

## **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;*
- 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.*

...

#### **§ 1 The EC Declaration of Conformity of machinery**

Annex II, 1 A concerns the EC Declaration of Conformity that must be drawn up by the manufacturer of machinery or his authorised representative in the Community

and that must accompany the machinery until it reaches the user – see §103, comments on Article 5 (1), and §109, comments on Article 7 (1). The EC Declaration of Conformity is a legal statement by the manufacturer or his authorised representative attesting that the machinery concerned complies with all of the relevant provisions of the Machinery Directive and, where appropriate, with the provisions of other applicable Community legislation.

The first paragraph of Annex II, 1 A entails that the EC Declaration of Conformity must be provided in the official Community language or languages of the Member State in which the machinery is placed on the market and/or put into service, under the same conditions as the instructions – see §246, comments on section 1.7.1, §255, comments on section 1.7.4, and §257, comments on section 1.7.4.1 (a) and (b) of Annex I.

The EC Declaration of Conformity must be typewritten (printed) or handwritten in capital letters. It may be included in the instruction manual or provided separately, in which case a document setting out the contents of the EC declaration of conformity must be included in the instruction manual – see §149, comments on section 1.7.4.2 (c) of Annex I.

The second paragraph of Annex II, 1 A underlines that the EC Declaration of Conformity relates only to the machinery as it has been designed, constructed and placed on the market by the manufacturer. The manufacturer is not legally responsible for any additions or modifications made to the machinery subsequently by the final user. This must be taken into account when machinery in use is examined by the market surveillance authorities – see §94, comments on Article 4 (1).

***Annex II, 1, A (continued)***

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*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;*

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.*
- ...

## **§ 2 The content of the EC Declaration of conformity**

The following comments refer to the numbered paragraphs in Annex II, 1 A:

1. The manufacturer's business name and full address are the same as those to be marked on the machinery – see §250, comments on section 1.7.3 of Annex I. Where the manufacturer has chosen to mandate an authorised representative in the Community to carry out all or part of his obligations set out in Article 5 – see §84 and §85, comments on Article 2 (j) – the particulars of the authorised representative must also be indicated in the EC Declaration of Conformity.
2. The person authorised to compile the technical file is a person, established in the Community, who has been entrusted by the manufacturer with the task of bringing together and making available the relevant elements of the technical file in response to a duly reasoned request from the market surveillance authorities of one of the Member States, – see §98, comments on Article 4 (3) and (4), and comments on Annex VII A (2) and (3). The person authorised to compile the technical file is not responsible for the design, construction or conformity assessment of the machinery, for affixing the CE marking or for drawing up the EC Declaration of Conformity.

All machinery manufacturers must indicate the name and address of a person authorised to compile the technical file. For manufacturers established in the Community, the person authorised to compile the technical file is a contact person belonging to the manufacturer's staff (who can be the same as the signatory of the EC Declaration of Conformity or another person). For manufacturers established outside the Community, the person authorised to compile the technical file may be any natural or legal person established in the Community who is entrusted with the task of bringing together and making available the technical file in response to a duly reasoned request. If a manufacturer established outside the Community has chosen to mandate an authorised representative in the Community to carry out all or part of the obligations set out in Article 5 – see §84 and §85, comments on Article 2 (j) – the authorised representative in the Community can also be the person authorised to compile the technical file.

3. The particulars required for the description and identification of the machinery are essentially the same as those to be marked on the machinery – see §250, comments on section 1.7.3 of Annex I. However, in the EC Declaration of

Conformity the particulars of the machinery must be given in full. The purpose of this information is to enable both the user and the market surveillance authorities to identify the machinery covered by the declaration without ambiguity.

In the case of one-off machinery or machinery produced in small series, the series number of the machinery covered by the EC Declaration of conformity should be indicated. In the case of machinery produced in large series, it is possible to draw up a single EC Declaration covering a range of series numbers or batches, in which case the range covered by the declaration must be indicated.

4. The sentence declaring that the machinery fulfils all the relevant provisions of the Machinery Directive is the key element of the EC Declaration of Conformity. By this statement, the manufacturer or his authorised representative attests that the machinery concerned complies with all of the applicable EHSRs of Annex I to the Machinery Directive and that the appropriate conformity assessment procedure has been carried out.

Where the machinery concerned is subject to other Community legislation in addition to the Machinery Directive, the conformity with the other Directives or Regulations concerned must also be declared – see §91 and §92, comments on Article 3. The manufacturer may draw up a single EC Declaration of Conformity for these other Directives or Regulations, provided that the declaration contains all the information required by each Directive. This may not be possible in all cases, since certain Directives specify a particular format for the Declaration of Conformity – see §89, comments on Article 3.

5. For machinery belonging to one of the categories listed in Annex IV where the manufacturer has chosen to follow the EC type-examination procedure, the particulars of the Notified Body which carried out the EC type-examination and the number of the EC type-examination certificate are to be indicated – see §129 and §130, comments on Article 12 (3) and (4). The name, address and four-figure identification number of the Notified Body to be indicated are given in the NANDO database – see §133, comments on Article 14.
6. For machinery belonging to one of the categories listed in Annex IV where the manufacturer has chosen to follow the full quality assurance procedure, the particulars of the Notified Body which approved the manufacturer's full quality assurance system are to be indicated see §129 and §130, comments on Article 12 (3) and (4). The name, address and four-figure identification number of the Notified Body to be indicated are given in the NANDO database – see §133, comments on Article 14.
7. The application of harmonised standards is not mandatory. There is thus no obligation to indicate the references of harmonised standards in the EC Declaration of Conformity. However a manufacturer who has applied the relevant harmonised standards has every interest in indicating their references in the EC Declarations of Conformity, since the application of harmonised standards the references of which have been published in the OJEU confers a

presumption of conformity with the EHSRs covered by the standards – see §110 and §111, comments on Article 7 (2), and §114, comments on Article 7 (3). If the reference of a harmonised standard is indicated in the EC Declaration of conformity, the market surveillance authorities are entitled to assume that the manufacturer has applied the specifications of the standard in full. If the manufacturer has not applied all of the specifications of a standard, he may still indicate the reference of the standard in the EC Declaration of conformity, but, in that case, he must indicate which specifications of the standard he has not applied.

8. Where harmonised standards have not been used, the manufacturer may indicate the references of other technical documents used to design and construct the machinery. It should be borne in mind that the application of such documents does not confer a presumption of conformity – see §162, comments on General Principle 3 of Annex I.
9. The indication of the place and date of the declaration are customary requirements for a signed legal document. The place to be indicated is usually the town where the head office of the manufacturer or his authorised representative is established. Since the EC Declaration of Conformity must be drawn up before the machinery is placed on the market or put into service – see §103, comments on Article 5 (1) - the date indicated in the declaration must be prior to the placing on the market or the putting into service of the machinery.
10. The identity of the person empowered by the manufacturer or his authorised representative to draw up the EC Declaration of conformity must be indicated above his or her signature. The identity comprises his or her name and function.

The EC Declaration of conformity can be signed by the Managing Director of the Company concerned or by another manager to whom this responsibility has been delegated. The original EC Declaration of Conformity shall be signed by hand and must be kept by the manufacturer or his authorised representative – see comments on Annex II, part 2. The signature can then be reproduced on the Declaration of Conformity that accompanies the machinery. It is advisable to print or copy the Declaration of Conformity on distinctive paper to discourage fraudulent copying.

## ***ANNEX II***

### ***1. CONTENT (continued)***

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### ***B. 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 I, 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.*
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### **§ 3 The Declaration of Incorporation of partly completed machinery**

Annex II, 1 B concerns the Declaration of Incorporation that must be drawn up by the manufacturer of partly completed machinery or his authorised representative in the Community and that must accompany the partly completed machinery until it reaches the manufacturer of the final machinery into which it is to be incorporated. The Declaration of incorporation shall then form part of the technical file for that machinery – see §104, comments on Article 5 (2), and §131, comments on Article 13. The Declaration of Incorporation is a legal statement by the manufacturer of the partly completed machinery or his authorised representative with the following main purposes:

- to inform the manufacturer of the final machinery which of the applicable EHSRs of Annex I to the Machinery have been applied and fulfilled and, where appropriate, to declare the conformity of the partly completed machinery with the provisions of other applicable Community legislation;
- to indicate 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 relevant provisions of the Machinery Directive.

The comments relating to the first paragraph of Annex II, 1 A apply also to the first paragraph of Annex II, 1 B.

The following comments refer to the numbered paragraphs in Annex II, 1 B:

1. The comments on paragraph 1 of Annex II, 1 A apply.
2. With respect to the person authorised to compile the technical documentation, the comments on paragraph 2 of Annex II, 1 A relating to the person authorised to compile the technical file apply.
3. The comments on paragraph 3 of Annex II, 1 A apply.
4. The Machinery Directive does not determine which of the applicable EHSRs must be applied and fulfilled by the manufacturer of partly completed machinery. The following considerations may be taken into account when deciding whether or not to apply and fulfil certain EHSRs:
  - it may not be possible for the manufacturer of the partly completed machinery to fully assess certain risks which depend on the way the partly completely machinery is incorporated into the final machinery;
  - the manufacturer of the partly completed machinery may agree with a manufacturer of final machinery on a 'division of tasks' whereby the application and fulfilment of certain EHSRs is left to the manufacturer of the final machinery.

The manufacturer of partly completed machinery must indicate in the Declaration of Incorporation precisely which of the applicable EHSRs have been applied and fulfilled. He must also state that he has compiled the relevant technical documentation showing how those EHSRs have been applied – see comments on Annex VII B.

Where the partly completed machinery (or part of it) is subject to other Community legislation in addition to the Machinery Directive, the conformity with the other Directives or Regulations concerned must also be declared – see §91 and §92, comments on Article 3. Where those Directives or Regulations foresee an EC Declaration of Conformity, a separate EC Declaration of Conformity according to those texts must be drawn up for the partly completed machinery.

5. Paragraph 5 concerns the transmission of relevant information on the partly completed machinery from the manufacturer of the partly completed machinery to the manufacturer of the final machinery. In most cases, the Declaration of Incorporation and the assembly instructions should provide sufficient information to enable the manufacturer of the final machinery to design, construct and assess the conformity of the final machinery. However, if the manufacturer of the final machinery needs further information on the design and construction of the partly completed machinery in order to assess the conformity of the final machinery, he can ask his supplier for the necessary explanations. If this fails, he ask the national authorities for assistance. The national authorities shall then address a reasoned request to the manufacturer of the partly completed machinery.

In response to such a reasoned request, the manufacturer of the partly completed machinery must transmit the necessary explanations to the

manufacturer of the final machinery, but is not required to transmit documents that may be considered as legitimate commercial secrets or that are covered by his intellectual property rights.

6. The statement required by paragraph 6 takes account of the fact that partly completed machinery cannot be considered safe until any EHSRs not applied and fulfilled by the manufacturer of the partly completed machinery have been fulfilled and any risks arising from the incorporation of the partly completed machinery into the final machinery have been assessed and the necessary protective measures have been taken to deal with them.
7. The comments on paragraph 9 of Annex II, 1 A apply.
8. The comments on paragraph 10 of Annex II, 1 A apply.

***ANNEX II (continued)***

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**2. CUSTODY**

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

*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.*

**§ 4 Custody of the EC Declaration of Conformity and the Declaration of Incorporation**

The period of custody of ten years set out in Annex II, 2 for the EC Declaration of Conformity and the Declaration of Incorporation is to enable the market surveillance authorities to verify these documents if necessary – see §98, comments on Article 4 (3) and (4).