

Quality & Compliance

A guide to purchasing compliant and certified PPE.

ISO13485 certified
supply chain management

The COVID-19 pandemic has caused demand to rapidly outstrip supply, unfortunately this provides an opportunity for non-compliant, non-certified, or worse, falsely certified PPE to fill the gap. Without valid testing and certification to prove it, you can not be sure the PPE is capable of providing the protection needed.

This guide has been compiled to advise you how to identify compliant and certified PPE. If you would like to understand Standards and CE Marks, please see our guide to understanding the system of Standards and CE Marks.



Ask for the Documentation.

There are two documents that will allow you to determine if the PPE you are purchasing is compliant and certified: a CE Certificate and a (EU) Declaration of Conformity.

The CE Certificate.

In the European market a CE Mark represents a manufacturer's declaration that a product:

- fulfills the requirements of relevant European product directives.
- meets all the requirements of the relevant recognised European harmonised performance and safety standards.
- is fit for its purpose and will not endanger lives or property.

A CE Mark does not guarantee evidence of third-party testing but is an indication that appropriate technical documentation supporting the use of the mark is available and can be provided. PPE Categories II & III are the exception, in these cases independent testing* is required before the CE Mark can legally be applied. It is not a legal requirement to supply a CE Certificate, however for all PPE most suppliers will provide a certificate to prove compliance.

The (EU) Declaration of Conformity.

The Declaration of Conformity is a formal declaration by a manufacturer that the product specified on the document complies with the requirements of all relevant safety directives and legislation applicable to that product.

PPE products are required to comply with the requirements of (EU) PPE Regulation 2016/425*

The Declaration of Conformity can be an individual document that is provided with each PPE product, or the user manual must contain an internet address at which the declaration can be downloaded.

It is a legal requirement for suppliers to provide the manufacturer's Declaration of Conformity that has been issued with a product. It is illegal to supply a product without a Declaration of Conformity.

How to check the documents are genuine and legal.

CE Certificate for PPE Categories II & III

Check the CE Certificate contains the following information to help you determine if it is genuine. If you are unsure of the certificate's authenticity then contact the named Notified Body. If you believe the certificate to be false report it to the relevant surveillance body.

The manufacturer's information:

- Full name.
- Address.
- Test report references.

Certificate Number or Reference.

A statement about which regulation the product has been manufactured in accordance with: PPE - (EU) 2016/425**

Certifying individual:

- Name.
- Signature.

The Notified Bodies information:

- Name.
- Four digit number.
- Address.

Relevant dates:

- Date of expiry. (maximum 5 years after date of issue)
- Date of issue. (after 29/04/18**)

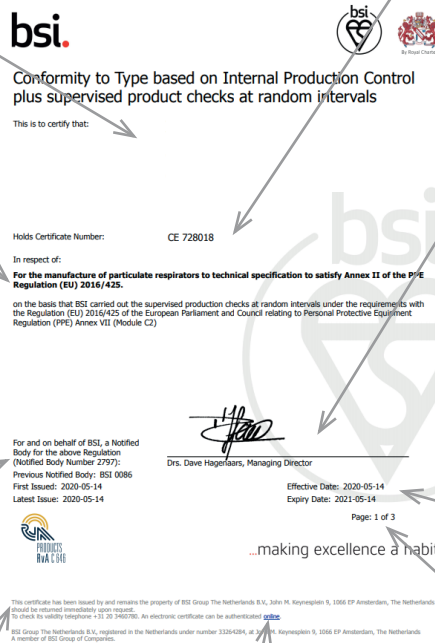
Remains the property of the Notified Body.

Terms and Conditions link or additional page.

Information about the product:

- a description
- a product number/code.
- Specifications.

May be shared on additional pages.



The certificate's format may vary according to the issuer. The certificate used is for illustration purposes only.

Declaration of Conformity

Check the Declaration of Conformity contains the following information to help you determine if it is genuine and legal. If you have any doubts about the report raise it with the supplier, manufacturer or the manufacturers authorised representative.

The manufacturer's information:

- Full name.
- Address.
- Authorise representative if relevant.

A statement that the declaration has been issued under the sole responsibility of the manufacturer.

Declaration of Conformity
The declaration of conformity is issued under the sole responsibility of the manufacturer

<p>Issuer</p> <p>Business name: Address: Country:</p>	<p>Product</p> <p>Name: Model: Serial number: Description:</p>
--	---

Product photo:

We declare that the product described above, to which this declaration of conformity refers to, is in conformity with the essential requirements of the following legislation:

- 2014/30/EU Electromagnetic Compatibility Directive (EMC) (example)

through the technical standards/specifications specified below:

- EN 61000-3-2:2014 - Electromagnetic compatibility (EMC) — Part 3-2: Limits — Limits for harmonic current emissions [equipment input current ≤ 16 A per phase] (example)

Signed for and on behalf of

_____	_____
Date and place of issue	Name and title

	Signature

Regulation, Standards & Technical Specifications:

- Statement Product is certified to relevant legislation.
- Any relevant harmonised Standards inc. dates
- Technical specifications inc. dates.
- EU Certificates inc. relevant numbers and statement of conformity.

Product(s) Information:

- Description
- Number/code
- Images

Individual from Manufacturer name and signature

At Hutchison we continually strive to conform to the highest and most current internationally recognised standards. We do this because it helps us to reduce waste and maintain the highest quality, but most importantly it means our customers can be confident in the products we supply. In today's climate that means they can trust the PPE we supply is fit for purpose and will not endanger lives.

'Big business results, small business values.'

We are Hutchison.'

* These tests are performed by a Notified Body. A Notified Body is a testing and certification body that is authorised to test, monitor and certify products, machines and equipment. In the UK the Notified Bodies are appointed and overseen by the Medicines and Healthcare products Regulatory Agency.

** The previous PPE Directive (89/686/EEC) was replaced by a new EU Regulation 2016/425 on the 21/04/18. EC type-examination certificates issued under Directive 89/686/EEC shall remain valid until 21/04/23 unless they expire before that date.