**Information Guide** 



# **Conformité Européenne** (CE) MARKING

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#### What is CE marking?

The CE marking is acronym of the word "conformite Europeene", which in French means conforms to European legislation. It is mandatory from the year 1985 that all the products sold in European market region should bear the CE mark on their products.

The products should meet the requirement of the EU directives & EU legislation depending upon the applicable requirements for the product. The CE mark is mandatory for the products that comes under the 24 European directives.

The CE mark on the product means that the manufacturer has taken the required actions to comply to the health, safety, performance & environmental requirements which has been stated in the EU directives & legislations. The CE mark is accepted in the 27 member's states of the European Union.

## What are the focus points of CE marking?

- Selection of the applicable directive as per product.
- Risk analysis of the product as per the directive.
- Provision for the User manual of the product.
- Declaration of Conformance to EU directives.
- Verification of the technical documents as per EU directives.
- Adhere to the requirements for imported products.
- Traceability of the product.

# Which Organization are eligible for CE marking?

All the organizations manufacturing products to be sold in European Union market region. The CE marking is applicable to all the products to be sold within the EU region.

#### What are the document requirements for CE marking?

To demonstrate the conformance to the applicable EU directives, the manufacturer has to prepare & maintain set of technical documents required and should be able to produce whenever requested

The documents which are required for CE marking

- Risk Assessment of the product.
- Product Description.
- Design records.
- Manufacturing records.
- Conformity assessment procedure.
- EU conformity declaration.
- User manual.
- List of applicable regulations to product.
- List of technical standard complied.
- List of parts used in product.
- Test reports & certificates..

#### How will CE marking Benefits your Organization?

- Entry passport to business in European market.
- Better customer satisfaction.
- Reduce Risk related to product.
- Recognition of the organization.
- Safe and Reliable product.
- Free movement of the product across EU region.
- Better business opportunity.
- Worldwide recognition of CE marked products.

## Which products does not require CE Certification?

• Chemicals, Pharmaceuticals, Cosmetics and Foodstuffs does not require CE Marking.

# Why Is It Important to be in Compliance with CE Standards?

 For objects that are required to fulfill this level of certification, obtaining a European conformity mark is vitally important. Companies may face penalties if they forge CE stamps or ignore CE compliance, while enforcement techniques differ. Fines, jail, product recalls, and product bans are all possible penalties.

# How will PQSmitra help you with Hassle - free Implementation process for CE Marking Certification?

PQSmitra Team helps organizations to implement the requirements of CE mark in the simplest and systematic manner. The methodology of system implementation covers Initial review, planning followed by implementation, and documentation. PQSmitra Team offers active support and hand-holding to organizations to achieve successful system implementation and positive audit results. 100% documentation support is offered to expedite the implementation process. The implementation process is described below:

- Initial visit at your organization to understand the applicable directive.
- Understand the requirements of the Directives or the harmonized standards.
- Gap analysis of the existing system with respect to applicable directives requirements.
- Determine whether self-assessment or independent conformity assessment is necessary.
- Testing of the product & its conformity to directive.
- Support for preparation of technical documentation.
- Affixing of the CE mark & draw up the European Union Declaration of Conformity



#### PQSmitraService Features appreciated by clients



Simple & Practical Approach



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5,56,000+ Consulting Hours



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