



The dangers of fake PPE



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British Dental Industry Association (BDIA), says that you must use suppliers you can trust, to avoid the dangers of fake and non-compliant PPE.

The COVID-19 pandemic has shone a spotlight on some of the amazing selfless and caring aspects of human nature. However, it has also highlighted some more unsavoury aspects, a key one being the manufacture and supply of fake and non-compliant personal protective equipment (PPE). Unfortunately, it does not come as a great surprise that in these very challenging times when there is unprecedented global demand for face masks and PPE, millions of counterfeit products are appearing on the market, largely on sale from online vendors and linked to resourceful and adaptive criminal gangs.

The British Dental Industry Association (BDIA) has been operating its Counterfeit and Sub-standard Instruments and Devices Initiative (CSIDI) awareness campaign in the dental press for several years now and is delighted with the significant increase in the dental profession's knowledge and understanding of the dangers of counterfeit and non-compliant dental devices. There is now significantly greater awareness of the issues and dangers associated with fake and non-compliant devices, the implications for users and patients and, very importantly, an understanding of the importance of purchasing from reputable suppliers, such as BDIA members, and being incredibly wary of 'too good to be true' online offers from unfamiliar suppliers.

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Against this background of growing awareness of fake and non-compliant products it is important to remind colleagues of the worrying trend in the sale of counterfeit and non-compliant surgical masks and PPE. Unscrupulous suppliers and middlemen are exploiting this global health crisis to peddle fake lifesaving PPE. These fakes pose a health risk to anyone wearing them because they will provide little protection against the Coronavirus.

The UK's medical and dental devices and pharmaceutical regulator, the Medicines and Healthcare products Regulatory Agency (MHRA), has warned all healthcare professionals and those responsible for purchasing of an increasing number of bogus PPE and medical products that are being sold through unauthorised websites. This advice is complemented by the Health and Safety Executive (HSE), the body responsible for PPE.

Colleagues at the US Center for Disease Control and Prevention (CDC) have also come across a significant number of counterfeit and non-compliant masks and respirators appearing on the US market. These products are displaying fake US NIOSH (National Institute for Occupational Safety and Health) and CE marking and represent a significant hazard to the unaware user.

The ongoing pandemic situation means that there remain some global and national supply issues regarding the availability of masks and PPE. Recently, with the resumption of more widespread dental activity, there has been a significant demand for PPE for use in dental practices, particularly for PPE required to undertake aerosol generating procedures (AGPS), namely disposable gloves, disposable gowns, filtering face piece respirators (FFP2 or 3) and eye protection.

The HSE, responsible for PPE in the UK, reminds us that personal protective equipment 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.

When it comes to the regulations covering legitimate products there is a difference in the rules covering the 'traditional' dental type 'surgical mask' and PPE. The MHRA publishes guidance which states the following:

'Unscrupulous suppliers and middlemen are exploiting this global health crisis to peddle fake lifesaving PPE. These fakes pose a health risk to anyone wearing them because they will provide little protection against the Coronavirus.'

'Surgical (medical/dental) face masks - This type of mask, traditionally used in dentistry, is intended to protect the patient, is a Class I medical device and must meet the design and safety requirements of the Medical Device Directive and be CE marked before they can be sold in the UK. The CE mark will be backed up by a Declaration of Conformity (DoC).

'FFP2/3 respirators (PPE/Respirator Protective Equipment RPE) - These are intended to protect the wearer, and they are regulated as personal protective equipment (PPE) and need to meet the regulations covering PPE products, which are the Personal Protective Equipment Regulations 2002, and they also need to be CE marked before they can be sold in the UK.

This PPE will need an independent Notified Body to verify the relevant requirements are met, and, again, the CE mark will be backed up by a Declaration of Conformity (DoC). These PPE respirators are not medical devices, and the appropriate regulatory and enforcement body is the HSE.'

Given the heightened concerns over counterfeit and non-compliant masks and PPE the BDIA strongly urges all purchasers to use existing, trusted suppliers, such as BDIA members. If any purchasers are looking at other sources of supply, they must be extremely diligent. If looking to purchase from a new or different supplier, the supplier or manufacturer should be asked to provide all necessary evidence to prove the legitimacy of their products.

The British Occupational Hygiene Society has developed a few simple points to help spot fake PPE:

- Examine the markings on the product
 - genuine products should show a Standard number, a manufacturer name, logo or number and an EU CE mark (and Notified Body number for FFP2/3)
 - are they all there and do they look correct?
- Is a copy of the EU certification/ CE marking and the Declaration of Conformity (DoC) available? - The EU DoC must be provided with the product or be available to download or on request from the PPE manufacturer/supplier
- Do the certificates and DoC contain the required information?
- Check the reference to the standard(s) on the product and on the certificates and DoC
- Are the manufacturers' user instructions provided?
- Does the product look and feel right?
- Are there any misspelt words?

More information complementing the above points is available from The British Safety Industry Federation - www.bsif.co.uk and The European Safety Federation - www.eu-esf.org/covid-19/4513-covid-19-suspicious-certificates-for-ppe.

The simple advice is to buy from your regular and trusted dental suppliers and the BDIA has set up new 'Return to Practice' webpages dedicated to showcasing resumption and mitigation products available from its members at www.bdia.org.uk/product-directory.

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