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.

bsi.

...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**