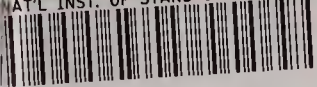


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# **A Guide to EU Standards and Conformity Assessment**

Helen Delaney  
Rene van de Zande  
Co-Editors

**NIST**

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

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<sup>2</sup>Some elements at Boulder, CO.

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## ABSTRACT

This guide is an easy-to-use introductory reference for industry and government officials on the general principles and concepts behind the European Union's (EU) "New Approach" laws and directives. It is designed to help business and government officials understand the new laws, the EU's standardization process, and the relationship between the European Commission and the European standardization bodies in the European Union. It also provides information on the EU's approach to conformity assessment and requirements for obtaining CE mark to gain access to the European Market. The guide offers explanations of such concepts and requirements as: notified bodies, conformity assessment modules, supplier's declaration of conformity, technical construction files, user manuals, authorized representatives, and product liability in the European Union.

Key Words: CEN; CENELEC; conformity assessment; directives; ETSI; European Union; modules; New Approach; notified bodies; product liability; standards; supplier's declaration of conformity; technical construction files; user manuals



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# A Guide to EU Standards and Conformity Assessment

## **Introduction to Europe: A Single Market**

Europe is a prize market, easier to access than ever before. Too many U.S. exporters, especially small and medium sized enterprises, avoid it because the technical requirements for entry seem too complicated, too difficult, or too expensive. U.S. manufacturers who have successfully accessed the European market know that the time to understand the European system is well worth the effort. The European Union alone is filled with affluent consumers, approximately 370 million of them. But the European market is a large area that comprises not only the 15 countries that presently make up the European Union (Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden, and the United Kingdom), but also the three countries that complete the European Economic Area (EEA) (Iceland, Liechtenstein, and Norway, i.e., EFTA countries except Switzerland.) In addition, there are approximately 11 other Central and Eastern European countries, such as the Czech Republic and Poland, which are candidates for future membership in the European Union. These countries are rapidly adopting European Union laws, standards, conformity assessment procedures, and the practice of CE marking.

For the exporter, therefore, Europe as a whole has become a market whose technical requirements have been greatly simplified. Before the creation of the European Union, each country imposed its own technical requirements. Different standards and conformity assessment procedures forced exporters to target one or two countries only, or to forego exporting to Europe altogether. The unification of 15 European countries into a European Union, and the consequent harmonization of laws, standards, and conformity assessment procedures, changed all that.

## **Harmonization: A New Approach to Lawmaking**

The formation of the single market in Europe, one in which there was a free flow of goods, had as one of its objectives the elimination of barriers to trade between the Member State countries. Differences between national laws, standards, and conformity assessment procedures made trade between the countries difficult, contentious, and expensive. In order to eliminate these barriers, a new legislative technique and strategy was instituted. The new approach was designed to envelop, or "harmonize," the health, safety, and environmental requirements of 15 Member States into one European-wide legislative package. The result of this new approach to lawmaking, or "harmonization," was a new set of laws that emanated from the European Commission in Brussels, Belgium, the capital of the European Union. They were called the New Approach Directives. In every case, one law replaced fifteen. Member States were required to adopt the new harmonized laws.

Regulating and harmonizing laws for every product with specific, highly technical requirements for each proved to be an impossible task. The new, more practical approach, the New Approach, was to govern families of products. Regulation of these products took on a more generic format, and was limited to “Essential Health and Safety Requirements.” Today, because these laws have replaced old national laws, products meeting these essential health and safety requirements can be placed on the market in any country within the European Economic Area (EEA) Union and move freely throughout all 18 countries. The families of New Approach products are listed below in Table 1.

**Table 1: New Approach Directives**

Directive Ref.	Directive Subject
90/396/EEC	APPLIANCES BURNING GASEOUS FUELS
93/68/EEC	CE MARKING DIRECTIVE (COUNCIL DIRECTIVE AMENDING OTHER DIRECTIVES)
89/106/EEC	CONSTRUCTION PRODUCTS
89/336/EEC	ELECTROMAGNETIC COMPATIBILITY
96/57/EC	ENERGY EFFICIENCY REQUIREMENTS FOR HOUSEHOLD ELECTRIC REFRIGERATORS, FREEZERS, AND COMBINATIONS THEREOF
94/9/EEC	EQUIPMENT AND PROTECTIVE SYSTEMS IN POTENTIALLY EXPLOSIVE ATMOSPHERES
93/15/EEC	EXPLOSIVES FOR CIVIL USES
96/48/EC	INTEROPERABILITY OF TRANS-EUROPEAN HIGH-SPEED RAIL SYSTEM
95/16/EC	LIFTS (ELEVATORS)
73/23/EEC	LOW VOLTAGE EQUIPMENT
98/37/EC	MACHINERY, SAFETY OF
96/98/EC	MARINE EQUIPMENT
90/385/EEC	MEDICAL DEVICES: ACTIVE IMPLANTABLE
93/42/EEC	MEDICAL DEVICES: GENERAL
98/79/EC	MEDICAL DEVICES: IN VITRO DIAGNOSTIC
90/384/EEC	NON-AUTOMATIC WEIGHING INSTRUMENTS
94/62/EC	PACKAGING AND PACKAGING WASTE
89/686/EEC	PERSONAL PROTECTIVE EQUIPMENT
COM(93)322	PRECIOUS METALS (NOT FORMALLY PROPOSED)
97/23/EC	PRESSURE EQUIPMENT
87/404/EEC	PRESSURE VESSELS, SIMPLE
1999/5/EC	RADIO EQUIPMENT AND TELECOMMUNICATIONS TERMINAL EQUIPMENT AND THE MUTUAL RECOGNITION OF THEIR CONFORMITY
94/25/EC	RECREATIONAL CRAFT
88/378/EEC	TOYS, SAFETY OF

*Obviously, not all products are governed by New Approach Directives. There are essentially three regulatory levels. Technical requirements differ for each of them. There*



*are the "old approach" regulations, which have technical specifications integrated into the annexes. Some of these products are regulated on a product-by-product basis. The New Approach Directives make references to harmonized standards. In the third level, products are unregulated at the EU level, but the products may be regulated at the national level and are governed by Member State laws. It must be remembered that the European Union is the newest economic region in the industrialized world and as such, is still a work in progress. This guide will cover only the products that fall under the New Approach Directives listed above.*

### **Essential Health and Safety Requirements: An Example**

Essential health and safety requirements are at the heart of the New Approach Directives. They are mandatory, legally binding obligations, and they are enforced. Following is one of the essential requirements taken directly from the Machinery Directive. It relates to the starting function:

"Starting. It must be possible to start machinery only by voluntary actuation of a control provided for the purpose. The same requirement applies when restarting the machinery after a stoppage, whatever the cause, when effecting a significant change in the operating conditions (e.g., speed, pressure, etc.), unless such restarting or change in operating conditions is without risk to exposed persons.

This essential requirement does not apply to the restarting of the machinery or to the change in operating conditions resulting from the normal sequence of an automatic cycle.

Where machinery has several starting controls and the operators can therefore put each other in danger, additional devices (e.g., enabling devices or selectors allowing only one part of the starting mechanism to be actuated at any one time) must be fitted to rule out such risks.

It must be possible for automated plant functioning in automatic mode to be restarted easily after a stoppage once the safety conditions have been fulfilled."

The aim of most essential requirements is the elimination of risks of accident to the extent possible. All manufacturers, domestic or foreign, are obliged to meet all the essential requirements pertaining to their product. The law does not distinguish between European manufacturers and manufacturers of other countries.

Conformity assessment in Europe, therefore, is the process by which compliance with essential requirements is determined. This process can be carried out with or without the use of standards. This last principle is important to manufacturers of new or innovative products for which standards do not yet exist, and ensures that standards annexed to New Approach Directives (which are voluntary) do not become *de jure* obligatory.

## **Technical Harmonization: Conformity Assessment**

Conformity assessment is defined by the International Organization for Standardization/International Electrotechnical Commission Guide 2: 1996 as:

“any activity concerned with determining directly or indirectly that relevant requirements are fulfilled.”

Typical examples of conformity assessment activities are sampling, testing and inspection, evaluation, verification and assurance of conformity (supplier's declaration), certification, registration, accreditation, and approval as well as their combinations.

Conformity assessment may also be the process by which it is determined that a product's design meets a specification or standard.

Conformity assessment may vary in levels of difficulty and complexity, depending on the level of risk associated with the product. If a Harmonized Standard is used to meet an essential requirement of a New Approach Directive, and if the risk of injury is low (See Risk Assessment), no third party conformity assessment procedure is required. (This is true regardless of the nationality of the manufacturer.) A manufacturer or supplier may declare, after performing the necessary product evaluations (through a Declaration of Conformity), that the product meets the essential requirements of a directive. As the risk of injury increases, the level of complexity of the conformity assessment process (and the cost) increases with it. The applicable directive will be the guide to the level of risk involved and the methods of conformity assessment that may be employed.

### **Harmonization: The Global Approach**

In Europe, the point of the New Approach Directives was to eliminate differences between national laws, thereby eliminating barriers to trade between the Member States. But differences in national standards and testing and certification procedures were the root causes of barriers to trade, and it followed that a new, integrated scheme for technical harmonization had to be implemented as well. The new scheme was embodied in two Decisions: (1) the Module Decision, and (2) the regulation on CE Marking. The policy was called the Global Approach. It incorporated conformity assessment procedures directly into the New Approach Directives.

### **Conformity Assessment: The Module Decision**

The Module Decision (90/683/EEC) set out the criteria and guidelines for conformity assessment procedures to be used in the New Approach Directives. The General Guidelines are as follows and are taken directly from the document as it appeared in the Official Journal of the European Communities No. L 380/14, dated December 12, 1990:



- “(a) the essential objective of a conformity assessment procedure is to enable the public authorities to ensure that products placed on the market conform to the requirements as expressed in the provisions of the directives, in particular with regard to the health and safety of users and consumers;
- (b) conformity assessment can be subdivided into modules which relate to the design phase of products and to their production phase;
- (c) as a general rule a product should be subject to both phases before being able to be placed on the market if the results are positive;
- (d) there are a variety of modules which cover the two phases in a variety of ways. The directives shall set the range of possible choices which can be considered by the Council to give the public authorities the high level of safety they seek, for a given product or product sector;
- (e) in setting the range of possible choices open to the manufacturer, the directives, will take into consideration, in particular, such issues as the appropriateness of the modules to the type of products, the nature of the risks involved, the economic infrastructures of the given sector (e.g., existence or non-existence of third parties), the types and importance of production, etc. The factors that have been taken into account must be explicitly spelled out by the Commission in these directives;
- (f) the directives will, in setting the range of possible modules for a given product or product sector, attempt to leave as wide a choice to the manufacturer as is consistent with ensuring compliance with the requirements;

The directives will set out the criteria governing the conditions in which the manufacturer shall choose the most appropriate modules for his production from the modules laid down by the directives;

- (g) the directives should avoid imposing unnecessarily modules which would be too onerous relative to the objectives of the directive concerned;
- (h) notified bodies should be encouraged to apply the modules without unnecessary burden for the economic operators. The Commission, in cooperation with the Member States, shall ensure that close cooperation is organized between the notified bodies in order to ensure consistent technical application of the modules;
- (i) in order to protect the manufacturers, the technical documentation provided to notified bodies has to be limited to that which is required solely for the purpose of assessment of conformity. Legal protection of confidential information shall be required;

- (j) whenever directives provide the manufacturer with the possibility of using modules based on quality assurance techniques, the manufacturer must also be able to have recourse to a combination of modules not using quality assurance, and *vice versa*, except where compliance with the requirements laid down by the directives requires the exclusive application of a certain procedure;
- (k) for the purposes of operating the modules, Member States shall notify on their own responsibility bodies under their jurisdiction which they have chosen from the technically competent bodies complying with the requirements of the directives. This responsibility involves the obligation for the Member States to ensure that the notified bodies permanently have the technical qualifications required by the directives and that the latter keep their competent national authorities informed of the performance of their tasks. Where a Member State withdraws its notification of a body, it shall take appropriate steps to ensure that the dossiers are processed by another notified body to ensure continuity;
- (l) in addition, with regard to conformity assessment, the sub-contracting of work shall be subject to certain conditions guaranteeing:
  - the competence of the establishment operating as sub-contractor, on the basis of conformity with series EN 45000 standards, and the capability of the Member State that has notified the sub-contracting body to ensure effective monitoring of such compliance;
  - the ability of the body notified to exercise effective responsibility for the work carried out under sub-contract;
- (m) notified bodies which can prove their conformity with harmonized standards (EN 45000 series), by submitting an accreditation certificate or other documentary evidence, shall be presumed to conform to the requirements of the directives. Member States having notified bodies unable to prove their conformity with the harmonized standards (EN 45000 series) may be requested to provide the Commission with the appropriate supporting documents on the basis of which notification was carried out;
- (n) a list of Notified Bodies shall be published by the Commission in the *Official Journal of the European Communities* and constantly updated."

*Note: Lists of Notified Bodies are published by the European Commission in the "Official Journal of the European Communities." A hard copy may be requested from Mrs. Janette AISTROPE, Tel: 011-322-299-9060, Fax: 011-322-296-0851, E-mail Janette.Aistrope@cec.eu.int. At present, these lists are not available electronically.*

### **Modules**

Modules are how conformity assessment procedures used in New Approach Directives are organized. Always found in an Annex to the Directives, the modules describe the

specific conformity assessment procedures to be applied to the products regulated by that directive.

Modules vary in complexity. For example, Module A permits the manufacturer to assume total responsibility for conformity assessment. If the product is manufactured to Harmonized Standards, and if the risk is not unusually high (as in most machinery, for example), the manufacturer may rely on internal manufacturing checks. He or she compiles a Technical File, issues a Declaration of Conformity to the appropriate directives, and if appropriate, standards, applies the CE marking, and places the product on the market.

Modules for active implantable medical devices, on the other hand, could call for a type examination of the product, plus a production quality assurance system that conforms to the ISO 9002 (EN 29002) standard. Another choice for a medical device manufacturer would be a complete quality assurance program that would conform to ISO 9001 (or EN 29001).

Where the risk is high and/or where Harmonized Standards are not used, the modules will call for the involvement of a third party. In Europe, these third parties are designated by authorities and are called Notified Bodies.

Each directive provides the module choices available, but there are no choices beyond the modules specified.



**Table 2: Modules: Conformity Assessment Procedures in European Legislation**  
(Taken from the *Official Journal of the European Communities* L 220, 4-39, August 8, 1993)

**DESIGN**

A. (Internal control of production)	B. (Type examination)	G. (Unit verification)	H. (Full quality assurance)
<b>Manufacturer</b> -Keeps technical documentation at the disposal of national authorities  <b>Aa</b> -Intervention of <b>notified body</b>	<b>Manufacturer</b> -Submits to notified body -Technical documentation -Type  <b>Notified Body</b> -Ascertains conformity with essential requirements -Carries out tests, if necessary -Issues EC type-examination certificate	<b>Manufacturer</b> -Submits technical documentation	<b>EN 29001</b> <b>Manufacturer</b> -Operates an approved quality system (QS) for design  <b>Notified body</b> -Carries out surveillance of the QS -Verifies conformity of the design -Issues EC design examination certificate



**Table 2: Conformity Assessment Procedures in European Legislation (Continued)**  
(Taken from the *Official Journal of the European Communities* L 220, 4-39, August 8, 1993)

**PRODUCTION**

A. (Internal control of production)	C. (Conformity to type)	D. (Production quality assurance)	E. (Product quality assurance)	F. (Product verification)	G. (Unit verification)	H. (Full quality assurance)
<b>Manufacturer</b>	<b>Manufacturer</b>	<b>Manufacturer</b>	<b>Manufacturer</b>	<b>Manufacturer</b>	<b>Manufacturer</b>	<b>Manufacturer</b>
-Declares conformity with essential requirements	-Declares conformity with approved type	-Operates an approved quality system (QS) for production and testing	-Operates an approved quality system (QS) for inspection and testing	-Declares conformity with approved type, or with essential requirements	-Submits product	-Operates an approved QS for production and testing
-Affixes the CE mark	-Affixes the CE mark	-Declares conformity with approved type	-Declares conformity with approved type, or to essential requirements	-Affixes the CE mark	-Declares conformity	-Declares conformity
<b>Aa</b>		-Affixes the CE mark	-Declares conformity with approved type, or to essential requirements		-Affixes the CE mark	-Affixes the CE mark
<b>Notified body</b>		<b>Notified Body</b>	<b>Notified Body</b>	<b>Notified Body</b>	<b>Notified Body</b>	<b>Notified Body</b>
-Tests on specific aspects of the product		-Approves the QS	-Approves the QS	-Verifies conformity	-Verifies conformity with essential requirements	-Carries out surveillance of the QS
-Product checks at random intervals		-Carries out surveillance of the QS	-Carries out surveillance of the QS	-Issues certificate of conformity	-Issues certificate of conformity	

## **Technical Harmonization: Standardization**

The harmonization of standards, like laws and conformity assessment procedures, has greatly simplified technical regulation in Europe. Prior to harmonization, each country developed its own standards through a national standards body. And, like differing and conflicting laws and conformity assessment procedures, fifteen sets of standards were not only costly, but also created technical barriers to trade between European countries. It became necessary to create a new, integrated, European system of standardization.

### **The European Standards Bodies: CEN, CENELEC, and ETSI**

The new system provides for three standards bodies to create standards on a Europe-wide level: (1) The European Committee for Standardization (CEN) in Brussels, Belgium; (2) the European Committee for Electrotechnical Standardization (CENELEC) in Brussels, Belgium; and (3) The European Telecommunications Standards Institute (ETSI), in Sophia Antipolis, France. CENELEC activities are in the electrotechnical sector, while ETSI specializes in telecommunications. All other sectors are covered by CEN.

CEN and CENELEC's principal members are national standards bodies (See Table 3 and Table 4). ETSI's membership incorporates a wider range of interested parties (See Table 5). These three are the only recognized bodies from which a European Standard (EN) can emanate. When the development of a European Standard begins in one of these organizations, development of a national standard must stop. European Standards, like European laws and European conformity assessment procedures, preempt national (Member State) standards, and replace them.

### **The Role of Standards in New Approach Directives**

The European Standards (ENs) that play a role in New Approach Directives are known as Harmonized Standards. Harmonized Standards are standards that support European legislation. They (1) have been mandated by the European Commission, (2) have been developed by the European Standards Bodies above, (3) address essential requirements of New Approach Directives; and (4) notification of their development has been published in the *Official Journal of the European Communities*.

For example, the following harmonized standards have met all the conditions above and relate to certain Essential Health and Safety Requirements of the Safety of Machines Directive (98/37/EC):

CEN	EN	Safety of machinery – Ergonomics requirements for the design of
	894-1	displays and control actuators – Part 1: General principles for human interactions with displays and control actuators
CEN	EN	Safety of machinery – Ergonomics requirements for the design of
	894-2	displays and control actuators – Part 2: Displays



Technically speaking, the use of a Harmonized Standard is voluntary. That is, a manufacturer can elect to use a Harmonized Standard (like the ones above), or elect to use a non-Harmonized Standard (an American Standard, for example) to meet essential requirements. When using a Harmonized Standard, however, the manufacturer is presumed in conformity with the law. On the contrary, using a standard that is not a Harmonized Standard will impose additional responsibilities. The use of anything but a Harmonized Standard places a burden of proof upon the manufacturer that the product meets essential requirements. This proof may be provided by the manufacturer's Technical File, by the employment of a third party (consultant, testing house, etc.), or by a combination of the two. (The directive will prescribe conformity assessment procedures that are commensurate with the risk of injury associated with the product.)

### **Harmonized Standards and the Presumption of Conformity**

Presumption of conformity is a legal concept surrounding Harmonized Standards that denotes the relationship between the legislative and standardization processes. The European Commission (the lawmaking body) and the European Standards Bodies collaborate to produce Harmonized Standards. They enter into a contractual relationship, with the Commission providing financial support when needed. The contract (or mandate) stipulates that the standards body will produce a standard that will provide a technical solution, or a technical interpretation, of an essential health and safety requirement. When the standard is completed and the conditions of the Commission's mandate are met, the Commission publishes the notice of its completion in the *Official Journal of the European Communities*. Once the notice is published, the standard takes on the presumption of conformity mantle. A manufacturer, therefore, using a Harmonized Standard in the design and/or production of the product, is presumed to be in conformity with the essential requirements of the law.

### **The Role of Standards in the Marketplace**

There is a vast body of European Standards (ENs) that is not mandated by the Commission; and these standards are not necessarily directed toward essential requirements. In theory, their use is voluntary, just as the use of harmonized standards is voluntary. These standards may or may not address health or safety aspects of products. They may define other characteristics, such as durability, appearance, quality levels, or even cultural preferences. They may be test methods, or measurement guides.

The use of a European standard in the European marketplace, however, has definite advantages. Chief among them is recognition. A standard that does not emanate from one of the European Standards Bodies is not always recognized by insurers, lending institutions, retailers, developers, conformity assessment bodies, and consumers, and may hinder acceptance of the product in the marketplace, particularly when a European Standard already exists for the same product.

## **European National Standards**

The harmonization, or the “Europeanization,” of standards is an ongoing process. There will be instances when no European Standard (EN) exists to cover essential requirements, or no European Standard exists that is applicable to a product that is unique, or innovative, or a product whose technology is developing rapidly. In this case, a Member State may inform the manufacturer of an existing national standard it considers relevant, or the use of a national standard may be permitted as a temporary solution to the proper implementation of the essential requirements. However, a national standard, (one produced by a European National Standards Body), like all other standards worldwide, does not carry with it the presumption of conformity, and the burden of proof that the product meets all the essential requirements still rests with the manufacturer.

### **National Standards (Mutual Recognition)**

National standards may still govern products regulated at Member State level. The harmonization of regulation is also an ongoing process, and some products that are unregulated at European level are still regulated by Member States. This means that some national standards act as national technical regulations.

(If products are unregulated at the European level, the European Court of Justice has decreed that Member States must recognize them in each other’s territory (i.e., acceptance in one Member State means acceptance in all) unless there are proven health or safety restrictions. This acceptance principle is known as mutual recognition. To this date, however, products outside of the food sector have not enjoyed a liberal and free exchange under the mutual recognition principle).



**Table 3: European Standards Bodies: CEN National Members**CEN Web Site: <http://www.cenorm.be>

<b>National Standards Body</b>	<b>Country</b>
ON <a href="http://www.on-norm.at">http://www.on-norm.at</a>	Austria
IBN/BIN <a href="http://www.ibn.be">http://www.ibn.be</a>	Belgium
CSNI <a href="http://www.csni.cz">http://www.csni.cz</a>	Czech Republic
DS <a href="http://www.ds.dk">http://www.ds.dk</a>	Denmark
SFS <a href="http://www.sfs.fi">http://www.sfs.fi</a>	Finland
AFNOR <a href="http://www.afnor.fr">http://www.afnor.fr</a>	France
DIN <a href="http://www.din.de">http://www.din.de</a>	Germany
ELOT <a href="http://www.elot.gr">http://www.elot.gr</a>	Greece
STRI <a href="http://www.stri.is">http://www.stri.is</a>	Iceland
NSAI <a href="http://www.nsai.ie">http://www.nsai.ie</a>	Ireland
UNI <a href="http://www.unicei.it">http://www.unicei.it</a>	Italy
SEE <a href="http://www.etat.lu/SEE">http://www.etat.lu/SEE</a>	Luxembourg
NNI <a href="http://www.nni.nl">http://www.nni.nl</a>	Netherlands
NSF <a href="http://www.standard.no/nsf">http://www.standard.no/nsf</a>	Norway
IPQ <a href="http://www.ipq.pt">http://www.ipq.pt</a>	Portugal
AENOR <a href="http://www.aenor.es">http://www.aenor.es</a>	Spain
SIS <a href="http://www.sis.se">http://www.sis.se</a>	Sweden
SNV <a href="http://www.snv.ch">http://www.snv.ch</a>	Switzerland
BSI <a href="http://www.bsi.org.uk">http://www.bsi.org.uk</a>	United Kingdom

**Table 4: European Standards Bodies: CENELEC National Members**  
CENELEC Web Site: <http://www.cenelec.be>

<b>National Standards Body</b>	<b>Country</b>
ÖVE <a href="http://www.ove.at">http://www.ove.at</a>	Austria
BEC/CEB <a href="http://www/bec-ceb/be">http://www/bec-ceb/be</a>	Belgium
CSNI <a href="http://www/csni.cz">http://www/csni.cz</a>	Czech Republic
DS <a href="http://www.ds.dk">http://www.ds.dk</a>	Denmark
SESKO <a href="http://www.sesko.fi">http://www.sesko.fi</a>	Finland
UTE <a href="http://www.ute-fr.com">http://www.ute-fr.com</a>	France
DKE <a href="http://www.dke.de">http://www.dke.de</a>	Germany
ELOT <a href="http://www.elot.gr">http://www.elot.gr</a>	Greece
STRI <a href="http://www.stri.is">http://www.stri.is</a>	Iceland
ETCI <a href="http://www.etcie.ie">http://www.etcie.ie</a>	Ireland
CEI <a href="http://www.ceiuni.it">http://www.ceiuni.it</a>	Italy
SEE <a href="http://www.etat.lu/SEE">http://www.etat.lu/SEE</a>	Luxembourg
NEC <a href="http://www.nni.nl">http://www.nni.nl</a>	Netherlands
NEK <a href="http://www.nek.no">http://www.nek.no</a>	Norway
IPQ <a href="http://www.ipq.pt">http://www.ipq.pt</a>	Portugal
AENOR <a href="http://www.aenor.es">http://www.aenor.es</a>	Spain
SEK <a href="http://www.sekom.se">http://www.sekom.se</a>	Sweden
CES <a href="http://www.sev.ch">http://www.sev.ch</a>	Switzerland
BEC <a href="http://www.bsi.org.uk">http://www.bsi.org.uk</a>	United Kingdom

### **Table 5: European Standards Bodies: ETSI**

ETSI Web Site: <http://www.etsi.org>

The European Telecommunications Standards Institute (ETSI) is composed of some 697 members from 50 countries, including the United States. They represent Administrations (8.7%), network operators (17.75%), manufacturers (51.27%), service providers (18.48%), and users (3.8%).

There are 552 full members from 35 countries, 62 observers from 18 countries (which category has the largest U.S. concentration), and 83 associate members from 15 countries.

### **Standardization in the EU and the United States: A Comparison**

Standardization, when used specifically to translate laws into technical solutions for implementation, is tantamount to technical regulation. Standards developed by private sector standards committees for this purpose, therefore, can have a profound effect on the regulation of trade. A standard can determine, by defining and delineating technical characteristics, what conditions will permit a product on the market. By excluding characteristics, a standard can also prohibit a product from being placed on the market. In non-regulated areas, standards can exert an equally powerful influence on the marketplace. It is important, therefore, that wherever possible, manufacturers participate in standards development where it impacts their targeted markets.

#### **Similarities**

The philosophy of standardization by committee and consensus is the same in the EU as it is in the United States. Technical experts and others participate voluntarily, and without compensation. The makeup of committees may be organized differently and roles may vary, but they generally follow a pattern that includes input from producers, users, government, and academia. On both sides, committees are fairly autonomous; and both sides have processes for the creation of subcommittees, drafting of standards, disseminating draft documents for comment, voting, and appeals. On both sides, decisions are reached by consensus. And on both sides, standards organizations provide management, administrative, and logistical support for standards activities. They also provide for the editing, printing, publishing, sale, and distribution of standards documents.

#### **Differences**

The differences between the United States and the EU are most notable in the way standards activities are organized. In Europe, the structure of centralized national standards bodies and centralized regional bodies (The European Standards Bodies) contrasts sharply with the decentralized structure and the myriad of bodies that develop



standards in the United States. Organized by nation in Europe, standards activities are organized by sector in the United States.

Another striking difference between the two is policy regarding membership in standards bodies. Membership in a national standards body in Europe requires that the member be European or have a business interest or manufacturing presence in Europe (membership in a national standards body is a prerequisite for participation in the European Standards Bodies, except for ETSI, where participation is open to other nationals). In the United States, in the large, full consensus standards developing bodies, membership is unrestricted. Depending on the sector and global interest in the subject, therefore, membership on a U.S. technical committee can be international in scope.

### **The Relationships**

There is a relationship between U.S. standards activities and those in the EU. Two organizations, the American National Standards Institute (ANSI) in the United States, and the International Organization for Standardization (ISO) in Geneva, Switzerland, act as bridges to CEN, and ANSI, via the United States National Committee (USNC), and the International Electrotechnical Commission (IEC) in Geneva, Switzerland, act as bridges to CENELEC.

The American National Standards Institute (ANSI) is the U.S. representative to the ISO. It is also, via the USNC, the U.S. representative to the IEC. Each European national standards body represents its country in the ISO and the IEC. The technical committees of both the ISO and the IEC, therefore, are where technical experts from the EU countries meet technical experts from the United States to develop international standards.

In addition, there are technical cooperation agreements between CEN and the ISO and CENELEC and the IEC. These agreements more closely align their work. These agreements are known as the Vienna (CEN/ISO) and Dresden (CENELEC/IEC) Agreements. In certain areas (such as recreational craft), the standards recognized for use in connection with European legislation are in effect the ISO standards.

It is also possible for U.S. interested parties to comment on draft CEN and CENELEC standards through ANSI.

### **ISO 9000**

The first quality management system standard was developed in Europe by the British Standards Institution (BSI) in 1979. BSI took the activity into the ISO, and the result was the ISO 9000 series of standards that are so well known and widely used throughout the world today. When the European Commission adopted these standards as part of the Global Approach, they became an integral and official part of the European conformity assessment scheme. The European designation for this set of standards is EN 29000 (See Modules). Two New Approach Directives (Active Implantable Medical Devices and the Radio Equipment and Telecommunications Terminal Equipment and the Mutual



Recognition of their Conformity) designate a full quality management system (EN 46001 for Medical Devices and EN 29001 for RTTE) as a full route to CE marking. However, a less comprehensive form of this standard may be used, along with other methods of conformity assessment, to meet the essential requirements of this directive and other directives as well.

Perhaps more importantly, ISO 9000 registration (or EN 29000 certification) is used voluntarily but extensively in Europe as a condition of acceptance of a manufacturer's product or as a means of recognition of the manufacturer's credibility. It is estimated that, as of 1994, 78% of all ISO certificates worldwide were issued in Europe. The U.S. exporter, therefore, should be aware not only of the use of EN 29000 in regulation, but of its use in contractual arrangements with a European customer.

*It is important to note that a manufacturer with a quality system in place (such as ISO 9000) should not automatically assume that his or her products are CE compliant because of the quality system alone. The appropriate New Approach Directive(s) will prescribe the correct and full route to conformity assessment.*

## **Introduction to the Basic Principles of Compliance**

### **CE Marking**

The CE mark is aptly called the passport to Europe for products. CE marking a product, like carrying a passport when entering a foreign country, is not an option. It is required by law if the product falls under one of the New Approach Directives. It is not a quality mark, nor is it a mark for consumers. Intended for Member State authorities, it is the visible sign to those authorities that your product is in compliance with the New Approach Directives. All manufacturers, European, American, Japanese, or other, are required to affix the CE mark to products that are governed by New Approach Directives. CE marking on a product 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.

### **Determining Which Directives Apply to the Product**

The first step to compliance is determining which directives apply to the product. A product may be regulated by more than one directive. For example, machinery is obviously regulated by the Machinery Directive (98/23/EC); but machinery that is powered by electricity is also regulated by the Low Voltage Directive (73/23/EEC). The LVD addresses the hazards associated with the electrical aspects of the machine. Likewise, all electrical products are governed by the Electromagnetic Compatibility Directive (89/336/EEC), which addresses the hazards associated with electromagnetic interference. Most machinery is regulated by at least three New Approach Directives: (1) Safety of Machinery, (2) Low Voltage, and (3) Electromagnetic Compatibility. But there may be others that apply. If a machine contains a pressure vessel, for example, it

would also be regulated by the Simple Pressure Vessel Directive (87/404/EEC). The CE marking affixed to a piece of machinery, therefore, would indicate to authorities that the product has addressed all the risks associated with the product, whether or not those risks are defined in the Machinery Directive, the Low Voltage Directive, the EMC Directive, or any other directive that addresses a risk associated with the machine. Before affixing the CE mark, therefore, the manufacturer must make sure the product complies with the law by (1) determining which New Approach Directives govern the product, (2) applying the appropriate standards, and (3) carrying out the appropriate method of conformity assessment.

The CE mark does not disclose which directive(s) or standards apply to the product, nor will it indicate the method of conformity assessment used to bring the product into compliance. This information is provided by other accompanying documents, such as the Declaration of Conformity.

### **Who Affixes the CE Mark**

The Manufacturer or the Authorized Representative affixes the CE marking to the product. It is not affixed by a Notified Body. The CE mark, consisting of the initials "CE," and appearing as follows,



**Figure 1. "CE" logo**

must be affixed to the product, to its data plate or, where this is not possible, to its packaging. Instructions for the graphic design are contained in Annexes to the Directives and in Directive 93/68/EEC, known as the "CE Marking Directive." The CE marking must be affixed visibly, legibly, and indelibly. Where special provisions do not impose specific dimensions, the CE marking must have a height of at least 5 millimeters.



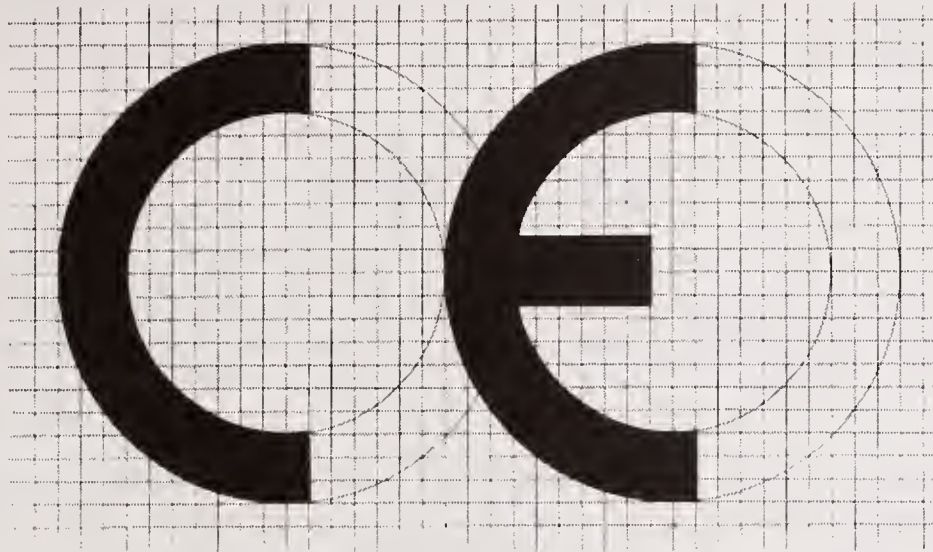


Figure 2: Actual layout for art work for the "CE " logo. NOTE: The grid is not actually seen on the final art work. See Figure 1 above.

If the CE marking is affixed to a product inappropriately, the product may be prohibited from being placed on the market or withdrawn from the market. Other marks may be affixed to the product, provided they do not reduce the visibility or legibility of the CE marking.

### **Placing on the Market**

The European Commission's *Guide to the Implementation of Directive based on the New Approach and Global Approach* (Brussels, August 1999) defines "placing on the market" as: "The initial action of making available on the Community market, for payment or free of charge, a product covered by the directive, with a view to distribution and/or use in the Community." This includes products that are manufactured within the European Union and products imported from a country outside the European Union.

The following situations involving products are not considered "placing them on the market:"

- Transfer of a product from a manufacturer in a country outside the European Union to his Authorized Representative in the European Union for the purpose of ensuring compliance;
- Importation of a product into the European Union for re-export outside the European Union;
- Transfer of a product produced in the European Union to a country outside the European Union;
- Exhibition of a product at trade fairs and exhibitions (where it must be clearly indicated that the exhibited product is not in compliance);
- Transfer of a product to a manufacturer for further measures (for example, assembling, packaging, processing or labeling); and



- Not (yet) granted release for free circulation by customs, or has been placed under another customs procedure (for example, transit, warehousing or temporary importation).

### **Self-Certification**

Most products covered by New Approach Directives can be self-certified by the manufacturer and do not require the intervention of a Notified Body. To self-certify, the manufacturer must assess the conformity of products to the applicable directives, and to the standards if applied.

The manufacturer may affix the CE marking to products or equipment (and prepare and sign the Declaration of Conformity) as long as he or she can prove conformity to the applicable requirements. Proof is provided in the Technical File that the manufacturer must compile.

Certain (high risk) products may not be self-certified, but must be subjected to an EC type-examination. This examination involves the inspection of a representative example by a Notified Body.

### **Notified Bodies**

Most products within the scope of European product legislation (New Approach Directives) can be self-certified by the manufacturer and do not require the intervention of a Notified Body.

There are products, however, which may not be self-certified, but must be subjected to an EC type-examination. This examination involves the inspection of a representative example by a Notified Body within the EEA.

Notified Bodies are independent testing houses, laboratories, or product certifiers authorized by the EU Member States to perform the conformity assessment tasks specified in directives. A Notified Body is appointed by a Member State and must have the necessary qualifications to meet the testing and/or certification requirements set forth in a directive. A Notified Body not only needs to be technically competent and capable of carrying out the specified conformity assessment procedures, but it must also demonstrate independence, impartiality, and integrity (The EN 45000 standard series addresses criteria for accreditation, assessment, and operation of conformity assessment bodies, i.e., Notified Bodies).

Notified Bodies may carry out their activities in one or more Member States or in countries outside the EEA. A Notified Body may also use a subcontractor to perform part(s) of a conformity assessment procedure. Many U.S. testing houses, for example, act as subcontractors to Notified Bodies. The Notified Body, however, is the ultimate

authority, is always responsible, and is the sole source of the certificate claiming compliance.

Manufacturers, inside or outside of the EEA, may choose any Notified Body that has been designated to carry out the conformity assessment procedure(s) specified in applicable directive(s). Certificates issued by a Notified Body in one Member State must be accepted throughout the EEA.

*Lists of Notified Bodies are published by the European Commission in the "Official Journal of the European Communities." A hard copy may be requested from Mrs. Janette AISTROPE, Tel: 011-322-299-9060, Fax: 011-322-296-0851, E-mail Janette.Aistrope@cec.eu.int. At present, these lists are not available electronically.*

### **Competent Bodies**

The Electromagnetic Compatibility Directive (EMC) is unique in that, in addition to Notified Bodies, it references Competent Bodies (accredited testing houses). According to the EMC Directive, a Competent Body must be consulted when the manufacturer has not used (all) applicable Harmonized Standards in the design or production of the product. This manufacturer's Technical File will have to contain a technical report or certificate obtained from a Competent Body. The role of the Competent Body, therefore, is to assist the manufacturer in assessing and elucidating the compliance of his product with the EMC Directive by issuing technical reports and certificates.

Notified Bodies, on the other hand, are specified within the EMC Directive to be consulted only for an EC type approval for transmitting equipment.

### **Competent Authorities**

Competent Authorities are Ministries of National Governments of EEA Member States and are responsible for the supervision of the market and products already on the market.



## **Mutual Recognition Agreements**

In December 1998, The European Union and the United States concluded Mutual Recognition Agreements (MRAs) on conformity assessment. The U.S. - EU MRA is a bilateral agreement between the United States and the European Union that establishes procedures to facilitate transatlantic trade. The MRA recognizes that certain conformity assessment bodies (CABs) in Europe can conduct - in accordance with U.S. regulatory requirements - product approval type testing and quality system evaluations in a fashion equivalent to those conducted by the FDA. Similarly, it recognizes that CABs in the United States can conduct type testing and quality evaluations according to the EU Medical Device Directive. The agreements cover several industrial sectors and are based on acceptance by both Parties of test reports, certificates, and reports of inspections issued by one another's conformity assessment bodies (CABs) and authorities.

MRAs include lists of conformity assessment bodies, inspection bodies, and authorities, in both the EU and the United States. The full text of the U.S.- EU MRA can be accessed at <http://www.ustr.gov/agreements/mra/mra1.pdf>

## **EC Type-Examination**

The EC type-examination is a procedure by which the Notified Body ascertains and attests that a specimen representative of production meets the provisions of the directive that applies to it. The manufacturer or his Authorized Representative established in the European Union may make application to the Notified Body of his choice.

### **Manufacturer**

The manufacturer is the person responsible for designing and manufacturing a product covered by a New Approach Directive, and whose intention is to place it on the European Union market. A manufacturer may contract out the design or production, may use finished products, parts or components. In all cases, however, he or she is ultimately responsible for the product and its compliance with the law.

The manufacturer is responsible for designing and manufacturing the product in accordance with the essential requirements of all relevant directives and following the conformity assessment procedures from the appropriate directives, such as compiling a Technical File, affixing the CE marking and drawing up of a Declaration of Conformity.

A manufacturer may be located inside or outside the European Union. Inside or out, he or she can appoint an Authorized Representative (who must be located in the European Union) to act on his or her behalf.

A person producing a new end product by assembling other existing products is also considered a manufacturer, and acquires the responsibilities of a manufacturer. The same is true of a person who changes the usage of a product, such as adding a new function to a machine or changing an existing function. The law treats these "modified"



products as new products, and they are held to the same certification requirements as any other new product.

### **The Importer**

An importer is a person legally established within the European Union who places a product from a country outside the European Union on the European Union market. Although the importer can provide the Surveillance Authority with the necessary documentation or information regarding a product when the manufacturer is not established in the European Union and the manufacturer has no Authorized Representative, he or she may not wish to assume this responsibility. The decision is declared in a contract between the importer and the manufacturer.

### **Private Labeler**

In accordance with European product liability legislation, a person *acting* as the manufacturer of the product, even if he or she is not the producer, is considered a manufacturer in the eyes of the law. This principle applies to the "private labeler." A private labeler is one who does not manufacture the product, but places it on the market under his or her private name or make. The "private labeler," therefore, as manufacturer, is ultimately responsible for compliance with all requirements.

### **Authorized Representative**

An Authorized Representative is the person appointed by the manufacturer and delegated to act on his or her behalf in carrying out certain tasks required by a New Approach Directive. This Authorized Representative must be established inside the European Union and available to Member State Authorities. The manufacturer, however, is ultimately responsible for the actions carried out by the Authorized Representative.

Manufacturers established outside the European Union are not necessarily required to have an Authorized Representative in the European Union. There are exceptions, however. Manufacturers who do not have a registered place of business in a Member State and whose products are governed by the Directives for Medical Devices, Active Implantable Devices and In-vitro Diagnostic Devices, must appoint an Authorized Representative established within the European Union.

The delegation of tasks from the manufacturer to the authorized representative should be arranged by contract.

Depending on the conformity assessment procedure and the directive, the following tasks can be delegated to the Authorized Representative. He or she can:

- declare that the product complies with the requirements;
- affix the CE marking;
- draw up and sign the Declaration of Conformity; and

- keep the Declaration of Conformity available for national surveillance authorities.

### **Technical File**

New Approach Directives contain more opportunities for self-declaration than mandated third party 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.

Most New Approach Directives allow the manufacturer to “self-declare” compliance with Essential Health and Safety Requirements, but some directives require Notified Body intervention (See Modules). For example, Annex IV of the Machinery Directive lists types of machines that must be submitted to a Notified Body for evaluation. Whether or not the judgment of a Notified Body is required, the manufacturer is required to prepare a Technical File.

The Technical File is the written justification that all aspects of a product are safe. For goods that must bear CE marking, this written justification must 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.

Any person placing a product on the market but not in possession of the Technical File must, on request from national Surveillance Authorities, 1) state where the Technical File is situated, and 2) produce the Technical File promptly. Most manufacturers already possess 90% of the material necessary to compile a Technical File.

### **Content of the Technical File**

The following main elements should be present in a Technical File:

- a general description of the product;
- design and production drawing and diagrams;
- detailed technical data for essential aspects of the product;
- a risk assessment;
- a list of standards and or solutions applied;
- reports of calculations and tests that have been carried out (calculations might include a bearing, belt, or pulley based on a chart in a catalog);
- certificates and inspection reports;
- in the case of series production, internal conditions that have been observed to safeguard compliance with the directive;
- a user’s manual; and
- a Declaration of Conformity.



A Technical File may cover a range of product models or options. Similar but simpler models may be considered within the scope of the most complex or most hazardous combination evaluated.

A Technical File is proprietary in nature. It need not be given to one's customers or competitors. The Technical File must be kept available for inspection or control by national Surveillance Authorities who may ask to see all or parts of the Technical File.

### **Risk Assessment**

Most New Approach Directives require a risk evaluation of the products they govern. Assessing risks in the design phase of a product is an established practice. A good designer examines all possible risks related to a design, and does everything possible to remove them. A designer must be able to (legally) defend the safety aspects of his design decisions for a period of at least ten years (five years for medical devices) after placing the product on the European Union market. A systematic risk assessment on the one hand, and good documentation of the design decisions concerning safety on the other, are essential components of a viable legal defense. A systematic risk assessment also forms the basis of self-certification and is the essence of the Technical File.

Two Harmonized Standards have been developed to assist the manufacturer in the risk assessment of Machinery (EN 1050) and Medical Devices (EN 1441).

Some manufacturers approach risk assessment by using a design standard. Conformity to a standard, however, does not necessarily mean that the manufacturer will escape liability for a faulty design. Conformity to a standard may only provide a rebuttable presumption of conformity with the safety requirements of the directive. The strongest defense against liability is the combination of the use of standards where reasonable, and a documented design review that shows how the manufacturer effectively minimized risk.

A good example is found in Annex I of the Machinery Directive titled "Essential Health and Safety Requirements Relating to the Design and Construction of Machinery." This Annex provides both a description of a safety-conscious design approach, and a list of desirable safety characteristics. The principles elucidated are sound principles that, when followed, will substantially support a legally defensible design. The list of safety characteristics is a reasonably thorough list that facilitates the critical design review process. This design review is often referred to as a Risk Assessment. By using the contents of Annex I, a manufacturer is more likely to prepare a complete Risk Assessment.

The self-declaring manufacturer is required to list the Essential Health and Safety Characteristics of the Machinery Directive (these are contained in Annex I), and describe the measures taken to minimize the hazards that are described therein. Basically, this aspect of the directive describes an obligation to engage in a critical design review, focused on product safety, with the results documented in writing. This is the step that



many manufacturers have not undertaken, prior to exporting to the European Union. The precise form of this exercise is left to the discretion of the manufacturer, and may be in the form of a Failure Modes and Effects Analysis, or a HAZOP (Hazard of Operations) analysis, or some other form that serves to direct the safety related aspects of designing a safe machine, and teaching people how to use it safely.

Some manufacturers are reluctant to prepare written design reviews. They reason that such reviews could be used against them in a product liability lawsuit. Not recognizing or effectively dealing with a hazard, however, is not a winning argument. A more powerful defense is available when the manufacturer can show awareness of hazards, and can also show how risks to the user were minimized through the thoughtful application of design, guarding, and instructions.

In all cases, the directive should be looked to for direction. For example, Annex I of the Machinery Directive contains specific detailed technical requirements that are to be followed in conducting a risk assessment.

### **User's Manual**

A user's manual is an essential safety requirement. A user's manual must contain all the information required for the correct and safe use of a product, including:

- information concerning risks;
- identification and discouragement of hazardous applications;
- instructions on how the product must be put to safe use;
- identification of those authorized to perform certain actions; and
- identification of appropriate safety precautions that have to be taken.

### **Language**

The user's manual must be written in one official language of the European Union (English is one of the official languages) and/or in the language of the country where the product will be used. Because its proper use is critical to the safety of the user, a prudent manufacturer will make sure that a competent technical translator translates the user's manual. Applying drawings and pictograms is widely accepted in the European Union and is cost effective from a translation point of view.

### **Declaration of Conformity**

After performing a critical design review, making changes to the product design that will minimize risks of harm, and compiling the Technical File, the manufacturer may affix the CE marking and prepare a Declaration of Conformity.

New Approach Directives require the issuance of a Declaration of Conformity by the manufacturer or his Authorized Representative. A Declaration of Conformity is a document informing Surveillance Authorities that the product meets the essential

requirements of the applicable directives, or that the product has been issued an EC type-examination certificate, and meets the essential requirements of the applicable directives.

Although the Declaration of Conformity is only required to be made available (by the manufacturer or his authorized representative) upon request by national surveillance authorities, it is better to include the Declaration with each shipment.

The Declaration of Conformity must contain:

- the product (name, type or model number, lot, batch or serial number);
- the name and address of the manufacturer or his Authorized Representative;
- the name and identification number of the Notified Body if required by the directive;
- standards or other normative documents applied to verify compliance with the directive(s). Declaration should also include reference to other directives if applicable;
- the date of issue; and
- the signature and title.

## Sample Declaration of Conformity

[PRINTED ON ORIGINAL COMPANY LETTERHEAD]

### **Sample Declaration of Conformity**

#### **Product Identification**

Product name :  
Brand :  
Cat. Number :  
Batch/Serial Nr.

#### **Manufacturer**

Name :  
Address :  
Country :  
Representative:

#### **Authorized Representative/Distributor in Europe**

Name :  
Address :  
  
Country :

#### **Means of Conformity**

\_\_\_\_\_ declares that the product listed is in conformity with the essential requirements and provisions of Council Directive \_\_\_\_\_ and conforms to standards \_\_\_\_\_

#### **Signature**

Place and date :

Signature :

Name : (Name, Title, and Signature of Authorized Person)



The Declaration of Conformity must be kept for at least ten years from the last date of manufacture of the product, unless the directive provides for a different duration. For example, the Directives for Medical Devices and Active Implantable Medical Devices require that the Declaration of Conformity be kept for five years.

Directives for Machinery, Equipment for Use in Potentially Explosive Atmospheres, Recreational Craft, and Lifts require that the Declaration of Conformity accompany each product. It is highly recommended that a Declaration of Conformity be included with shipments of products that fall under other directives as well, although it is not necessary to include it with each product.

### **Language**

The Declaration of Conformity must be in one of the official languages of the European Union (English is one of the official languages). For products that must be accompanied by a Declaration of Conformity (i.e., products covered by Directives for Machinery, Potentially Explosive Atmospheres, Recreational Craft, and Lifts), the Declaration of Conformity must be in the language of the country of use. It is recommended that the Declaration of Conformity that is required by directives other than the ones listed above also be in the language of the country where the product or equipment will be used.

### **Signature of Declaration of Conformity**

The Declaration of Conformity must be signed by a person who is authorized to bind the company, as the Declaration is, in essence, a statement by the company. The person who signs should be one who has responsibility for determining that the design of the product is reasonably safe and has authority to direct changes to the design. It is not necessary for the signatory to be domiciled in the European Union.

The person who will be placing his signature on the Declaration of Conformity must act in good faith: i.e., he must be informed that anything stated on the document is believed to be correct. Everything stated on the Declaration is stated in good faith and can be backed up by a solid Technical File.

### **Declaration of Incorporation**

Annex II of the Machinery Directive lists the information that must appear in the Declaration of Conformity. It is the only directive that also calls for more than one type of Declaration. Machines that operate standing alone are covered by a Declaration of Conformity as described in Part A of Annex II. But, where the maker of a larger machine integrates or incorporates a subassembly, the manufacturer of the subassembly is required to issue a Declaration of Incorporation (Part B of Annex II).

The general principle behind a Declaration of Incorporation is that the manufacturer of a subassembly cannot be required to foresee all the ways the subassembly may be

incorporated, and, more importantly, may not be able to provide all the safety aspects of the larger machine.

The Declaration of Incorporation includes a statement that protects the subassembly manufacturer, and transfers the responsibility for safe incorporation to the builder of the larger system. Annex II part B contains suggested language for this statement by the manufacturer of the subassembly: "This machinery may not be put into service until the machinery into which it is to be incorporated has been declared in conformity with the provisions of the Directive."

## Sample Declaration of Incorporation

[PRINTED ON ORIGINAL COMPANY LETTERHEAD]

### Sample Declaration of Incorporation

#### Product Identification

Product name :  
Brand :  
Cat. Number :  
Batch/Serial Nr.

#### Manufacturer

Name :  
Address :  
Country :  
Representative:

#### Authorized Representative/Distributor in Europe

Name :  
Address :  
  
Country :

#### Means of Conformity

\_\_\_\_\_ declares that the product listed is in conformity with the essential requirements and provisions of Council Directive \_\_\_\_\_ and conforms to standards \_\_\_\_\_

*The equipment above must not be put into service until the machinery into which it is to be incorporated has been declared in conformity with the provisions of the Directive.*

#### Signature

Place and date :  
  
Signature :  
  
Name : (Name, Title, and Signature of Authorized Person)



## **Product Liability**

New Approach Directives do not always provide guidance on how to implement, nor do they provide interpretations of the law. Legal critiques of design(s) are conducted in hindsight at trials, where the issue may be whether or not the manufacturer was negligent, and whether or not the designer produced a reasonably safe design. When these are the issues, a national European court will inquire as to how the manufacturer of the product applied (or didn't apply) good safety engineering practices.

A review of the law will show that some designs are deemed "not reasonably safe," and that some manufacturers have judgments rendered against them for failing to exercise reasonable engineering practices. The legal obligation to use good engineering practices in safety matters is not embedded in directives, but exists independently of them.

This does not make design decisions straightforward for the manufacturer, but it does place the manufacturer in a unique position. A manufacturer, or more precisely the designer, is the only one who can evaluate and change the design of a product before it is put on the market. It follows, then, that in the event of a breach of safety, the manufacturer and/or the designer will be the responsible parties required to defend the design decisions related to the product.

The legal concept of product liability is the same in the European Union as it is in the United States, although the scale of award in the United States is considerably higher. Any product manufactured or imported into the European Union which causes damage to individuals or property is covered by the Product Liability Directive (85/374/EEC). This directive provides the right of civil action for product liability to all citizens of the European Union.

The Product Liability Directive covers all moving parts, electricity, raw materials, and components for final products, and holds the manufacturer liable for all damages. If the manufacturer cannot be identified, each supplier of the product becomes liable.

Certain directives require that critical design review processes be documented in writing. In addition, a manufacturer should not consider making a product "safer" for one market than for another.

Manufacturers that place products on the European Union market should reach contractual agreements with customers that include liability issues. In addition to the sales contract, liability aspects should be covered in the Declaration of Conformity, the Technical File, and the User's Manual.

The General Product Safety Directive (92/59/EC) describes the obligations to a manufacturer when no other directive or regulation applies (for example, a wind-powered artistic mobile that is not a machine or a toy). According to this directive (and according to well-established United States law) a manufacturer is expected to consider and deal with the risks involved in the intended use and foreseeable misuse of its products. The scope of this directive includes packaging and instructions. This is not a "CE Marking" directive, and in fact the General Product Safety Directive expressly says that the CE mark is not to be affixed to products that are covered by the directive.

### **National Marks**

New Approach Directives requiring CE marking were intended to replace national law product requirements and multiple national safety markings.

Market forces, however, may still continue to drive manufacturers to use national markings in addition to CE marking. In addition, manufacturers may encounter national testing houses that promote their own "marks" to be used in addition to CE marking.

Member States may not maintain or introduce new markings that will denote compliance with requirements of the New Approach Directives. The CE marking is the only marking which implies conformity of a product to New Approach Directives. A product may bear other markings provided they do not reduce the visibility or legibility or create confusion with respect to CE marking.

### **Surveillance Authorities**

Member State Authorities, appointed for the purpose of market surveillance, are responsible for the enforcement of the New Approach Directives. The purpose of market surveillance is to ensure that the provisions of the directives are complied with throughout the European Union.

These public authorities can be the Department of Health, Department of Industry, Department of Labor, or other established inspection authorities of a Member State.

In case of an incident or random check, the surveillance authority may require access to the manufacturer's Declaration of Conformity and Technical File. The manufacturer, his authorized representative or importer, must be able to provide the Technical File within seven to ten days as of the date of request by the surveillance authority. If the product is found to be non-compliant, corrective action will depend on and be appropriate to the level of non-compliance.

The surveillance authority will hold the person responsible for affixing the CE marking to a non-compliant product accountable. Others who are responsible for the non-compliance of the product will be held accountable as well. Penalties, which may include imprisonment, are determined by National law.

Surveillance authorities monitor products placed on the market as follows. They will:

- visit commercial, industrial and storage premises on a regular basis;
- visit work places and other premises where products are put into service and used;
- organize random checks;
- take samples of products and subject them to examination and testing; and
- require all necessary information.



# *NIST* Technical Publications

## *Periodical*

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**Journal of Research of the National Institute of Standards and Technology**—Reports NIST research and development in those disciplines of the physical and engineering sciences in which the Institute is active. These include physics, chemistry, engineering, mathematics, and computer sciences. Papers cover a broad range of subjects, with major emphasis on measurement methodology and the basic technology underlying standardization. Also included from time to time are survey articles on topics closely related to the Institute's technical and scientific programs. Issued six times a year.

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