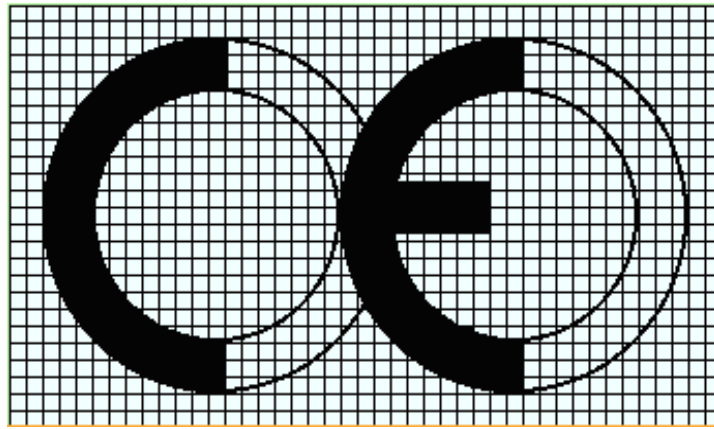


CE Marking:



Your Key to Entering the European Market

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N. Gerard Zapiain
U.S. Department of Commerce
International Trade Administration
Office of Health and Consumer Goods



I. The European Economic Area (EEA) and the “New Approach.”

The EU¹ has developed a system of directives to safeguard public health, as well as to ensure conformity to safety and health requirements throughout its member countries and members of the European Free Trade Association (EFTA).²

In 1994, the EU and the EFTA (with the exception of Switzerland) joined to become the European Economic Area (EEA). An evolutionary standardization process is underway in the EEA, with procedures established to cover compliance with directives designed to allow products legally marketed within one member state to move throughout the rest of the expanded European community. Moreover, numerous product safety, machinery and electromagnetic compatibility standards called “ENs” have been published to support the directives’ requirements.

The Council Resolution of 1985 set forth a regulatory scheme leading to technical harmonization and standardization. This “New Approach” is based on the following principles:

- \$ harmonization is limited to essential requirements
- \$ only products fulfilling these essential requirements may be enter the market
- \$ harmonized standards a presumed to conform to corresponding essential requirements
- \$ application of harmonized standards is voluntary: manufacturers may choose any solution that provides compliance with essential requirements³
- \$ manufacturers may choose whatever conformity assessment procedures provided in the applicable directive

European standards organizations⁴ define harmonized standards within the definition of the New Approach and submit them to the Commission for their possible adoption.

New Approach directives apply to products to enter into the commerce of the EEA, including new, used, and products imported from third countries. A subject product can only enter the

¹EU member countries include Austria, Belgium, Cyprus, Czech Republic, Estonia Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxemburg, Netherlands, Poland, Portugal, Spain, Sweden and the United Kingdom..

²EFTA member countries include Iceland, Switzerland, Liechtenstein and Norway.

³Directive 98/34/EC defines European standards as technical specifications adopted by European standards organizations for consistent use, compliance with which is not obligatory.

⁴CEN (European Committee for Standardization); Cenelec (European Committee for Electrotechnical Standardization); and ETSI (European Telecommunication Standards Institute)

commerce of the EEA when it conforms with the provisions of all applicable directives, and when conformity assessment has been carried out in accordance with all applicable directives.

The intent of New Approach directives is to protect the public interest, including public health and safety. Their object is to prevent, wherever possible, the placement of unsafe products on the market.⁵

II. What is CE Marking?

CE marking is an indication that a product complies with the essential requirements of applicable directives and that the product has been subject to conformity assessment procedures as provided in the directives. It allows the product to be freely marketed within the EEA. The marking applies only to products regulated by European health, safety and environmental protection legislation.

CE marking is the only indication that signifies conformity to all obligations incumbent on manufacturers for the product as required by the applicable directives providing for its affixing. CE marking replaces all other requisite conformity markings having the same meaning in existence before harmonization took place. Other national conformity markings would constitute an infringement on applicable New Approach directives.

Consumers may erroneously believe that CE marking is a quality symbol or a marketing tool. CE marking is the declaration by the manufacturer (and acceptance by a European-authorized conformity assessment body for higher risk medical devices) that the product complies with all applicable directives. CE marking relates to the national surveillance authorities or “designated authorities” of the member states. The declaration of conformity filed with the application for CE marking contains the details of the directive(s) to which the product complies and the standards that were relied upon in assuring compliance.

The directives provided for CE marking generally follow the principles of the New Approach.

Significance for Manufacturers and Exporters

The clearest benefit in CE marking is that it results in only one set of laws and regulations to comply with in designing and manufacturing for the entire expanded European marketplace. The multiple and conflicting national restrictions on regulated products are eliminated.

⁵To promote public safety, the Product Liability Directive (84/374/EEC) (*see* section IV below) pertains to all products covered by New Approach Directives. This directive applies to defective products only, placing the liability on the producer.

Additional benefits may include products being made safer for consumers as well as reduced damage claims and liability premiums.

With this harmonization come other issues that may cause difficulties to experienced firms exporting to the European market. The new product directives may exceed current national laws and regulations in some European countries. These increased or new requirements may require a manufacturer to change its design or production processes to continue or enter into this market. Products not bearing CE marking would not be in compliance with the directives, might be restricted, prohibited from sale, or forced to withdraw from the expanded European market.

The manufacturer must remain in control of production and retain the necessary competence to take responsibility for the product. The manufacturer is also obliged to be accountable that a product intended to be placed in the commerce of the EEA is in conformity with the essential requirements in accordance with the provisions of the applicable New Approach directives. To that end, the directives require that a responsible person or “authorized representative” be accountable in Europe to ensure adherence to these directives. This authorized representative must have a legal presence in Europe and declare that all requirements for applicable directives have been met.

III. Which products require CE Marking?

In addition to medical devices, including active implantables and *in vitro* diagnostic devices⁶, the following products require CE marking to enter into the commerce of the EEA:

- Toys
- Construction products
- Pressure vessels
- Telecommunication equipment
- Machinery
- Personal protective equipment
- Satellite station equipment
- Gas appliances
- Pressure vessel equipment
- Appliances (other than gas)
- Recreational craft
- Elevator equipment
- Equipment and protective systems for explosive atmospheres
- Non-automatic weighing equipment
- Measuring instruments

⁶Custom-made devices and devices intended for clinical investigations are exempt from the CE marking requirement.

Marine equipment
Electrical products
Civil explosives

This list may not be exhaustive. For a complete list of products, directives, and related standards, please visit <http://www.newapproach.org/directiveList.asp>.

IV. Procedures for CE Marking

Before CE marking can be affixed to the product, the manufacturer must follow certain procedures which may differ for each directive and each product.

A manufacturer must 1) identify which New Approach directives apply to the product; 2) prepare the Declaration of Conformity, 3) draw up the Technical Construction File (TCF)⁷, and 4) compile the CE User Manual.

Directives Which May Apply to Particular Medical Devices

Before application of the mandatory CE marking, certain products may need to comply with more than one directive. If a product is subject to several directives providing for CE marking, the marking indicates that the product conforms to the provisions of all these directives. Following are some directives that may affect manufacturers of medical devices:

\$ Medical Device Directive (MDD): 93/42/EEC.

This directive concerns many medical products defined, in part, as “any instrument... or other article... to be used on human beings for the purpose of:

- ▶ diagnosis, prevention, monitoring, treatment or alleviation of disease;
- ▶ diagnosis, monitoring, treatment, alleviation of or compensation for any injury or handicap;
- ▶ investigation, replacement, or modification of the anatomy or of a physiological process; and
- ▶ which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means...”

⁷In the case of Class III (highest risk) medical devices, the manufacturer must prepare a Design Dossier *in lieu* of a TCF.

Specific MDD procedures require medical device manufacturers to adhere to specific provisions for conformity assessment. These procedures are based on risk assessment categories established by the MDD: Class I, Class IIa, Class IIb, and Class III⁸. For more information on these special provisions, please visit <http://www.europa.eu.int/comm/enterprise/newapproach/standardization/harmstds/reflist/meddevic.html>

- \$ Active Implantable Medical Devices: (90/385/EEC).
This directive concerns products defined as any medical device intended to be introduced into the human body which is intended to remain after the procedure.
- \$ *In Vitro* Directive (98/79/EEC).
This directive, which will become effective in December 2003, concerns itself with the elimination or reduction of infection related to *in vitro* diagnostic medical devices. These devices include blood glucose monitoring systems for management of diabetes as well as all other medical diagnostic devices used outside the body.
- \$ Low-Voltage Directive: (73/23/EEC).
This directive concerns products with 50 to 1000 VAC or 75-1500 VDC input. This directive has been in effect since 1973 and was amended by 93/68/EEC⁹ by adding the CE marking requirement.
- \$ Electro-Magnetic Compatibility (EMC) Directive: 89/336/EEC.
Medical devices are required to meet this directive that sets the specifications for control of emissions and immunity.
- \$ Machinery Safety Directive: 98/37/EEC.
This directive applies to risks arising from the use of machinery and specific safety components.

Besides these directives, there are others called Basic Directives that apply to all manufacturers. These Basic Directives concern trade, enforcement, liability and other issues. Besides the Product Liability Directive (85/374/EEC) mentioned above, some of the Basic Directives include:

⁸These same risk classes apply to active implantable and *in vitro* medical devices, and generally correspond to FDA risk categories, with the exception that FDA category Class II does not subdivide in to Class IIa, and Class IIb. Risk assessment is based on three principles: the continuous use of the device, its degree of invasiveness, and if the device is implantable.

⁹Directive 93/68/EEC also describes the proper application of CE marking, described in section V below.

- \$ General Product Safety Directive: 92/59/EEC
- \$ Conformity Assessment Procedures and CE Marking Rules: 93/465/EEC
- \$ CE Marking Amendment: (Rules for Affixing and Use of CE Conformity Marking) 93/68/EEC – amends most of the above-mentioned directives.

These lists are not exhaustive, and not all medical devices would be deemed to necessarily be in compliance with each of these directives. Furthermore, the directives are subject to change. For updated information on EC directives, visit

<http://europa.eu.int/comm/enterprise/newapproach/standardization/harmstds/reflist.html>.

Declaration of Conformity: The declaration of conformity must contain the following information: product identification; the EU directives with which the product complies; standards used to verify compliance with the directives; name of the Notified Body¹⁰ used (if its use is required by applicable directives – *see* below); signature on behalf of the manufacturer or the authorized representative; and the manufacturer's name and address.

Technical Construction File (TCF): Most directives require the manufacturer or the authorized representative to provide a technical file which demonstrates the technical basis for conformity of the product to the requirements of the directive. The manufacturer must implement internal measures to ensure that the product remains in conformity. The file is intended essentially for the use of competent authorities. The TCF must be kept at the disposal of national surveillance authorities (called Designated Authorities for medical devices) for inspection and control purposes, and be available for at least ten years, starting from the production date of the final product. The main elements comprising a TCF are the following:

- \$ description of the product;
- \$ design and production drawing and diagrams;
- \$ detailed technical data for essential aspects of the product;
- \$ list of standards and or solutions applied;
- \$ report of calculations and tests that have been carried out;
- \$ certificate and inspection reports; and
- \$ in the case of series production, the internal conditions that have been observed to safeguard compliance with the directive.

¹⁰Notified Bodies are independent testing facilities or laboratories authorized by EEA member states to perform the conformity assessment tasks specified in directives. Manufacturers and exporters may choose a Notified Body in any EEA member state. Notified Bodies may be authorized for specific industries or specific products. For a current list of Notified Bodies please visit

<http://www.europa.eu.int/comm/enterprise/newapproach/legislation/nb/listnotifiedbodies.pdf>

CE User Manual: Information provided to a user plays an essential role in avoiding or reducing safety risks. Thus, a user manual is often an essential safety requirement. A user manual must contain all the information required for the correct and safe use of a product.

Language Requirements

EEA Member States have dictated that their national language(s) must appear on device packaging, labels and user manuals when the product is sold in their country. Advertising slogans, the name of the manufacturer and authorized representative address are exempt from this requirement.¹¹

Putting it all together: Evaluation of Conformity

For most products, depending upon the product and the nature of the risks it presents, there are several routes to evaluation of conformity and the ultimate CE marking of a product. An assessment must be made and documented in the manufacturer's TCF before CE marking is affixed and before the product is made available or put into service.

After determining which directive or directives apply to the product and establishment of conformity with the essential requirements for design and manufacturing to the applicable directives, the manufacturer must determine conformity assessment procedures from the options each directive prescribes. The guidelines often use a series of questions about the nature of the product to classify the level of risk. For more information on these guidelines, please visit <http://www.europa.eu.int/comm/dg03/directs/dg3d/d2/meddev/guide/md-aimd/aborder.htm>

When must a Notified Body be used?

Options for medical devices with minimal risk include self-certification where the manufacturer prepares a declaration of conformity and affixes the CE marking to the product. Other products with greater risks call for voluntary certification by a Notified Body. Other medical devices may not be self-certified, but must be subjected to the EC type-examination. This examination involves the inspection of a representative example by or on behalf of an external inspection organization or Notified Body within the EEA. Devices with even greater risks require tests, audits or additional certificates from a Notified Body before CE marking can be affixed.

Another avenue for U.S. manufacturers of medical devices to access the EU market is using the procedures outlined in the Medical Device Annex of the U.S. - EU Mutual Recognition

¹¹These requirements concern CE marking only. Member states may have additional language requirements that do not conflict with these.

Agreement. For information on this agreement, click visit <http://www.ita.doc.gov/td/mdequip/mrabrochure.html>).

V. Finally: Affixing the CE Marking

Directive 93/86/EEC delineates the requirements for how CE marking should ultimately be affixed. CE marking must be affixed to the product, or, when this is not possible to its packaging, if any, and to the accompanying documents by the manufacturer, the authorized representative in the community or, in exceptional cases, by those responsible for placing the product on the market. Where special provisions do not impose specific dimensions, CE marking must have a height of at least five (5) millimeters. When a Notified Body is used, its number must appear below the CE marking.

The actual CE marking is the letters “CE:” an abbreviation of a French phrase “Conformité Européenne.” The marking indicates that the manufacturer has conformed with all the obligations required by the legislation. Initially, the phrase was “CE mark:” however, the term “CE marking” was legislated as its replacement in 1993.

VI. For More Information on Policies Concerning Your Exports of Medical Devices to Europe

For general product legislation, please visit http://europa.eu.int/comm/enterprise/policy_en.htm

For detailed information regarding the New Approach and how it applies to CE Marking see *The Guide to the Implementation of the Directives Based on the New Approach and on the Global Approach* at

<http://europa.eu.int/comm/enterprise/newapproach/legislation/guide/legislation.htm>

Additional up-to-date details on CE marking are available in the Official Journal of the European Communities.