

**Date:**  
25/03/2020

## CE Declaration of Conformity

I Declare, on behalf of Virustatic Ltd, that the Personal Protective Equipment Device described hereafter:

Virustatic® Shield™ Anti-Viral 360 degree Protective Face Mask – AVM96

Has been classified as Class II and is in conformity with the Essential Health & Safety Requirements (FFP2 R) and provisions of PPE Regulation (EU) 2016/425.

**Classification criteria:**

Class II

The Device complies with the following respiratory standard: BS EN 149.2001 and has been classified as FFP2 R in conformity with the Essential Health & Safety Requirements (Class II) and provisions of PPE Regulation (EU) 2016/425 and recommendation (EU) 2020/403



Paul Hope  
Technical Director



# Virustatic® Shield™ AVM96

## Anti-viral 360° Protective Face Mask

The Virustatic Shield has been developed primarily to reduce pathogenic microbial intake into the human respiratory system. Respiratory protective equipment regulations inappropriately include a statement on inhalation of these microbes, when the RPE is principally designed to protect the user from toxic particles.

An example of this is the regulatory fundamental requirement that RPE mask materials are hydrophobic. This requirement is necessary when dealing with toxic aerosols, powders and particulates, however, is contactually dangerous when dealing with pathogen carrying aerosols. The Virustatic Shield's functional principal is to absorb the aerosols in order to inactivate the pathogens within.

Virustatic maintains that the Virustatic Shield fundamentally complies with the requirement of BS EN 149:2001 and classification FFP2 R. It stops over 95% of aerosolized pathogens from passing through the mask. It does not make any claims regarding particulates listed 1-7 below.

In-line with the objectives and provisions of the PPE Regulation (EU) 2016/425 and the recommendation of (EU) 2020/403, Virustatic has self-certified the Virustatic Shield to provide protective equipment for the SARS-CoV-2 Pandemic.

As the equipment is intended to protect against harmful biological agents, such as viruses, according to Annex I of Regulation (EU) 2016/425, this should be categorised as Category III. The recent Recommendation (EU) 2020/403 states that the health and safety of the public is of utmost priority and it is of paramount importance to ensure appropriate PPE and medical devices are made swiftly available to those who need them most. As part of this, where market surveillance authorities find that PPE meet adequate levels of health and safety in accordance with Regulation (EU) 2016/425, they are making available these products on the market for a limited period of time, while necessary procedures are being carried out.

Therefore, in line with this, it is Virustatic's intention to categorise the Virustatic Shield as Category III, which requires further assessment and application through a notifiable body.

## Respiratory Protective Equipment

RPE can protect against a range of hazardous substances, and it is essential employers understand what these substances are, the forms they take and the ill-health conditions they can cause. Common respiratory hazards for which RPE may be required include:

- 1 Vapours generated by petrol, solvents, thinners, paints and varnishes
- 2 Gases such as chlorine, ammonia and carbon monoxide
- 3 Solids and dusts such as powdered chemicals, flour, cement dust, silica dust from stone, wood dust, lead dust, engine exhaust particles, shot blasting dusts
- 4 Solids that produce dangerous gases with moisture – for example, phosphide – or which give off vapours, such as phenol
- 5 Fumes arising from welding, soldering and burning metals
- 6 Fibres such as asbestos, glass wool and refractory ceramic fibres
- 7 Mist and sprays such as battery acid mist from re-charging or from tasks such as paint spraying or use of metalworking fluids
- 8 Bacteria, viruses and parasites.

Exposure to these substances can cause a wide range of serious ill-health conditions, some of which can prove fatal. For example, silica dust – which is found in stone such as concrete – can cause silicosis, a disabling lung disease; while lead dust and fumes – created during certain soldering activities, for instance – can cause problems such as kidney damage. Meanwhile, exposure to certain respiratory sensitisers – such as isocyanates found in certain paints, flour, grain and wood dust, and resins – can cause occupational asthma.

# Virustatic® Shield™ AVM96

## Anti-viral 360° Protective Face Mask

### The Law

The main law covering the provision of RPE at work is the Control of Substances Hazardous to Health Regulations 2002 (COSHH). COSHH requires all employers to ensure suitable RPE is supplied and used whenever there are risks to health and safety that cannot be adequately controlled by any other means. In short, this means employers must carry out a risk assessment to identify the dangers from hazardous substances before work begins, and take steps to prevent or adequately control exposure, including the provision of RPE if necessary.

### CE Marking

Personal Protective Equipment Regulations 1992 require employers to ensure that RPE is CE-marked. This is designed to ensure the equipment meets the minimum legal requirements for its design and manufacture.

### Virustatic Shield Self Certification

Class II: The Device complies with the following respiratory standard: BS EN 149:2001 and has been classified as FFP2 R in conformity with the Essential Health & Safety Requirements (Class II) and provisions of PPE Regulation (EU) 2016/425 and recommendation (EU) 2020/403

### Classification

Classified as Class II and is in conformity with the Essential Health & Safety Requirements (FFP2 R) and provisions of PPE Regulation (EU) 2016/425.



### Classification criteria:

Class II

The Device complies with the following respiratory standard: BS EN 149:2001 and has been classified as FFP2 R in conformity with the Essential Health & Safety Requirements (Class II) and provisions of PPE Regulation (EU) 2016/425 and recommendation (EU) 2020/403

### Personal Protective Equipment (PPE) – Regulation (EU) 2016/425

Within the European Union (EU), was regulated by Directive 89/686/EEC and covered most domestic, leisure and professional safety products, requiring all PPE products to meet Basic Health and Safety Requirements (BHSR), as defined in Annex II. In order to reflect current technologies and processes for developing and bringing PPE to the market, it was superseded by PPE Regulation (EU) 2016/425 on April 21, 2018.

### Virustatic Anti-viral Shield

Disposable and re-usable face masks ensuring protection against particulate hazards, which are used for prevention and protection against harmful biological agents such as viruses are products falling within the scope of the Regulation (EU) 2016/425.