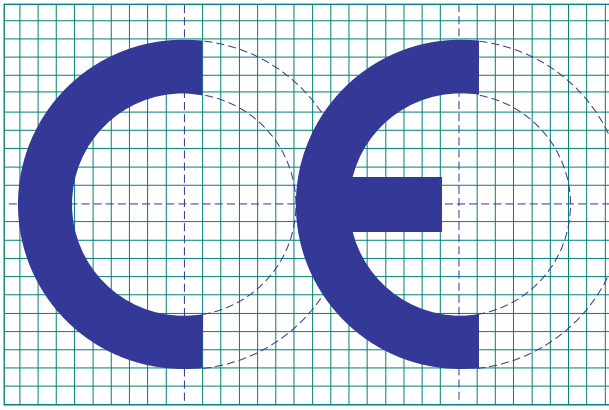
TO U.S. MANUFACTURERS:

ALERT

PRODUCT "MARK" REQUIRED FOR U.S. EXPORTS TO EUROPE!



U.S. Department
of Commerce

Technology
Administration

National Institute
of Standards
and Technology

International Trade
Administration

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NIST
**National Institute of
Standards and Technology**
Technology Administration
U.S. Department of Commerce

INTRODUCTION

The "CE" mark is now mandatory for a wide range of products sold in the European Union. Several other nations also require conformance to EU product safety, health, and environment legal mandates. The European Commission describes the CE mark as a "passport" that allows manufacturers to trade industrial products freely within the internal market of the EU. The letters "CE" indicate that the manufacturer has undertaken all assessment procedures required for the product. The CE mark is not a quality mark and does not indicate conformity to a standard; rather it indicates conformity to the legal requirements of the EU directives. **Obtaining authority to attach the CE mark to products manufactured in the United States is often thought to be difficult and time-consuming. In many cases it is not, and this advisory note shows U.S. manufacturers how to meet the CE mark requirement.**

While manufacturers are not required to refer to European standards in certifying compliance with the mandate of the directives, **manufacturers can find it easier to self-declare or certify that their product meets the legislative requirements** by using European standards to provide the technical definition to satisfy the legislative mandate. **Many of the products sent to the European market can be tested and marked by the U.S. manufacturer,** though the manufacturer is responsible to review the appropriate directives that apply to his product and test his product as specified in those directives.

There are about 30 directives, either adopted or under consideration, which require that products be marked with the CE mark. More than one directive can apply to any given product.

At first, the obstacles to securing a CE mark may appear overwhelming—especially when a manufacturer considers the various alternatives to gaining product acceptance in Europe as indicated in Figure 1 (see page 9). Only "Module A" of the nine alternative paths for demonstrating product conformance allows for a manufacturer to self-declare or, as we say in the United States, self-certify that the product meets specific requirements. Since many of the products we export to Europe fall within the scope of Module A, U.S. manufacturers can readily apply the CE mark to demonstrate conformance of their product to the legal requirements set out in the "essential requirements" of the various directives.

RECOMMENDATIONS
for United States Manufacturers

As a manufacturer you need to secure copies of the directives and judge whether they apply to your product. The European Commission does not publish a list of products to which their laws apply; they require the manufacturer to determine the applicability of directives to any given product. The European Standards that are presumed by the European Commission to provide technical definition for demonstrating conformance to the "essential requirements" in the directives are published in the Official Journal of the European Community. While other national, regional, or international standards can be used as well, European standards are preferred since they are presumed by the European Commission to address the "essential requirements" contained in the directives. You can then test your product to determine its conformance to the appropriate legal requirements and construct a corresponding technical file that can be located, if required, in Europe with your authorized representative or importer. You would also affix the required CE mark to your product before shipment to Europe.

Again, in many cases you can self-certify that your product meets the legal requirements contained in the directives. In most instances, such a self-certification requires the use of European standards. There are some products, such as medical devices or dangerous machines, which require third-party review

or assessment by a laboratory in the United States that is designated by the Europeans as a "competent laboratory." The U.S. Department of Commerce maintains a list of companies in the U.S. which provide services related to obtaining the CE mark.

You must also prepare a "Declaration of Conformity." The declaration must contain the following information: product identification; the European directives complied with; standards used to verify compliance with the directives; name of notified body if required; be signed on behalf of the manufacturer or the authorized representative and identify that signatory; and the manufacturer's name and address. If you do not have a representative in the EU, you can issue the Declaration of Conformity to the importer. The Declaration of Conformity and technical files need only be written in English; however, instruction manuals need to be in the local language of the end user.

It is important when reviewing the directives to address all the possible "essential requirements" having applicability to your product and its foreseeable use. If there is any doubt as to whether you need a CE mark it would be wise to undertake an evaluation of your product against legislative requirements prior to export rather than experience the higher costs associated with delayed entry of your product into the European market because of a possible challenge by customs officials or some competitor in an EU nation.

AN EXAMPLE
considering the EMC Directive

Figure 2 (see page 11) depicts the various scenarios that must be considered in self-declaring whether a product satisfies the "essential requirements" contained in the EMC Directive. This legislation covers a variety of electrical products, e.g., household appliances (light dimmers, washing machines, vacuum cleaners, water heaters, cooking equipment, etc.), lamps and light fixtures, radio and television sets, information technology and telecommunications equipment, scientific and medical instruments, etc. There are a number of European standards that can be used by the manufacturer as a basis to test for EMC requirements. Other directives may also be applicable to a given product.

In Summary, the General Steps for Getting the CE Mark are:

1. Identify all applicable EU directives (laws).
2. Assess your product to the "essential requirements" contained in the directives.
3. Choose the appropriate conformity assessment module (Figure 1); i.e., self-certification or manufacturer's declaration under Module A, or one of the other modules where the use of third parties is required.
4. Determine the applicable standards–international, European, or national.
5. If required, choose a "competent body" in the U.S. to perform tests on products (an updated list is maintained by the U.S. Department of Commerce).
6. If desired, choose an authorized representative for your company in the EU.
7. Prepare a technical file, including a users manual, particularly for products with high risk hazards.
8. Assemble the required approvals and certificates and prepare a Declaration of Conformity for each applicable directive. Declarations of Conformity and technical files can be maintained in English.
9. Affix the CE mark in accordance with the laws (the format of the CE mark and its proper location is described in Directive 93/68/EEC, Dated 22 July 1993).

INFORMATION RESOURCES

A **The Department of Commerce's International Trade Administration (ITA) can assist any U.S. manufacturers by providing them with:**

(1) complete copies of directives;

(2) a listing of appropriate European standards; and

(3) a list of companies or European designated "Competent Bodies" in the United States providing CE mark testing and related services.

B **Current sources for copies of European standards are given in Table 1.**

U. S. Department of Commerce contacts include:

International Trade Administration
Office of European Union and Regional Affairs
Herbert C. Hoover
Building, Room 3513
Washington, DC 20230
Ph: (202) 482-4496
Fax: (202) 482-2897
Email: Robert_Straetz@ita.doc.gov

Commercial Service
U.S. Mission to the EU
40 Boulevard du Regent
B-1060 Brussels, Belgium
Ph: 32-2-508-2674/2675
Fax: 32-2-513-1228
Email: sylvia.mohr@mail.doc.gov

National Institute of Standards and Technology
National Center for Standards and Certification Information (NCSCI)
Building 820, MS 2160
Gaithersburg, MD 20899-2100
Ph: (301) 975-4040
Fax: (301) 926-1559
Email: ncsci@nist.gov

C **Internet sites of potential interest to U.S. exporters include:**

http://ts.nist.gov/europe
To obtain a copy *SP 951: A Guide to EU Standards and Conformity Assessment* as well as other guides to understanding specific EU directives.

http://web.ita.doc.gov/ticwebsite/FAQs.nsf/6683DCE2E5871DF9852565BC00785DDF/ED3167DEE3B48B03852569B400586FFB?OpenDocument
To obtain information from ITA's Trade Information Center on CE Marking.

http://ts.nist.gov/ts/htdocs/210/gsig/mra.htm
To obtain information on the EU-US Mutual Recognition Agreement (MRA), including a list of U.S. conformity assessment bodies (CABs) that have been formally accepted under the MRA.

http://europa.eu.int/comm/enterprise/newapproach/standardization/harmstds/index.html or http://www.newapproach.org/
To obtain a list of all current New Approach Directives and the harmonized standards pertaining to each directive.

http://europa.eu.int/comm/enterprise/newapproach/legislation/nb/notified-bodies.htm
To obtain a list of all notified bodies.

TABLE 1[1]

ANSI - American National Standards Institute
(Electronic Copies Only)
25 West 43rd Street, Fourth Floor
New York, NY 10036
Tel: (212) 642-4900
Fax: (212) 398-0023
E-mail: info@ansi.org
Internet: www.ansi.org or www.nssn.org

British American Chamber of Commerce
41 Sutter Street, #303
San Francisco, CA 94104
Tel: (415) 296-8645
Fax: (415) 296-9649
E-mail info@baccsforg
Internet: www.baccsf.org

Document Center, Inc.
III Industrial Way, Unit 9
Belmont, CA 94002
Tel: (650) 591-7600
Fax: (650) 591-7617
E-mail info@document-center.com
Internet: www.document-center.com

DECO - Document Engineering Co.
15210 Stagg Street
Van Nuys, CA 91405
Tel: (818) 782-1010
Fax: (818) 782-2374
E-mail doceng@doceng.com
Internet: www.doceng.com

Global Engineering Documents
I5 Inverness Way East
Englewood, CO 80112-5704
Tel: (800) 854-7179 or (303) 397-7956
Fax: (303) 397-2740
E-mail: global@ihs.com
Internet: http://global.ihs.com

ILI - ILI Infodisk,Inc
610 Winters Avenue
Paramus, NJ 07652, USA
Tel: (201) 986-1131
Fax: (201) 986-7886
Email: sales@ili-info.com
Internet: www.ili.co.uk

TECH STREET
1327 Jones Drive
Ann Arbor, MI 48105
Tel: (800) 699-9277 or (734) 302-7801
Fax: (734) 302-7811
E-mail: service@techstreet.com
Internet: www.techstreet.com

Euroconsult Inc.
29 Waterman Road
Gloucester, MA 01930-1437
Tel: (978) 282-8890
Fax: (978) 282-7888
E-mail: info@euroconsult.com
Internet: http://euroconsult.com/index.htm

QSI - Qualified Specialists Inc.
5915 Lookout Mountain Drive
Houston, TX 77069
Tel: (281) 444-4950
Fax: (281) 448-5181
E-mail: qsiinfo@isoconsultants.com
Internet: www.isoconsultants.com

SIMCOM International Holdings, Inc.
6111 Peachtree Dunwoody Road
Building E
Atlanta, GA 30328
Tel: (770) 730-9980
Fax: (770) 730-9976
E-mail: service@esimcom.com
Internet: www.esimcom.com

Emergo Group
2519 McMullen Booth Rd.,
Suite 510-295
Clearwater, FL 33761
Tel: (727) 797-4727
Fax: (727) 797-4757
E-mail: info@emergogroup.com
Internet: www.emergogroup.com

[1] *The most current listing is available from NCSCI*

FIGURE 1. CONFORMITY ASSESSMENT PROCEDURES IN COMMUNITY LEGISLATION.

A. Internal control of production	**B. (type examination)**				**C. (unit verification)**	**H. (full quality assurance)**
Manufacturer keeps technical documentation at the disposal of national authorities. At the request of authority: intervention of notified body	Manufacturer submits to notified body — Technical documentation — Type Notified Body — Ascertains conformity with essential requirements — Carries out tests, if necessary — Issues EC type-examination certificate				Manufacturer ■ submits technical documentation	EN 29001 Manufacturer ■ operates an approved quality system (QS) for design Notified Body ■ carries out surveillance of the QS ■ verifies the conformity of the design ■ issues EC design examination certificate
	C. (conformity to type)	**D. (production quality assurance)**	**E. (production quality assurance)**	**F. (product verification)**		
Manufacturer ■ declares conformity with essential requirements ■ affixes the CE marking At the request of authority: Notified Body ■ tests on specific aspects of the product ■ product checks at random intervals	Manufacturer ■ declares conformity with approved type ■ affixes the CE marking Notified Body ■ tests on specific aspects of the product ■ product checks at random levels	EN 29002 Manufacturer ■ operates an approved quality system (QS) for production and testing ■ declares conformity with approved type Notified Body ■ approves the QS ■ carries out surveillance of the QS	EN 29003 Manufacturer ■ operates an approved quality system (QS) for inspection and testing ■ declares conformity with approved type or essential requirements ■ affixes the CE marking Notified Body ■ approves the QS ■ carries out surveillance of the QS	Manufacturer ■ declares conformity with approved type or essential requirements ■ affixes the CE marking Notified Body ■ verifies conformity ■ issues certificate of conformity	Manufacturer ■ submits product ■ declares conformity ■ affixes the CE marking Notified Body ■ verifies conformity with essential requirements ■ issues certificate of conformity	Manufacturer ■ operates an approved QS for production and testing ■ declares conformity ■ affixes the CE marking Notified Body ■ carries out the surveillance of the QS

DESIGN

PRODUCTION

FIGURE 2.
POSSIBILITIES TO GET ACCESS TO THE SINGLE MARKET OF THE EU CONSIDERING THE EMC DIRECTIVE.