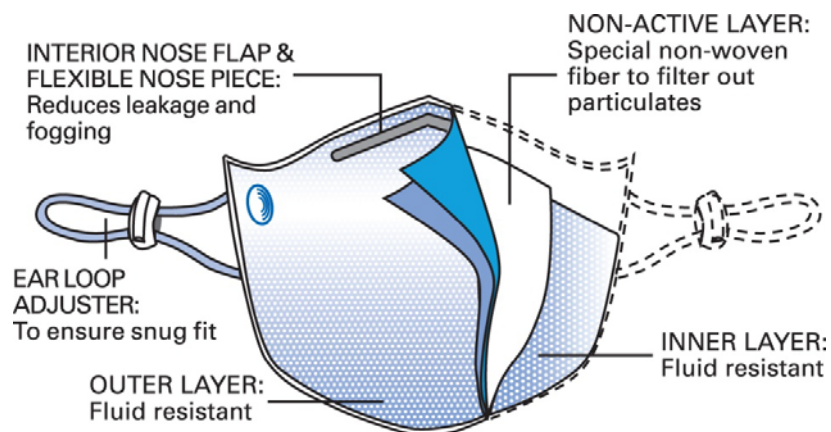


 **BioFriend**<sup>TM</sup>  
**BIO  
MASK**<sup>TM</sup>

## Frequently Asked Questions



## Table of Contents

Frequently Asked Questions .....	1
1. What viruses and bacteria does the BioMask™ detect, trap and kill?.....	3
2. How does the BioMask™ work? What is the active ingredient? .....	3
3. Can the microbe-killing mechanisms or ingredients harm me? If the BioMask™ can kill germs so effectively, why doesn't it harm me? .....	3
4. What tests have been conducted to ensure that the BioMask™ is safe for humans? .....	4
5. What is the CE mark and the significance of CE certification? .....	4
6. Can such an anti-microbial product reduce my or my family's immunity? .....	4
7. Can the BioMask™ create resistant germs?.....	4
8. How does the BioMask™ compare with ordinary face masks? With N95's? .....	4
9. Is the BioMask™ breathable and comfortable to wear for long periods?.....	5
10. How long can the BioMask™ be worn?.....	5
11. Is the BioMask™ effective when wet? Can I wash and reuse it? .....	6
12. Does the BioMask™ come in child sizes?.....	6
13. Can the BioMask™ provide protection during an influenza pandemic, such as swine flu? .....	6
14. How can the BioMask™ help humanitarian efforts? .....	6
Important Information – Frequently-Asked Questions .....	6

## 1. What viruses and bacteria does the BioMask™ detect, trap and kill?

The BioMask™ detects and traps most bacteria and viruses and kills them within minutes. It particularly targets and destroys those that cause infectious respiratory diseases such as:

- Influenza Viruses – which include seasonal and potential pandemic strains like H5N1 (bird flu) H1N1 (swine flu)
- Common cold viruses and other respiratory viruses – which include Rhinovirus and SARS
- Microbacteria – which include the agents causing tuberculosis and their drug-resistant forms
- Bacteria-causing pneumonia – which includes *Streptococcus pneumoniae*
- Measles virus

It is also effective against germs that cause non-respiratory diseases, such as MRSA (methicillin-resistant *Staphylococcus aureus*), a leading cause of hospital-acquired infections, and Herpes Simplex Virus. The active BioFriend™ textile is shown to kill most germs within minutes of contact. For further technical details, see Summary of Independent Laboratory Testing.

## 2. How does the BioMask™ work? What is the active ingredient?

In summary, the BioFriend™ textile **CAPTURES** pathogens by mimicking the attachment sites on human cells to which they normally bind and **DESTROYS** them by disruption of their surfaces (viruses) and cell walls (bacteria).

Many viruses, including influenza viruses, are known to bind to human cells through oligosaccharides attached to cell membrane glycolipids or glycoproteins and, specifically, to a terminal sialic acid residue on a surface oligosaccharide of the cell membrane. The binding agent in the BioFriend™ textile mimics the binding action of sialic acid on influenza viruses. This technique is often called 'molecular mimicry'.

A safe component approved by the USA FDA functions as the binding agent. This component creates a negative charge at the molecular level, attracting microbes through electrostatic forces. Copper and zinc ions then kill the microbes. These metal ions kill pathogens by disrupting their viral envelope and bacterial walls, as well as by creating an ion imbalance in the bacteria or virus that inhibits normal metabolism.

## 3. Can the microbe-killing mechanisms or ingredients harm me? If the BioMask™ can kill germs so effectively, why doesn't it harm me?

The BioMask™ is deemed safe when used as intended. It has met or exceeded ISO standards for biocompatibility. See FAQ 4 (below). The anti-microbial components have been approved for biomedical use by the USA FDA in sutures and contact lenses, for example. Copper and zinc are essential to human health and are an important part of a human being's daily nutritional intake because they contribute to the function of numerous essential processes in the body, including wound healing.

Multi-cellular higher organisms, such as humans, possess mechanisms which bind or transport away copper and zinc ions. Single-cell organisms, such as bacteria and viruses, don't possess such efficient mechanisms and are easily killed by miniscule

amounts of these compounds. Therefore, copper and zinc are very toxic to bacteria and viruses but not to humans.

#### 4. What tests have been conducted to ensure that the BioMask™ is safe for humans?

The BioMask™ achieved CE certification on 13 February 2009. Filligent, the manufacturer has met or exceeded the requirements of CE certification relating to human safety for a device of this kind. Independent studies of the BioMask™ confirm that, when assessed in terms of all the major routes of exposure, oral, dermal and inhalation, the active ingredients used in the BioMask cause no harmful effects on isolated human cells.

Pursuant to CE requirements, the BioMask™ has been tested for dermal biocompatibility following internationally recognised standards set out in ISO 10933: Biological Evaluation of Medical Devices. Tests were conducted to evaluate cytotoxicity to cells, skin irritation on contact, and skin sensitisation after repeated contact. No cytotoxicity, irritation or incidence of sensitisation was observed.

For further technical details see Summary of Independent Laboratory Testing.

#### 5. What is the CE mark and the significance of CE certification?

The CE (Conformité Européenne) mark is a conformity mark required to market certain products in the European Community. The CE mark is mandatory for certain product groups to indicate conformity with the essential health and safety requirements set out in European Directives. The BioMask™ has achieved certification pursuant to the European Community's Medical Devices Directive 93/42/EEC, meaning that Filligent has met the stringent EU requirements for design, efficacy and safety for this type of medical device.

#### 6. Can such an anti-microbial product reduce my or my family's immunity?

No. The immune system is inside the body and is activated only when pathogens enter inside the body. The BioMask™ keeps germs outside the body and kills germs before they enter the body. Therefore it has no effect on the body's immune system.

#### 7. Can the BioMask™ create resistant germs?

Germs can only develop defence mechanisms (i.e resistance mutations) when proliferating inside the human body in the presence of a drug. The BioMask™ keeps the germs outside the body and kills microbes before they can enter the body. Therefore, use of the BioMask™ does not result in microbes developing resistance to either the BioMask or drugs.

#### 8. How does the BioMask™ compare with ordinary face masks? With N95's?

**Typical face masks (including standard surgical masks and N95's) do not kill airborne pathogens.** They are based on a passive mechanical filtration design, where the live bacteria and viruses in droplets are drawn, by the breathing of the wearer, *on to* the surface of the mask. Sometimes live micro-organisms are also drawn *in to* the mask material layers, where the pathogens are captured by simple mechanical filtering. Many more are too small to be captured and are inhaled by the wearer. The microbes on the

surface of the mask and/or trapped inside the mask can stay alive for many hours. These live pathogens can now be transmitted to the wearer and other people.

As part of the CE testing process, the BioMask™ was sprayed with live aerosolised Influenza A virus equivalent to 50 times the amount contained in a normal sneeze. (Bird flu and Swine flu are strains of the Influenza A virus.) the BioMask™ killed this massive viral load, with more than 99.9% of the viruses killed after less than one minute. Tests were conducted on other key pathogens, with similar results. In a direct comparison between the BioMask™ and the leading N95, no surviving virus was recovered from the BioFriend™ active layer after 10 minutes of contact with live Influenza A viruses, whereas 50,000 viruses remained alive within the layers of the leading N95 mask at the end of the same period. For further technical details, please consult our Summary of Independent Laboratory Testing.

In the case of a standard surgical or N95 mask, cross-contamination can easily occur by touching the microbe-laden mask. This is a particularly risk for mask disposal. Ill-fitting, uncomfortable or poorly-ventilated masks exacerbate handling and cross-contamination.

Filligent's BioMask™ uses a special 'intelligent filtration' system, designed specifically to overcome these major drawbacks and presents a significant level of increased protectiveness. The BioMask™ is fabricated from a scientifically designed and tested multilayer material which has in its internal structure a unique active layer which has highly targeted anti-microbial properties. This active layer aggressively detects, traps and then rapidly kills pathogens without affecting airflow.

A high density non-woven textile layer behind the active layer also captures any pathogens that may happen to penetrate beyond the active layer. Any such pathogens are then held in close proximity to the BioFriend™ textile and killed rapidly.

**When compared to the N95, the BioMask™ is far superior in terms of comfort, breathability AND efficacy: the mechanical filtration of the BioMask™ is as effective as the N95's PLUS the BioMask™ kills microbes.** Testing with an aerosol challenge of Influenza A virus showed the BioMask™ to have comparable mechanical filtration to the N95 with >99% of viruses filtered. Because N95's rely entirely on physical barrier and filtration design, they are very tight-fitting, uncomfortable and hard to breathe in.

## 9. Is the BioMask™ breathable and comfortable to wear for long periods?

Yes, it provides all-day comfort and use. The intelligent filtration system in Filligent's BioMask™ allows for a mask design where pressure drop across the face mask layers is kept low, making the mask highly breathable. Heat and moisture do not build up, allowing for comfortable wear over long periods. By contrast, N95 masks are noted for causing hypoxia (oxygen deprivation) in wearers as there is a high pressure drop across the mask layers. These masks easily become hot and saturated with moisture which further reduces breathability.

## 10. How long can the BioMask™ be worn?

The BioMask™ is effective for all-day wear. Due to its ability to kill pathogens, the BioMask™ is self-sanitising and can be worn, without replacement, for an entire day, unless excessively soiled. Other masks are not self-sanitising and are therefore easily

prone to contamination when handled or wet, meaning they must be replaced 6-8 times a day, on average.

**11. Is the BioMask™ effective when wet? Can I wash and reuse it?**

Wetting the BioMask™ will not affect its safety or efficacy. DO NOT wash and reuse the BioMask™. See packaging for intended use.

**12. Does the BioMask™ come in child sizes?**

Children's masks are currently not available in the EU.

**13. Can the BioMask™ provide protection during an influenza pandemic, such as swine flu?**

The BioMask™ is effective against influenza viruses, including swine flu and potential pandemic strains. It can be considered a vital tool in any pandemic toolbox. It should be used in conjunction with good hygienic practices, such as thorough and frequent hand sanitisation.

**14. How can the BioMask™ help humanitarian efforts?**

The BioMask™ can provide advanced mask that detects, traps and then rapidly kills bacteria and viruses on contact, while retaining high levels of breathability and comfort. Its anti-microbial properties also reduce the (i) cross-contamination of disease between people and (ii) re-contamination of the wearer, caused by ordinary face masks.

The BioMask™ also provides a high level of protection from the inhalation of fine particulates (greater than 0.1 microns in size) such as dust and aerosolised debris.

**Important Information – Frequently-Asked Questions**

Please contact us directly for copies of the studies described herein. For more information on the BioMask™ and its intended use in your jurisdiction, please see packaging details or visit the Filligent website at [www.filligent.com](http://www.filligent.com). Nothing in this document should be construed as expanding the intended use of the BioMask™ beyond that permitted by the regulatory certifications and / or approvals that apply to the BioMask™ in the EU.

Although every effort has been made to ensure their accuracy and completeness, these test results may contain technical inaccuracies or typographical errors, and Filligent or its Representatives may revise them without notice. Filligent or its Representatives may make improvements and/or changes to the BioMask™ at any time without notice.

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