

What should be in a Declaration of Conformity?

A Declaration of Conformity (DOC) is a declaration made by the manufacturer of equipment that equipment is in conformity with the requirements of an EU Directive.

A Notified Body does not issue a DOC. It issues a certificate of conformity or similar document stating that it believes that the equipment and the documentation that accompanies it are in conformity with the requirements of a directive based on examination of a technical file. It makes no guarantee that the equipment that the manufacturer actually places on the market is in conformity with the directive.

The DOC is issued by the manufacturer to accompany each item they sell. It declares that they guarantee that each piece of equipment sold is in conformity with the Directive(s) mentioned.

A DOC can cover one directive or several directives. Where equipment is covered by several directives, e.g. MD, LVD, EMC, PED it can be covered by one DOC that covers the requirements of all the directives or by several different DOCs that each cover one or more directives.

Different directives have different requirements for content of a DOC.

A manufacturer can only put a CE marking on a piece of equipment if it meets the requirements of all relevant directives.

Each piece of equipment placed on the market must be accompanied by DOCs covering the relevant directives. The DOC could be on a separate sheet, but a good place for it is in the operation manual. The new MD makes it mandatory that the MD DOC is in the manual.

The basic requirements for all DOCs are:-

1. Identify the directive(s) with which conformity is claimed.
2. Identify the manufacturer of the equipment
3. Identify any European representative of the manufacturer.
4. Identify any EN harmonised standards used.
5. Signed and dated by a person with enough responsibility to ensure that the Declaration is true, for example a Director or Chief Engineer.

Appendices

Appendices to this document show the text of the directives relating to content of DOCs and Appendix 5 has my suggested minimum content for a DOC/DOI.

Any other content in a DOC is not mandatory and would be better put somewhere else in the manual to avoid confusion and clutter.

Standards quoted on a DOC

There is no formal guidance about which standards should be included. Very many standards are used in the design of a machine (down to the dimensions of the heads of the bolts!) and it is not necessary to include them all. I suggest that only C type standards and any important B type standards like EN60204-1:2006 Electrical Equipment of Industrial machines, EN999:1998 Positioning of Protective Equipment (For light curtains) are included (if they are used).

A guideline is that only standards for which there is checklist, test report or calculations in the Technical File need be included.

It is important to include the year of a standard used, since different versions of some standards are quite different E.g. EN60204-1:2006 and :1993.

I like to see at least an abbreviated version of the standard name as well as its number for clarity.

Where several directives are covered on one DOC, then standards relevant to them E.g. EMC standards must be quoted as well.

European Representative

Where a manufacturer has an office or a recognised main distributor in the EU, their name should also appear on the DOC. The EU representative gives an easy first point of contact for EU enforcement authorities wishing to investigate any problems.

Under the new MD it is mandatory for an EU contact where the technical is available to be quoted. I suggest that we do not add this until the position is made clearer. I am trying to clarify if that can be CCQS UK office if the manufacturer does not have their own EU representative.

Person signing the DOC

The “responsible person” mentioned in the UK regulations which implement the MD in the UK is not necessarily the person signing the certificate. Under UK law a limited company is also a “person”, the declaration is made by the company. The actual person signing the DOC represents the company.

The DOC must include a printed version of name and the job title of the person signing. Also the date and place (new MD) of signature.

The EU authorised representative can sign the DOC instead of the manufacturers. If they do, they are taking legal responsibility for the conformity of the equipment with the directives.

New MD

We should aim to produce a DOC which satisfies the requirements of both old and new MD. The key point is to ensure that the DOC is added to the manual.

The requirement for an EU location for the technical file needs to be clarified but where a manufacturer has an EU representative that address can definitely be used..

Declaration of Incorporation vs Declaration of conformity

A declaration of incorporation is used for MD where a piece of machinery does not meet the EHSRs because it is not complete. An example could be an automatically loaded press which is not fully guarded to allow access to the loading equipment which is supplied by another manufacturer.

Equipment with an MD DOI must not carry a CE marking (even if it conforms with requirements of all other relevant directives).

Equipment with a DOI must not be put into use until the safety of the complete system has been assessed and the DOI must state that.

Another Technical article will be produced discussing partly completed equipment and declarations of incorporation later.

Directives other than MD

Some other directives may have specific requirements for the contents of a DOC. If a multi directive DOC is issued, the requirements of any other directives quoted must be checked.

Serial number of equipment

The directives require a serial number to be quoted. This is particularly important where the DOC refers to one specific machine. This requirement is often ignored but an easy way to comply with it is to refer to “Serial Number 12334566 onwards” alternatively you might quote a range of serial numbers.

Appendix 1

Old MD DOC content from the Directive

Annex II of Machinery Directive 98/37

A. Contents of the EC declaration of conformity for machinery (1)

The EC declaration of conformity must contain the following particulars:

- name and address of the manufacturer or his authorised representative established in the Community(2),
- description of the machinery (3),
- all relevant provisions complied with by the machinery,
- where appropriate, name and address of the notified body and number of the EC type-examination certificate, *(for MD Annex IV equipment)*

(for presumption of conformity from standards, we do not use this)

- where appropriate, the name and address of the notified body to which the file has been forwarded
in accordance with the first indent of Article 8(2)(c),
- where appropriate, the name and address of the notified body which has carried out the verification referred to in the second indent of Article 8(2)(c),
- where appropriate, a reference to the harmonised standards,
- where appropriate, the national technical standards and specifications used,
- identification of the person empowered to sign on behalf of the manufacturer or his authorised representatives.

For a Declaration of Incorporation (DOI)

- a statement that the machinery 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,

The UK MD regulations also require that for annex IV equipment there must be a statement that the item of machinery to which the declaration refers conforms to the sample presented for EC Type examination and certification by a notified body.

Appendix 2 **New MD DOC content**

ANNEX II **Declarations**

1. CONTENT

A. EC DECLARATION OF CONFORMITY OF THE MACHINERY

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

This declaration relates exclusively to the machinery in the state in which it was placed on the market, and excludes components which are added and/or operations carried out subsequently by the final user.

The EC declaration of conformity must contain the following particulars:

1. business name and full address of the manufacturer and, where appropriate, his authorised representative;
2. name and address of the person authorised to compile the technical file, who must be established in the Community;
3. description and identification of the machinery, including generic denomination, function, model, type, serial number and commercial name;
4. a sentence expressly declaring that the machinery fulfils all the relevant provisions of this Directive and where appropriate, a similar sentence declaring the conformity with other Directives and/or relevant provisions with which the machinery complies. These references must be those of the texts published in the *Official Journal of the European Union*;
5. where appropriate, the name, address and identification number of the notified body which carried out the EC type-examination referred to in Annex IX and the number of the EC type-examination certificate;
6. *where appropriate, the name, address and identification number of the notified body which approved the full quality assurance system referred to in Annex X; (CCQS will not use this)*
7. where appropriate, a reference to the harmonised standards used, as referred to in Article 7(2);
8. where appropriate, the reference to other technical standards and specifications used;
9. the place and date of the declaration;
10. the identity and signature of the person empowered to draw up the declaration on behalf of the manufacturer or his authorised representative.

Appendix 3 **LVD Annex II DOC content**

B. EC declaration of conformity

The EC declaration of conformity must contain the following elements:

- name and address of the manufacturer or his authorised representative established within the Community,
- a description of the electrical equipment,
- reference to the harmonised standards,
- where appropriate, references to the specifications with which conformity is declared,
- identification of the signatory who has been empowered to enter into commitments on behalf of the manufacturer or his authorised representative established within the Community,
- the last two digits of the year in which the CE marking was affixed.
(I think that can count as part of the date of signature)

Appendix 4 **EMC Annex IV DOC content**

2. EC declaration of conformity

The EC declaration of conformity must contain, at least, the following:

- a reference to this Directive,
- an identification of the apparatus to which it refers, as set out in Article 9(1),
- the name and address of the manufacturer and, where applicable, the name and address of his authorised representative in the Community,
- a dated reference to the specifications under which conformity is declared to ensure the conformity of the apparatus with the provisions of this Directive,
- the date of that declaration,
- the identity and signature of the person empowered to bind the manufacturer or his authorised representative.

Appendix 5

Suggested minimum mandatory content for a DOC.

If used as template, delete any parts which are not appropriate.

This template only addresses MD, LVD, EMC compliance.

Other directives may require further content.

Declaration of Conformity/Incorporation

The equipment which accompanies this declaration is in conformity with EU Directive(s):-
83/37/EC Machinery Directive
2006/95/EC Low Voltage Directive
2004/108/EC Electromagnetic Compatibility Directive
Etc.

Manufacturer Name, Address

Represented in the EU by:- (Optional)

Name, EU Address

A copy of the Technical file for this equipment is available from:- *(for new MD)*

The EU address above *or:-*

Name, EU Address

Description of Equipment

“Generic denomination, function, model, type, serial number and commercial name”

Only for MD Annex IV machinery.

A sample of this machinery has been presented to Notified Body number 1105.

CCQS UK Ltd., Suite B Regal Court, 112 London Road, Headington, Oxford OX3 9AW UK

Who have issued an EC type-examination certificate

Number CE-C-nnnn-nn-nn-5A dated yyyy.mm.dd.

The equipment in respect of which this declaration is made conforms to the example to which that certificate relates, and that certificate remains valid.

Only for Declaration of Incorporation

This machinery must not be put into service until the relevant machinery into which it is to be incorporated has been declared in conformity with the provisions of the Machinery Directive

The following harmonised standards have been used:-

E.g. EN60204-1:2006 Electrical Equipment of Industrial machines

Etc. Quote date and description..

Authorised signatory of manufacturer/authorised EU representative

Signature

Name of signatory

Position in company

Place and Date