

# CE Marking

## Coordination Services Fact Sheet



### What is CE Marking?

CE Marking is a mark affixed to a product by the manufacturer, to designate that the product complies with all applicable European new approach Directives.

CE Marking indicates to officials that the product may be legally offered for sale in any country within the European Economic Area.

### How to Obtain CE Marking

To qualify for CE Marking, manufacturers must complete a conformity assessment process for the product by preparing the Technical File and drawing a Declaration of Conformity.

Different products have different conformity assessment routes:

- For Low Risk Products, the application for CE Marking is by self-declaration
- For High Risk Products, the application for CE Marking is by assessment of the product and quality system by a European Notified Body.

The conformity assessment routes are specified in the New Approach Directives published by the European Union.

### Steps in CE Marking

The manufacturer must take the following steps and comply, in general, with the appropriate Directive(s) requirements:

- Identify the applicable Directive/ Regulations for the product concerned
- Meet the requirements of any Regulations (implementing EU Directives) that deal with specific risk

- Comply with the Essential Health and Safety Requirements (EHSRs). Carry out testing to European Harmonized Standard(s)
- Provide information on use, safety, maintenance, training, supervision and personal protective equipment
- Compile and keep available a Technical File
- Make a Declaration of Conformity

**Note:** There are several requirements for certain machines/ parts/components that may involve an EC Type examination by an Approved Body and the issue of a Certificate of Adequacy.

- Put certain information, such as maker's name, on the product in accordance with the Regulations
- Affix CE Mark on the product in accordance with the Directive(s).

Please complete the Pre-Application Questionnaire and send it back to SAI Global to enable us to kick-start the CE Marking project.

Send your email to [product@saiglobal.com](mailto:product@saiglobal.com).

