

**KN95 safety alert – Internal Briefing Document  
V1.0 – 11/6/20 – PPE Unit**



Health and Safety  
Executive

| <b>HEALTH AND SAFETY EXECUTIVE - SAFETY ALERT</b>  |  |
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| <a href="#">create a drop down box for options</a> |  |
| <b>Department Name:</b>                            | <i>EPD – PPE Team</i>  |
| <b>Bulletin No:</b>                                | <i>(Bulletin number to be allocated by STSU, Safety Unit 2)</i>                  |
| <b>Issue Date:</b>                                 | <i>June 2020</i>   |
| <b>Target Audience:</b>                            | <i>All industry</i>  |
| <b>Key Issues:</b>                                 | <i>Quality of KN95 face masks and lack of compliance with European standards</i> |

**Use of face masks designated KN95**

**Introduction**

A substantial number of face masks, claiming to be of KN95 standards, provide an inadequate level of protection and are likely to be poor quality products accompanied by fake or fraudulent paperwork. These face masks may also be known as filtering facepiece respirators.



KN95 is a performance rating under the Chinese standard GB2626:2006, the requirements of which are broadly the same as the European standard BSEN149:2001+A1:2009 for FFP2 facemasks. However, there is no independent certification or assurance of their quality and products manufactured to KN95 rating are declared as compliant by the manufacturer.

Personal protective equipment (PPE) cannot be sold or supplied as PPE unless it is CE marked. The **only** exception is for PPE that is organised by the UK Government for use by NHS or other healthcare workers where assessments have been undertaken by HSE as the Market Surveillance Authority.

### **Action required**

KN95 **must not** be used as PPE at work as their effectiveness cannot be assured.

Masks that are not CE marked and cannot be shown to be compliant must be removed from supply immediately. If these masks have not been through the necessary safety assessments, their effectiveness in controlling risks to health cannot be assured for anyone buying or using them. They are unlikely to provide the protection expected or required.

If any are CE marked, suppliers must be able to demonstrate how they know the documentation and CE marking is genuine, supported by Notified Body documentation showing compliance with the essential health and safety requirements as required by the Personal Protective Equipment Regulations (EU) 2016/425.

### **Relevant legal documents**

Personal Protective Equipment Regulations (EU) 2016/425  
Personal Protective Equipment (Enforcement) Regulations 2018

### **Further information**

**<https://www.hse.gov.uk/>**

**<https://www.hse.gov.uk/respiratory-protective-equipment/index.htm>**,

## **Annex 2 - HSE Press Notice**

### **HSE safety alert issued against KN95 facemask**

The Health and Safety Executive (HSE) is warning against the use of KN95 facemasks as Personal Protective Equipment (PPE).

A safety alert has been issued today, Thursday 11 June 2020, urging all employers and suppliers not to purchase or use KN95 facemasks as PPE.

KN95 is a performance rating that is broadly equivalent to the EU standard for FFP2 facemasks. Products manufactured to KN95 requirements rely on a self-declaration of compliance by the manufacturer. There is no independent certification or assurance of their quality.

This respirator has been identified as suspect by HSE experts and locally arranged testing has confirmed they would not meet requirements, including to protect against the ongoing coronavirus pandemic. About 90% of the PPE concerns and queries currently being received by HSE involve KN95 masks which are often accompanied by fake or fraudulent paperwork.

HSE has quarantined around 1.5 million KN95 masks, prevented 25 million items claiming to be FFP3 respirators entering the supply chain and prevented a further four lines consisting of many millions of items entering the supply chain.

Rick Brunt, HSE's Director of Operational Strategy said: "The KN95 facemask should not be purchased or used.

"KN95 has not been a principal source of PPE for the NHS, who has already made the decision not to supply this respirator to frontline clinicians fighting the coronavirus pandemic.

"We have found that the lack of independent testing has contributed to there being a substantial quantity of inadequate and poor-quality masks on the market, claiming to comply with the KN95 standard.

"We understand a lot of people, mainly in sectors outside of healthcare, have bought these facemasks without realising they are non-compliant. We are concerned that people wearing them are not being protected from breathing in harmful substances in the way they expect. Protective equipment must protect."

Domestic, European and international organisations continue to raise concerns regarding KN95 masks, including details of counterfeit and illegal products. HSE is working to remove them from the supply chain with colleagues in the Office for Product Safety and Standards (OPSS), Border Force, the Medicines and Healthcare products Regulatory Agency (MHRA)

and Trading Standards to identify manufacturers and suppliers of these masks and prevent them entering the UK.

The safety alert does not relate to N95 masks which are manufactured to a US Standard and have been given permission for use specifically in UK healthcare settings.

A copy of the alert can be found [here](#).

### **About HSE**

The Health and Safety Executive (HSE) is Britain's national regulator for workplace health and safety. We prevent work-related death, injury and ill health through regulatory actions that range from influencing behaviours across whole industry sectors through to targeted interventions on individual businesses. These activities are supported by globally recognised scientific expertise. [www.hse.gov.uk](http://www.hse.gov.uk)

## Annex 3 – Q&A

### KN95 masks – Q&A

#### 1. What are KN95 masks?

KN95 is a Chinese performance rating (under GB2626:2006), the requirements of which are broadly the same as the European Standard BS EN149:2001 for FFP2 facemasks. However, products manufactured to KN95 rating are declared as compliant by the manufacturer and there is no independent certification or assurance of their quality.

#### 2. What about similar masks described as KN5, KNP5 or KN99?

There have been several examples of masks with these designations being offered for sale or imported. These designations are not known and would indicate significant concerns as to the provenance of the masks. These masks should not be purchased, supplied or used.

#### 3. Why has HSE released this safety alert now?

HSE is concerned about the substantial number of inadequate and poor-quality masks in the supply chain and freely available on the market that state compliance with KN95 standards. They are often accompanied by fake or fraudulent paperwork along with claims they offer the same levels of protection as FFP2 and/or FFP3 masks. These masks have rarely demonstrated compliance with the relevant European Standard, BS EN149:2001, and therefore may not offer protection to the wearer to prevent risks to health, both Covid-19 related and other respiratory risks in the workplace. We are aware people have purchased these masks without realising they are non-compliant and/or properly checking the accompanying paperwork.

Domestic, European and international organisations continue to raise concerns regarding KN95 masks, including details of counterfeit/illegal products. Some countries have already banned the marketing of a number of KN95 masks - evidence of this is shown on [RAPEX](#) and [NIOSH](#) websites.

There is other useful information to help identify products that do not conform to relevant standards:

- British Safety Industry Federation (BSIF): See CE Certification guide at [www.bsif.co.uk](http://www.bsif.co.uk)
- British Occupational Hygiene Society (BOHS) – Spotting a fake respirator - <http://www.bohs.org/covid-hub-technical-information/>
- European Safety Federation (ESF): Suspicious certificates for PPE - <https://www.eu-esf.org/covid-19/4513-covid-19-suspicious-certificates-for-ppe>
- Investigative Reporting Project Italy: The great bazaar of certifications for masks from China - <https://www.bsif.co.uk/wp-content/uploads/2020/05/OCCRP-Article-002.pdf>