CERTIFICATION – CE MARKING PROCESS

I. General information on CE Marking

The European Commission’s New Approach to harmonisation came into force in 1985 to guarantee a minimum level of product safety and to facilitate the free circulation of goods within the single Market. It concerns a set of essential requirements in matters of safety, health, environment and consumer protection.

The New Approach directives (Community level legislation which is mandatory in all countries of the European Union when transposed into national law) impose a set of “essential requirements” along with the affixing of a visual symbol to demonstrate that a product complies with “CE marking” requirements. These directives are based on harmonised European standards, or European Technical Approval Guidelines which translate the essential requirements into technical specifications.

CE marking is therefore a mandatory European label for all products which are subject to one or more European Directives.

It is an obligatory and visible sign which indicates that the products concerned can be placed on the market in the European area. It demonstrates the attestation of conformity system which the manufacturer, or the one responsible for first placing it on the market, has used to ensure that the product complies with all of the provisions in the relevant directive(s) (these provisions deal in particular with matters of safety, public health and consumer protection).

Member States have a dual commitment:

- to check that the manufacturer is justified in placing products on the market within the framework of the essential requirements of the directive or directives
- to allow free circulation of CE marked products in their country, regardless of where they originate

Each directive describes the means by which a product must demonstrate compliance with the essential requirements. Depending on the nature of the risks inherent in a product, CE marking can then be affixed:

- either under the sole responsibility of the manufacturer
- or following third party conformity assessment and compliance checks which are adapted within each directive according to the product family (tests and initial type testing, fabrication control, quality assurance).
The European “Construction Products” directive is already applicable to certain products. Eventually, all products will have to carry the CE Mark.

II. CONSTRUCTION PRODUCTS AND CE MARKING

1) Characteristics of the Constructive Products Directive (DPC)

The Construction Products Directive is a New Approach Directive concerned with harmonisation of Member States’ legislative, regulatory and administrative arrangements for construction products, in as far as essential requirements for construction works are related to them. Adopted in December 1988, following publication of reference 89/106/CEE in the OJ, its aim is to harmonise regulations in each of the Member States in order to facilitate the free circulation of construction products in Europe, and at the same time allow Member States to guarantee a high level of safety and health for construction end users.

The CPD determines the general essential requirements and refers to harmonised technical specifications when setting out the required characteristics for construction products.

The CPD therefore provides a guarantee that construction products placed on the Community market are suitable for their intended use i.e. that they display the characteristics which will allow the construction works in which they are incorporated to satisfy the essential requirements.

These essential requirements, which are intended for works and not products are:

- Mechanical resistance and stability
- Safety in case of fire
- Hygiene, health and the environment
- Safety in use
- Protection against noise
- Energy economy and heat retention

These requirements must be satisfied for an “economically reasonable working life”.

For each of these requirements, the directive sets out that “interpretative documents” give concrete form to the product characteristics which are specified in detail in the harmonised standards, or European technical approval guidelines, used for application of the directive.

The CPD has been transposed into French law by decree no. 92-647 (revised by decree no. 95-1051). This decree requires the CE mark to be affixed to construction products placed on the market, as and when harmonised technical specifications (harmonised European standards and European technical approvals) relevant to these products become available.
and their references published in the Official Journal of the European Community. Successive French ministerial orders reflect these Community measures nationally.

There is an obligation for CE marking to be implemented on a product by product basis.

_N.B._: Revisions to regulatory arrangements will no doubt be necessary in order to accommodate harmonised technical specifications.

2) Distinction between product and works

*Construction products* are either base products, finished products or semi finished products fabricated from certain base materials and which are placed on the market.

The CPD defines these products as: *“any product which is produced for incorporation in a permanent manner in construction works, including both buildings and civil engineering works”* (article 1 CPD).

For the purpose of the CPD, *construction product* fulfils these four conditions:

- It is pre-fabricated
- It is placed on market
- It is to be incorporated in a permanent manner in construction works
- It is subject (directly or indirectly) to building regulations in at least one Member State.

Several market products together can constitute Kits which, for the purpose of the Directive, are treated in a similar way to products.

*Works* are constructed from products which are CE marked and their characteristics can only be defined after assembly of the products and installation on site (e.g. a civil engineering works such as a bridge, a retaining wall, a building or a part of a building such as a heating installation etc.).

Works are not subject to CE marking. The characteristics and performance of works can be described in building standards but cannot, in any circumstance, be integrated in the harmonised part of the standards for products.

It is important to clarify the distinction between *products* and *works*. The Construction Products Directive regulates the placing of products on the market by the affixing of a CE mark and imposing compliance with relevant technical specifications.

3) Conformity assessment systems and product conformity
The European Commission defines a system of conformity assessment for each product characteristic and its intended use. This ranges from a self declaration by the manufacturer to third party certification.

In all cases, the manufacturer is responsible for the CE marking affixed to his products and for any related information.

For all systems of conformity assessment, the manufacturer must be able to demonstrate proof of:

- “initial type testing” to determine the characteristics which are referenced in the information which accompanies the CE mark
- “factory production control” which allows the manufacturer to ensure that the characteristics evaluated during initial type testing are not subsequently modified.

These systems determine whether or not an independent organisation called a “notified body” should be involved. Depending on the system, the notified body may be responsible for carrying out:

- “initial type testing”
- “continuing surveillance of factory production control”
- “product certification”

CE marking is considered a sine qua non condition for placing relevant products on the market.

The products concerned are those for which the European Commission has issued a mandate for harmonised technical specifications. As these specifications become available, their terms of reference are published in the Official Journal of the European Community.

In France, these references appear in a decree and official notice which set out this legal obligation.

CE marking and its accompanying measures (manufacturer’s declaration of conformity and, if need be, certificate of conformity) demonstrate compliance of the product with the appropriate Community regulations in force. Accordingly, they demonstrate that products concerned by the Construction Products Directive comply with the respective harmonised specifications (harmonised standard or European technical approval).

Attestation of the conformity of a product depends on an evaluation which involves various tasks.
The Construction Products Directive (article 13.3) states that:

“The fact of attesting the conformity of a product presupposes:

a) that the manufacturer has a factory control system adequate to give confidence that his processes can produce products that comply with the relevant technical specifications;

or

b) that, for specific products listed in the relevant technical specifications, and in addition to a factory control system, an authorised certification body undertakes the evaluation and surveillance of the factory production controls or of the products themselves”.

There are, accordingly, two types of task:

a) The manufacturer’s factory production control

b) Evaluation and surveillance of the production control or products themselves by a notified body.

In Annex III, the Construction Products Directive specifies the different systems of attestation and conformity. The system selected for each type of product is defined in Annex ZA of the harmonised standards and in the appropriate section of the European Technical Approvals. French decrees and official notices also refer to the European Commission ruling.
There are two types of system:

- **Certification** of conformity of the product by a notified certification body for systems 1 and 1+. Tests and inspections are organised by the certificating body in accordance with the technical terms of reference in the standards (harmonised part) or in the European technical approvals. The declaration of conformity of the product by the manufacturer is based on the certificate of conformity delivered by this body.

- **The declaration** of conformity of the product by the manufacturer. Tests and inspections carried out under the responsibility of the manufacturer, if necessary by test laboratories (system 3) or notified inspection bodies (system 2 and 2+) which undertake tasks in accordance with the technical terms of reference in the standards (harmonised part) or in the European technical approvals.

4) **Factory Production Control**

In Article 13.3 (a) the directive stipulates that CE marking which attests the conformity of a product with the directive can only be affixed if the manufacturer has a factory production control (FPC) which ensures “that production complies with the relevant technical specifications”.

Annex III of the directive defines the FPC as “a permanent internal control, undertaken by the manufacturer”. “All of the components, requirements and measures adopted by the manufacturer shall be systematically documented in the form of written operating and processing instructions. This documentation on the factory control system must ensure a common understanding of the quality checks and allow verification of the characteristics required for a product as well as an efficient production control”. 
As a rule, the technical specifications (either harmonised European norms or European technical approvals, as appropriate) describe the information which manufacturers require in order to put in place an FPC which complies with the requirements of the Directive.

In order to assist standards bodies and European technical approval bodies in this task, the European Commission has published a Document Guide (GP B) which sets out the procedures which must be considered when developing a factory control system, and specifies that the requirement of the Directive must not be confused with a quality assurance system such as defined in the family of ISO 9000 standards.

Where the requirements of the harmonised specifications are not sufficiently clear in respect of the CPD, producers can use the contents of the Guide to determine the procedures which must be implemented. This guide sets out general terms and conditions such as:

- The manufacturer’s responsibility to organise the FPC and identify tasks and responsibilities
- The need to have up to date documentation which defines the CPD
- The specification and verification of raw materials and testing frequency

These are followed by test methods and verification for:

- Continuous surveillance
- The tests themselves and a record of these
- Identification and correction of non-conformities
- Maintenance of a register
- Traceability

III. NOTIFIED BODIES FOR CONFORMITY ASSESSMENT

The Construction Products Directive expects each Member State to notify bodies to the European Commission. These bodies will be responsible for conformity assessment for the purpose of CE marking:

- Certifying body (when the attestation level is 1 or 1+)
- Inspection body
- Testing body

This notification assumes that a certain number of conditions are respected by the notified body. These are defined in Annex III paragraphs III.3 and III.4 of the Directive.
In order to affix CE marking, the manufacturer or organisation responsible for placing the relevant construction products on the market can request certificates or test reports (as appropriate) in respect of tasks to be undertaken by notified bodies for the purpose of CE conformity:

- In the case of attestation of conformity of a product which corresponds to system 1 or 1+, from a certifying body of their choice which must be notified to the Commission by one of the Member States,
- For attestation of conformity systems 2, 2+ or 3, from inspection and testing bodies of their choice, which must be notified to the Commission by one of the Member States.

Once the appropriate attestation of conformity system has been selected for a product, according to its intended use, the tasks of the notified bodies are defined for each type of product use (in Annexes Z of the harmonised standards and in the relevant section of the ETAG).

CTICM is a **Notified Certification Body** in respect of conformity certification for CE marking of construction products.

CTICM is also pre-notified for other types of products which fall under our areas of expertise in steel construction and fire safety; please consult the downloadable file **CTICM Notifications and pre-notifications**. The « pre-notifications » are confirmed as soon as harmonised specifications become available.

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**IV. TECHNICAL SPECIFICATIONS : STANDARDS AND ETAGs**

1) **Standards**

The Directive defines the **harmonised standard** as a technical specification established by CEN or CENELEC or by these two bodies on mandate of the European Commission. This “status” is ratified as soon as the appropriate references are published in the OJ (articles 4.1 and 7.3 of the directive).

The “harmonised standard” or “harmonised part” of the standard describes procedures for verification of compliance with the standard. It refers to the attestation level of conformity to be applied (in order to affix the CE mark), as per the European Commission mandate (Decision of attestation of conformity published in the OJ).

In practice, a single standard incorporating a “ voluntary standard” and “harmonised standard” is published, with an annex reference ZA, which sets out the specifications that appear in the text of the standard and which belong to the “harmonised part”, namely:

- Characteristics used to describe the product (as performance based as possible) with an indication, wherever possible, of intended use;
minimal performance or type of product performance if necessary;

Testing or performance evaluation methods (these can be described in the testing standards. In this case, the product standard makes reference to the test standards);

Evaluation clauses for product compliance with the standard, including conditions for factory production control;

Annex ZA will also refer to the conformity assessment method.

The harmonised part of the standard deals with requirements introduced by the Construction Products Directive: *(Member states take all measures necessary to ensure that the (construction) products ... destined to be used in works can only be placed on the market if they are suitable for their intended use, that is that they have characteristics such that the works in which they are incorporated ... can satisfy the essential requirements (article 1 of the CPD).)*

“Member states shall assume that the products are fit for their intended use ... comply with (harmonised) standards (article 4.2 of the CPD), compliance attested by the CE mark.

2) European Technical Approval Guides (ETAGs)

The European Technical Approval (ETA) solution is imposed by the European Commission where no relevant harmonised standard exists or can be developed yet.

ETAs are delivered by approval bodies which are members of EOTA (European Organisation for Technical Agreement). In this case, individual evaluation is carried out by a body authorised for this specific task, for the purpose of establishing compliance with the essential requirements of the Directive. As with European harmonised standards, ETAs constitute a technical specification which is applicable to a specific product.

One the ETA has been secured, and in order to affix the CE mark, manufacturers are required to implement the attestation of conformity system in accordance with the directive.

Organisations competent to instruct and deliver European Technical Approvals are designated by the Member States which draw up a list for the European Commission. Competent organisations make up a European group known as EOTA, which develops procedural rules for requirements, preparation and granting of European Technical Approvals.

EOTA organises, amongst its members, the development of European Technical Approval Guidelines (ETAGs), which comprise common evaluation rules for products. It then submits these for endorsement by the European Commission.
In product areas where no ETAG exists, ETAs can be awarded where assessment of the products is adopted by the Approval Bodies acting jointly in EOTA. This is known as the Common Understanding for Assessment Procedure (CUAP).

It is up to each manufacturer (or body responsible for placing the product on the market) to apply for a European Technical Approval through the approvals body of their choice. Costs are borne by the client. The approval body informs EOTA of all requests logged and ETAs delivered.

V. STEPS TO AFFIXING AND USE OF CE MARKING ON YOUR PRODUCTS

1) First step : Identify text relevant to your product

In order to check if the product which you manufacture or import is subject to mandatory CE marking, you need to refer to the CPD (or appropriate Member State regulations e.g. decrees and formal notices in France).

2) Second step : Respect essential safety requirements

**Essential safety requirements** are published in annex I of the relevant directive; it is important to be aware of these.

- Mechanical resistance and stability
- Safety in case of fire
- Hygiene, health and the environment
- Safety in use
- Protection against noise
- Energy economy and heat retention

For compliance purposes, the CPD refers to European harmonised standards and to ETAs.

3) Third step : Procedure for conformity assessment

CE marking can be affixed once an attestation of conformity procedure has demonstrated compliance with the essential requirements. This system relies in great part on the involvement of various bodies :

- Certification bodies
- The manufacturer
- Test laboratories
- Inspection bodies
Depending on the risks associated with a product, this procedure varies from simple conformity assessment by the manufacturer to verification by a notified body or implementation of a quality assurance system (ISO 9001 standard), controlled by an accreditation body.

4) Fourth step : Affixing of CE mark

*Directive 93/68 of 22/7/93 (OJEC L220 of 30/8/93) regulating the use and affixing of CE marking.*

Once a product complies with the directive’s essential safety requirements, you can affix the CE mark. This is the visible sign of a product’s conformity.

The look and proportions of the CE mark are described below:

- The mark must be visible, legible and indelible.
- It must be affixed on the product or its identification sheet, or, if this is not possible, on the packaging, usage instructions and guarantee.
- Size : in principle, CE marking components must not be less than 5 mm long (there is no upper limit).
- The choice of colour and labelling method (label, engraving etc.) is at the discretion of the manufacturer.
- In addition, it is possible to affix voluntary application marks attesting compliance with national or European standards, on condition that these are not confused with CE marking.

5) Fifth step : Attestation of conformity

It is necessary to attest conformity of the product to the essential mandatory safety requirements. This attestation is based on a declaration and technical file.

The manufacturer or their representative established in one of the EEA countries must produce a CE declaration of conformity, even if they have used a third party checking body.

It is a document which the manufacturer must use to attest that the product complies with the “essential health and safety requirements” of the relevant regulation and for which he takes full responsibility.
In general this information includes:

- The name and address of the manufacturer or their representative
- A description of the product
- Reference to the harmonised standards or other specifications used
- Identification of the signatory

If necessary, this document is accompanied by an attestation delivered by a notified body.

The declaration must be produced in one of the formal languages of the EEA. However, it is strongly recommended that the declaration of conformity be translated into the language of the country to which the product is destined, for obvious commercial reasons and in order to facilitate relations with the Member State authorities responsible for checking.

According to the directives, this declaration must be delivered to the end user or kept available to the Member States authorities for ten years from the date of manufacture of the product.

6) Sixth step: The consequences of CE marking

No product subject to the CPD can be placed on the market without CE marking.

Once it has obtained the CE mark, a product can circulate freely on the European market without any formality, national safety standard or new test being required.

National authorities responsible for surveillance of product safety (customs, ministerial departments in charge of competition, consumption and anti-fraud) can only demand the declaration of conformity and technical dossier in order to check the validity of the marking. These documents must be produced within a reasonable length of time. When a check takes place, and CE marking is either absent or fake, national authorities can penalise the manufacturer through administrative and criminal procedures (fines and removal of products from market).

VI. REFERENCES

http://ec.europa.eu/enterprise/construction
http://www.gnb-cpd.eu
http://www.dpcnet.org
http://www.eic.ccip.fr