A Guide to Understanding European Technical Regulations and CE Marking
CE 123...

A Guide to Understanding European Technical Regulations & CE Marking

by

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CE Marking Products & Services

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• Training – Public and On-Site Customized Formats
• Guidance Manual with Supplementary CD-ROM
• Directive Handbooks
• Harmonized EN Standards Sales Point

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About CITRA

The Center for International Regulatory Assistance (CITRA) is a non-for-profit program provided by the Duquesne University Chrysler Corporation Small Business Development Center to help companies comply with the European CE marking product compliance and marking system. The Duquesne University Chrysler Corp. SBDC has been helping companies access international markets for over 20 years.

CITRA was created out of the need for comprehensive and independent European regulatory consulting and training services. U.S. manufacturers are increasingly realizing the importance of European technical regulations and CE marking. CE marking is now mandatory for over half of all U.S. exports to the European Union. CITRA technical advisors travel extensively throughout Europe to offer you the most comprehensive and “up to date” technical information and compliance strategies available.

CITRA CE marking products and services include direct assistance, public and private training programs and CE marking guidance manuals and CD-ROMs. Our products and services offer a practical and systematic approach to the steps and procedures needed to confidently walk a product through the CE marking system.

Supplementary CD-Rom

CE 123… A Pocket Guide to Understanding European Technical Regulations & CE marking

- Multimedia CE marking learning experience.
- Full-text European directives (official).
- PowerPoint presentations for training staff.
- Video highlights.
- Interactive participating countries mapping program.
Foreword

CE 123… provides a practical and systematic review of the CE marking system. This multi-layered training manual begins each chapter with layer one, the fundamentals of each step of the CE Marking system. The second layer will provide you with in-depth information on each of the elements of the CE marking system to assist you with making your product conformity decisions. The third layer of CE 123… provides you with detailed strategic considerations and examples of real scenarios regarding CE marking. CE 123… focuses on:

- CE marking your goods for export to Europe in a rapid and cost-efficient manner. Our overview of the organization and functioning of the CE marking system is matched with a series of check-off lists covering what you will have to do to qualify your products for sale in European markets.

- The best practices in complying with CE marking requirements, including advice on how best to select and work with outside groups such as notified bodies, surveillance authorities and authorized representatives. These different groups approach CE marking in many different ways. CE 123… emphasizes how manufacturers can best work with these groups.

- Integrating your CE marking decisions into your overall strategic marketing plan for European exports. At many stages of the process, you will be asked to make judgments and choose among many alternatives about the design, manufacturing and marketing of your product. These CE marking decisions will have a significant impact on your European sales.

- The European Communities’ regulation of other aspects of your marketing and distribution plans. Topics covered include product promotional materials, agent-principal relations, product packaging and packing requirements and bans on anti-competitive distribution agreements. Although most of these requirements are outside of the CE marking system directly, CE 123… provides you with the information needed to market and ship in good conscience to European countries.

- Throughout this manual, the term “manufacturer” will refer to a company that has the responsibility for CE marking a product, regardless of whether they are the actual manufacturer, distributor or some other entity that places a product on the market, or into service in the European Union.
“Obtain Your Product’s European Passport Today”
Introduction

CE Marking & the European Union

The letters “CE” are an abbreviation for “Conformité Européene,” which is French for European Conformity. CE marking is mandatory European product compliance and marking system for many manufactured products. The CE marking system covers most manufactured products other than agricultural materials, chemicals, pharmaceuticals, cosmetics and transportation equipment.

The European Union (EU) developed CE marking to cover product safety and environmental concerns in order to reduce technical barriers to trade within Europe. Before the CE marking system, manufacturers had to comply with multiple, and often inconsistent, national systems of product requirements and standards. Now, once products comply with CE marking, they may be freely sold to and within all CE marking participating countries. The CE marking systems supercedes previous national mandatory marking and compliance systems.

The CE Marking system was developed, and continues to be developed by Directorate General Enterprise, a body in the European Commission. The Commission is the bureaucratic arm of the EU, approximately equivalent to the cabinet agencies in the U.S. federal government. The Commission is divided into a series of “Directorates General.” Directorate General Enterprise is approximately equivalent to the U.S. Department of Commerce, without the trade promotion functions undertaken by the U.S. agency.

Under the “subsidiarity” principle, the EU can only act in areas in which the member states are unable to act. For CE marking purposes, the subsidiarity principle means that the basic policies are set at the European Union level, but implementation is delegated to member countries and/or non-governmental organizations. This delegation is reflected in the roles of groups such as the European standards development organizations, notified bodies and surveillance authorities.
Participating Countries

The European CE marking participating countries offer a highly sophisticated market of 360 million people with a buying power over $8 trillion dollars. This is the only market in the world that is comparable to the United States in size, prosperity and freedom of trade. The “CE market” is becoming even larger with the expected admission of several more Eastern European countries within the next few years. Many other countries outside of Europe are also considering using the CE marking system. CE marking is rapidly becoming a global product compliance scheme.

CE marking Participating Countries

<table>
<thead>
<tr>
<th>European Union Countries:</th>
<th>EFTA countries¹:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
<td>Iceland</td>
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<tr>
<td>Belgium</td>
<td>Norway</td>
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<tr>
<td>Denmark</td>
<td>Liechtenstein</td>
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<td>Finland</td>
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<td>France</td>
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<td>Germany</td>
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<td>Greece</td>
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<td>Luxembourg</td>
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<td>Netherlands</td>
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<td>Portugal</td>
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<td></td>
<td>Spain</td>
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<td></td>
<td>Sweden</td>
</tr>
<tr>
<td></td>
<td>U.K.</td>
</tr>
</tbody>
</table>

Anticipated Participation 2004:
- Cyprus
- Czech Republic²
- Hungary
- Latvia
- Lithuania

Anticipated Participation Year 2007:
- Bulgaria
- Romania

¹ The European Free Trade Association (EFTA) is an international organization comprised of four countries, Iceland, Liechtenstein, Norway and Switzerland. Switzerland rejected the European Economic Area (EEA) agreement between the EU and EFTA, and is therefore not obligated to participate in the CE marking system.

² Czech Republic, Hungary, Latvia and Lithuania currently accept CE marked products under the Protocol to European Conformity Assessment and Acceptance (PECA) agreements.
Technical Harmonization

The “New Approach”
The European Union has been gradually developing and implementing the “New Approach” to technical harmonization since 1985. This “New Approach” to product regulation has been created to overcome the difficulties of the “Old Approach” system, which contained highly technical directives that made decision making virtually impossible for manufacturers regarding product conformity with European directives.

The “New Approach” to technical harmonization now drives the CE marking system. The “New Approach” directives now contain only the essential requirements, or desired outcome of the legislation, leaving the detailed technical specifications (harmonized standards) to be developed and approved by private standards organizations.

Under the “New Approach,” each directive sets forth a set of health, safety and/or environmental requirements with regard to the protection of people, animals, property and the environment. These directives do not mandate how these requirements are to be achieved; however, they do describe the general principles and procedures that must be met for compliance.

This framework provides the standards development agencies of the European Union, the notified bodies (private conformity certification organizations) and the national surveillance authorities with some latitude in the interpretation and enforcement of these requirements.

The “Global Approach”
In 1989, a “Global Approach” to technical harmonization and EU product regulation was introduced to expand upon the “New Approach”. The “Global Approach” borrows some of the elements of the “New Approach” system, but does not include an obligation to use the CE marking logo. The “Global Approach” directives may also affect products covered by “New Approach” directives.

The “Global Approach” also covers to the use of European standards relating to quality assurance systems; the implementation of accreditation systems; the use of inter-comparison techniques among member states; and the promotion of mutual recognition agreements concerning testing and certification of products outside of the European Union.
Products & Concerns Covered

By the year 2004, approximately half of all U.S. exports to the EU will be required to comply with the CE marking system. Raw materials and primary products such as agricultural, pharmaceutical, cosmetics and transportation products are all still regulated by the “Old Approach” directives, which are outside of the CE marking. Some products are still primarily regulated at the national level. These generally include simple household durables such as clothes, mattresses, sheets, etc. Given these exceptions, it is very likely that some sort of EU product regulatory scheme will cover your product.

CE marking covers the following products and product attributes:

<table>
<thead>
<tr>
<th>Machinery</th>
<th>Medical Devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electromagnetic Compatibility</td>
<td>Active Implantable Medical Devices</td>
</tr>
<tr>
<td>Low Voltage Equipment</td>
<td>In vitro Medical Devices</td>
</tr>
<tr>
<td>Pressure Equipment</td>
<td>Personal Protective Equipment</td>
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<tr>
<td>Simple Pressure Vessels</td>
<td>Explosive Atmosphere Equipment</td>
</tr>
<tr>
<td>Hot Water Boilers</td>
<td>Explosives for Civil Use</td>
</tr>
<tr>
<td>Construction Products</td>
<td>Recreational Craft</td>
</tr>
<tr>
<td>Non-Automatic Weighing Instruments</td>
<td></td>
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<tr>
<td>Radio &amp; Telecommunications Equipment</td>
<td></td>
</tr>
<tr>
<td>Noise Emission</td>
<td>Refrigeration Appliances</td>
</tr>
<tr>
<td>Cableway Installations Designed to</td>
<td></td>
</tr>
<tr>
<td>Carry Passengers</td>
<td>Gas Fired Appliances</td>
</tr>
<tr>
<td></td>
<td>Lifts</td>
</tr>
<tr>
<td></td>
<td>Ballasts for Fluorescent Lighting</td>
</tr>
</tbody>
</table>

Products and product attributes regulated by the “New Approach,” but do not require CE marking:

- Marine Equipment
- High Speed Rail Systems
- Packaging & Packaging Waste
- Waste Electrical and Electronics (WEEE)
- Removal of Hazardous Substances (ROHS)
- Interoperability of the Trans-European Conventional Rail System
- Transportable Pressure Equipment

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How Does this Affect Your Product?

CE marking will cover a wide range of activities in the design, development, production, documentation, sale and distribution of your product. There will be major differences in the product requirements a manufacturer must fulfill for products being manufactured for sale in the U.S. versus Europe. The general categories of product modifications and concerns have been in the following areas:

- Product design
- Material acceptability
- Product labeling
- Product Documentation
- Quality control & manufacturing process
- Packaging & packing
- Distribution requirements

Here are a few common examples of the modifications manufacturers have made to their products and/or production procedures to comply with CE marking:

- Provide a “Declaration of Conformity.” Certain products for sale in the EU require a “Declaration of Conformity.” This is a document that attests that the manufacturer has complied with all CE marking requirements.

- Include new safety measures. The machinery directive sets forth additional requirements for “positive failsafe interlocks” on certain equipment, not required in the same instances in the U.S.

- Added elimination of electrical risks. The electromagnetic compatibility directive calls for the addition of an extra filter to be placed between the motor and the source of current in electric handheld power tools.

- European approvals for materials. U.S. manufacturers of pressure vessels must utilize European approved materials, and meet certain specifications and verifications for weld procedures.

- Required quality assurance systems. Some products require manufacturers to implement an ISO 9000 quality assurance system before they can place their products on the European market.

- Different electrical systems. Producers of electrical equipment have been required to make significant changes to their products’ voltage, cycle, amperage, cable polarity and/or ground requirements.

- Obtaining certifications from European testing organizations. High-risk medical equipment and machines are often required to be tested and certified by European testing and certification organizations.
Who is responsible for CE Marking?

Under EU law, the company that “places a product on the market” or “puts it into service” is responsible for all CE marking requirements. This may be a manufacturer, distributor, agent, representative, etc. In most cases the actual manufacturer will be responsible for CE marking a product.

You may transfer the responsibility for CE marking to another party by making them the owner or vendor of record. They must have title to the product, explicitly undertake responsibility for CE marking, have the capacity to ensure CE marking compliance, and be listed as the responsible party on the product nameplate and documentation. This transfer of responsibility for CE marking is common for products that have been manufactured by a subcontractor.

CE Enforcement/Surveillance

Enforcement of the CE marking system is delegated to each EU country. These countries assign different organizations enforcement responsibilities. Collectively, these agencies are known as “surveillance authorities.”

In most European countries, customs enforces the use of CE marking and is similar to such agencies as OSHA and the FDA. Most European customs offices commonly do not get involved in CE marking compliance issues unless they have been directed to do so by a surveillance authority. In France, however, customs authorities take the initiative in checking CE marking documentation for imported products.

Surveillance authorities usually only investigate CE marking compliance when questions have been raised about a product, or when someone has been injured or killed. Often, inspection officials, competitors and/or employees raise questions about product compliance. Conversely, Germany has a series of systematic programs and procedures in place to constantly review products within their country.

If questions are raised about your product, the surveillance authorities will first want to review your product’s technical file. This file must be available for review within a short period of time, usually one working week. You may want to appoint an authorized representative in the EU to hold your file, and meet with the surveillance authorities. Surveillance authorities are expected to refer all questions about your product to the surveillance authority in the country where your authorized representative is located.

If the surveillance authorities believe that one of your products presents a danger of causing death, injury and/or destruction of property, they can pull it out of service, and/or immediately bar any further importation of it or any similar products your are placing on the market. In addition, the surveillance authorities may impose national penalties, which may include civil and/or criminal penalties.
Time and Cost Considerations

The cost and time involved in the CE marking process will vary considerably depending on the technical complexity and possible risks and hazards posed by a product. The more complex; the number of directives that apply; the number of product standards for your product; and the risk classification of a particular product are all reason that may increase you CE marking costs and time.

CITRA has found the most common costs associated with CE marking to be:

- Direct Labor Costs (research and application)
- Product Standards
- Product Testing (internal)
- Laboratory Costs (external)
- Product Redesign
- Notified Body Costs (if required)
- ISO 9000 Costs (if required)
- System Audits
- Consulting Fees
- Technical File Construction
- Literature Translation fees
- Authorized Representative
- Legal Counsel

Major sources of delays for companies have come from difficulty in getting accurate, comprehensive, and current CE marking information on directives and standards. Slow turns around times from product testing and notified bodies have also been causes for delays. Delays may be minimized if a manufacturer is diligent with keeping up to date with directives, guidance documents and European harmonized standards. This will allow a manufacturer to design and manufacture a product that complies with CE marking from the very beginning; eliminating costly and time consuming redesigns and retesting.
CE Benefits

Manufacturers who understand and comply with CE marking will enjoy many benefits. These may be direct, or of a consequence of implementing CE marking procedures.

European Market Growth Potential
Complete market access to 22 European countries under one uniform set of product requirements. Eight more countries have applied for participation in the EU and CE marking.⁴ CE marking is growing as the “global system” for product conformity and marking with talks underway in many other countries around the world.

Lower Product Liability Risks
Products complying with CE marking will enjoy lowered product liability judgments in the instance of an accident or injury. CE marking products for sale within the United States may also enjoy a lower exposure to product liability.

Enhanced Product Design
Going through the steps in the CE marking will result in a thorough review of your product design. This process may bring about a new innovative, and/or cost-effective design.

Improved Production
Some of the conformity assessment modules require the existence of a quality assurance program. Used intelligently, these systems can simplify procedures, lower costs and improve product quality.

CE Marking for Sale in the United States
Many U.S. companies are “indirect exporters.” U.S. manufactures produce components for other U.S. manufacturers that export to European countries. CE marking products and components for sale within the United States will lower the ultimate manufacturer’s landed product cost in Europe. This will give you a competitive advantage within the U.S. market place.

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⁴ Countries that have applied for participation in European Union and accepting CE marking are Bulgaria, Poland, Slovenia, Slovakia, Estonia, Romania, Malta, and Cyprus.
CE Challenges

Complying with all of CE marking’s regulations can be a difficult and time-consuming process. You will be challenged throughout the CE marking process to make complex decisions among many alternatives. These decisions will have a significant impact on your long and short-term European goals.

General Directives
The “New Approach” directives set forth basic principles for broad classes of products. The EU’s efforts to make the directives less technical have created many areas for interpretation.

Lack of Harmonized Standards
If there are no European harmonized standards for the relevant risk areas for the type of product you are exporting, you will have to find other standards that can be used to reduce these risks to acceptable levels. You will then have to justify your choice of standards in your technical documentation.

New Directives
New directives are continually being developed that address different product safety and environmental issues. You should regularly check for new directives that may apply to your product. Although new directives are not applied retroactively to products already placed on the market or put into service, they will apply to new products manufactured and placed on the market after their effective dates.

CE Marking Costs
To comply with CE marking requirements, you may have to pay for consultants, standards, standards testing, notified body services, etc. This will be, for the most part, a one-time expense that will give you free access to the only market in the world that is as large as the U.S. economy. These service providers’ skills, expertise and costs will vary significantly. You should seek competitive bids for all products and services.

Other Laws Outside of CE marking
If the CE marking system does not cover your product, it may be subject to other “Old Approach” directives and/or national product requirements. The “Old Approach” system is still in force for many products in the areas of transportation equipment; pharmaceuticals; cosmetics; and agricultural and industrial commodities.
The CE marking Process

The CE marking process below is in basic form, and is intended only to offer an easy visualization of the CE marking process. There are countless alternatives and variations of the process that can be utilized to comply with CE marking. Each of these steps, along with its variants, will be further examined, detailing all of the issues and questions one might have in order to comply with CE marking. The following chapters will elaborate, in detail, each of these steps.

The CE Marking Process

1. Identify applicable EU Directive(s) for your product.
2. Assess your product to the essential requirements contained in the directive(s).
3. Apply relevant product standards; first consideration given to European harmonized standards.
4. Conduct any required testing.
5. Choose the appropriate conformity assessment module.
6. If required, select a notified body.
7. Assemble and submit all necessary documentation.
8. Appoint an authorized representative, if necessary.
   --Affix CE marking logo and place your product on the market--
9. Consider European recycling and disposition requirements.
10. Review other European marketing requirements.
CHAPTER 1
-“New Approach” Directives-

1. Introduction to the “New Approach” directives.
2. How to read a directive.
3. The scope and limitations of coverage of a directive.
4. How to determine the applicability of a directive.
5. Strategic Considerations.
6. Chapter check list.

1. “New Approach” Directives
2. Essential Requirements
3. Product Standards
4. Testing Requirements
5. Conformity Assessment
6. Notified Bodies
7. Documentation Requirements
8. Authorized Representation
9. Recycling & Disposition
10. European Market Planning

Affix CE marking logo and place product on the market.

This is a preview of “CE 123.”. Click here to purchase the full version from the ANSI store.
The “New Approach” Directives

A “directive” is an order from the EU Commission to member states governments to develop their own legislation in a particular product area or to comply with the required objectives set forth in the Commission directive.

Currently, there are 23 “New Approach” directives that are relevant for U.S. manufacturers. Each directive covers a different type of product, product component, or product performance. Refer to Table 1 for a list of the “New Approach” directives, their amendments, dates of application, and end of transitional period. In addition there are five directives that follow the principles of the “New” or “Global Approach,” but do not provide for the CE marking.

The “New Approach” directives come into force in two stages, the “date of application” and the “end of transitional period.” The “date of application” is the date on which the directive first comes into effect. A transition period allows manufacturers to rely on either pre-existing national regulations or some other “New Approach” directive until they can comply with the new directive.

The “end transitional period” is when a new directive transition period has ended, and products must comply fully with the requirements set forth in the new directive. Manufacturers no longer have the choice of using preexisting national regulations or some superceded directive.