



CE MARKING GUIDANCE: PARTLY COMPLETED MACHINERY

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CE MARKING
ASSOCIATION™

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Introduction to the Guide

The CE Marking Association is an independent organisation set up to assist manufacturers and other economic operators with understanding their CE marking (and other relevant European product conformity) requirements. We often come across similar questions being asked, so where it is appropriate, we like to develop short guidance notes to help provide further information around the common question being asked. This guide seeks to provide further information about Partly Completed Machinery.

Please note that the text within this document should only be used for guidance and cannot act as a substitute for the Directives. The guide has no legal force and is not an authoritative interpretation of the Directives, which is a matter for the Courts. Please be aware that even subtle changes between products, or the way they are intended to be used can put them within the scope (or take them out of the scope) of various CE Marking legislation. To be sure that all the relevant legislation has been identified and complied with it is important to look at products on a case by case basis. Always ensure that you refer to the full text of the applicable Directives.

Background to the CE Marking Association

The CE Marking Association was originally set up by the DTI (now the Department for Business Innovation and Skills) as one of several national EMC & CE Marking clubs, which has over time become one of leading providers of help, testing and training for CE Marking & Product Conformity.

The CE Marking Association, now the trademark of Wemtech Ltd, leads companies through the maze of product conformity legislation to help them understand and fulfil their legal requirements, to enable them to CE mark their products. Traditionally, the main focus has been assisting persons with CE marking electrical products, machines and medical devices, however this has been vastly expanded to cover other Directives and Regulations, such as the Construction Products Regulation, as and when they have been implemented into UK and EU law.

Whilst you do not need to be a member to access our consultancy, testing and training services, membership still remains at the heart of the CE Marking Association. Our engineers provide on-going support and advice for companies of all sizes, from sole traders to global brands & companies. More information about the CE Marking Association can be found on our website: www.cemarkingassociation.co.uk

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ABSTRACT

Definition of Partly Completed Machinery

"'partly completed machinery' means an assembly which is almost machinery but which cannot in itself perform a specific application. A drive system is partly completed machinery. Partly completed machinery is only intended to be incorporated into or assembled with other machinery or other partly completed machinery or equipment, thereby forming machinery to which this Directive applies"

Difference between the Conformity Procedure for Machinery as opposed to Partly Completed Machinery

The conformity procedure is the same for Machinery & Partly Completed Machinery except that the manufacturer of partly completed machinery or his authorised representative shall, before placing it on the market, ensure that:

- a. the relevant technical documentation described in Annex VII, part B of the Machinery Directive 2006/42/EC* is prepared;
- b. assembly instructions described in Annex VI of the Machinery Directive 006/42/EC* are prepared;
- c. a declaration of incorporation described in Annex II, part 1 ,Section B of the Machinery Directive 2006/42/EC* has been drawn up.

The Assembly Instructions and the Declaration of Incorporation shall accompany the partly completed machinery until it is incorporated into the final machinery and shall then form part of the technical file for that machinery.

Summary of the Conformity Process for Partly Completed Machinery

1. Identify the relevant product Directives/Regulations
2. Identify the applicable requirements of the Directives/Regulations
3. Identify an appropriate route to conformity
4. Identify the relevant Standards & Harmonised Standards to which product could be designed.
5. Design the product to the requirements of the Directives/Regulations/Standards
6. Ensure the Operating, Maintenance & Assembly Instructions meet the requirements of the identified Directives/Regulations/Standards
7. Carry out & Document a Risk Assessment for the Product
8. Assess the product against the requirements of the appropriate Directives/Regulations/Standards
9. Compile the Technical File
10. Produce and Sign the 'Declaration of Incorporation'
11. DO NOT display the CE Mark

*This information is included in Annex 1, 2 & 3 of this document.

WHAT IS PARTLY COMPLETED MACHINERY?

The Machinery Directive 2006/42/EC Article 2 (g) states that:

"'partly completed machinery' means an assembly which is almost machinery but which cannot in itself perform a specific application. A drive system is partly completed machinery. Partly completed machinery is only intended to be incorporated into or assembled with other machinery or other partly completed machinery or equipment, thereby forming machinery to which this Directive applies"

It should be noted that partly completed machinery is not among the products designated by the term 'machinery' used in the broad sense. Partly completed machinery subject to the Machinery Directive is a product intended to form machinery that is in the scope of the Machinery Directive after incorporation.

'An assembly which is almost machinery' means that partly completed machinery is a product that is similar to machinery in the strict sense referred in 2006/42/EC Article 1 (1) (a), that is to say, an assembly consisting of linked parts or components at least one of which moves, but which lacks some elements necessary to perform its specific application. Partly completed machinery must thus undergo further construction in order to become final machinery that can perform its specific application. This further construction is NOT the fitting of a drive system to machinery supplied without a drive system where the drive system to be fitted is covered by the manufacturer's conformity assessment or the connection on site or with sources of energy or motion.

Partly completed machinery should also be distinguished from machinery ready to be installed on a means of transport or in a building or a structure.

Machinery that can in itself perform its specific application but which only lacks the necessary protective means or safety components is NOT to be considered as partly completed machinery.

Since partly completed machinery is 'almost machinery', it is to be distinguished from machinery components that are not subject to the Machinery Directive as such. Machinery components can usually be integrated into a wide range of categories of machinery with different applications.

The second sentence of the definition of partly completed machinery states: "... a drive system is partly completed machinery." This provision also applies to drive systems ready to be fitted to machinery and not to the individual components of such systems, for example, an internal combustion engine or a high voltage electric motor placed on the market ready to be fitted to machinery subject to the Machinery Directive are to be considered as partly completed machinery.

The procedure for placing Partly Completed Machinery on the market is similar to the procedure for placing completed Machinery on the market, with the only differences being that:

- assembly instructions need to be supplied with the product;
- the technical documentation needs to comply with the requirements of Annex VII, part B of the Machinery Directive as opposed to Annex VII, part A;
- a Declaration of incorporation has been drawn up
- the CE Mark must NOT be attached to the Partly Completed Machine.

MACHINERY DIRECTIVE CONFORMITY PROCEDURE FOR PARTLY COMPLETED MACHINERY

(The differences between the conformity procedure for Machinery as opposed to Partly Completed Machinery are highlighted in points: 9(a); 15(a); 17(a); and 18(a))

1. Identify the relevant product Directives/Regulations**
2. Identify the applicable requirements of the Directives/Regulations
3. Identify an appropriate route to conformity
4. Identify the relevant Harmonised Standards to which product could be designed.**
5. Identify any other relevant Standards to which the product could be designed (if necessary)
6. Design the product to the requirements of the Standards
7. Ensure the design of the product meets the requirements of the appropriate Directive/Regulation
8. Ensure the product is Marked as per the requirements of the identified Directives/Regulations/Standards
9. Ensure the Operating, Maintenance & Assembly Instructions meet the requirements of the identified Directives/Regulations/Standards
 - a. Assembly Instruction requirements for Partly Completed Machinery as taken from The Machinery Directive (2006/42/EC) are noted in Annex 1 below.
10. Complete and Document a Product Risk Assessment (It is advised that the Harmonised Standard EN ISO 12100:2010 is used for guidance)
11. Take action against any issues identified in the Risk Assessment
12. Assess the product against the requirements of the appropriate Standards
13. Assess the product directly against the requirements of the appropriate Directives/Regulations
14. Take an action against any non-conformities identified in the Standard/Directive/Regulations Assessments. (Actions taken should be documented where necessary)
15. Identify the documents which need to be included in Technical File (Technical File requirements can be found the relevant product Directives/Regulations identified in point 1 above)
 - a. Technical File requirements for Partly Completed Machinery as taken from The Machinery Directive (2006/42/EC) are listed in Annex 2 below.
16. Compile the Technical File
17. Produce and Sign the 'Declaration of Conformity' or 'Declaration of Incorporation'
 - a. Declaration of Incorporation requirements for Partly Completed Machinery as taken from The Machinery Directive (2006/42/EC) are listed in Annex 3 below.
18. Display the CE Mark on the product (Unless the product is classed as Partly Completed Machinery)
 - a. If the product is classed as Partly Completed Machine only the Declaration of Incorporation and Assembly Instructions are required to be supplied to demonstrate conformity to a third party.

**The following link provides:

- i. A list of the Directives/Regulations with links to the documents
- ii. Access to the Standards which give a presumption of conformity to the whole or part of the Directive/Regulation with which they have been harmonised.

http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/index_en.htm

ANNEX 1 - ASSEMBLY INSTRUCTIONS FOR PARTLY COMPLETED MACHINERY

The assembly instructions for partly completed machinery must contain a description of the conditions which must be met with a view to correct incorporation in the final machinery, so as not to compromise safety and health.

The assembly instructions must be written in an official Community language acceptable to the manufacturer of the machinery in which the partly completed machinery will be assembled, or to his authorised representative.

ANNEX 2 – RELEVANT TECHNICAL DOCUMENTATION FOR PARTLY COMPLETED MACHINERY

This part describes the procedure for compiling relevant technical documentation. The documentation must show which requirements of this Directive are applied and fulfilled. It must cover the design, manufacture and operation of the partly completed machinery to the extent necessary for the assessment of conformity with the essential health and safety requirements applied. The documentation must be compiled in one or more official Community languages.

It shall comprise the following:

- a. a construction file including:
 - the overall drawing of the partly completed machinery and drawings of the control circuits,
 - full detailed drawings, accompanied by any calculation notes, test results, certificates, etc., required to check the conformity of the partly completed machinery with the applied essential health and safety requirements,
 - the risk assessment documentation showing the procedure followed, including:
 - i. a list of the essential health and safety requirements applied and fulfilled,
 - ii. the description of the protective measures implemented to eliminate identified hazards or to reduce risks and, where appropriate, the indication of the residual risks,
 - iii. the standards and other technical specifications used, indicating the essential health and safety requirements covered by these standards,
 - iv. any technical report giving the results of the tests carried out either by the manufacturer or by a body chosen by the manufacturer or his authorised representative,
 - v. a copy of the assembly instructions for the partly completed machinery;
- b. for series manufacture, the internal measures that will be implemented to ensure that the partly completed machinery remains in conformity with the essential health and safety requirements applied.

The manufacturer must carry out necessary research and tests on components, fittings or the partly completed machinery to determine whether by its design or construction it is capable of being assembled and used safely. The relevant reports and results shall be included in the technical file.

The relevant technical documentation must be available for at least 10 years following the date of manufacture of the partly completed machinery or, in the case of series manufacture, of the last unit produced, and on request presented to the competent authorities of the Member States. It does not have to be located in the territory of the Community, nor does it have to be permanently available in material form. It must be capable of being assembled and presented to the relevant authority by the person designated in the declaration for incorporation.

Failure to present the relevant technical documentation in response to a duly reasoned request by the competent national authorities may constitute sufficient grounds for doubting the conformity of the partly completed machinery with the essential health and safety requirements applied and attested.

ANNEX 3 - DECLARATION OF INCORPORATION OF PARTLY COMPLETED MACHINERY

This declaration and translations thereof must be drawn up under the same conditions as the instructions (see Annex 1, section 1.7.4.1(a) and (b))^{***}, and must be typewritten or else handwritten in capital letters.

The declaration of incorporation must contain the following particulars:

1. business name and full address of the manufacturer of the partly completed machinery and, where appropriate, his authorised representative;
2. name and address of the person authorised to compile the relevant technical documentation, who must be established in the Community;
3. description and identification of the partly completed machinery including generic denomination, function, model, type, serial number and commercial name;
4. a sentence declaring which essential requirements of this Directive are applied and fulfilled and that the relevant technical documentation is compiled in accordance with part B of Annex VII, and, where appropriate, a sentence declaring the conformity of the partly completed machinery with other relevant Directives. These references must be those of the texts published in the Official Journal of the European Union;
5. an undertaking to transmit, in response to a reasoned request by the national authorities, relevant information on the partly completed machinery. This shall include the method of transmission and shall be without prejudice to the intellectual property rights of the manufacturer of the partly completed machinery;
6. a statement that the partly completed machinery must not be put into service until the final machinery into which it is to be incorporated has been declared in conformity with the provisions of this Directive, where appropriate;
7. the place and date of the declaration
8. the identity and signature of the person empowered to draw up the declaration on behalf of the manufacturer or his authorised representative

The manufacturer of partly completed machinery or his authorised representative shall keep the original declaration of incorporation for a period of at least 10 years from the last date of manufacture of the partly completed machinery.

^{***} The Machinery Directive 2006/42/EC, Annex 1 Section 1.7.4.1

(a) The instructions must be drafted in one or more official Community languages. The words 'Original instructions' must appear on the language version(s) verified by the manufacturer or his authorised representative.

(b) Where no 'Original instructions' exist in the official language(s) of the country where the machinery is to be used, a translation into that/those language(s) must be provided by the manufacturer or his authorised representative or by the person bringing the machinery into the language area in question. The translations must bear the words 'Translation of the original instructions'.