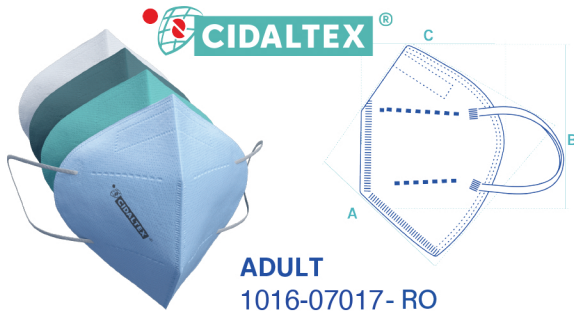


## The Mask



## Dimensions and Weight

<b>Masks</b>	A	127 ± 5 mm
	B	160 ± 5 mm
	C	107 ± 5 mm
<b>Elastic Straps</b>	Length	180 ± 10 mm
	Thickness	3 ± 1 mm
<b>Nose Clip</b>	Length	100 ± 10 mm
	Width	5 ± 1 mm
	Thickness	0.6 ± 0.1 mm
<b>Weight</b>		0.25g
<b>Packaging</b>	Pouch	5 masks

## Main Characteristics



**Medical Device conformed to European Directive 2017/745 Certified to EN 14683 Standard**

- Superior filtration and breathability (EN 149, FFP2 grade)



**Made in France**

- Production factory in Troyes
- Raw European materials

**FFP2 grade advanced filtration reduces risk of transmission via droplets and aerosols.**

- Bacterial Filtration Efficiency\* > 98%
- Differential pressure < 60 Pa / cm<sup>2</sup>
- Splash resistance pressure ≥ 16kPa
- Penetration of liquid and solid aerosols\*\* < 6%
- Average inward leakage < 8%

**CIDALTEX®**

**Air Decontamination Technology**

- Integrated within the filtration layer of the mask **CIDALTEX® eliminates viruses and bacteria.**
- Reduction of 4 log (99.99% effective) in 2hr. for *E. coli* and *S. aureus*\*
- > 3.4 log (99.96% limit of detection) in 20min. for Human Coronavirus 229E

**99.99% efficacy in 2h. for SARS-CoV-2 (hCoV-19/France/OCC-IHAP-VIR12/2020).**

**Breathable and Comfortable Mask**

- Soft interior surface upon the skin
- Efficient air permeability allows for natural breathing (breathability according to standard EN149)
- Recommended wear time: 4h

## Description

Recommended for healthcare professionals who work in areas with medium to high probability of viral presence in the ambient air.

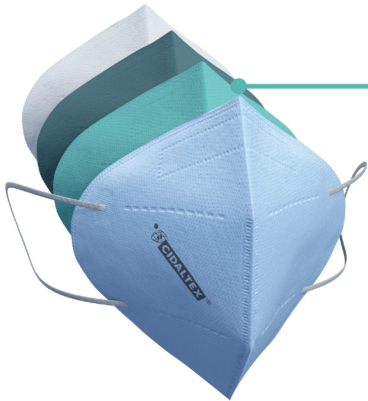
*Viruses are transmitted through droplets, emitted when a person speaks, coughs, sneezes; or are spread through viral aerosols at high concentrations in ambient air.*

The **CIDALTEX® FFP Medical Mask Dual Action – Filtration & Decontamination** is a medical device manufactured by BioSerenity that combines the filtration efficiency of FFP2 grade masks with the air decontamination technology of **CIDALTEX®**, which integrates antibacterial and antiviral properties.

The mask retains the filtration quality of FFP2 masks, which not only lowers the risk of transmission (if the wearer is infected), but also substantially reduces the risk of contamination by environmental factors. The user is effectively protected against infectious agents transmitted by "aerosols" or "droplets" (via inhalation/exhalation).

The addition of **CIDALTEX® technology** to one of the mask's filter layers permits the decontamination of air inhaled and exhaled by trapping infectious agents and destroying them via a decontaminant agent. This layer significantly enhances the user's level of protection by eliminating bacteria and viruses filtered within the mask.

**CIDALTEX® technology provides anti-bacterial and anti-viral protection**

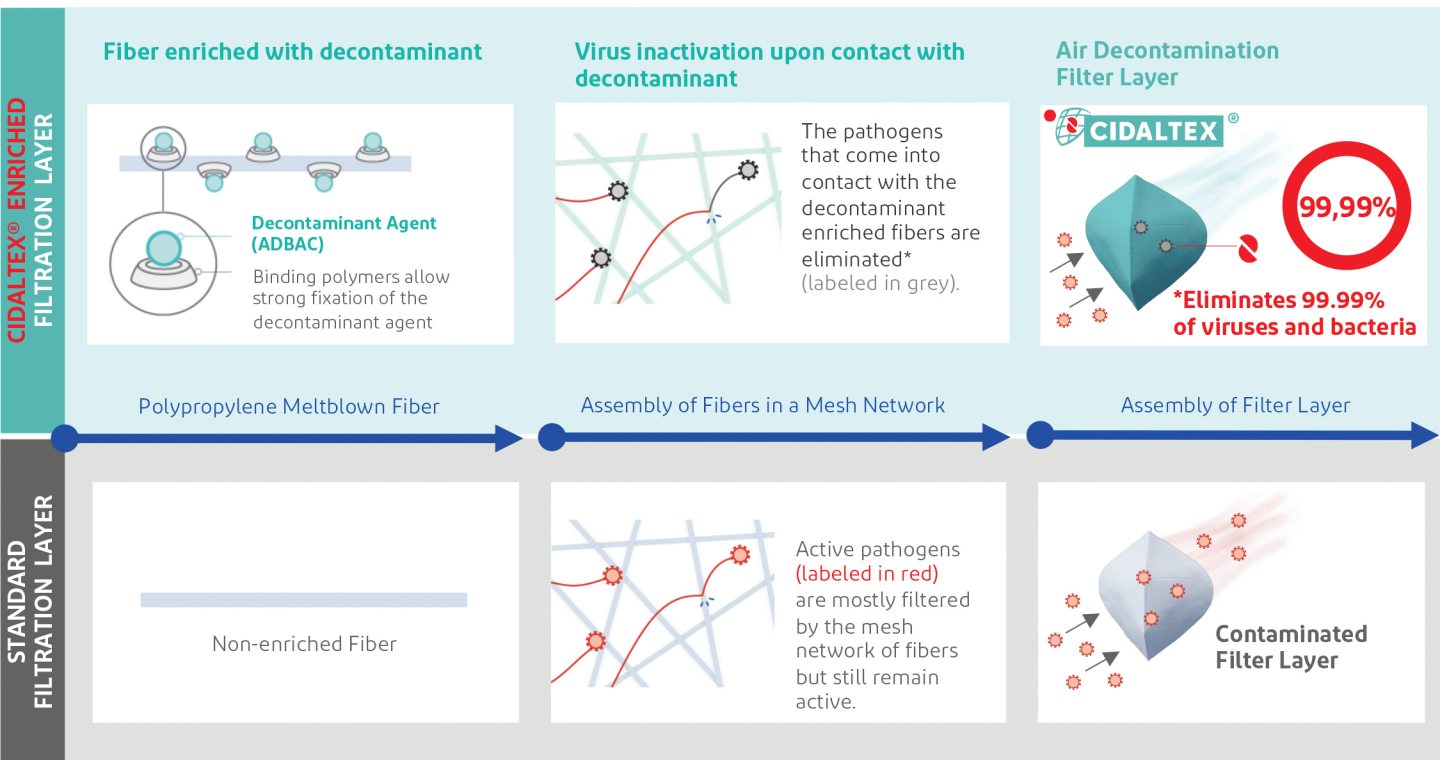


**Decontamination Filter Layer**

Isolated between protective mask layers to avoid direct contact between the decontaminant and the skin.

Technology developed by BioSerenity in collaboration with the **University of Lille and INSERM**.

The layer functionalization grafting process is based on the scientific work from the **University of Lille**.



**ADBAC, a well-known decontaminant with a wide range of action**

The decontaminant agent contained in the mask polymers is Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC), and has properties against viruses, bacteria, and fungi.

This antibacterial agent is widely used in many pharmaceutical products such as sanitary skin solutions, body lotion, and hand wipes. It is also known as benzalkonium chloride (BAC).

**A technology with 99.96% efficacy, and tested in accredited laboratories**

The mask was tested for decontaminant leakage: under normal conditions of use, the decontaminant (ADBAC), contained within the internal functional layer, **does not detach nor escape outside of the mask**, and thereby avoids any direct contact between the skin and the decontaminant agent.

**The efficacy of the decontaminant on the mask was tested:**

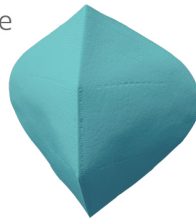


**i-CARE LAB**  
 Performed mask tests for bacterial filtration and microbial cleanliness. (Standard EN 14683)

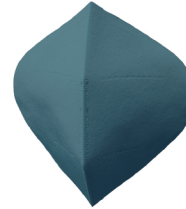
\* 4 log (99.99% efficacy) in 2h. for *E. coli* and *S. aureus*; > 3.4 log (limit of detection: 99.96%) in 20min. for Human Coronavirus 229E  
 99.99% efficacy in 2h. for SARS-CoV-2 (InCo / 19/France/CCG II/AF / B12/2020).

## Composition

- Ear Loops :** polyamide and elastane, latex, and rubber free
- Nose Clip :** flexible composite (presence of polyethylene, steel)



Isolated between protective mask layers to avoid direct contact between the decontaminant and the skin.



Layer	Exterior (1)	Air Flow Decontamination	Filter (3)	Interior (4)
<b>Purpose</b>	Anti-droplet protection and mask barrier	Advanced filtration and inactivation of infectious particles	Advanced filtration FFP2 grade	Protection, mask wear and comfort
<b>Substance</b>	Polypropylene	Polypropylene	Polypropylene	Polypropylene
<b>Non-Woven Fiber</b>	Spunbond	Meltblown and Spunbond	Meltblown	Spunbond
<b>Density</b>	25 ± 5 g/m <sup>2</sup>	50 ± 10 g/m <sup>2</sup>	25 ± 5 g/m <sup>2</sup>	25 ± 5 g/m <sup>2</sup>
<b>Color</b>	Blue	White	White	White

## Certifications (CE marked)



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

MANUFACTURER / FABRICANT: BioSerenity, ICM IPEPS, 47, Boulevard de l'Hôpital, 75013 Paris, France

DESIGNATION: Biocide - FFP Mask

PRODUCT REFERENCE / REFERENCE PRODUIT: 1016-07013-FR

UDI NUMBER / NUMERO IUD: 08615220002535

GMDN CODE / CODE GMDN: 35177

CLASSIFICATION: I rule 1, II rule 1

CONFORMITY ASSESSMENT ROUTE / EVALUATION DE LA CONFORMITE: Annex VII - CE declaration of conformity

We hereby declare that the above-mentioned products meet the transposition into national law provisions of council Directive 93/42/EEC for medical devices as amended by Directive 2007/47/EC. All supporting documentation is retained at the premises of the manufacturer.

PLACE: Paris

DATE OF ISSUE / DATE: February 16<sup>th</sup>, 2021

SIGNATURE: 

NAME / NOM: Julien Dupont

POSITION / TITRE: Quality and Regulatory Affairs Director / Directeur Qualité et Affaires Réglementaires

Biocide FFP2\_Mask\_CE Declaration of conformity - C0C-00054A

## Precautions for Use

### Security

- Do not use in the case of a known allergy to benzalkonium chloride
- Medical device containing an enclosed air decontaminating layer with anti-viral and anti-bacterial actions verified in accredited laboratories.
- Laboratory-tested fixation of the decontaminant agent (ADBAC) to avoid skin contact or inhalation under the recommended conditions of use.
- In the event of an allergic reaction, remove the mask immediately.
- Do not touch the front of the mask with your hands while wearing it.
- Change the mask as soon as it becomes wet, at least every 4 hours.

### Storage

- Store away from direct sunlight, dust, and humidity.
- Masks can be stored for 5 years.

### Discard and replace the mask if it:

- is damaged or becomes wet
- interferes with breathing
- is contaminated with one or more fluids, bodily or any other infectious elements.

## Superior filtration and breathability (EN 149, FFP2 grade)

Inward Leakage (EN 149 chap.7.9.1)	< 11%
Average Inward Leakage	< 8%
Penetration of Filter Material (EN 149 chap.7.9.2)	Solid (NaCl) : < 6% Liquid (paraffin oil) : < 6%
Breathing Resistance – Inhalation (EN 149 chap.7.16)	30 L/ min : 0.7 mBar 95 L/min : 2.4 mBar
Breathing Resistance – Exhalation	160 L/min : 3.0 mBar
Advised Wear Time	4 hours