



CE marking

The fast route to compliance
in the European Union

bsi.

...making excellence a habit.™

What is CE marking?

Products to be sold in the European Union (EU) that come under certain European Directives/Regulations must bear the CE mark – it is a legal requirement.



CE marking on a product is the manufacturer's declaration that the product complies with the essential requirements of all the Directives/Regulations that apply to it. It indicates to the appropriate bodies that the product may be legally offered for sale in their country.

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 may be as simple as formulating a technical file, or as complex as having to submit your products to regular independent scrutiny.

Third party testing, systems assessment and technical file assessments may be mandatory, but sometimes the manufacturer's unverified claim is all that's asked for.



How can BSI help you with 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", "Competent" or "Approved" Body. This is an organization that has been notified to the European Commission by a Member State. BSI is a Notified Body (number 0086) for many Regulations and the New Approach Directives.

Requirements for CE marking range from a manufacturer's declaration, up to mandatory full Notified Body assessment of the product and manufacturing controls.

When you choose BSI, you can be confident that you will benefit from our experience and expertise as a Notified Body.



BSI – your route to compliance

We strive to deliver outstanding value to our customer base. At every step of the CE marking process, we are committed to your success by providing rapid turnaround, value-based pricing, technical assistance, key account management and accurate reporting.

These commitments enable our clients to improve the quality of their products, the image of their brand and get their products to market quickly and efficiently. The measure of success of our long-term client partnerships is not only based on greater product safety and performance, but also in our client's financial return on their investment.

BSI is currently a Notified Body for the following New European Directives and Regulations:

Construction Products Regulation (CPR)
 Low Voltage Directive (LVD)
 Pressure Equipment Directive (PED)
 Lifts Directive (LD)
 Marine Equipment (MED)
 Personal Protective Equipment (PPED/PPER)
 Gas Appliance Directive (GAD)
 Gas Appliance Regulation (GAR)
 Boiler Efficiency Directive (BED)

Transportable Pressure Equipment Directive (TPED)
 Radio Equipment & Telecommunications Terminal Equipment (RTTE)
 Radio Equipment (RED)
 Measuring Instruments Directive (MID)
 Non-automatic Weighting Instruments Directive (NAWI)
 In Vitro Diagnostics Directive (IVDD)
 Active Implantable Medical Devices (AIMDD)
 Medical Devices Directive (MDD)

BSI make the CE marking process simple

Compliance can be a complex and somewhat daunting process. The CE marking requirements vary from Directive to Directive, and even within Directives. Our team of experts understand all these requirements and can help and advise you throughout **every step** of the process, from identifying appropriate Directives, to correct application of the CE mark on your product.

1

CE Requirements

Manufacturer to assess whether a Notified Body is required for CE marking, or talk to BSI

5A

Module or system

This step differs according to the product category and requirements stated in the EU Directive or Regulation

2

Client Application

Manufacturer submits application

5B

Self-Declaration

The manufacturer may be able to test own products and/or factory production control

3

Contract Review

- BSI reviews application
- Requests additional information
- Prepares quote

5C

Notified Body (BSI)

BSI may be required for initial inspection and/or continuous surveillance, initial type testing, audit testing and issue EC/EU certificate

4

Client Accepts Quote

Manufacturer/Service Provider accepts quotation

6

CE marking

Manufacturer applies the CE mark for their products

Why choose BSI as your Notified Body?

BSI will deliver a comprehensive and tailored service to take a product through the CE marking process quickly and efficiently. The BSI experts assigned to work with you will be able to advise every step of the way. Our aim is to provide a high quality, fast, reliable and stress-free service to meet your deadlines.

BSI carries out independent testing and assessments on products before they go on sale in the EU, whether CE marking is mandatory or not. This gives manufacturers confidence and is sound evidence of due diligence through the approval of one of the world's most respected testing and certification bodies.

BSI offers all the services required by the European Directives and Regulations such as:

- 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

To start your route to CE marking compliance with BSI, contact us:

Call: **+852 3149 3300**

Email: **hk@bsigroup.com**

or visit: **bsigroup.com/en-HK**