

PPE Buying: A Quick Guide for Procurement

	<u>Index</u>	<u>Page</u>
1	Introduction	1
2	Classifications	2-4
3	Checklist for Certifications	5
4	Counterfeit Products	6-7

1. Introduction

Due to the COVID-19 pandemic, there is currently a huge influx of offers to supply PPE to the Welsh public sector. Critical items such as face masks and gloves fall into various classes and categories of both Medical Devices and PPE. Guidance on understanding whether products being offered are approved for sale in the UK is therefore published by various organisations and can't easily be accessed from one place.

NPS, following consultation with a number of organisations such as BSIF, SMTL, MHRA and its supply base, have collated this guidance for their Procurement Staff which attempts to identify commonly procured items and provide details of what documentation you should expect to see if authorised for sale in the UK.

NPS are currently seeing a huge amount of suspect PPE Documentation from a wide variety of sources. We will also provide guidance on what to look out for in this regard.

Any queries can be directed to NPSCorporateServices@gov.wales.

2. Classifications

MEDICAL DEVICES				
Product	Type	Standard	Classification	Document Requirements
Surgical Masks	I, II and IIR	EN14683	Class I CE Marked – self declaration	<ul style="list-style-type: none"> • Must be CE marked* • EC Declaration of Conformity from manufacturer or EU Authorised Representative • Test report to relevant EN standard • If sterile require a CE certificate from a Notified Body
Examination Gloves	* Most commonly purchased - nitrile gloves (non sterile). Vinyl and latex options. NHS nitrile only.	EN455 (min standard for Covid re gloves), EN ISO 374-2	Class I CE Marked – self declaration	<ul style="list-style-type: none"> • Must be CE marked* • EC Declaration of Conformity from manufacturer or EU Authorised Representative • Test report to relevant EN standard • If sterile require a CE certificate from a Notified Body
Examination Gloves	Surgical gloves	EN455 EN374	Class IIa Class III CE marked - with Notified Body.	<ul style="list-style-type: none"> • Must be CE Marked with Notified Body No.* • EC Declaration of Conformity from a Notified Body. • EU Authorised Representative • Test report to relevant EN standard
Surgical Gowns		BS EN 13795-1 2019: Surgical clothing and drapes. BS EN ISO 22610: 2006/2018:		<ul style="list-style-type: none"> • Test report to relevant standard.

		Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment		
<p>*NOTE: If the product is not yet CE marked i.e. a new product, the product must be in the process of conformity assessment with a Notified Body. (BSI, SGS, CCQS UK, Shirley Technologies Limited, trading as BTTG, INSPEC international, SIRA Certification Service, ITS Testing Services, UL international, SATRA). The Notified Body must attest that the product would pass the conformity assessment process if it was to complete the process.</p> <p>Section 7 - NHS Only exemption. Products can be approved by the cross Government Decision Making Committee.</p> <p>Can send to MHRA for checking - Devices.Compliance@mhra.gov.uk; Devices.Regulatory@mhra.gov.uk</p> <p>NANDO Notified Bodies Link</p>				
PPE				
Face Masks	FFP1, FFP2, FFP3 (N95, KN95, KF95)	EN149	Category 3	<ul style="list-style-type: none"> • Must be CE marked* • DoC or temporary EU type certificate from a Notified Body • User Instruction Sheets if available

PPE	Face Masks	FFP1, FFP2, FFP3 (N95, KN95, KF95)	EN149	Category 3	<ul style="list-style-type: none"> • Must be CE marked* • DoC or temporary EU type certificate from a Notified Body • User Instruction Sheets if available
Protective Gloves	Not effective in preventing spread of Covid. Gloves used for chemical handling etc.		EN420:2003	Category 2	<ul style="list-style-type: none"> • Must be CE marked* • DoC or temporary EU type certificate from a Notified Body • User Instruction Sheets if available
Visors/Face Shields			EN166	Category 2	<ul style="list-style-type: none"> • Must be CE marked*

				<ul style="list-style-type: none"> • DoC or temporary EU type certificate from a Notified Body • User Instruction Sheets if available
Isolation gowns		BS EN 14605:2005+A1: 2009, BS EN 13034:2005 +A1:200, EN14126	Category 3	<ul style="list-style-type: none"> • Manufacturer must have quality management system in place such as evidence of compliance to ISO 9001 or BS EN 13485
Coveralls	Type 4B, 5B, 6B	Type 5B/6B - BS EN 13034:2005+A1:2009, EN14126. Type 4B - BS EN 14605:2005+A1: 2009, EN14126	Category 3	<ul style="list-style-type: none"> • Manufacturer must have quality management system in place such as evidence of compliance to ISO 9001 or BS EN 13485.
Disposable Aprons	On a roll	Specs, Specs2. Must conform to British Standard (BS) 3314:1982. Elements of this standard still relevant are the dimensions and thickness.	Category 2 preferably	
<p>*NOTE: If the product is not CE marked yet i.e. a new product, the product must be in the process of conformity assessment with a Notified Body. (BSI, SGS, CCQS UK, Shirley Technologies Limited, trading as BTTG, INSPEC international, SIRA Certification Service, ITS Testing Services, UL international, SATRA). The Notified Body must attest that the product would pass the conformity assessment process if it was to complete the process.</p> <p>Section 7 - NHS Only exemption. Products can be approved by the cross Government Decision Making Committee.</p> <p>Can send to BEIS for checking - OPSS.enquiries@beis.gov.uk</p> <p>NANDO Notified Bodies Link</p>				

Hand Sanitiser	Biocide	<ul style="list-style-type: none"> • If the hand sanitiser contains ethanol and meets the WHO specified formulation (https://www.who.int/gpsc/5may/Guide_to_Local_Production.pdf) then product authorisations for the UK market are no longer required. • If the hand sanitiser contains propan-2-ol there is a WHO specified formulation available. Derogation from HSE is required for this. • - If the hand sanitiser contains propan-1-ol no WHO specified formulation exists. Derogation from HSE is required for this. 	Request evidence of manufacture to WHO formula. >60% alcohol content. Derogation from HSE for propan-1-ol and propan-2-ol. Test report to EN 14476
Anti-Viral Sprays and Wipes		<ul style="list-style-type: none"> • EN14476 	Test report to relevant standard

Can send enquiries to - biocidesenquiries@hse.gov.uk

3. Checklist for Certifications

The British Safety Industry Federation have developed two handy to use checklists for use in evaluating CE Certificates and Declarations of Conformity for PPE supplies.

The checklists can be found here

4. Counterfeit Products

All certificates must be in English, not redacted, amended or written over.

At some point in your certification reviews you will come across a CE certificate like the one below from ECM or ICR Polska. They are attached to many of the offers we receive from individuals and suppliers offering to import stock from the Far East.



It is important to be aware that....

- ECM and ICR Polska are not notified bodies for PPE. They are a notified body in relation to other legislation but not the PPE Regulation (EU) 2016/425.
- ECM have received a letter from the Italian accreditation body (Accredia) requiring them to stop issuing those kind of certificates, otherwise they will lose the accreditation they have and they will be removed from accredited lab list
- ECM and ICR Polska certificates, despite appearances are NOT CE Type Certificates – they are certificates that allow manufacturers to place the ECM/ICR Polska stamp on their products, which has no meaning in relation to CE Marking.
- There are many other examples of fake certification and guidance can be found via the European Safety Federation note on fake certification

- We have also received a recent update from BSIF in relation to the supply of Gloves. The Malaysian Rubber Glove Manufacturers Association (MARGMA) have reported large numbers of counterfeit gloves and urge buyers to check their website for approved manufacturers.
<http://www.margma.com.my/ordinarymembers/>
- For your information The European Commission have developed “The Safety Gate rapid alert system” which enables quick exchange of information between EU/EEA member states, the UK and the European Commission about dangerous non-food products posing a risk to health and safety of consumers. You can register to receive weekly updates which can be filtered by category ie PPE.
https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/content/pages/rapex/index_en.htm