



Understanding CE Marking Requirements for the European Union

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Sample Lead In...Exporting to Europe? Selling equipment that will be incorporated into equipment being sold into Europe? Either way, the CE marking requirements cannot be ignored.

Abstract: This article provides an introduction into the legal and technical safety requirements that affect equipment being sold in the EU. These requirements are also quickly becoming customer imposed requirements (regardless of the final point of destination). Compliance with these requirements can be a comprehensive task and the purpose of this article is not to explain all the steps necessary to comply in detail, but rather to provide an overview so that manufacturers will have a fundamental understanding of the important concepts. Early awareness and understanding of these requirements can save companies tens of thousands of dollars and prevent them from losing market share.

New European laws (referred to as directives) have gone into effect during the past several years that have a broad impact on wide variety of industrial and consumer products, including welding equipment, pressure equipment and vessels. US businesses still generally misunderstand the content of these new laws. The primary purpose of these directives is to ensure products are safe for use and that they do not impose unreasonable risks to an operator or exposed person. For US firms exporting their goods to the European Economic Space (EES) (refer to Sidebar 1), it is a legal requirement that products, in order for them to be placed on the market (or sold) within the EU, that are within the scope of such directives comply with these requirements. Compliance to these New Approach Directives is evidenced by the affixing of a CE marking (refer to Figure 1) to the product, which in most cases can be applied by the manufacturer.

There are many laws related to conducting business in the EU. Some of these laws relate to employers and some cover equipment that is to be sold in the applicable countries. Approximately 20 New Approach Directives exist that cover a range of products from toys to simple pressure vessels to machines. They also cover phenomenon such as electromagnetic compatibility and electrical safety. As should be apparent, a given product can be affected by more than one of these directives. If a New Approach Directive covers a finished product, it must carry the CE marking (and in most cases be accompanied by a declaration of conformity). For some directives, unfinished equipment still must comply with applicable requirements, but it does not need to carry the CE marking. Each directive has its own procedure for how a manufacturer can demonstrate

conformance – for some directives, self certification is allowed, for others a third party (or notified body) is required to verify designs or perform testing (for example).

Too often, companies have signed contracts or submitted quotes to their customer agreeing to provide equipment that complies with CE marking requirements. It is only after the designers begin their design-related activities that CE marking requirements are investigated. This can result in increased costs due to a hurried and irrational decision making process (required by the directives) or may lead to the firm completely ignoring the requirements because the perceived (or actual) compliance cost would eliminate their equipment profit margin.

Welding equipment will most likely be covered by three directives (refer to Sidebar 2): The Machinery Safety Directive, The Low Voltage Directive and the Electromagnetic Compatibility Directive. These directives are organized by recitals, articles and annexes, with the most important part of the directive consisting of the Essential Health and Safety Requirements (EHSR). The EHSRs contain general safety requirements and objectives that could apply to all products within the directive's scope. The manufacturer must determine which EHSR apply to their product and then determine the most effective compliance process. Typically, the most effective way to demonstrate compliance is through the application of European Norm (EN) standards that have been written specifically to support the EHSRs. While some of these standards are generic for all types of equipment, many standards exist for welding equipment (refer to Sidebar 3). Use of an EN standard can be best demonstrated in the following example: An ESHR may require (for automatic welding equipment) that guarding be in place to prevent a robot arm from inadvertently moving in the way of and injuring an operator. An EN standard would provide the requirements for designing a guard or installing a light curtain or a guard interlock to prevent access while the equipment is operating.

The directives do not only relate to welding equipment but also to welding practices and equipment, such as pressure vessels, constructed using welding techniques. These requirements are contained in the Simple Pressure Vessel Directive and the new Pressure Equipment Directive (PED). Builders of equipment should be cautioned that simply because pressure vessels are constructed in accordance with ASME regulations does not automatically infer that the equipment will meet the conformance requirements of the directive. The PED is a new directive, in particular, that will have broad ranging implications for pressure vessels and related equipment. The scope of the PED applies to the “design, manufacture and conformity assessment of pressure equipment and assemblies with a maximum allowable pressure greater than 0.5 bar.” In this context, pressure equipment means vessels, piping, safety accessories and pressure accessories where flanges, couplings and the like are included in this definition. There are some specific exclusions from the directive such as well control equipment used in the oil and gas industry.

Like other directives, the PED contains EHSRs that the equipment must comply with. The topics include ensuring the equipment is designed for adequate strength based on specified design calculations, provisions to ensure the safe handling and operation of the equipment, good manufacturing procedures, requirements for material selection, etc.

Depending on the pressure rating of the vessel, means of demonstrating conformance can range from self-certification to having a notified body review the designs and examine the manufacturing of the equipment. The directive should be consulted carefully in order to avoid excessive and undo costs associated with certification. The manufacturer also must ensure that they are in compliance will all other conformity assessment procedures contained in all applicable directives.

To be sure, the directive compliance process can be costly and requires significant time and involvement by senior design personnel to understand the requirements and develop systems to ensure that the equipment complies. Obviously, the amount of time is a function of how complex the equipment is, but additional engineering hours can easily tally hundreds of hours to fully review the requirements and carry out the necessary actions.

Manufacturers of equipment covered by these directives would be wise to begin their investigation into these requirements prior to accepting an order for equipment to be sold to the EU. While the compliance process involves many steps, it essentially involves these primary processes:

1. Determining which directives apply to your equipment and understanding the compliance options associated with each directive
2. Comprising a listing of standards that will be used to meet the directive's requirements
3. Assessing existing designs versus (or building new designs in accordance with) the directive's and standard's requirements. This design process includes in most instances, performing a hazard analysis and risk assessment of the equipment.
4. Documenting how these requirements have been met (commonly referred to as a technical file)
5. Documenting the instructional manuals and any applicable certifications that must accompany the equipment.

The cost to companies if they do not follow these steps is great and may include lost customers and increased risks due to product liability claims. What is the Return on Investment (ROI) for complying with these requirements? For most mandatory requirements, companies often think that the ROI is negative. However, when applied correctly, an effective compliance strategy can provide a firm with a competitive edge as they will be able to sell equipment to industrial purchasers where their competitors will not. Another primary benefit to a firm includes having equipment that is designed intrinsically safe thereby reducing the chance of injury to exposed operators – to a company, this minimized risk is a very valuable benefit to a firm's primary stockholders, its management and its employees.

In today's economic competition, firms cannot afford to be shut out of markets or have products returned from their customer. Awareness is the first step to becoming prepared.

Since many of the EU Directive and standard requirements are being recognized as the best in the world for ensuring safe products, manufacturers would be prudent to take notice and investigate CE marking requirements further. Many firms have also reported end users outside of the EU (primarily large multinational firms) also requiring CE marking compliance as a means of ensuring that they are purchasing safe equipment (to be used by their employees).

Sidebar 1

The European Economic Space

Countries of the EU	Countries of the EFTA
Austria	Iceland
Belgium	Norway
Denmark	Switzerland
Finland	Liechtenstein
France	
Germany	
Greece	
Ireland	
Italy	
Luxembourg	
The Netherlands	
Portugal	
Sweden	
Spain	
United Kingdom	

*The European Economic Space is comprised of EU and EFTA countries (except Switzerland and Liechtenstein). The EU directives apply to all countries of the EES.

Sidebar 2

A listing of New Approach Directives (requiring the affixing of the CE marking) that would apply to welding equipment or pressure related equipment constructed by Welding techniques.

New Approach Directive Title (Summary)	Effective Date	Scope (Summary) *
Machinery Safety Directive	January 1, 1995	Applies to all machines, which are defined, in part, as an assembly of linked parts, at least one of which moves, which are arranged to perform a specific function.
Low Voltage Directive	January 1, 1997	Applies to electrical equipment between 50 and 1,000 VAC and 75 to 1,500 VDC.
EMC Directive	January 1, 1996	Applies to all electrical and electronic equipment containing electrical and/or electronic components liable to cause EM disturbance or the performance of which may be affected by such disturbance
Simple Pressure Vessel Directive	July 1, 1992	Applies to non-alloy quality (simple) pressure vessels manufactured in series with an internal gauge pressure greater than 0.5 bar.
Potentially Explosive Atmospheres	July 1, 2003 (Note: Transitional period began March 1, 1996)	Applies to equipment and protective systems used in explosive atmospheres
Pressure Equipment Directive	May 29, 2002 (Note: The Transitional Period begins November 29, 1999)	Applies to pressure equipment and assemblies with a maximum allowable pressure greater than 0.5

New Approach Directive Title (Summary)	Effective Date	Scope (Summary) *
		bar.

* - This table only contains a summary of the scope of the directive. Manufacturers are cautioned to consult the actual text of the directive to determine whether their product actually is within the scope of the directive.

Sidebar 3

A listing of typical harmonized European standards that may apply to welding equipment*

Standard Number	Title
EN 60974-1	Safety requirements for arc welding equipment – Power Sources
EN 1050	Safety of machinery – Risk Assessment
EN 349	Safety of machinery – Minimum gaps to avoid crushing parts of the human body.
EN 563	Safety of machinery – Temperatures of touchable surfaces – Ergonomics data to establish temperature limit values for hot surfaces
EN 953	Safety of machinery – General requirements for the design and construction of guards
EN 1127-1	Safety of machinery – Fire and explosions – Part 1: Explosion prevention and protections
EN 50199	EMC – Product standard for arc welding equipment

* - This table is a listing of only some of the standards that may apply to welding equipment. Manufacturers are cautioned to consult reference books such as the New Approach to determine a comprehensive listing of standards.