



A Brief Introduction to CE Marking

CE marking a product is not an option; it is required by law if the product falls under one of the European Union New Approach Directives. By adding the mark, the manufacturer, their authorized representative, or an importer is declaring that the products meet all the essential requirements of all applicable EU directives. Effectively a CE mark indicates to all authorities that the product is in compliance with the essential health and safety requirements of all directives that apply to the product

CE marking a product is required **if** the product falls under one of the appropriate EU Directives. The converse is also true, if a product is not covered by an appropriate directive then it should not be CE marked.

With the exception of some high-risk products, most products can be "self-assessed" by the manufacturer. The meaning of the CE Mark is widely misunderstood, it is not a quality mark" or "certificate of approval", it is a declaration of the supplier's own responsibility and it allows only for the free movement of the item with the EEA it also enables the withdrawal of non-conforming products to be accomplished more easily.

When considering any new product development or improvement it is essential to consider the regulatory requirements. It is always easier to design in compliance rather than to try and sort things out once the product has been made.

What does CE Marking stand for?

There is some debate... but it is generally thought that CE stands for "Conformité Européen". It is intended to facilitate the free movement of products within the EU by signifying that essential health and

safety requirements have been met. It is not a quality mark or a specific statement concerning the test methodology that has been employed.



Some frequently asked questions

What is CE Marking? The CE mark is the manufacturers (or distributors) claim that the product meets the essential requirements of all relevant EU directives are satisfied. If a product requires CE-marking, it cannot be legally "taken-into-use" in any of the

The term "taken-into-use" applies to a wide range of situations including,

- Sold and delivered to a customer
- Hired out
- Given away!
- On loan *
- Demonstration equipment *
- Your own in-house equipment *

** For most products you get a 3 months "grace period" in these situations*

Why have CE Marks? CE marking was introduced throughout the EU for the following reasons,

- To harmonise standards through the EU
- Create a single European market
- Protect the consumer/customer
- Protect the environment
- Simplify the lives of manufacturers!

The last point often comes as a surprise to people involved in the manufacture of products, however before the introduction

of these harmonized standards it was not uncommon for a manufacturer involved in export to have to "jump through a variety of compliance hoops" for each European country.

What types of products need to be CE marked? The official answer to this is anything that is covered by the regulations! These include,

- Medical devices of all types
- Stand-alone electrical products
- "Working" sub-assemblies
- Installations
- Custom-designed units
- Second-hand equipment
- Upgraded installations or equipment

Should all products be CE marked? The simple answer is NO! Only products within the scope of the "CE Marking" directives should bear the CE Mark. Increasingly manufacturers are being asked to CE marked "inappropriate" products

Does my Product need CE marking? A simple question which can take a while to answer! So give us a call or email us. We don't charge for initial discussions and a lot of people go away happy without ever paying for our services!

I just sell/import, does CE marking affect me? Any product offered for sale in the EU must be CE marked (if it is covered by the directives); if the product is not CE marked by the manufacturer then you will be responsible for the CE mark.

Is third party testing/involvement required? There is no simple answer, some compliance requirements involve the mandatory use of approvals or certification bodies other don't. In some cases the requirement for the involvement of a "Notified body" depends on the route chosen to demonstrate compliance.



What is a notified body? These are organizations appointed by each Member State under the appropriate national regulations to conduct third-party conformity assessment procedures to the product in question or its production processes, as required by the Directives, in order that it may be CE-marked. The procedures vary according to the Directives and third-party involvement is not compulsory for all products. Manufacturers can use the services of Notified/Approved/ Competent Bodies in any member State of the European Community.

Is PCL a notified body? No, however we do work closely with Notified bodies as required. Being an independent organization we are able to provide detailed assistance concerning solutions to problems and even help to implement those remedial actions. When a project does require the involvement of a notified body, we can help to define the scope, identify a suitable body and act as liaison throughout the project.

What does the CE mark signify? CE marking is a declaration by the manufacturer (or distributor/ importer) that the product meets all the appropriate provisions of the relevant legislation implementing certain European Directives.

What is a declaration of conformity? A declaration of conformity (DoC) is a

document (usually a single page) that is produced by the Manufacturer (or distributor/importer) that provides additional details in support of the CE mark. The detailed requirements for a DoC depend on the individual directives but a typical DoC will include the following

- Contact details for the manufacturer (or distributor/importer)
- Information concerning which directives have been covered and any standards that have been used and
- Details of the designated signatory
- Details of any notified body that might have been involved.

It is common for customers or prospective customers to ask for copies of the Declaration. They must be supplied on request.

What is the process? The process that you need to go through to be able to CE-mark your products vary widely and depends on a number of things including,

- The applicable Directives
- The product itself
- The target user/customer
- The market requirements

In a majority of situations, the New Approach Directives allow self-declaration in place of third party (notified body) involvement; but the right to self-declare compliance with the law means that a manufacturer must be responsible for completing all the procedures required by the law and must be able to prove it. This is done by the production of a Technical File. The Technical File is the written justification that all aspects of a product are safe and should be prepared before the product is placed on the market. The Technical File includes information that demonstrates the technical basis for conformity of the product to the applicable requirements of the directive. The manufacturer must keep the Technical File for ten years after the last unit is placed

on the market, unless the directive provides for a different duration.

What is a technical file? The CE marking process revolves around the construction of a technical file for the product. This is intended to cover all of the essential details that show that the product complies. It supports the DoC but is a company confidential document and need only be produced in the event of a legal challenge, or in some instances when requested by government bodies.

How long do we need keep the file? Normally the technical file must be kept for 10 years after the product is withdrawn from the market. Although it should be noted that some directives indicate that a shorter retention period is acceptable for some products.

Who enforces - and what would happen if I don't CE mark a product that should be marked? In the UK, enforcement varies according to the Directives. Some are enforced by local Trading Standards Departments, others by HSE and yet others by the Medical and Healthcare Products Regulatory Agency and the Vehicle Certification Agency. Except where safety is at risk, the relevant enforcement authority will usually provide you with an opportunity to ensure that your product is correctly CE-marked. If you fail to comply then you will be obliged to take your product off the market, and you may also be liable to a fine and/or imprisonment.

What is the PCL approach? Understanding the requirements for CE Marking can be complex and time consuming and is something of a diversion from most the mainstream of most businesses. Our assumption is that you do not want to become an expert on CE-marking; you just want the problem solved quickly and with the minimum disruption to your business. That's what we do!

Over the years we have found that the most effective way of establishing a sustaining CE –marking process within a business is for us to lead the process and assemble the technical files etc for the first product. We use this time to transfer the knowledge to people within the business so that when we leave the process is sustainable and can be applied to subsequent products. In these circumstances we can provide assistance to your in-house team in the following areas,

- Determining the relevant directives
- Review of product and process
- Practical advice and assistance with problems
- Preparation of the Technical File
- Assistance with 3rd party testing if required
- Provision of Declaration of Conformity (or Incorporation) formats
- Assistance with modification of user documentation
- General advice and assistance

Our approach differs from many other “Compliance organizations”, as a result of our personnel’s many years of experience in the product development and manufacture. We will never just accept that a product fails a particular test; we will delve into the reasons and try practical solutions to remove the issues. Ultimately a problem may be too serious and require redesign or remanufacture but you can rest assured that Petts Consulting Limited will have made it best effort to ensure that the product legitimately passes the assessments

What will it cost? Costs vary greatly depending on the product, the directives and the requirement for the involvement of notified bodies. We can usually provide a fairly good estimate of the likely costs once we have information concerning the product. The more information you can

give the better service we can give you. All information is kept in strictest confidence.

How long does it take? Again this is highly product dependent, we have done the process in less than a week and have been involved in large factory installations that take many months however typically an elapse time of 1-2 months is more normal.

Who can help? We can! , give us a call.

What sort of businesses have PCL helped? We have helped a wide range of businesses with everything from basic guidance, through mentoring Clients staff in the process, right through to providing a complete “sub-contract” approach for the whole process, including the management of the involved of notified bodies (where required).

Given below are some examples from a variety of business sectors.

- High power laser systems
- Complex scientific equipment
- Diesel Generators
- Simple electrical goods
- Simple and Complex Toys
- Salon equipment
- Basic Medical devices
- Catering equipment
- Machinery
- Automated production lines
- Geotechnical equipment
- Electronic instrumentation

Important statement: *Petts Consulting Limited will provide the Company with the knowledge of the Directives and an appropriate process which when applied correctly will demonstrate due-diligence. However, the CE-mark is the manufacturers claim that the product meets the essential requirements of all relevant European Directives. The process to be carried out is a self-certification process and the responsibility for any decisions lie with the management of the Company. During the course of the project Petts Consulting Limited will provide guidance and advice but ultimately it cannot be held responsible for such decisions.*

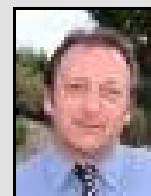
Dr Colin R Petts: Colin is an Associate Member of the Institute of Management Consultancy. He was educated at University College London where he obtained a 1st Class Honours degree in Applied Physics and a PhD in Electronic Engineering. He has worked in high-tech manufacturing and service industries for over 20 years. During this time he has had a variety of roles including research and development, product engineering, operations management, strategic planning and control. He has board level experience in medium-sized businesses and an intuitive understanding of the problems encountered by such businesses. As a result he has gained extensive experience of business restructuring, unit integration and the associated change management.



Bob Bell: Bob has extensive experience in managing Test departments, Production departments and Product management in High tech manufacturing and Pharmaceutical and semi-conductor plant manufacture both mechanical and electrical. He has been involved with the implementation of change within these environments. Previously Bob has also been responsible for the design and production of electronic units used in scientific instruments, and the maintenance of medium sized manufacturing plants. In addition to his involvement with PCL, Bob is a partner in an Electrical testing and Mechanical services company.



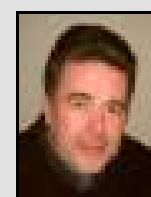
Peter Metcalfe: Peter is an Honours Graduate in Electronics and has over twenty years lecturing experience in Analogue and Digital Electronics and Communications Systems. He has been a qualified, active Radio Amateur for thirty-five years, with all the RFI experience that this entails. He is responsible for the design, construction and management of the Sussex Euro Compliance Group (SECG) test facility, and has over ten years experience of EMC testing with the SECG. He is a member of EMCTLA, EMCIA and ETSI Technical Group 17.



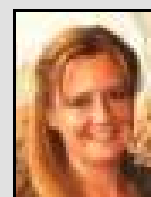
Jim Mackenzie: Jim is an experienced Medical Devices and In Vitro Diagnostics manufacturing and quality /regulatory professional having implemented Food and Drug Administration Part 820, ISO 9001 and ISO 13485 Quality Management Systems Worldwide including systems and Technical Files for 510k clearance and CE marking. He has provided Quality Management System training programmes on Medical Devices and In Vitro Diagnostics within multi national organisations. Jim has also acted as a senior representative for several well-known Quality Certification Bodies (Notified Bodies) implementing training and auditing assignments Worldwide for all the Medical Devices Directives as well as auditing for CE marking, ISO 9001, ISO 13485 and Canadian CMDCAS requirements.



John Field MBA: John has worked in high-technology environments in practically every function and at a senior level including product design, project management, product management, customer support, technical authoring, knowledge management, strategy development and training. His previous work being characterised by troubleshooting roles requiring focus, excellent communications and strategic thinking to bring about successful and sustainable change. John has travelled extensively to work with technologists around the world in companies such as Intel, Samsung, IBM and many others. John has a BSc in Applied Physics, an MBA and is a fully qualified NLP Master Practitioner, Trainer and Coach.



Marja C Petts MA - Company Secretary: Marja was educated at St Hugh's College Oxford where studied English. She speaks German and French. Over the years she has worked in a number of administrative roles and in recent years she has trained as a nurse. In Petts Consulting Limited her responsibilities include web design, administration and aspects of finance.



Directive	Short title of directive	Can we help?
2006/95/EC	Low Voltage	
87/404/EEC	Simple Pressure Vessels	
88/378/EEC	Safety of toys	
89/106/EEC	Construction products	
2004/108/EC	Electromagnetic compatibility (EMC)	
98/37/EC To be replaced by 2006/42/EC on 29/12/09	Machinery	
89/686/EEC	Personal protective equipment (PPE)	
90/384/EEC	Non-automatic weighing instruments	
90/385/EEC	Active implantable medical devices	
90/396/EEC	Appliances burning gaseous fuels	
92/42/EEC	Efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels	
93/15/EEC	Explosives for civil uses	
93/42/EEC To be replaced by 2007/47/EC on 21/03/2010	Medical devices	
94/9/EC	Equipment explosive atmospheres (ATEX)	
94/25/EC	Recreational craft	
95/16/EC	Lifts	
97/23/EC	Pressure equipment	
98/79/EC	In vitro diagnostic medical devices	
1999/5/EC	Radio Equipment and Telecommunications Terminal Equipment and the Mutual Recognition of their Conformity	
2000/9/EC	Cableway installations designed to carry persons	
2004/22/EC	Measuring instruments	