

CE MARKING
OF
AUSTRALIAN PRODUCTS
FOR EXPORT
TO THE
EUROPEAN UNION

A guide for Australian Manufacturers and Exporters

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Glossary - a glossary of terms are found in the companion guide, The European Union Standards and Conformance Assessment System

Disclaimer

While every effort has been made to ensure that the information in this guide is accurate, it is not an official publication of the European Commission and does not purport to be a comprehensive statement of EC law relating to CE marking requirements.

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CE MARKING OF AUSTRALIAN PRODUCTS FOR EXPORT TO EUROPEAN UNION COUNTRIES

INTRODUCTION

This guide answers frequently asked questions about CE marking. It is intended for Australian manufacturers who wish to take advantage of market opportunities in Europe and who manufacture products that must bear the CE marking.

CE marking allows a range of products to be imported into the European Union (EU) single market and be freely traded between EU Member States. CE marked products can be sold in all 15 member states of the European Union plus Norway, Iceland and Liechtenstein, which collectively make up the European Economic Area (EEA).

Only products covered by so called new approach directives are allowed to bear the CE marking. Besides safety requirements, these directives also contain rules how products shall be assessed to determine that they fulfil the mandatory requirements. A separate guide - The European Union Standards and Conformance Assessment System - provides more detailed information about European technical legislation. If you intend to export products to the EU you should obtain copies of these publications and determine the requirements that apply to your product **before taking any steps to send a product to Europe.**

The Mutual Recognition Agreement (MRA) on Conformity Assessment between Australia and the European Community¹ is designed to facilitate trade between these regions. It provides for certain Australian products to be assessed in Australia against European requirements. In that way the process of CE marking and access to the European single market is simplified.

.Some of the products which are subject to CE marking requirements are not covered by the MRA. Exporters also need to be aware that products may be subject to other obligations under EC legislation which are not discussed in this guide.

¹ The European Union is the term used to describe collectively the 15 member States, while the term European Community represents the legal entity for actions to achieve a European Single Market.

Steps to be followed for attaching the CE marking

Before a manufacturer attaches the CE marking to a product he or she needs to find out the following information:

1 Which new approach directive or directives apply to the product?
What are the essential requirements specified in the applicable directive(s)?

2 The essential requirements can be met either by applying European harmonised standards or in some other technically feasible way.
Are harmonised standards available?
Which harmonised standards apply to the product?

3. Is the product going to be manufactured to conform to harmonised standards or to some other standard or specification? (The procedures for conformity assessment normally differ depending on which option is chosen.)
What are the conformity assessment procedures according to the applicable directive(s) for the option chosen for the manufacture of the product?

4. Is third party intervention by a notified body in Europe or a designated conformity assessment body in Australia required? (Designated bodies in Australia are available for products covered by the MRA between Australia and the EU).
Which body should be used?

5. Is Type Examination required?
Are any of the following certificates required from a notified or designated body before the CE marking can be attached?

An "EC type examination certificate" (module 13), and/or a "Certificate of conformity" (modules Ca, F & G) or an "EC design examination certificate" (module H)?

6 Is any type of quality assurance system necessary for design, production, final product inspection, testing?
Does the quality assurance system need to be approved by a notified body in Europe or a designated body in Australia?

7 What kind of technical documentation is required and in which language it be written
(including instructions for the product)?

8 Normally an EC declaration of conformity must be issued before the CE marking can be attached?

What information shall the EC declaration of conformity contain?

9 Where a notified or designated body has been utilised during the production stage, what is its identification number ? (it needs to be attached together with the CE marking).

Questions and Answers

1. What is the CE marking?

The CE marking consists of the letters CE

CE marking indicates that the product may legally be sold in all 18 Member States of the European Economic Area.^{1,2} Each Member State must accept CE-marked products without requiring any further testing or approval in relation to requirements covered by new approach Directives.

The MRA between Australia and the EC allows Australian manufacturers to affix the CE marking on a range of products manufactured and tested or certified in Australia against European requirements

2. What does the CE marking mean?

CE marking means that the manufacturer verifies that the product meets the requirements of all new approach directives that apply to the product. It also means that the manufacturer confirms that the product has been assessed according to one of the prescribed procedures to determine that it fulfils the mandatory requirements.

3. What is the purpose of the CE marking?

CE marking has two purposes. One is to indicate to EEA Member State market surveillance authorities that products placed on the market conform to all mandatory requirements of the relevant new approach directives. The second is to provide assurance for consumers that CE marked products provide a high level of protection with regard to health, safety and environmental hazards.

4. What is a new approach directive?

A new approach directive is a form of European Community technical legislation that replaces various non-uniform rules previously applied in the 18 Member States of the EEA. New approach directives are written in accordance with an EU policy published in 1985 called *the new approach to technical harmonisation and standards*. Directives are implemented by national legislation in each Member State.

Each new approach directive requires that a group of products meets certain specified *essential requirements*. These requirements define which characteristics a product must have-and the risks that have to be dealt with before a product can be put on the European market. The Directives do not specify technical solutions. These are provided by appropriate voluntary European *harmonised standards*. Products manufactured in accordance with these harmonised standards are presumed to meet the essential requirements of applicable directives. The manufacturer does not have to use these harmonised standards, but in this situation he/she must demonstrate compliance with the essential requirements in another way as specified in the Directive.

In addition to essential requirements, each new approach directive also contains rules as to how the manufacturer may demonstrate that a product meets the relevant requirements. (See question 6 for a more detailed explanation of conformity assessment procedures.)

As at June 2001 some 21 new approach directives have been adopted, and a number of further proposals in preparation. These are listed in Appendices 1 and 2.

¹ The European economic Area (EEA) consists of the following 15 Member States of the European Union and three out of four Member States of the European Free Trade Association (EFTA) . Member States of the EU: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Spain, Sweden, United Kingdom. Member States of EFTA: Iceland, Liechtenstein, Norway, Switzerland (Switzerland is not a signatory to the EEA agreement.)

5 How do I find out which directives apply to my product?

The manufacturer of a product is responsible for ensuring that the product complies to the applicable directives. As a first step manufacturers should consult the list of new approach Directives in Appendix 1.

It is quite possible that a product may be covered by more than one directive. This is because different risks are dealt with under various directives. For example, the mechanical risks of a machine are dealt with by the directive relating to machinery. At the same time, however, the electromagnetic compatibility aspects of the same machine are covered by the directive relating to EMC. In such cases the manufacturer needs to obtain the relevant directives and determine how the essential requirements of each directive apply to the product and what are the appropriate routes to demonstrating compliance.

Where there is any doubt about the applicability of a directive to a product, the manufacturer should obtain a copy of each directive that might apply and study it. See Annex 3 for a list of sources from where EC directives may be obtained.

In the event that the above process does not provide a definite outcome, the manufacturer should seek advice from an appropriate designated conformity assessment body in Australia or New Zealand, or refer to the national authorities of the country or countries in the EU to which they intend to export the product.

6. How do I demonstrate that my product complies with the requirements of relevant directives?

Each new approach directive defines various *procedures for conformity assessment* - rules about how a product shall be examined to determine that it fulfils the essential requirements. A manufacturer needs to study each directive that applies to a product to find out what the requirements are. For individual product sectors covered by the MRA, summary descriptions are given in separate publications.

The procedures for conformity assessment are divided into *modules*. These cover both the design and production of manufactured items. The requirements in different modules vary depending on the types of risks that are associated with a product. For some products it is sufficient that the manufacturer compiles technical documentation to demonstrate -that the product meets the essential requirements and issues an *EC declaration of conformity* (module - see question 10 for further detail.

Other products may require that certain tasks in the conformity assessment be undertaken by a special body called a *notified body* in Europe, or a *designated body*² in Australia for products covered by the MRA. Examples are:

a notified body must determine and testify that a representative specimen of the envisaged production meets the requirements of the directive and issue a *type examination certificate* (module B);

a notified body must *test specific aspects* of the product or carry out *product checks at random intervals* (modules Aa & Ca);

the manufacturer must operate a *quality system* approved by, or subject to, surveillance by a notified body (modules D, E & H); or

² "designated body" is an abbreviation of "designated conformity assessment body"

a notified body shall verify conformity of production and issue a *certificate of conformity* (modules F & G).

EC Council Decision 93/465/EEC describes the modules for conformity assessment and the rules for affixing and use of the CE marking. A summary description of these is given in the separate guide *The European Union Standards and Conformance Assessment System*.

For most products individual directives give the manufacturer options to use alternative procedures to demonstrate that a product meets the essential requirements. There is, for example, a difference in the procedures depending on whether or not a product is manufactured according to harmonised standards. Some new approach directives also distinguish between different categories within their scope, with different conformity assessment procedures applicable, depending on to which category a particular product belongs. An example is "dangerous machinery" according to the machinery directive.

7. Who can test my product for conformance with CE marking requirements?

The testing required before the CE marking can be affixed to a product varies depending on what are the requirements for conformity assessment for that product. In general, some testing is always required to demonstrate that a product meets the essential requirements. In many cases these tests may be performed by the manufacturer or by a commercial testing laboratory on his or her behalf. Depending on the types of risks that are associated with a product, some testing by a notified body may be required. For Products covered by the MRA, designated bodies in Australia can perform the testing as well as other parts of the conformity assessment procedures that otherwise are required to be performed by a notified body

8. How do I go about obtaining authority to put the CE marking on my product?

It is the responsibility of the manufacturer to determine whether or not a product is eligible to be CE marked. After the product has been assessed according to one of the conformity assessment procedures required in the applicable directive(s) and the manufacturer is satisfied the product meets the essential requirements of the directive(s) which apply to the product, the general requirement is that a responsible officer of the manufacturer completes an *EC declaration of conformity*.

The manufacturer can then affix the CE marking to a product. The manufacturer can transfer his responsibilities with regard to CE marking to his authorised representative established within the EEA.

9. What are the specifications for the CE marking?

Graphically the CE marking takes the following form

Although CE marking is based on two circles, the "C" and "E" are not formed by perfect semi circles with the top and bottom arms extending one square beyond the semi circles and the middle arm of the E stopping one square short.

The CE -marking may be enlarged or reduced as appropriate for reproduction on individual products provided that:

The height of the letters is at least 5 mm (or as specified in the relevant directive), and the proportions of the drawing above are maintained.

The CE marking must be attached to the product or to its data plate. In cases where this is not possible or reasonable due to the nature of the product, it must be printed on the packaging, if any, and on any accompanying documents.

The CE marking must be affixed visibly, legibly and indelibly.

If a notified body in Europe or a designated body in Australia has been involved in conformity assessment procedures during the production stage of manufacture, the CE marking must be followed by the *identification number* of the body. These identification numbers are assigned by the European Commission.

10. Who issues an EC declaration of conformity?

The manufacturer does. However, before making an *EC declaration of conformity*, he or she must establish technical documentation which enables the conformity of the product to be assessed by an appropriate authority when required for market surveillance purposes. This documentation must describe the design, manufacture and operation of the product and must be available to the surveillance authorities of EU Member States for 10 years. Specific content requirements for technical documentation are specified in each directive.

In the context of the MRA between Australia and the EC such documentation may be kept in Australia but must be accessible in a reasonable time to EU authorities if required.

Appendix 4 sets out the general requirements for an *EC declaration of conformity*.

11. Once a product has a CE marking, can it be circulated without restrictions in the EU?

Yes. Products with CE marking can be circulated freely within and between the 18 countries of the EEA provided that all examples of ongoing production meet the essential requirements for the product.

12. Does the CE marking have to go on everything that is exported to the EU?

No. The CE marking may only be put on products covered by new approach directives. There are currently 18 new approach directives, which are listed in Appendix 1.

There are also several hundred old approach directives, each covering a specific product. Some of these old directives prescribe other marking such as "e" marking for pre-packed goods, measuring instruments and some motor vehicle components.

13. Can the CE marking be taken away?

Yes. If at any time a product does not meet the essential requirements, the authorities of a Member State can order that the product be withdrawn from the market in that State.

Through coordinated actions taken by the European Commission, a withdrawal from the market in one Member State may lead to withdrawal from the markets of all 18 Member States of the EEA.

The Member States are responsible for surveillance of their domestic markets. Where a product is withdrawn from the market through official action, the manufacturer is obliged to modify the product so that it complies with all applicable directives before it can again be sold.

All items of products bearing the CE marking must meet the requirements of the appropriate new approach directives. The manufacturer, through appropriate quality control, is responsible for ensuring that this is the case.

14. What happens if the CE marking is put on a product which doesn't comply with relevant directives?

When a Member State finds that the CE marking has been put on a product improperly, the manufacturer is obliged to correct the product and to end the violation under conditions imposed by the Member State. If the manufacturer fails to do so, the Member State must take steps to restrict or prohibit the product from being placed on the market and to ensure that it is

withdrawn from the market in accordance with the procedures laid down in the individual directives.

15. Can the CE marking be placed on products together with other marks?

Yes. Provided such marks do not cause confusion with the CE marking, a product may bear other marks such as:

- manufacturer's logo;
- certification marks indicating conformity to national or European standards;
- marks indicating conformity with old approach directives to the extent that these cover risks which are not covered by new approach directives;
- European Community voluntary environmental marking (in accordance with Council Regulation 92/880/EEC).

Other marks may only be put on the product, its packaging or its documentation, however, on condition that the legibility and visibility of the CE marking is not reduced.

16. What are the "e" and epsilon marks?

The "e" mark indicates that the product complies with EU net amount (weight) rules for prepackaged goods. Bottled fluids marked with the "e" mark comply with the corresponding rules for pre-packaged liquid products. Pre-packaged goods which bear these markings may legally be sold anywhere on the European market.

Some old approach directives prescribe the "c" marking for other products, such as motor vehicle components. EFTA has also had a similar system of "e" marking of motor vehicle components.

List of new approach Directives which have been adopted (as at 1 July 2001)

Appendix 4

Directive	Reference	Date of adoption	Date of entry into force	Date of end of period of transition
1 Low voltage ⁽¹⁾	73/23/EEC 93/68 EEC ⁽²⁾	19.02.73 22.07.93	18.08.74 01.01.95	n.a. ³ 01.01.97
2 Simple pressure vessels	87/404/EEC 93/68 EEC ⁽²⁾	25.06.87 17.09.90 22.07.93	01.07.90 01.07.91 01.01.95	01.07.92 n.a. 01.01.97
3 Safety of toys	88/378/EEC 93/68 EEC ⁽²⁾	03.05.88 22.07.93	01.01.90 01.01.95	n.a. 01.01.97
4 Construction products	89/106/EEC 93/68 EEC ⁽²⁾	21.12.88 22.07.93	27.06.91 01.01.95	not fixed 01.01.97
5 Electromagnetic compatibility (EMC)	89/336/EEC 92/31/EEC 93/68 EEC ⁽²⁾	03.05.89 28.04.92 22.07.93	01.01.92 28.10.92 01.01.95	31.12.95 n.a. 01.01.97
6 Safety of machines	98/37/EEC			31.12.94 31.12.94 31.12.96 01.01.97
7 Personal protection equipment (PPE)	89/686/EEC 93/95/EEC 93/68 EEC ⁽²⁾	21.12.89 29.10.93 03.09.95 22.07.93	01.07.92 29.01.94 01.01.95 01.01.95	30.06.95 n.a. n.a. 01.01.97
8 Non-automatic weighing instruments	90/384/EEC 93/68 EEC ⁽²⁾	20.06.90 22.07.93	01.01.93 01.01.95	01.01.2003 01.01.97
9 Active implantable medicinal devices	90/385/EEC 93/42 EEC 93/68 EEC ⁽²⁾	20.06.90 14.03.93 22.07.93	01.01.93 01.01.95 01.01.95	31.12.94 14.06.98 01.01.97
10 Appliances burning gaseous fuels	90/396/EEC 93/68 EEC ⁽²⁾	29.06.90 22.07.93	01.01.92 01.01.95	31.12.95 01.01.97
11 Telecommunications terminal and satellite earth station equipment	98/13/EEC			n.a. n.a. 01.01.97
12 New hot-water boilers fired with liquid or gaseous fuels	92/42/EEC 93/68 EEC ⁽²⁾	21.05.92 22.07.93	01.01.94 01.01.95	31.12.97 01.01.97
13 Explosives for civil uses	93/15/EEC	05.04.93	01.01.95	31.12.2002
14 Medical devices	93/42/EEC	14.06.93	01.01.95	14.06.98

15	Equipment in explosive atmospheres (ATEX)	94/9/EC	23.03.94	01.03.96	30.06.2003
16	Recreational crafts	94/25/EC	16.06.94	16.06.96	16.06.98
17	Lifts for persons	95/16/EC	29.06.95	01.07.97	30.06.99
18	Energy efficiency requirements for household electric refrigerators and freezers	96/57 EC	03.09.96	08.10.96	03.09.99
19	Pressure equipment	97/23/EC	29.05.97	29.11.99	29.05.2002
20	Medical devices: Invitro diagnostic	98/79/EC			
21	Cableway installations designed to carry persons	00/9/EC			

This Directive predates the New Approach, but is nevertheless on the principle of reference to standard and can therefore, in this respect, be considered to be precursor of the New Approach Directive.

Appendix 2

List of Proposed New Approach Directives

Proposed Directive	Reference
1 Precious metal Amendment	COM/93/322 COM/94/267
2 In vitro diagnostic Amendment	COM/95/130 COM/96/643
3 Connected telecommunications equipment	COM/97/257
4 Machinery (modification to 89/392/EEC)	Proposal in preparation
5 Minimum efficiency standards for ballast for fluorescent lighting	Proposal in preparation
6 Recreational craft (modification to 94/25/EC)	Proposal in preparation
7 Measuring instruments	Proposal in preparation

Appendix 3

Sources of further information

Copies of EC Directives may be obtained from the following sources:

Help Desk, NSW State Library
Telephone (02) 9230 1421 Fax: (02) 9221 5260

Business Information Service, Victorian State Library
Telephone: (03) 9669 9845 Fax: (03)9669 9052

Alternatively, they may be purchased from:
Hunter Publications
58 Gipps Street
COLLINGWOOD VIC 3066
Telephone: (03) 9417 5361 Fax: (03) 9419 7154

Information about Australian and European standards is available from:

Standards Australia
PO Box 1055
STRATHFIELD NSW 2135
Telephone: 13 00654646 Fax: (1300 654949
Internet: <http://www.standards.com.au>

Further information about EU Conformity Assessment requirements and CE marking may be obtained from:

The Delegation of the European Commission to
Australia and New Zealand
18 Arkana Street
YARRALUMLA ACT 2600
Telephone: (02) 6271 2777 Fax: (02) 6273 4445
Email: australia@ecdel.org.au
Internet: <http://www.ecdel.org.au>

Appendix 4

General requirements for an EC declaration of conformity

Each individual new approach directive specifies the information that must be contained in an EC declaration of conformity. In most cases the declaration of conformity must contain the following elements:

- name and address of the manufacturer or his authorised representative established within the EEA;
- description of the product;
- reference to harmonised standards or other specifications under which conformity is declared;
- identification of the person empowered to sign on behalf of the manufacturer or his authorised representative established in the EEA; and
- where appropriate, reference to the EC type-examination certificate issued by a notified body.

The manufacturer must also establish technical documentation which enables the conformity of the product to be assessed. Each individual new approach directive specifies the information that must be contained in the technical documentation. A Member State may require part of the technical documentation and/or the instructions for the product to be translated into its official language.

The manufacturer or his authorised representative established in the EEA shall keep a copy of the declaration of conformity together with the technical documentation for at least 10 years from the last date of manufacture unless the specific directive states any other period of time.

If an Australian manufacturer does not have an authorised representative established within the EEA, the importer who places the product on the European market is responsible for keeping a copy of the manufacturer's declaration and the technical documentation. On request the importer shall submit these documents to the market surveillance authorities.