

ESCC Guidance for local businesses on sourcing Personal Protective Equipment (PPE) & Medical Devices

Introduction

Throughout the COVID-19 pandemic, there has been a nationwide shortage of Personal Protective Equipment (PPE), creating a high demand for these products. As a local business you may need to procure PPE for your staff, sourcing and/or importing items like face masks, gloves or other protective clothing.

Think carefully about your procurement process, as we are aware that a number of these products are not clinically effective and in some cases the suppliers are operating fraudulently.

This document aims to support local businesses to understand how to work safely during the COVID-19 pandemic, keeping as many people as possible safe by procuring products that meet the essential safety requirements which provide adequate protection from COVID-19.

Counterfeit PPE and in particular, counterfeit supporting documentation are on the increase. Well-known brands and Notified Bodies (please see the definition below) are being targeted and there are products being offered that make claims of compliance to BS, EN & ISO standards but offer dubious proof that this is the case. This guide offers advice on how to check if the supporting documentation for your PPE is genuine.

Current Conformity Requirements

The essential health and safety requirements (listed in Annex II of EU Regulation 2016/425) apply to all PPE within the scope of that Regulation. Under article 19, all PPE within scope must undergo a conformity assessment procedure in accordance with its risk categorisation (specified in Annex I) to demonstrate compliance with the essential requirements.

Under the easements in Recommendation 2020/403, PPE specifically necessary for protection in the context of the COVID-19 outbreak must continue to meet the essential safety requirements.

For a limited time, where COVID-19 related PPE is being purchased by the Government/NHS bodies for use by healthcare workers, it does not need to be conformity assessed providing it has been manufactured either in line with a relevant European Standard, in accordance with a standard referenced in the WHO guidelines, or to an alternative technical solution that delivers adequate safety. Products procured in this way must be approved by the Market Surveillance Authority. [Standards relevant to PPE for COVID-19](#) are available free from the British Standards Institution.

Please note - that any COVID-19 PPE approved without undertaking any conformity assessment can only be supplied as part of a Government procurement for use by healthcare workers during the current health crisis and **may not** be supplied to other parties or for any other uses.

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Detailed guidance on the EU Regulation on Personal Protective Equipment 2016/425 can be found [here](#).

Principles to apply when sourcing PPE

PPE protects the user against health or safety risks at work. It can include items such as:

- gloves
- gowns
- eye protection
- safety footwear
- respiratory protective equipment, such as face masks.

All PPE must be supplied with instructions for use and be appropriately tested and marked with a CE marking. It must also be supplied with an EU-Type Examination certificate in accordance with Module B of the regulation, plus monitoring of ongoing production conformity in accordance with either Module C2 or Module D of the regulation, issued via a Notified Body or a link to a website where it can be downloaded. Without these, the product is illegal to use as protective equipment in the workplace.

[Notified Bodies](#) are independent organisations appointed by EU Member State governments and notified to the European Commission to carry out the procedures for conformity assessment and certification set out in the Regulations. You will need to verify any certification with the awarding Notified Body, and will need to check it against the current [list of fake/dubious certificates](#) from The European Safety Federation list. Many of the EU Notified Bodies provide a facility to check certificates directly on their websites.

It is also good practice to obtain a Declaration of Conformity from the manufacturer. Manufacturers need to ensure that when PPE is supplied to an end user, it is accompanied by either a full hard copy of the declaration, or the internet/website address where the declaration can be accessed. In situations where an item of PPE is covered by several EU harmonised legal acts, these should be addressed by a single declaration of conformity, albeit this could be in the form of a compilation document.

Data sheets and photographs of the PPE packaging should be obtained from the supplier. This will help to ensure that the batch of equipment checked and purchased accurately reflects the product you receive.

Where concerns regarding the acceptability of a product remain, then the purchase should not be progressed further. We would also recommend that an initial search of the supplier and manufacturer is undertaken via the internet, as this may alert you of any anomalies or inconsistencies at the outset of the procurement process.

Principles to apply when sourcing Medical Devices

Some types of products that appear to be similar to PPE may actually be regulated as medical equipment, if their main purpose is to protect others from the user. Ensuring that products meet the health & safety requirements is most difficult in the case of disposable masks (EN 14683 Type IIR), where a key characteristic is their level of splash repellence. The primary way to ascertain whether they meet the health & safety requirements is through the relevant product test certification. Unfortunately many sources of supply either do not have the necessary product certification in place, or they present certificates which cannot be substantiated or which turn out to be fakes.

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Therefore, to ensure compliance with any required standard, third-party test certification should be requested from the supplier. Test certificates must be written in English, with no apparent amendments to the original version. Test certificates will need to be verified directly with the testing company. Checks should also be undertaken to ensure the legitimacy of that company. Products should not be accepted without suitable test certification, plus the manufacturer's Declaration of Conformity, in place. Leading test companies such as Bureau Veritas, Intertek, SGS, TUV, provide lab testing services for face mask compliance.

The following [guidance published by BSI](#) clearly summarises the main characteristics of the four most common categories of mask and face covering available in the UK that health workers and the public may use.

Further information about the regulation and safety of medical devices is provided on [GOV.UK](#)

PPE in non-health and non-care settings

COVID-19 is unprecedented. It is therefore understandable that people outside of health and social care sectors want to know more about use of PPE as they respond to this outbreak.

We understand the important role that those outside the health and care system are playing in society's COVID-19 response. However, it is vital that employers and local businesses take an evidence-based approach for the use of PPE to ensure that appropriate PPE can be provided for those who work in genuinely higher risk areas.

The following guidance covers a range of different types of work. Many businesses operate more than one type of workplace, such as an office, factory and fleet of vehicles. You may need to use more than one of these guides as you think through what you need to do to keep people safe.

Guidance to help employers and local businesses understand how to work safely during the coronavirus pandemic can be found [here](#).

Verified Suppliers & Products

The document in Annex 1 contains a list of suppliers that East Sussex County Council (ESCC) have successfully been able to verify for PPE and/or medical devices as per our guidance. You may want to utilise these suppliers as the risk of receiving counterfeit products may be lower. Checks to ensure that each individual batch of product that you purchase is bona fide and meets the published standards will still need to be undertaken as per this guidance.

Purchasing, pricing and availability of equipment

Since the start of the COVID-19 outbreak, due to high demand worldwide, pricing and availability of PPE and medical devices have varied greatly. Stock levels are now starting to stabilise, and prices are now lower than they were a month ago. Type IIR face masks, which were originally costing approximately £1 per item, can now be procured at much lower prices. Currently, items such as nitrile gloves, gowns and FFP3 respirator face masks still remain in high demand and are therefore difficult to source. Due to the lack of availability, these items may still command a higher price.

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When ordering regulated equipment that you have verified as authentic, you should ensure that the full specification of the items is indicated on your quote/invoice. For example if you are ordering gloves, make sure your invoice clearly states “EN 445 nitrile gloves size medium + name of the brand you verified”. This should prevent suppliers substituting items for products which may not be compliant to the PPE standards and regulations or are counterfeit.

Latest advice from the Health & Safety Executive (HSE)

The Health and Safety Executive (HSE) is warning against the use of KN95 facemasks as Personal Protective Equipment (PPE). A safety alert was issued on 11 June 2020, urging all employers and suppliers not to purchase or use KN95 facemasks as PPE.

Alert can be found [here](#).

List of verified Suppliers & Products

In Annex 1, you will find a list of verified suppliers & products.

Additional Support

In Annex 2, you will find helpful links to additional support and resources.

Annex 1: Verified Suppliers & Products

Below is a list of suppliers and products (as at 9 June 2020) that East Sussex County Council (ESCC) have successfully been able to verify for PPE and/or medical devices, as per our guidance.

Supplier	Product Description	Contact
Acopia Group Ltd	Nitrile Gloves	jake.elkins@acopia.co.uk
ADC London	Type IIR Surgical Face Mask, Face Shield, Protective Disposable Apron, Goggles, Nitrile Gloves	stephen.galea@adclimited.co.uk
ADS Direct	FFP3 Face Mask	dave.grieves@adsdirect.org.uk
Altinet/Fonebox	Type IIR Surgical Face Mask, Vinyl Gloves	henry.doyle@altinet.co.uk
Better Healthcare Services	Type IIR Surgical Face Mask, Vinyl Gloves	marc@betterhealthcare.co.uk
Blueleaf	Type IIR Surgical Face Mask	everard.payne@blueleafcare.com
CAD PPE	Type IIR Surgical Face Mask	chris.vize@cadppe.co.uk
Carbyne Solutions	Type IIR Surgical Face Mask	info@carbinesolutions.com
Cooneen	Nitrile Gloves, Type IIR Surgical Face Mask	scott.hetherington@cooneen.com
DEOS Group	Nitrile Gloves	callum@deosgroup.co.uk
Dr Adams Laboratories	Hand Sanitiser	billy@dradamlaboratories.com
DTS Trading	Type IIR Surgical Face Mask, FFP3 Face Mask, Nitrile Gloves	mitch@dtstrading.com
Eaton PPE Supplies Ltd	Nitrile Gloves, FFP2 Face Mask, FFP3 Face Mask	mat@eatonppesupplies.co.uk
Fluidbranding	Type IIR Surgical Face Mask	tariq.tonna-morgan@fluidbranding.com
Forthbrae	Type IIR Surgical Face Mask, FFP3 Face Mask, Nitrile Gloves	iffat.Malik@forthbrae.co.uk
Gifffinder	Type IIR Surgical Face Mask	lyle.purdum@gifffinder.uk.com
Green Cloud IT	Nitrile Gloves	Liam@greencloudit.co.uk
Hygenical	Type IIR Surgical Face Mask	Jon@hygienical.co.uk
Hyproc International	Type IIR Surgical Face Mask, Nitrile Gloves	sales@hyproc-intl.com
Ibrolly / Logotek	Nitrile Gloves, Vinyl Gloves	matthew@ibrolly.com
Imperial Polythene Products Ltd	Protective Disposable Apron	Graham@imperialpolythene.co.uk
Inkerman NYC	Type IIR Surgical Face Mask	jeannie@inkermannyc.com
Mondiale	Type IIR Surgical Face Mask	cblackettord@mondiale.com
My Beauty and Care	Type IIR Surgical Face Mask	Veer@mybeautyandcare.com
Naeco	FFP2 Face Mask	jeremy@naeco.co.uk
Northern Safety Supplies	Nitrile Gloves	jordan@northernsafetysupplies.co.uk
Opalion	Nitrile Gloves	clive@opalion.co.uk
Orcagel	FFP3 Face Mask	fraser.johnston@orcagel.com
Pinpoint PPE	Type IIR Surgical Face Mask	contact@pinpoint-ppe.com
ProGarm	Protective Disposable Apron	lynn.palmer@progarm.com
Safpro	FFP2 Face Mask	Royce.Devenish@safpro.co.uk
Schottlander	Nitrile gloves	ISchottlander@schottlander.co.uk

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Selkent Fastenings	Hand Sanitiser	karl.bushnell@selkentfastenings.com
SMI Group	Protective Disposable Apron, Nitrile Gloves	giles.prisgrove@smigroupuk.com
Sportex Global	FFP3 Face Mask	charlie@sportex-global.com
Springfield Supplies	FFP2 Face Mask	brianbaker@springfieldsupplies.com
TAD Global	FFP2 Face Mask, FFP3 Face Mask	tom@tadglobal.co.uk
Tsingbay-smarhome	Nitrile Gloves	mawz@tsingbay-smarhome.com
Vestaplas	Nitrile Gloves	bruce.k@vestaplas.com
Whiteman & Parish	Hand Sanitiser	support@wightmanandparrish.co.uk
Wylabs	Type IIR Surgical Face Mask, Nitrile Gloves	graham.thompson@whylabs.co.uk

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Annex 2: Additional Support & Guidance

Notified Bodies – certification checking services & enquiries

[BSI](#)

[CCQS](#)

[SATRA](#)

[TUV Rheinland](#)

[TUV SUD \(Germany\)](#)

[Universal Certification](#)

[Dekra](#)

Additional Support & Guidance

[BSI Certificate Checklist](#)

[Public Health England - Covid-19 Personal Protective Equipment \(PPE\)](#)

[Health & Safety Executive Guidance - FFP2 Face masks/aprons/gowns/eye protection](#)

[European Safety Federation - Misleading and fake certificates](#)

[European Safety Federation - Suspicious PPE certificates](#)

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