



CE marking with BSI

European market access with a trusted Notified Body

Introduction

The European Union is the world's largest trading block and consists of some 500 million consumers. It's therefore no surprise that organizations from around the world choose to access this important market. CE marking is mandatory for many products placed on the European market, so it's crucial that organizations understand the steps they need to take as they navigate this regulatory landscape.

What is CE marking?

CE marking on a product is the manufacturer's declaration that their product complies with the essential requirements of all the EU Directives/ Regulations that apply to it. It is a legal requirement to place certain products on the market in the European Union.

The requirements for CE marking differ across all the Directives and Regulations and may also vary for different products within a Directive/Regulation. Depending on the product, CE marking could purely require a technical file to be compiled, or it could be a more involved process requiring the product to be submitted for regular independent scrutiny.

The role of a Notified Body in CE marking

Where a Directive or Regulation requires products or systems to be independently tested, certified or inspected you will need to use the services of a Notified Body. This is an organization that has been notified to the European Commission by a Member State. BSI is a leading Notified Body (number 2797), covering a number of Directives and Regulations enabling you to achieve European market access with the CE marking.

Requirements for CE marking range from a manufacturer's declaration, up to mandatory full Notified Body assessment of the product and manufacturing controls. BSI can work with you throughout this process, so when you choose BSI, you can be confident that you're working with a trusted brand with a strong international reputation and world-class expertise in product certification.



...making excellence a habit.™

Services to support your CE marking

BSI can work with you to affix the CE marking and we are a Notified Body for the following:

- Construction Products Regulation (CPR 305/2011)
- Gas Appliance Regulation (EU 2016/426)
- Pressure Equipment Directive (PED) 2014/68/EU
- Personal Protective Equipment (PPE) Regulation (EU 2016/425)
- Marine Equipment Directive (MED) 2014/90/EU
- Medical Devices and IVDs*

Directives such as Low Voltage Directive (LVD) and Electro Magnetic Compatibility (EMC) and the Machinery Directive (excluding Annex IV products) are self-declaration and do not require the services of a Notified Body, but we are still able to deliver services such as issuing reports to clients which can be used to provide evidence of compliance.

*Note: CE marking services for Medical Devices and IVD's are operated by BSI Regulatory Services

At every step of the CE marking process we are committed to delivering an excellent service and working with you so that you can bring new products to market, innovate, comply and build resilience in your organization.

We offer a comprehensive range of services to support your CE marking requirements including:

- Standards identification
- Technical file evaluation
- Gap analysis
- Initial type testing
- Type examination
- Quality system assessment
- Factory production control (FPC) system assessment
- EC certificate or certificate issue (where applicable)
- Surveillance of product and quality system or FPC
- Verification certificates



The CE marking process with BSI

Our step-by-step CE marking process will take you from your application with BSI through to a certificate to support your CE marking declaration being issued to your organization. Although CE marking requirements vary from Regulation to Regulation, and even within Regulations, our team of trusted experts understand these requirements and can work with you at every stage, so you can achieve compliance and remain resilient. From the moment your application is submitted to the moment the CE marking is affixed to your product we are here to work with you in a partnership of trust.

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| Step 1 | CE marking requirements Identify the Directive(s) / Regulation(s) that apply to your product. Determine whether a Notified Body is required for CE marking. Understand the requirements of the Directive(s)/Regulation(s) that are applicable. If unsure, talk to BSI. |
| Step 2 | Client application Send your application to BSI |
| Step 3 | Contract review BSI will review your application We will request any additional information (if required) We will prepare your quotation for your review |
| Step 4 | Quote acceptance When your quotation is accepted we will move to the next stage of your CE marking journey |
| Step 5A | Module or system This step differs according to the product category and requirements stated in the EU Directive or Regulation |
| Step 5B | Self-declaration The manufacturer may be able to test their own products and / or Factory Production Control (FPC). |
| Step 5C | Notified Body (BSI) BSI may be required for an initial inspection and / or continuous surveillance, initial type testing, audit testing and issuing of the EC/EU certificate |
| Step 6 | CE marking You affix the CE marking to the product and produce an EU Declaration of Conformity. (Also known as Declaration of Performance for construction products). |

Transfer your certification to BSI

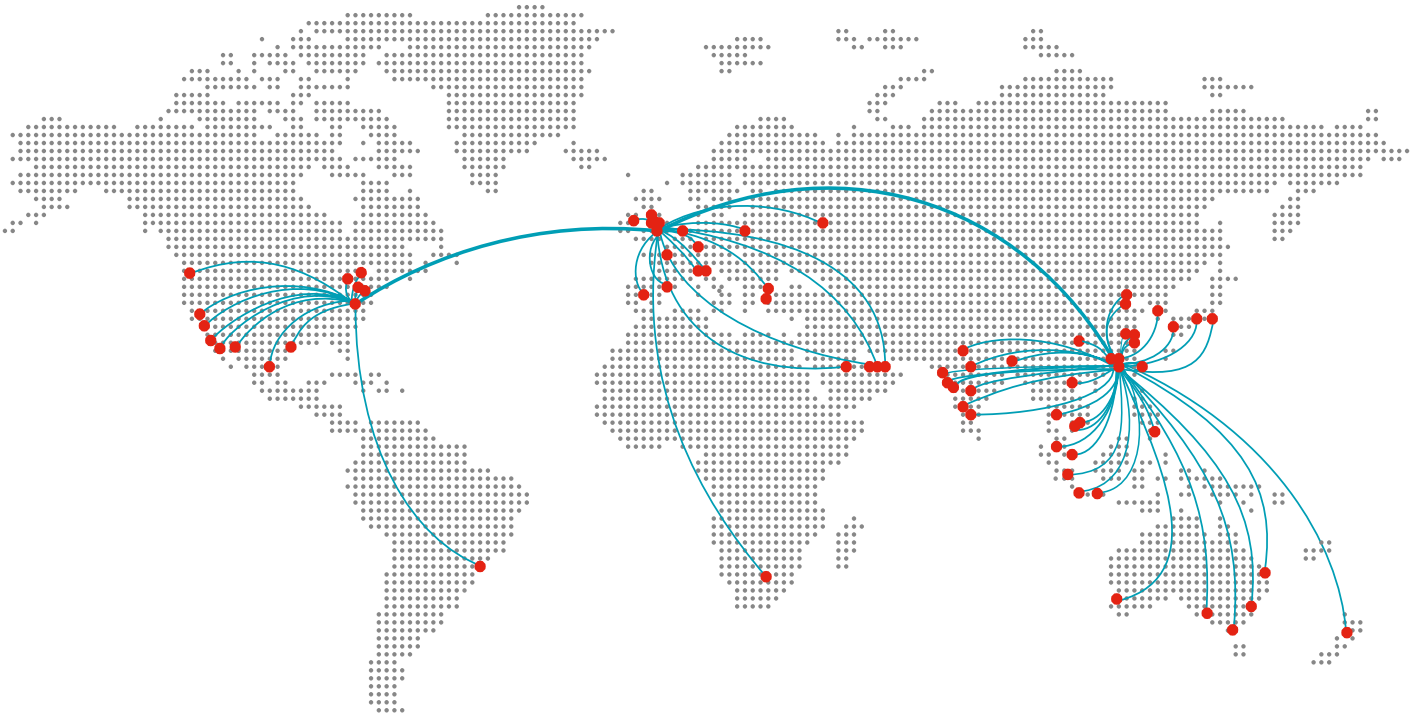
At BSI, we understand that having confidence in your Notified Body to deliver an efficient and robust CE marking service is important. BSI is ideally placed to work with organizations who need to access multiple markets and we can offer a transfer service with comprehensive support so as to reduce the risk of any disruption to your business.

Why choose BSI as your Notified Body for CE marking?

We are committed to working with you to build a trusted partnership as you grow your business for the long-term. When you need to keep up-to-date and comply with the latest regulatory requirements BSI is ideally placed to support your market access needs. With 83 offices worldwide, our global reach combined with our local presence means we are never far away and always on hand to work with you. What's more, our teams of trusted experts have an in-depth knowledge of standards and market access requirements that can enable you to successfully navigate the evolving regulatory landscape, so your business remains resilient.

Build resilience and access global markets with BSI

When world-class expertise in standards and regulations is needed, manufacturers, exporters and distributors from around the world trust BSI so they can bring safe, secure, sustainable and compliant products to market.



BSI/UK/1917/PC/0121/EN/GRP



To start your route to CE marking,
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