The Canadian Trade Commissioner Service

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A Canadian Trade Commissioner Service White Paper

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Six steps to CE marking

CE

Foreign Affairs, Trade and Development Canada
Trade Commissioner Service

Affaires étrangères, Commerce et Développement Canada
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Contents

Introduction to this white paper

CE marking can be confusing, costly, complex, and can take up a lot of a company's precious time.

This white paper, produced by the Canadian Trade Commissioner Service, is a primer on CE marking. This guide is not comprehensive and companies are strongly encouraged to consult the web resources listed on page 16.

The six steps of this white paper bring together insight on CE marking from experts and Trade Commissioners alike, as well as key EU resources.

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CE

What is the CE mark?

The CE mark (above) is a symbol that a manufacturer (see definition below) affixes to a product so that it can be sold in Europe. The mark is mandatory for products which fall under one of 24 European directives. The CE mark means that the manufacturer takes responsibility for the compliance of a product with all applicable European health, safety, performance and environmental requirements. CE stands for "Conformité Européenne," the French for European conformity.

The mark is required in all 27 member states of the EU, as well as Iceland, Norway, and Liechtenstein. Switzerland accepts the CE mark for some products and Turkey actually requires that many products be CE marked.

The bottom line: CE marking provides access to a market of over 500 million consumers.

Definition of manufacturer:

The natural or legal person with responsability for the design, manufacture, packaging and labelling of a device before it is placed on the market under its own name.

CE is not like other certification marks.

The Canadian Standards Association (CSA) or the Underwriters' Laboratories (UL) marks, for example, can only be used when those organizations have determined that a product meets applicable standards. European organizations do not grant authorization to use the CE mark as it is not owned by any particular body. The manufacturer is responsible for its proper use.

The manufacturer, whether established inside or outside the EU, is ultimately responsible for affixing the CE mark and is also responsible for its proper use. The manufacturer established outside the EU may appoint an authorized representative established in the EU to act on his behalf. CE marking is about more than affixing a symbol to a product.

Follow the subsequent six steps to learn about the CE marking process.

Step 1

Find the CE directive(s) that applies to your product.

How do you know if your product requires a CE mark? The first step is to see if your product is covered under one or more of the 24 CE directives below. If your product falls under any of these directives, it needs to be CE marked.

Visit the websites of the European Commission for more detail and updates.

Directive Number	Product Category
2006/95/EC	Low Voltage
2009/105/EC, (ex. 87/404/EEC)	Simple Pressure Vessels
2009/125/EC	Ecodesign for Energy-related Products
2000/14/EC	Noise Emission for Outdoor Equipment
2009/48/EC 88/378/EEC, 93/68/EEC	Toy Safety
89/106/EEC, 93/68/EEC	Construction Products
2004/108/EC	Electromagnetic Compatibility
2006/42/EC	Machinery
89/686/EEC, 93/68/EEC, 93/95/EEC, 96/58/EC	Personal Protective Equipment
2009/23/EC (ex. 90/384/EEC)	Non-automatic Weighing Instruments
2009/142/EC (ex 90/396/EEC)	Appliances Burning Gaseous Fuels
92/42/EEC, 93/68/EEC, 2004/8/EC, 2005/32/EC	Hot-water Boilers (liquid or gaseous fuels)
93/15/EEC	Explosives for Civil Uses
93/42/EEC, 98/79/EC, 2000/70/EC, 2001/104/EC 2007/47/EC	Medical Devices
90/385/EEC, 93/42/EEC, 93/68/EEC, 2007/47/EC	Active Implantable Medical Devices
98/79/EC	In Vitro Diagnostic Medical Devices
94/9/EC	Equipment Explosive Atmospheres
94/25/EC, 2003/44/EC	Recreational Craft
95/16/EC	Lifts
97/23/EC	Pressure Equipment
99/5/EC	Radio Equipment and Telecommunications Terminal Equipment
2000/9/EC	Cableway Installations to Carry Persons
2004/22/EC	Measuring Instruments
2007/23/EC	Pyrotechnic Articles

What is a directive?

A directive is a legislative act of the European Union which requires member states to adapt their national laws to achieve a particular result that is harmonized to EU rules in this area.

For example, the EU directive for products which fall under the electromagnetic compatibility category (directive number *2004/108/EC*) calls for member states to ensure that electrical devices that fall under this category meet certain requirements:

> *The EMC directive first limits electromagnetic emissions of equipment in order to ensure that, when used as intended, such equipment does not disturb radio and telecommunication as well as other equipment. The directive also governs the immunity of such equipment to interference and seeks to ensure that this equipment is not disturbed by radio emissions when used as intended.*
>
> *– European Commission*

! Be prepared for this:

Determining whether your product falls under one or more directives can be difficult. For example, if you manufacture electronic packaging machines with a conveyer belt, several directives will impact you. If you want to know which directives apply, you will have to go through each of the 24 directives (product coverage is sometimes found in an annex). There is no reference tool or database that lists which directives might be applicable to certain products. A trade commissioner can help you navigate these complexities.

Next step.

Once you have figured out if your product falls under one or more directives, it's time to assess if your product conforms to the applicable directive(s) and, if not, how you will achieve conformity.

Step 2

Know the essential requirements for your product

Each directive details what the EU legally requires for your product to be compliant. These are formally referred to as "essential requirements" in the directive. These requirements are very general in nature. The directives do not detail how to design a product in a way that it meets the essential requirements.

Harmonized standards

The European Commission often provides mandates to European organizations (CEN, CENELEC and ETSI) to develop standards which are harmonized with the essential requirements of the directives. To see if a harmonized standard exists for your product, visit www.newapproach.org, an official website of the European Commission. A product which conforms to harmonized standards is deemed to comply with the essential requirements of applicable directives. For information about the content and availability of these harmonized standards, contact the following organizations:

CEN (European Committee for Standardization)
CENELEC (European Committee for Electrotechnical Standardization)
ETSI (European Telecommunications Standards Institute)

Other Standards

In many cases, manufacturers may rely on standards other than harmonized standards in order to demonstrate compliance with the essential requirements in the directives. One notable exception to this rule is the Construction Products Regulation (soon to replace the Construction Products Directive) which makes the use of harmonized standards mandatory.

European Commission guidelines

The European Commission often provides detailed guidelines on the application of specific directives, including details on the interpretation of the essential requirements of the directive. While these guidelines do not have legal value (only the official text of the directive does), they are often written in consultation with Member State authorities that enforce the directives.

! Be prepared for this:

A harmonized standard can cost anywhere from 300 to 1,500 Euros. These may be expensive but could be worth the investment. While a manufacturer does not need to buy these documents to meet the essential requirements of the directive, European authorities often use them to determine whether a product meets the essential requirements. Working from the same document can help you to avoid potential technical disputes over whether your product meets the essential requirements of the directive. Again, essential requirements are often vague — leaving lots of room for technical interpretation.

Example:

Below is an excerpt of a table of harmonized standards for construction products, though not all tables have the same format:

ESO	Reference and title of the harmonized standard (and reference document)	Reference of superseded standard	Date of applicability of the standard as a harmonised European standard	Date of the end of the co-existence period Note 4
CEN	EN 1:1998 Flued oil stoves with vaporizing burners		01/01/2008	01/01/2009
	EN 1:1998/A1:2007	Note 3	01/01/2008	01/01/2009
CEN	EN 40-4:2005 Lighting columns – Part 4: Requirements for reinforced and prestressed concrete lighting columns		01/10/2006	01/10/2007
	EN 40-4:2005/AC:2006		01/01/2007	01/01/2

Column 1: ESO, or the European Standards Organization, is the group responsible for the adoption and publication of EU standards. For the construction products above, the European Committee for Standardization (CEN) is the author.

Column 2: Refers to the title of the harmonized standard and its reference document

Column 3: The reference to the previously upheld standard, if applicable.

Column 4: The date the standard came into effect.

Column 5: The date after which the old standard can no longer be used.

Next step.

Once you have identified the essential requirements in the directives and harmonized standards applicable to your product, you need to determine whether your product meets the applicable requirements, and whether you need to have a conformity assessment body test and certify your product to ensure that this is the case.

Step 3

Determine if you need third-party assessment

Some directives require that products be tested and certified by a third-party organization in order to ensure their conformity with applicable essential requirements. Whereas these organizations are known worldwide as conformity assessment bodies, they are also known in Europe as notified bodies (NB). If applicable directives do not require the use of an NB, manufacturers may rely on their own in-house facilities to assess their product's conformity.

A notified body is an entity authorized by European authorities to assess a product's conformity to the essential requirements set out in the applicable directives. An NB also conducts an audit to make sure manufacturers have completed steps 1 and 2 — that they have identified the directives and essential requirements applicable to their product.

Some directives indicate that a manufacturer **must** use an NB for some products. These directives include the *Medical Devices* directive, the *Equipment and Protective Systems in Potentially Explosive Atmospheres* directive, the *Pressure Equipment* directive, the *Appliances Burning Gaseous Fuels* directive, and the *Simple Pressure Vessels* directive.

Other directives do not require that manufacturers rely on NBs if the manufacturer uses a harmonized standard (see step 2) to determine conformity with applicable essential requirements. On the other hand, the use of an NB is required for some of the products covered under these directives if a manufacturer does not use the applicable harmonized standard. These directives include the *Machinery* directive and the *Toy Safety* directive.

The EU has reduced the number of products that require NB assessment. The *Low Voltage* directive, for example, does not require the use of an NB. European authorities are increasingly putting the onus on manufacturers to prove their products are compliant.

! Be prepared for this:

To find the notified bodies appointed by European authorities to carry out conformity assessment, use NANDO — the *New Approach Notified and Designated Organisations* database. Manufacturers can search for a notified body by country and by directive. While the vast majority of notified bodies are located in Europe, a number of them have subsidiaries or contractual relations with certification bodies or testing laboratories located in Canada or in the United States to service North American clients.

Step 4

Assess product conformity

How do you know that your product complies with the essential requirements in the applicable directives? You will have to test and document that your product actually conforms. Each directive outlines which conformity assessment procedures – also referred to as modules – a manufacturer can undertake. There are 8 conformity assessment modules. The applicable directives outline which module(s) apply for a particular product category.

Module A: Internal production control

Module B: EC type examination

Module C: Conformity to type

Module D: Production quality assurance

Module E: Product quality assurance

Module F: Product verification

Module G: Unit verification

Module H: Full quality assurance (EN ISO 9001)

Using module B as an example, the chart below gives an overview of the tasks that a manufacturer and the notified body must carry out, as well as the tasks that the manufacturer can delegate to an authorized representative. Generally, the closer a product gets to Module H, the more important an NB becomes.

Module	Manufacturer	Manufacturer or authorized representative	Notified body
B	establishes technical documentation regarding the design, manufacture & operation of the product	• applies for the EC type examination • places at the disposal of the notified body one (or more) specimen(s), which is (are) representative of the production envisaged • informs the notified body of all modifications to the approved product • keeps the technical documentation, including a copy of the EC type examination certificate, at the disposal of the surveillance authorities	• ascertains, by performing or having performed examinations and tests, that the specimen(s) meet(s) the applicable provisions and is manufactured in accordance with the technical documentation • issues an EC type examination certificate • keeps a copy of the certificate and a record of other relevant technical information • communicates to the other notified bodies the relevant information concerning the EC type examination certificates

These 8 procedures can be boiled down to two approaches:

1. **Assessment of conformity by the manufacturer:**
The manufacturer can hire a service provider for their access to test facilities but will pay simply for testing or other elements of conformity assessment, not consulting and certification, which is also what an NB is hired to do. A company can assess conformity of products by itself if it has the required facilities to test its product. This method is much less expensive.

2. **Assessment of conformity by an NB:**
The manufacturer is required to use an NB to assess conformity and certify its products, but it ultimately remains responsible for their conformity with EU essential requirements.

Conformity assessment to the European directives for CE marking may consist of different activities, including product testing, visual inspection, risk analysis as well as a review of product labels and instructions. Typical steps which may be involved in the assessment of conformity include:

- A review of the technical documentation related to the design, manufacture and/or operations of the product;
- Testing of one or more specific aspects of each product, or of a sample of the products, or of a representative specimen of the product;
- Assessment of the production quality systems of the manufacturer; and
- Ongoing verification of product unit conformity.

! Be prepared for this:

Many directives allow the manufacturer to choose among different conformity assessment procedures for the same product. Knowing all your options can yield significant savings in time and money.

Next step.

Your product has been tested and meets all relevant European Community standards. Now, your technical documentation must be in order.

Step 5

Create and maintain technical documentation

All CE marking directives impose an obligation for the manufacturer to create and make available technical documentation (or a technical file) containing information that demonstrates the product conforms to the requirements of the directive.

Technical documentation relevant to a CE-marked product must be kept for at least 10 years from the last date the product was manufactured, unless the directive provides for a later date. The technical documentation must be provided on demand to enforcement authorities, often within short timelines. The technical documentation needs to be kept up-to-date, especially when the product is modified or is subject to updated conformity assessment procedures.

Translation

Although several of the CE marking directives and European national laws impose that user information (e.g., user manuals) be translated into the official languages of the countries where they are sold, the rest of the technical documentation can be maintained in any EU language (including English or French).

Location of the technical documentation

EU law does not require that the technical documentation be located in Europe. The situation is different for the Declaration of Conformity (See step 6). However, EU importers must ensure that the exporter provides that file to EU enforcement authorities. Furthermore, EU importers or distributors marketing products under their own names are required to have a copy of the complete technical documentation.

EXAMPLES

Technical Document Required for the *Low Voltage* Directive

- details of the design, manufacture and operation of the electrical equipment in so far as these details are needed to assess the conformity of the electrical equipment with the requirements of the directive.
- a general description of the electrical equipment;
- design and manufacture drawings plus diagrams of components, subassemblies, circuits, etc;
- descriptions and explanations needed to understand the above mentioned drawings and diagrams plus the operation of the electrical equipment;
- a list of the standards used, in full or in part, and a description of the solutions employed to meet the safety aspects of this directive when harmonized standards have not been applied;
- the results of design calculations and of checks carried out, etc.; and
- test reports (either by the manufacturer or a third party).

Technical Document Required for the *Electromagnetic Compatibility* Directive (EMCD)

- An identification of the product covered by the technical documentation. This identification should allow unambiguously linking between the technical document and the product;
- A general description of the apparatus. The amount of information required will depend on the complexity of the apparatus. Simple apparatus may be fully defined in one line whereas more complex apparatus may need a complete description (a picture may be included);
- If European harmonized standards have been applied then evidence of compliance is required. At a minimum this will be a dated list of the European harmonized standards applied and the results obtained on their application;
- If European harmonized standards have not been applied or have been applied only in part, then a description of the steps taken to meet the essential requirements – an EMC Assessment described in Annex II of the directive – must be included. The documentation includes test reports, design calculations made, examinations carried out etc.;
- If a manufacturer is using the procedure of Annex III of the EMCD, then the notified body statement shall be included.

Step 6

Declaration of Conformity & affixing the CE mark

The document certifying compliance with CE marking directives is the Declaration of Conformity. The Declaration of Conformity is an acknowledgement by the manufacturer that they are responsible for the compliance of its products with the applicable directives.

This document is the manufacturer's sole responsibility, and the establishment of the Declaration of Conformity is a legal obligation.

The declaration should be available to authorities at the EU point of entry. Contrary to the complete technical documentation (which does not necessarily need to be shared with importers and distributors in some cases – see step 5), the Declaration of Conformity should be made available to EU distributors, who may be required to provide it to national authorities immediately upon request.

The Declaration of Conformity is generally a one-pager that includes the following:

- who you are,
- what product it refers to,
- what directives are involved,
- which standards have been used,
- where test results can be found,
- who is responsible in your company.

EXAMPLE

Note: The Declaration of Conformity required for your product may be different from the example below (Personal Protective Equipment or PPE). Check your directive for guidance.

EUROPEAN DECLARATION OF CONFORMITY

MODEL EC DECLARATION OF CONFORMITY
The manufacturer or his authorized representative established in Community (1)

.....

declares that the new PPE described hereafter (2)

.....

.....

is in conformity with the provisions of Council Directive 89/686/EEC and, where such is the case, with the national standard transposing harmonized standard No ..... (for the PPE referred to in article 8 (3))

is identical to the PPE which is the subject of EC certificate of conformity No ..... issued by (3)(4)

.....

.....

is subject to the procedure set out in article 11 point A or point B (4) of Directive 89/686/EEC
under the supervision of the notified body(3)

.....

.....

Done at ....., on .....

.....
Signature (5)

(1) Business name and full address; authorized representatives must also give the business name and address of the manufacturer.

(2) Description of the personal protective equipment (make, type, serial number, etc.).

(3) Name and address of the approved body.

(4) Delete whichever is inapplicable.

(5) Name and position of the person empowered to sign on behalf of the manufacturer or his authorized representative.

Affixing the CE mark

The CE mark must be: affixed to all new products, whether manufactured in the Member States or in third countries; to used and second-hand products imported from third countries; and to substantially modified products that are subject to directives as new products.

Directives may exclude the application of the CE mark on certain products (specified below), even if the directive otherwise applies to the product. These specific exceptions vary from directive to directive.

The CE mark may not, in principle, be affixed until the conformity assessment procedure has been completed to ensure that the product complies with all the provisions of the relevant directives. This will usually be at the end of the production phase. However, if the CE mark forms an inseparable part of the product, or of a component, for example by stamping or casting, the mark can be affixed at any other stage of the production phase, provided that the conformity of the product is verified as appropriate throughout the production phase.

The CE mark shall, as a rule, be affixed to the product or to its data plate. However, it may instead be affixed to the packaging or to the accompanying documents if:

1. affixing the mark is impossible;
2. it's not possible under reasonable technical or economic conditions, where the minimum dimensions could not be respected; or
3. it could not be ensured that the CE mark was visibly, legibly and indelibly affixed (manufacturers may not do so on purely aesthetic grounds).

The CE mark consists of the letters 'CE', sometimes followed by the identification number of a notified body, as below. The identification number of the NB is added only when that NB has been involved in the production phase of the product.

CE 2150

Sometimes several notified bodies are involved in the production phase, where more than one directive is applicable. In these situations, several identification numbers follow the CE mark.

! Be prepared for this:

The CE mark must be easily seen and accessible for all parties. It could, for instance, be affixed on the back or underside of a product. A minimum height of 5 mm is required to ensure that it is legible. It shall also be indelible so that it cannot be removed under normal circumstances without leaving noticeable traces. For example, some product standards use a rub test with water and petroleum spirits. However, this does not mean that the CE mark must form an integral part of the product.

Web resources

New Approach Standardisation in the Internal Market

Guide to the Implementation of Directives Based on New Approach and Global Approach

European Commission

Enterprise Europe Network

NANDO database of notified conformity assessment bodies

European co-operation for Accreditation

CEN – European Committee for Standardization

CENELEC – European Committee for Electrotechnical Standardization

ETSI – European Telecommunications Standards InstituteTrade Commissioner Service