CE marking of Personal Protective Equipment (PPE) for use in healthcare settings

Frequently Asked Questions

Introduction

Demand for PPE for use in healthcare settings is at an all-time high due to the COVID-19 pandemic. To be safe, it's important PPE is correctly tested and certified. In Europe all PPE must comply with the Personal Protective Equipment Regulation, (EU) 2016/425, and show the CE marking. However, many organizations are now navigating this regulatory landscape for the first time. As such it can appear confusing. Our team of experts have created this document to help those manufacturing PPE, involved in the sourcing and procurement of PPE, and also wearers of PPE to understand this landscape. We address questions such as how to check the validity of a certificate for PPE to ensure it's compliant, the different levels of testing required, and the process involved.

This document describes the requirements set out in the Regulation. The European Commission has made a recommendation that an expedited procedure is followed to reach certification during the COVID-19 pandemic (Recommendation 2020/403). This is just as relevant for PPE manufactured during this time. For more information on the expedited procedure, visit our website.

Frequently Asked Questions (FAQ's)

Section 1. About the PPE regulation (EU) 2016/425

All PPE placed on the market in Europe must comply with this regulation.

Q. Please can you explain what PPE categories I,II and III products mean and what are the differences between them?

A. The 2016/425 EU regulation divides all PPE into three different categories according to the degree of risk. The higher the risk the PPE needs to protect against, the more stringent the certification procedure.

- PPE used in healthcare settings, such as those used to protect against COVID-19 fall in category II & III
- Category I PPE must be supported by a manufacture's self-declaration. PPE designed to protect against the lowest level of risk falls into this category
- Category II PPE applies to products designed to protect against normal risks. For this, the manufacturer submits a model of the PPE for EC type-examination whereby a notified body such as BSI certifies the PPE in question. This is called a module B certificate
- Category III covers the PPE designed to protect against the highest level of risk. This PPE is intended to protect against mortal danger or against dangers which may represent serious and irreversible damage to health.

For these products a module B certificate and a module C2 or module D certificate is required

Q. What is Nando in the context of PPE? How can I use it to verify BSI's (or other institutions) notified body number?

A. NANDO is the EU database for regulations and notified bodies. BSI's notified body numbers are 0086 in the UK and 2797 in The Netherlands. Our scope can be checked at: https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=notifiedbody.main

Q. Is there any way to make the PPE certification procedure faster, for example in the case of a large order?

A. Unfortunately this is not possible.

Q. Can BSI test EN 149 filtering facepiece respirators, (sometimes known as disposable respirators)?

A. Yes, contact us at product.certification@bsigroup.com. These are subject to various regulatory standards.

Section 2. About the documentation and the marking of PPE

Q. Is it compulsory for PPE to display the notified body number (e.g. in the user instructions, on packaging, or on the Declaration of Conformity)?

A. For products requiring ongoing production surveillance (such as face masks meeting the requirements of the EN 149 standard), it requires the notified body number of the body performing the surveillance to be displayed together with the CE marking on the product itself. The Declaration of Conformity (DoC), must also state the notified body number.

Q. I understand from BSI that my product has met the requirements of the PPE regulation, but I do not yet have a copy of the certificate. Can I now affix the CE marking to these products which are now being manufactured?

A. Products may not be placed on the market until the certification process is complete including certificate issue. However, we will work with clients to agree at what stage the notified body number and CE marking can be applied as marking, labelling and literature all need preparation in advance of being placed on the market.

Q. How is a DoC different to a certificate? Is this an acceptable document for clearance at EU customs for my ordered facemasks?

A. The DoC is the declaration by the manufacturer or authorized representative that the products meet all the legislative requirements for CE marking products to allow them to be placed on the EU market. It must include details of the certificates issued by a notified body.

Q. Does the test report I have received from my supplier mean that the PPE is compliant?

A. A test report is a supporting document used by a notified body to issue a Type Examination certificate. It is more important for you to confirm the validity. You should not rely solely on a test report as that is not proof of certification.

Q. Can BSI share more information on products such as user manuals, test reports, protection class of the face masks etc.

A. Sorry, we do not supply this. Please check with your supplier or manufacturer's website for product information.

Section 3. About BSI certificates for PPE

Q. Can you supply us with a copy of the original certificate as we have only been given a photograph of it or just the certificate number from our supplier?

A. Unfortunately we are unable to supply copies of certificates. You should request these from your supplier. You can also visit our online validation directory where you can check the certificate number. If you do have access to a copy of the original PDF certificate issued by BSI, click the online validation link in the certificate footer.

Q. How is the certificate number constructed? Is there any information that we need to look out for in these numbers?

A. BSI certificates issued to support the CE marking of PPE under the PPE regulation usually contain the prefix CE followed by a string of numbers, however there is no defined structure to BSI certificate numbers relating to PPE which falls under the scope of the PPE regulation.

Q. If there is a valid certificate number, does this automatically mean that the product can be sold in the EU market? Is this the only requirement?

A. A valid certificate supports the placing of products into the EU market. The requirements for PPE will be for an EU type examination certificate (Module B) and depending on the type of PPE (used to protect against a high or lower risk), a product or production surveillance certificate (known as Module C2 or D) may also be required.
In addition to having a certificate from a Notified Body such as BSI, clients must also complete and make available a DoC, to confirm how they meet the legal requirements. There are also further CE marking requirements to include the notified body number with the CE Marking on the product. PPE certified by BSI will display either 0086 or 2797.

Q. Why is there another certificate number referenced on the certificate we have obtained? For example, the certificate we have refers to a "module D" on a "module B" certificate. What are these and how are they linked to each other?

A. A valid certificate supports the placing of products into the EU market under the PPE Regulation. The requirements for PPE will be for an EU Type Examination certificate (Module B) and depending on the type of PPE, a Product or Production surveillance certificate (Module C2 or D) is also required. These are often referenced on the Module B certificate to show that surveillance (to ensure ongoing compliance of the product) is also being carried out.

Q. If I don't have the latest issued version of a certificate from a supplier, is this a problem?

A. Yes. You should always have the latest version of the certificate in order to check it is valid and the model references are the same as the purchased product.

Q. Why has the BSI certificate been issued twice within five months and from different countries and notified bodies? Is this a problem?

A. As long as there is a valid reason for the certificate updates and the validity of the certificates can be verified there should not be a problem. This is especially relevant in recent months where BSI certificates covered under the PPE Regulation have been transferred from our UK notified body (0086) to our Netherlands notified body (2797). This is because of the UK's recent departure from the EU.

Q. Where can I find an example of a BSI certificate?

A. Please ask your supplier for the relevant official digital certificate. BSI does not provide examples.

Other questions

Q. There are no photos of products on the BSI certificate, how do we check what we buy is real? Does the photograph we obtained from the supplier match BSI's records?

A. Certificates often have many (sometimes hundreds) of models and variations so it is not possible to include photos on certificates. Also, a photo will not prove whether a product is genuine, so we are unable to confirm the validity of a product just from a photograph.

Q. Who polices the market, and where do the responsibilities lie for products certified by BSI?

A. Policing of the market is the responsibility of EU national enforcement within each member state. This will often be through customs authorities, local trading standards authorities or other market surveillance bodies. BSI will take steps to police the use of our certificates and notified body numbers and inform authorities of any breeches.
If you suspect the product is a fake, please seek clarification from your supplier, or contact the local market surveillance authorities where the product is being sold.

Q. Can BSI validate certificates from other notified bodies?

A. No, please contact the relevant notified body.

Q. What happens if a genuine BSI certificate has been suddenly withdrawn on request of the supplier due to being targeted by scams, and there is a batch of facemasks needed to get cleared through EU customs on that one certificate?

A. A BSI certificate would not normally have been withdrawn unless BSI or the manufacturer had concerns over the validity of the products being supplied. There is therefore a risk that there may be fake products being supplied. It is the responsibility of the market surveillance authorities to determine the validity of the incoming batch and decide what restrictions to place on the supply into the market.

Q. Can I call a BSI expert directly to validate a certificate?

A. The online validation directory should give you faster access to the information any time you require it. If you have identified a fake BSI certificate or test report please send a copy and full details to product.certification@bsigroup.com.

Why BSI?

The BSI Personal Protective Equipment (PPE) team have a combined experience of over 100 years working in the PPE industry, from manufacturing to product testing and certification. These trusted experts lead the way in the certification of respiratory, head, eye and face protection, hearing protection, suits, hand and footwear helping to keep people safe.

All our experts are passionate about ensuring products have been tested to the highest level, so that they will perform as expected and protect people, property and the environment, and will provide the protection they claim to achieve.

Our unique offering of certification, testing and market access solutions for PPE including, CE marking for Europe, Benchmark certification for Australasia, ESMA certification for the UAE and BSI Kitemark certification enables manufacturers to be resilient and sell their products around the world.

Our products and services

Knowledge

The core of our business centres on the knowledge that we create and impart to our clients. In the standards arena we continue to build our reputation as an expert body, bringing together experts from industry to shape standards at local, regional and international levels. In fact, BSI originally created eight of the world's top 10 management system standards.

Assurance

Independent assessment of the conformity of a process or product to a particular standard ensures that our clients perform to a high level of excellence. We train our clients in world-class implementation and auditing techniques to ensure they maximize the benefits of standards.

Compliance

To experience real, long-term benefits, our clients need to ensure ongoing compliance to a regulation, market need or standard so that it becomes an embedded habit. We provide a range of services and differentiated management tools which help facilitate this process.

BSI/NL/1755/PC/0520/EN/GRP

For more information
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