



SURGICAL FACE MASK WITH ELASTICS, TYPE II, 3-PLY, WHITE



Non-contractual photo

Manufacture Française
des Pneumatiques Michelin

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Société en commandite par actions
au capital de 504 000 004 d'Euros.

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N° identification TVA FR 33855200507
Code Européen : 2211z





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Type II surgical masks are a medical device used to limit the transmission of viruses in particular airborne transmission. These masks are designed to prevent the projection of the wearer's upper respiratory secretions.

Designation

- Type II (*BFE \geq 98%) single-use surgical masks compliant with standard EN14683: 2019.
- Class I Medical Device pursuant to annex VIII of Regulation (EU) 2017/745 on medical devices.
- CE marking in compliance with Regulation (EU) 2017/745 on medical devices.
- CND code (Medical Device Nomenclature): T020699
- **Documentation for this mask (product data sheet, order form, EU declaration of conformity) can be found on our website: protective.michelin.eu**
- Made in France on the La Combaude site, Clermont-Ferrand, Puy de Dôme.

Description

- Flat mask made of three layers of non-woven polypropylene.
- Elastic loops on each side of the mask to secure it over the ears and ensure a good fit.
- Flexible metal nose strip so the mask can be adjusted for a close yet comfortable fit. It creates a tight seal for reduced fogging on glasses.

Manufacturer



MFPM Michelin
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63100 CLERMONT-FERRAND
France

**Single Registration Number
(SRN-Eudamed):**
FR-MF-000002723

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*BFE: Bacterial Filtration Efficiency

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Technical characteristics

Dimensions	175mm x 95mm
Color	WHITE
Unit weight	<4 gr
Materials	3 layers of non-woven polypropylene: Two inside and outside layers made of a spunbond non-woven textile for a soft feel on the wearer's face. An internal layer made of a meltblown non-woven textile for a high level of filtration and easier breathing. Hypoallergenic, latex-free, fiberglass-free. Elastics: round elastane/nylon or round elastane/polypropylene Nose strip: polypropylene-coated metal wire
Welding	Additive-free ultrasound (adhesive- and dye-free)
Sterile	No
Reference	White mask, per blister of 5: 707649 - White mask, without blister: 464395
Basic UDI-DI	0086699CHIRIU4

Technical performances

	Standard specification	Performance
Bacterial filtration efficiency: (Average particle size: $3\mu\text{m} \pm 0.3$)	$\geq 98\%$	$\geq 98\%$
Breathing resistance	<40 Pa/cm	<40 Pa/cm ²
Microbial cleanliness	≤ 30 UFC/g	<30 UFC/g
Biological Risks – Cytotoxicity	ISO 10993-5	Result in accordance with the standard
Biological Risks - Sensitization and Irritation	ISO 10993-10	Result in accordance with the standard

Packaging

- Box of 50 masks, 10 blisters of 5 masks
- or
- Box de 50 masks, without blister

Maintenance and storage condition

- Keep away from humidity and sunlight
- Storage temperature between 5°C and 35°C
- Period of validity of the product: 2 years

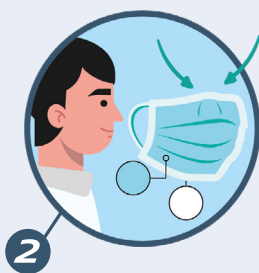
Terms of use

- **Single use**
- **Usage time:** 4 hours maximum. Change the mask if it is wet
- **Mask wearing direction:** Logo outward and positioned on the right cheek

HOW TO USE A SURGICAL FACE MASK ?



1 Wash hands with soap or hydroalcoholic gel.



2 Place and put on the mask: metal strip upwards and Michelin logo on the outside.



3 Tie it behind the ears with the rubber bands.



4 Pinch the metal strip (the hard edge) of the mask to fit the shape of the nose.



5 Pull the bottom of the mask to cover the mouth and chin.



6 Wash hands with soap or hydroalcoholic gel before removing the mask.



7 Remove mask without touching the front, away from face and clothing.



8 Immediately after use, dispose of the mask in a closed trash bag.



9 Wash hands with soap or hydroalcoholic gel.

Indications/contraindications

Indications :

Wearing a mask may be indicated in the event of a viral pandemic to prevent or lower the risk of airborne transmission. Wearing a mask is also recommended when treating a patient in order to avoid any risk of airborne transmission of a disease from the healthcare worker to the patient.

Contraindications:

There are no strict contraindications to wearing a surgical mask. In the event of intolerance, seek medical advice quickly.

Benefits/Risks

As there is no identified risk and the effectiveness of a surgical mask in preventing the risk of transmission has been demonstrated, the benefit/risk ratio of wearing a mask is high.



Special precautions

SINGLE-USE: do not wash masks

Failure to comply with recommended wearing times and/or reusing masks reduces the level of protection afforded and may affect the user's health.

Warning: this product is not personal protective equipment. To protect yourself from solids or liquids suspended in the air, use a respirator that complies with the standard EN149:2001 (Regulation (EU) 2016/425 on personal protective equipment).

In the event of a serious incident in connection with a mask, please email us at: protective@michelin.com

Significance of symbols used



Manufacturer



Catalog reference



Expiration date



Manufacturing date



Batch code



Store away from sunlight



Protect from humidity



Temperature limit



Single use