

# OCOV<sup>®</sup> mask positioning

## Alternative half mask usable more than 100 times



### 1. Certification

- The OCOV<sup>®</sup> mask in accordance with Regulation (EU) 2016/425 is subjected to an application for an EU type examination certificate according to standard EN 1827: 1999 + A1: 2009 with the competent notified body.
- Recommendation 2020/403 of March 13, 2020 of the European Commission establishes a temporary derogation from the prior obtaining of the EU certificate for the authorization to market COVID 19 protective masks.
- The authorization to place on the market the OCOV<sup>®</sup> mask is based on a technical and compliance file which meets the requirements for alternative masks and standard EN 1827.

### 2. Reminder

<p><b>Surgical mask:</b> Standard EN 14683 "Mask for medical use"</p> <ul style="list-style-type: none"> <li>• Cover the nose, the mouth and the chin.</li> <li>• Only made of a filter material.</li> </ul>  <p>"Alternative » Ouvry surgical mask"      Surgical mask</p>	<p><b>Mask FFP (Face Filter):</b> Standard EN 149 "Filter mask against particles"</p> <ul style="list-style-type: none"> <li>• Cover the nose, the mouth and the chin.</li> <li>• Mainly made of a filter material, with a possible exhalation valve.</li> </ul>  <p>Mask FFP2</p>	<p><b>Mask model FMP (Face Mask):</b> Standard EN 1827 "Mask with removable filters against particles"</p> <ul style="list-style-type: none"> <li>• Made of a face piece covering the nose, the mouth and the chin with replaceable filters.</li> <li>• Airtightness maintained even on wet skin, when the wearer moves his head and speaks.</li> <li>• The inhaled and expired air are filtered.</li> </ul>  <p>OCOV<sup>®</sup></p>
<p>Works from the inside to the outside to limit the transmission of infectious agents from caregivers to patients.</p>	<p>Work in both directions:</p> <ul style="list-style-type: none"> <li>- Protect the carrier from infectious particles and aerosols coming from outside.</li> <li>- Avoid projection of bronchial secretions outwards,</li> </ul>	

### 3. Standards

Type of mask:		Surgical	FF	FM
Standard:		EN 14683	EN 149	EN 1827
Filter:	Particles size	3µm	0,06µm-0,1µm	<b>0,06µm-0,1µm</b>
	Filtration	Type I > 95%	P1 > 80%	<b>P1 &gt; 80%</b>
		Type II > 98%	P2 > 94%	P2 > 94%
		Type IIR : projections	P3 > 99%	P3 > 99,95%
		<u>Exemption DGA/DGE for alternative masks (3µm):</u> <b>Categorie 1 &gt; 90%</b> Categorie 2 > 70%		
Mask:	Leakage rate to the inside	Non applicable	P1 < 22% P2 < 8% P3 < 2%	<b>P1 &lt; 2%</b> P2 < 2% P3 < 2%
	Fit test	Non applicable	Fit test (without negative pressure)	<b>✓ Fit test</b>
Resistance to inspiration 95l/min		<u>DGA/DGE recommendations for alternative masks:</u> <b>Air-permeability &gt; 96l/m<sup>2</sup>/S</b>	P1 : 2,1 mbar P2 : 2,4 mbar P3 : 3 mbar	<b>P1 : 2,1 mbar</b> P2 : 2,4 mbar P3 : 4,2 mbar
Resistance to exhalation 95l/min			3 mbar	<b>3 mbar</b>

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### 4. Technical statements of the OCOV® mask

Parameters:	Standards:	Results:	Classification:
<b>Protection:</b>			
Particle filtration rate 0,1µm mono-disperse	EN 1827	> 80% - tested at CEA*	Protection level equivalent to FM P1 according to EN 1827
Particle filtration rate 3µm	EN 14683 according to DGE/DGA 04/2020 recommendations	> 99% - tested at DGA*	
Average leakage rate inward	Portacount	< 2%*	
Inhaled CO2 rate	EN 1827	< 1%	
<b>Ergonomics:</b>			
Ergonomists evaluation (industrial, health)*	No voice attenuation, no fogging Compatible with glasses, helmets and long-term wear		
<b>Maintenance:</b>			
Reusable filters	Each reusable filter is disinfected 20 times. Reusable filters can be disinfected by a heat treatment 1h at 75°C ± 5°C: in a dryer (subject to putting the filters in a wash net), or flat drying in an oven, or in an autoclave (subject to placing the filters in an airtight bag and adjusting the autoclave to 75°C ± 5°C).		
Mask	Apply an alcohol spray or a virucid solution wipe after possible cleaning by soaking the mask in soapy water for very dirty masks (blood, secretions, grease, ...)		
<b>Non-toxicity:</b> Does not contain latex. FDA skirt material. REACH-compliant strap material. *			

These results are applicable for both reusable and non-reusable filters.

	Conception - Ergonomics	Protection	Ecological	Cost	Availability	Autonomy
<b>FFP / surgicals</b>	Disposable filter material and elastics	+	-	Very high cost of use: 1 to 2€	High risk of supply disruption	Importation
<b>OCOV®</b>	Real light and comfortable mask, disinfected and changeable filters	+++ Better fit	++ RSE	Cost of use between 0,10€ et 0,25€ (public rate)	> 3 months of use before supply of consumable filters. 5 years lifetime.	Made in France

1 OCOV® mask replaces 100 disposable masks

### 5. \*List of tests reports:

- Protection performances:**
  - DGA report RP203230: 3µm particles penetration test
  - CEA report 0,1µm particles filtration performances
  - PORTACOUNT report measure of adjustment coefficient : NT-20-1185
  - Report on evaluation of maintain of filtration and breathability performance after disinfection of the filters : NT-20-1158
- Breathability performances:**
  - DGA report RP203230: measurement of air permeability
  - Measurement of respiratory resistances on OUVRY test bench according to EN 136 :1998 NT-20-1153
  - Report on respiratory resistance after humidification NT-20-1183
  - INPP report : 2020-27-RAP-MASQUE OCOV S
  - Report of inhaled CO2 rate IRBA : NT-10-1160
- Ergonomics / field performance testing:**
  - CEA report : field performance testing
  - CHU Grenoble report : ergonomic evaluation report
  - HCL report : ergonomic evaluation report
  - Field performance testing OUVRY: NT-20-1154
- Other:**
  - OCOV® technical datasheet FT-100011AA
  - OCOV® operating instruction NT-20-1137
  - OCOV® marking : NT-20-1152
  - Set up and removal tutorial
  - Filters change tutorial
  - Filters and mask maintenance tutorial
  - Accelerated aging report : NT-20-1164
  - Expert report on disinfection methods
  - Interfacing tests NT-20-1166
  - Certificate FDA/REACH/CEKO-TEX/skin compatibility of OCOV® mask components NT-20-1190
  - Filters SDS - Safety Data Sheet
  - Flame resistance properties of OCOV® mask : NT-20-1187

Requirements EN 1827:	OCOV® compliance*:
7.1 General	✓ CONFORM
7.2 Nominal values and tolerances	✓ CONFORM
7.3 Visual inspection	✓ CONFORM
7.4 Materials	✓ CONFORM
7.5 Flammability	Non applicable
7.6 Cleaning and disinfection	✓ CONFORM
7.7 Filter material	✓ CONFORM
7.8 Finishing of parts	✓ CONFORM
7.9 Removable parts	✓ CONFORM
7.10 Straps set	✓ CONFORM
7.11 Connections	✓ CONFORM
7.12 Expiratory valves	Non applicable
7.13 Packaging	✓ CONFORM
7.14 Weight	✓ CONFORM
7.15 Capacity of the antigas filter	Non applicable
7.16 Penetration of the particulate filter	✓ CONFORM
7.17 Clogging (optional)	Non applicable
7.18 Compatibility with the skin	✓ CONFORM
7.19 Carbon dioxide content of inhaled air	✓ CONFORM
7.20 Respiratory resistance without clogging	✓ CONFORM
7.21 Leakage to the inside	✓ CONFORM
7.22 Visual field	✓ CONFORM
7.23 Practical tests of performance	✓ CONFORM
9. Marking	✓ CONFORM
10. Manufacturer operating instructions	✓ CONFORM

**"They protect us, let's protect them"**

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