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Compliance requirements for EU market- The CE marking

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Short Communication

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Abstract

This article is a simple overview of the CE compliance process useful for startups and manufacturers. It covers the entire process and dos and don'ts while obtaining a CE mark.

Keywords: Directives, Standards Marking, Conformance, Regulatory Compliance, Technical File.

1.0 Introduction: The importance of CE marking for manufacturers in India.

CE(Conformitie Europeanne) mark means European conformity in French. A product bearing this mark indicates that it complies with all European regulatory requirements. This marking offers great advantages to trade and industry in India for the reasons cited below.

The single European market is a great benefit for export markets. The free movement of goods, services, capital, and labour creates the economic space that provides a foundation for prosperity in the European Union and its trade partners. Earlier, Indian manufacturers and exporters have had to deal with various sets of national legislation within Europe. Thanks to the introduction of the CE marking, the trade constraints between the Member States of Europe have disappeared. The CE marking thus becomes the "trade passport" for products to be exported to Europe. The other key advantage is the standards considered by EU-known as EN (European norme) standards are derived from the IEC (International Electrotechnical Commission) and ISO (International Organization for Standards), the same source for Indian standards! This makes the conformity path for Indian manufacturers easy.

Since 1985, the European Union has developed original and innovative instruments to remove barriers to the free circulation of goods. Among these, the NEW approach to product regulation and the Global approach to conformity assessment are two of the most prominent. This legislation is expressed in the form of NEW approach Directives, which are based on the following principles:

- Harmonization is limited to essential requirements concerning health, safety, environment, and consumer protection.
- Only products fulfilling the essential requirements may be placed on the market and put into service.
- Harmonized standards, the reference numbers of which have been published in the official journal and which have been transposed into national standards, are presumed to conform to the corresponding essential requirements.
- Application of harmonized standards of other technical specifications remains voluntary, and manufacturers are free to choose any technical solution that provides compliance with the essential requirements.
- Manufacturers, may choose between different conformity assessment

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procedures provided for in the applicable directive.

Essential requirements set up by New Approach directives may overlap or complement each other and the product may fall under the scope of more than one directive. The CE Marking symbolizes the conformity of the product with the provisions of all applicable directives, and that the conformity assessment has been carried out through appropriate procedures as mentioned in the directives. A product bearing the CE marking can be traded in every country of the European Union.

2.0 Directives

Directive is the most important instrument in the CE marking process. The main objective of the directives is to guarantee the free movement of apparatus and to create an acceptable environment in the EUROPEAN UNION (EU) territory. As a result, it lays down general apparatus protection requirements and leaves it to the standards, primarily European harmonized standards, to define technical requirements to achieve the level of protection required.

The Directives are basically legislation, covering a wide range of policies and developed by the European Council, Commission, or Parliament. **Member nations are required to implement this into national law.**

There are more than 30 directives dealing with various product families. The most prominent ones are Low Voltage Directive, EMC (Electromagnetic Compatibility) Directive, Machinery Directive, Medical Devices Directive, and Pressure Equipment Directive. Each directive outlines the scope of what it covers.

For example, the Low Voltage Directive states that "*This Directive shall apply to electrical equipment designed for use with a voltage rating of between 50 and 1,000 V for alternating current (AC)and between 75 and 1,500 V for the direct current (DC).*"

3.0 Regulations:

In contrast to Directives, Regulations are directly applicable and do not need to be transposed into national law. This means the Regulations lower the risks of discrepancies in interpretation across the EU.

The new regulations introduce stricter pre-market control of high-risk devices, strengthen post-market surveillance. Medical Device Directives/PPE (Personnel protection equipment /IVD (In vitro diagnostic devices) have been changed into regulations.

4.0 Compliance Mechanism

The process of achieving compliance to enable the application of the CE mark is described briefly in the following paragraphs.

4.1 Selection of Directive:

Identify the most suitable directive for your product. Little use of common sense and reading the scope of the directive will help to identify the right one e.g. In the case of a **Household drill**, the Low Voltage DirectiveLVD), Electromagnetic Compatibility Directive (EMC), RoHS, (Restriction of use of Hazardous substances) and the machinery directive are applicable. This is because it operates on supply voltage (within the scope of LVD). It has a commutator type of motor within the scope of EMC. And it has to undergo risk assessment as per the Machinery directive. RoHS Directive now applies to all electrical and electronic equipment. This means that the product before qualifying for the CE marking has to meet all the above directives.

4.2 Identification of Standards:

To comply with the directive, the easiest route is to make use of harmonized EN standards as compliance to these standards means compliance to the directive. More than 90% of the EN standards are same as the IEC standards with minor or no changes. The same standard numbers are allocated to these, for e.g., IEC 60896 and EN 60896 (lead acid batteries).

Standards fall into 3 categories. Basic, Generic, and Product family/product-specific standards.

a. Basic Standards: For every parameter considered, say Insulation resistance for example, these standards provide a method of test and description of the test facilities required to perform. It also provides the details of the measuring equipment to be used. These standards are not linked to any type of apparatus and do not contain any performance criteria. The applications of these standards do not authorize a manufacturer to affix the CE marking. Basic standards are, therefore, not published in the Official Journal of the European Union. *These are given as cross-references in the other standards.*

E.g., EN 60695 - Fire hazard testing,

EN 61000 – Series – Basic standards for EMC testing.

b. Product Family Standards: These standards are intended in principle for all products in use in a particular environment i.e. for a group of related products. The standards contain the limit values that must be generally applied. For the test methods, reference is made to the basic standards. The performance requirements are also indicated, usually in general terms.

E.g., EN 60335-1-1 Safety household and similar appliances -general requirements,

EN 60598-1 general requirements for luminaires.

Product Specific Standards: Product standards detail technical requirements as applicable to the particular product. Test levels and limit values are prescribed and usually deviate from the general standard. Product (group) standards are eligible for harmonization and therefore for publication in the Official Journal of the EU and can be used for certification within the context of the CE marking. Product standards always take precedence over general standards!

Eg., EN 60335-2-80 Fans

EN 60400 Lamp holders for tubular fluorescent lamps and starter holders.

4.3 Assessment Procedure:

The directives provide various modules of assessment. Module A is the simplest where the manufacturer can do a self-assessment by testing and evaluating in his own or any independent laboratory and qualify himself.

Module H is the most severe where a notified body from the European Union is involved and also the quality system of the manufacturer is assessed. This is mostly applicable to invasive, implantable medical devices, products used in hazardous areas, etc.

Each Directive specifies the type of applicable modules. The manufacturer then chooses the most suitable module.

4.4 Technical File:

This is the objective evidence of all the evaluations done to comply with the Directive/ Standards. This has to be compiled and maintained by the manufacturer or his agent for a period of 10 years from the date of stoppage of selling that particular product in the EU. Some directives have revised this to 10 years from the date the product was launched. (e.g. Low voltage directive).

4.4.1 Content List for TF

Part I: Description of the apparatus:

- Identification of Product
- A technical description

Part II: Procedures used to ensure conformity of the product to the applicable requirements:

- A Technical rationale;
- Details of significant design elements;
- Photographs and illustrations.
- Test evidence (test reports of independent or manufacturer's own showing compliance to the relevant standard);
- Justification of sampling where a family of products are involved;
- Description of manufacturing process;
- Ongoing compliance mechanism;
- User manual/installation instructions.

Part III: A report or certificate from a "Competent Body" (this is applicable only for EMC directive in situations where there is a family of products and the manufacturer wants to test only 1 or 2 on a sample basis and justify that the entire family meets the EMC requirements).

Part IV: Declaration of Conformity: This is the document which accompanies the consignment and authorizes the manufacturer to put the CE mark on the product. Signed by the CEO or any responsible person, this document relates the product to the directive and standards used and shall be in the prescribed format as per EN 17050-1 and -2. A sample DOC is annexed at the end of the article.

5.0 CE Marking:

Having complied with the requirements as stated above the product is now ready for CE marking. CE stands for "Conformite Europeanne", a French word meaning European Conformity. The marking placed on a product is the sole responsibility of the manufacturer. No organization can award or supply a CE mark. Only a report that may justify the application of the marking can be provided. Its purpose is to satisfy a customs official or the relevant country administration. It is not intended for the customer; it is not meant to be a quality mark. The CE conformity

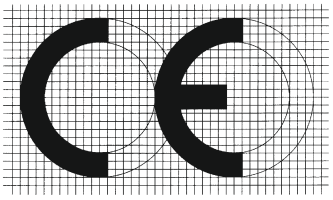

Figure 1.1-2: The form of the CE-Marking.

marking shall consist of the initials "CE" taking the following form.

- If the CE marking is reduced or enlarged then the proportions given in the above graduated drawing must be respected.
- The CE marking indicates that the product bearing this mark meets all applicable directives/regulations.
- However, where one or more of these Directives allow the manufacturer during a transitional period, to choose which arrangements to apply, the CE marking shall indicate conformity only to the Directives applied by the manufacturer. In this case, particulars of the Directives applied must be given in the documents, notices, or instructions required by the Directives and accompanying such apparatus.
- The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm.

6.0 Controlling And Monitoring Of CE Marking:

The CE marking is controlled and monitored in the European Union by the following authorities.

A. *Competent Authorities* – A Competent Authority is the body that has the authority to act on behalf of the government of a Member State to ensure that the directive's requirements are carried out in that Member State. They may take appropriate measures to remove unsafe devices from the market and communicate with the EU Commission on incident involving devices.
E.g.: Ministry of Industries in Italy.

B. *Notified Bodies* – A notified body is a certification organization that the Competent Authority of a member state designates to carry out one or more of the conformity assessment procedures for a given directive. Make sure the NB is qualified to do your Job.
http://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=country.main
E.g.: SEMKO, VDE.

C. *Competent Body* – Competent Bodies are EMC Testing laboratories designated by a 'Notified body' to perform EMC testing for defined types of equipment.
E.g. SEMKO, VDE.

7.0 Rohs Requirements:

Directive 2011/65/EU lays down rules on the restriction of the use of hazardous substances in electrical and electronic equipment (EEE)

with a view to contributing to the protection of human health and the environment, including the environmentally sound recovery and disposal of waste EEE. All categories of electrical and electronic equipment are covered under 'Restriction of Hazardous Substances (RoHS) Directive'.

With effect from July 22nd, 2021, the maximum concentrations permissible by weight for the following elements are specified:
Cadmium (0.01 %),
Lead (0.1 %),
Mercury (0.1 %),
Hexavalent chromium (0.1 %),
Polybrominated biphenyls (PBB) (0.1 %),
Polybrominated diphenyl ethers (PBDE) (0.1 %),
Bis(2-ethylhexyl) phthalate (DEHP) (0.1 %),
Butyl benzyl phthalate (BBP) (0.1 %),
Dibutyl phthalate (DBP) (0.1 %),
Di isobutyl phthalate (DIBP) (0.1 %),

It also becomes the responsibility of the manufacturer to get the products tested for compliance with the above requirements and thereafter maintain constant control of the raw materials sourced from their vendors. These days, certification agencies are also offering services to maintain RoHS compliance throughout the supply chain and provide even a mark which can be put on the final product. There are a number of labs that are qualified to test for RoHS.

8.0 Brexit:

Following a referendum on 23 June 2016, Brexit officially took place at 23:00 GMT on 31 January 2020 (00:00 1 February 2020 CET). The UK is the only sovereign country to have left the EU.

- If you currently 'CE' mark your product under existing EU rules, you will be required to continue to do so post-Brexit if you wish to continue placing it on the market in the EU post-Brexit,
- UK Notified Bodies will lose their status as EU Notified Bodies
- If you or one of your product suppliers rely on a UK Notified Body for certification of conformity for 'CE' marking purposes, you will need to obtain alternatives
- While 'CE' marking for products may no longer be a legal requirement in the UK post-Brexit, it is likely that the UK market will still require evidence of conformity of products.
- UKCA marking will be required instead of CE marking.
- All UK Notified Bodies will become UK 'approved bodies.
- This will apply to products to be placed on the UK market and will denote compliance for authorities (not a consumer mark). Legislation is now a force that enables the UKCA marking to be placed on a label affixed to the product or on a document accompanying the product until 11:00 pm on 31 December 2027.

9. Conclusion: In summary, all one has to do is to identify the applicable directive, look at the route for conformity, self-declaration, or notified body, get the product tested at an accredited lab, or get it witnessed by a certification body competent to do so. Thereafter, draw up the technical file, sign the declaration of conformity, and sell. A word of caution here is to ensure that the notified body is accredited and the product covered is within its scope. This can be checked from the link provided under the section 6. This is because there is no regulation in India for creating certification bodies, and many unauthentic certificates are being issued every year. The accreditation status can also be checked from the NABCB website for bodies operating in India and the IAF website for international agencies. Let us hope to make India a global hub for quality and safe manufacturing.