



masksafe

MADE IN UNITED KINGDOM

www.masksafe.co.uk

CERTIFICATION - SARS-CoV-2



This certification note clarifies the current levels of protection and legislation in relation to respiratory half masks during the ongoing **COVID-19 Pandemic**.

Prior to **COVID-19** the full **EN 149:2001 + A1:2009** legislation was in use to provide industry with respiratory protection to **FFP3** and **FFP2** standards. This meant that dust and particle would be filtered to a level of 99% for **FFP3** and 94% for **FFP2**. Following the onset of the **COVID-19** Pandemic the World Health Organisation issued guidance for FFP3 or FFP2 half face respirators to be used in aerosol generated environments where **COVID-19** was present.

Unfortunately, there were not enough legitimate certified **FFP3** and **FFP2** masks on the market to supply front-line key workers and supply chain issues commenced. Organisations started to procure respiratory protection which had poor face fitting properties from ear loop securing as opposed to head harness securing. In June 2020, the UK HSE released a bulletin identifying Chinese **KN95** masks as sub standard and non-compliant with European conformity. It was advised that **KN95** Chinese standard masks should not be used in the UK for protection against **COVID-19 (SARS-CoV-2)**.

<https://www.hse.gov.uk/safetybulletins/use-of-face-masks-designated-kn95.htm>

To enable suitable and sufficient respiratory protection to meet supply the European Commission provided emergency legislation which is newly documented in **PPE-R/02.075 Version 2**. Masks certified under this legislation will be evaluated to provide protection for the **COVID 19 / SARS-CoV-2** virus only.

The assessment creates efficiencies in testing, by considering the **EN 149** standard, omitting **COVID-19 (SARS-CoV-2)** nonspecific parts, and prioritising virus protection thus bringing the correct product to market in order to safe guard our health care and frontline workers.

Masksafe Ltd currently manufacture the full range to PPE-R/02.075 version 2.

The full PPE-R/02.075 Version 2 European Legislation can be viewed below via the link.

https://www.ppe-rfu.eu/app/uploads/sites/10/2020/07/RfU-02.075_02_Regulation.pdf

The table below demonstrates the testing required for COVID-19 as opposed to the previous full **EN149** spec.

Filtering half mask against SARS-CoV-2 Covid-19 PPE-R/02.075 Version 2	Standard EN149 Mask
<ol style="list-style-type: none"> 1. Practical Performance 2. Compatibility with skin 3. Penetration of Sodium Chloride 4. CO2 Content of the inhaled air 5. Head harness 6. Field of vision 7. Exhalation valves 8. Breathing resistance 	<ol style="list-style-type: none"> 1. Practical Performance 2. Compatibility with skin 3. Penetration of Sodium Chloride 4. Penetration of Paraffin Oil 5. CO2 Content of the inhaled air 6. Head harness 7. Field of vision 8. Exhalation valves 9. Breathing resistance 10. Clogging

Under the new **COVID-19** Legislation Masksafe's respiratory half masks shall be marked as follows, as per section 4.2 of the **RFU**:

- 1- Standard **PPE-R/02.075 version 2**
- 2- Manufacturer's name or brand: Masksafe Ltd
- 3- PPE reference: Masksafe model number
- 4- CE and notified body marking: **CE 0194**
- 6- Classification: **COVID-19**

Product Name	Product Code
Medical Professional Range	
SARS-CoV-2 (Valved), Duckbill Respirator	MS/DBV/SC2
SARS-CoV-2 (Un-Valved), Duckbill Respirator	MS/DBU/SC2
SARS-CoV-2 (Valved), Fold-Flat Respirator	MS/FFV/SC2
SARS-CoV-2 (Un-Valved), Fold-Flat Respirator	MS/FFU/SC2