Steps to Certification / CE Marking

Step 1 The applicant identifies which products or activities are to be Certified and confirmed which standards apply *(Note: only products which are covered by a harmonized CEN Standard can be CE marked)*

Step 2 The applicant develops and implements a quality system which meets the requirements of the relevant standards. Once this is in place, the Certification process can commence. (If CE marking is possible then this would follow on from Certification). Enquiries and a request for application forms can be submitted to PTS

Step 3 The applicant completes an Application Form, which provides the necessary information/detail to PTS Certification for a quotation to be prepared.

Step 4 PTS reviews the application and any supporting documents to ensure that Information about the client and product is sufficient for the certification process, the scope of certification sought is defined and PTS has the means to perform all evaluation activities including competence and capability of certification personnel

Step 5 You may choose to opt for a "pre-assessment" to provide you with a preliminary evaluation of your management system, enabling you to identify opportunities for improvement and potential non-conformances before beginning the accredited Certification process.

Step 6 Stage 1 Assessment

The stage one audit is performed by a lead auditor at your premises, this is to audit your management system documentation and to evaluate site-specific conditions and to undertake discussions with your personnel to review your status and understanding regarding the requirements of the standard, and operation of your management system. To provide a focus for planning for stage 2 by gaining a sufficient understanding of your system to determine the preparedness for the stage 2 audit. After the stage one audit the lead auditor submits his findings and recommendations in a written report.

The interval between stage 1 and stage 2 audits is determined with consideration given to the needs of the client to resolve areas of concern identified during the stage 1 audit. PTS also considers whether any revisions are required to its arrangements for the stage 2 audit.

Step 7 Stage 2 Assessment

The stage two audit is to evaluate the implementation, including effectiveness of your management system and Factory Production Control (where relevant). The stage 2 audit takes place at your site(s). It seeks evidence about conformity of operations and production control to all the requirements of the applicable management system standard or other normative document. After the stage two audit the auditor submits his findings and recommendations in a written report.

Step 8 Review

All the client information and the audit reports are forwarded to the PTS Decision Committee to enable decision to be made. This information includes audit reports, comments and non-conformities and where applicable, the correction and corrective actions taken. The Lead Auditor's recommendation whether or not to grant certification together with any conditions or observations is considered.

Following the award of Certification, surveillance audits will commence on site bi-annually/annually to ensure that the certified systems complying with the relevant standards and demonstrate continual improvement. Surveillance audits cover representative areas and functions covered by the scope of the client's management system on a regular basis as above with a 3 year re-certification during which, all areas of the scope are audited.

CE Marking

1. Identify the directive(s) and harmonised standards applicable to the product

There are more than 20 directives setting out the product categories requiring CE marking. The essential requirements that products have to fulfil, eg safety, are harmonised at EU level and are set out in general terms in these directives. Harmonised European standards are issued with reference to the applied directives and express in detailed technical terms the essential requirements.

2. Verify the product-specific requirements

It is up to you to ensure that your product complies with the essential requirements of the relevant EU legislation. Full compliance of a product to the harmonised standards gives a product the presumption of conformity with the relevant essential requirements. The use of harmonised standards remains voluntary. You may decide to choose other ways to fulfil these essential requirements.

3. Identify whether an independent conformity assessment is required from a Notified Body

Each directive covering your product specifies whether an authorised third party (Notified Body) must be involved in the conformity assessment procedure necessary for CE marking. This is not obligatory for all products, so it is important to check whether the involvement of a Notified Body is indeed required. These Bodies are authorised by national authorities and officially 'notified' to the European Commission and listed in the NANDO (New Approach Notified and Designated Organisations) database.

4. Test the product and check its conformity

Testing the product and checking its conformity to the EU legislation (Conformity Assessment Procedure) is the responsibility of the manufacturer. One part of the procedure is, as a general rule, a risk assessment. By applying the relevant harmonised European standards, you will be able to fulfil the essential legislative requirements of the directives.

5. Draw up and keep available the required technical documentation

The manufacturer has to establish the technical documentation required by the directive(s) for the assessment of the product's conformity to the relevant requirements, and for the risk assessment. Together with the EC DoC (Declaration of Conformity), the technical documentation must be presented on request to the relevant national authorities.

6. Affixation of the CE marking to your product and EC Declaration of Conformity (DoC)

The CE marking must be affixed by the manufacturer, or by his authorised representative within the EEA or Turkey. It must be affixed according to its legal format visibly, legibly and indelibly to the product or its data plate. If a Notified Body was involved in the production control phase, its identification number must also be displayed. It is the manufacturer's responsibility to draw up and sign an 'EC DoC' proving that the product meets the requirements. That's it - your CE-marked product is ready for the market.

Review

The CE mark is valid for a period of a maximum of 5 years so long as no change to the declaration of performance is made. Should a change be made to the Declaration of Performance, the producer/manufacturer shall notify PTS (Notified Body) of the change. PTS shall conduct a review and re-assessment as appropriate. The CE mark is valid subject to continued compliance with the Standard following a successful assessment.

Further information

ec.europa.eu/enterprise/policies/...mark**et.../**cemarking**.../**ce_**brochure_e...**