400 mm x 400 mm or 2500 pieces, 11.5 kg/carton

### Standard labelling:

- Model Reference
- Product Reference
- Batch No.
- Quantity
- Date of manufacture
- Expiry date
- Barcode (optional QR code)

## CUSTOM PRINT FEATURES

### ONE-COLOR OR FOUR-COLOR 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

##### Color yellow :

###### Mixtures

Chemical name	Common name and synonyms	CAS number	%
Water		7732-18-5	70-90
2-pyrrolidone		616-45-5	<10
Pigment Yellow*		Proprietary*	<5
2,4,7,9-Tetramethyl-5-decyne-4,7-diol		126-86-3	<1
1,2-Benzisothiazolin-3-one		2634-33-5	<0.1
2-methyl-2h-isothiazol-3-one		2682-20-4	<0.1

##### Color blue :

###### Mixtures

Chemical name	Common name and synonyms	CAS number	%
Water		7732-18-5	70-90
2-pyrrolidone		616-45-5	<10
Pigment Blue*		Proprietary*	<5
2,4,7,9-Tetramethyl-5-decyne-4,7-diol		126-86-3	<1
1,2-Benzisothiazolin-3-one		2634-33-5	<0.1
2-methyl-2h-isothiazol-3-one		2682-20-4	<0.1

##### Color red :

###### Mixtures

Chemical name	Common name and synonyms	CAS number	%
Water		7732-18-5	70-90
2-pyrrolidone		616-45-5	<10
Pigment red*		Proprietary*	<2.5
2,4,7,9-Tetramethyl-5-decyne-4,7-diol		126-86-3	<1
1,2-Benzisothiazolin-3-one		2634-33-5	<0.1
2-methyl-2h-isothiazol-3-one		2682-20-4	<0.1



## **STORAGE AND STORAGE CONDITIONS**

### **Normal storage and storage conditions:**



- Does not store in the sun
- Store UV-free
- Store in a protected location



- Store between 5°C and 40°C



- Store between 5°C and 40°C
- Do not store in a damp and weatherproof place Store in a dry place
- 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 4 hours Close box after use
- Mask to be discarded after use in a designated garbage
- Can and not in the wild

## **WARNING**

- The mask is not designed to protect its wearer from gases
- The mask cannot be used in an explosive atmosphere
- 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

## **CERTIFICATE OF CONFORMITY**



**DECLARATION DE CONFORMITE CE**  
**EC DECLARATION OF CONFORMITY**



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

**MASQUE CHIRURGICAL A USAGE UNIQUE TYPE IIR**

Marque : F-MASK – Modèle : MACH2R

**SINGL USE SURGICAL MASKS TYPE IIR**

Brand: F-MASK - Model : MACH2R

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

- Est classé comme Dispositif Médical de Classe I  
Has been classified as Class I Medical Device
- Répond aux exigences de l'annexe II  
Fullfills to requirements of Annex II
- Répond aux exigences de l'annexe VII+  
Fullfills to requirements of Annex VII+
- Est conforme à la norme EN 14683+AC:2019  
Complies with EN14683+AC:2019

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

**Lieu, date et signature :** Frontignan, le 24 Juillet 2021  
Place, date and signature : Frontignan, July 24 2021



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

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-001-QUA V1 – 24/07/2021

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





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

For any complaint, it should be sent by post,  
specifying the batch number and mask number:

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

100% French confection mask, by PRISM



CREATEUR	DATE	SIGNATURE
M.Krencker	24/07/2021	
APPROBATEUR	DATE	SIGNATURE
C.Curel	24/07/2021	

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

