

DGUV Test Information

Date of Issue: 01/2023

Declaration of Conformity and Declaration of Incorporation as specified in Directive 2006/42/EC

In accordance with the EC Machinery Directive, machinery manufacturers or their authorised representatives must issue an EC Declaration of Conformity before placing their product on the market. Correspondingly, manufacturers of partly completed machinery have to issue a Declaration of Incorporation. These declarations are legal documents stating that the (partly completed) machinery meets all of the relevant requirements of the Machinery Directive.

The declaration must be enclosed with the (partly completed) machinery until it reaches the user. It can be included in the instructions; if it is supplied separately, however, its contents – apart from the serial number and signature – must also be included in the instructions.

Form and language of declarations

The declaration must either be typewritten or handwritten (in capital letters). The Machinery Directive does not make any further specifications concerning form.

The declaration and translations thereof must be drawn up under the same conditions as the instructions (Annex I, 1.7.4). Thus, the declaration must be written in the official language of the Member State in which the (partly completed) machinery is placed on the market or put into service. It must be marked “Original” or “Translation” as appropriate.

Person authorised to compile the technical file

The declaration must give the name of a person authorised to compile the technical file in response to a duly reasoned request by the market surveillance authorities. The authorised representative can be a natural or a legal

person. In the role of authorised representative, this person is not responsible for the design, conformity assessment procedure, drawing-up of documents or signing of the EC Declaration of Conformity. In the case of manufacturers whose headquarters are in the EU, the authorised party can be the manufacturer.

Scope of the declaration

The Declaration of Conformity relates exclusively to the machinery in the state in which it was placed on the market. If the end user adds parts to the machinery or alters the machinery, the EC Declaration of Conformity does not cover those additions or alterations.



Description and identification of the (partly completed) machinery

The declaration must include detailed product information. The Directive requires a description and identification of the (partly completed) machinery, including a generic denomination, function, model, type, serial number and commercial name. The aim is to enable users and market surveillance authorities to identify beyond doubt the machinery covered by the declaration in question. The serial number must always be cited. In the case of mass-produced (partly completed) machinery, the declaration can relate to a range of serial numbers or a specific batch.

Declaration of Conformity with the EC Machinery Directive

The core of the Declaration of Conformity is a sentence explicitly stating that the machinery meets all of the relevant safety and health requirements set out in Annex I and that an appropriate procedure for assessing conformity has been carried out.

In the case of partly completed machinery, it is usually not possible to assess all of the risks before the machine is incorporated into the final machine. Consequently, it might prove impossible to apply all of the essential safety and health requirements set out in Annex I. The Declaration of Incorporation must specify precisely which Annex I requirements are fulfilled. Statements such as “... to the extent possible with the product delivered” are not sufficient. An additional EC Declaration of Conformity must be issued for the partly completed machinery if required by other EC directives (e.g. the EMC Directive).

Declaration of the harmonised standards fulfilled

The manufacturer benefits from the presumption of conformity created by the use of harmonised standards only if those standards are listed in the declaration. In the case of Annex IV machinery, internal checks can only be used if the harmonised standards are cited in the Declaration of Conformity.

Signature

The declaration must include the signatory's name and position. It can be signed by a member of the manufacturer's board of management/the manufacturer's managing director or by an employee who has been given responsibility for signing it.

Custody

The manufacturer must keep the original of the declaration for at least ten years from the last date of manufacture of the (partly completed) machinery.

Further informationen

- Information on the EC Machinery Directive:
www.dguv.de, Webcode e24330
- Guide to EC Machinery Directive 2006/42/EC:
www.dguv.de, Webcode e24330
- Comparison of the CE mark and certification marks:
www.dguv.de, Webcode p012399

DGUV Test– A wealth of expertise in machinery safety

Our customers benefit directly from our decades of experience in safety testing during and after the design phase. Voluntary tests and certification help manufacturers, importers and dealers to meet the requirements of the EU legislation and the German Product Safety Act and to avoid product liability issues.

For a list of our testing and certification bodies, see:
www.dguv.de, Webcode e24697.

**Sample EC Declaration of Conformity of Machinery
(Annex II 1 A of EC Machinery Directive 2006/42/EC)**

– Original –*

**EC Declaration of Conformity
Any Company Ltd.
24 Machinery Road, 54322 Any Town, Germany**

Authorised representative**

We, Any Company Ltd., hereby declare that the following machinery

Any machine Type sample 222, Serial number 20081264

fulfils all of the relevant requirements of EC Machinery Directive 2006/42/EC.

Declaration that the machinery fulfils additional EC directives,
e.g. the EC Electromagnetic Compatibility Directive, 2004/108/EC.***

Name, address and identification number of the notified body which
– carried out the EC type examination, along with the number of the EC type
examination certificate,
or
– approved the full quality assurance system.

The following harmonised standards were used:****
– EN 415-7 (2009-12): Safety of packaging machines – Part 7: Group and secondary
packaging machines
– ...

The following other technical standards and specifications were used:***
– ...

The party authorised to compile the technical file is:
[company or natural person, established in the EU]

Signature

Signatory's surname, first name(s) and position
Any Town, 01 January 2015

* The word "Original" must be shown on the language versions for which the manufacturer or the manufacturer's authorised representative is responsible. Translations must be marked "Translation".
** If there is an authorised representative, he or she should be named here.
*** To be cited as appropriate.
**** To be cited as appropriate. If internal checks are carried out on Annex IV machinery, this information must be given.

**Sample Declaration of Incorporation of Partly Completed Machinery
(Annex II 1 B of EC Machinery Directive 2006/42/EC)**

– Original –*

**Declaration of Incorporation
Any Company Ltd.
24 Machinery Road, 54322 Any Town, Germany**

Authorised representative**

Description and identification of the partly completed machinery:

Any machine Type sample 222, Serial number 20081264

The following essential requirements of EC Machinery Directive 2006/42/EC have been applied and fulfilled***:

- 1.1.2, 1.1.4, 1.3.1, 1.5.12

The relevant technical documentation has been compiled in accordance with Annex VII, Part B of EC Machinery Directive 2006/42/EC. We undertake, in response to a reasoned request, to supply it *in electronic form***** to the market surveillance authorities within a reasonable period.

The party authorised to compile the technical documentation is:
[company or natural person, established in the EU]

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 the Machinery Directive.

Signature

Signatory's surname, first name(s) and position
Any Town, 01 January 2016

* The word "Original" must be shown on the language versions for which the manufacturer or the manufacturer's authorised representative is responsible. Translations must be marked "Translation".

** If there is an authorised representative, he or she should be named here.

*** The exact requirements concerned must be cited.

**** The method in which the documentation will be supplied must also be cited.

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Further information:

