

## II

*(Acts whose publication is not obligatory)*

## COUNCIL

## COUNCIL DIRECTIVE 93/68/EEC

of 22 July 1993

amending Directives 87/404/EEC (simple pressure vessels), 88/378/EEC (safety of toys), 89/106/EEC (construction products), 89/336/EEC (electromagnetic compatibility), 89/392/EEC (machinery), 89/686/EEC (personal protective equipment), 90/384/EEC (non-automatic weighing instruments), 90/385/EEC (active implantable medicinal devices), 90/396/EEC (appliances burning gaseous fuels), 91/263/EEC (telecommunications terminal equipment), 92/42/EEC (new hot-water boilers fired with liquid or gaseous fuels) and 73/23/EEC (electrical equipment designed for use within certain voltage limits)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission <sup>(1)</sup>,

In cooperation with the European Parliament <sup>(2)</sup>,

Having regard to the opinion of the Economic and Social Committee <sup>(3)</sup>,

Whereas the Council has already adopted a series of Directives designed to remove technical barriers to trade in accordance with the principles established in its Resolution of 7 May 1985 on a new approach to technical harmonization and standards <sup>(4)</sup>; whereas each of these Directives provides for the affixing of the 'CE'

marking; whereas, therefore, in the interests of simplifying Community legislation and making it more consistent, these various provisions need to be replaced by uniform prescriptions; whereas it is therefore necessary to harmonize these provisions, particularly with regard to products which may fall within the scope of several of these Directives;

Whereas, in its communication of 15 June 1989 on a global approach to certification and testing <sup>(5)</sup>, the Commission proposed that common rules be drawn up concerning a 'CE' conformity marking with a single design; whereas, in its Resolution of 21 December 1989 on a global approach to conformity assessment <sup>(6)</sup>, the Council approved as a guiding principle the adoption of a consistent approach such as this with regard to the use of the 'CE' marking;

Whereas the two basic elements of the new approach which must be applied are therefore the essential requirements and the conformity assessment procedures;

Whereas this harmonization of the provisions concerning the affixing and use of the 'CE' marking requires that existing Directives undergo detailed amendment to bring them into line with the new arrangements,

<sup>(1)</sup> OJ No C 160, 20. 6. 1991, p. 14; and OJ No C 28, 2. 2. 1993, p. 16.

<sup>(2)</sup> OJ No C 125, 18. 5. 1992, p. 178; OJ No C 115, 26. 4. 1993, p. 117; and Decision of 14 July 1993 (not yet published in the Official Journal).

<sup>(3)</sup> OJ No C 14, 20. 1. 1992, p. 15; and OJ No C 129, 10. 5. 1993, p. 3.

<sup>(4)</sup> OJ No C 136, 4. 6. 1985, p. 1.

<sup>(5)</sup> OJ No C 231, 8. 9. 1989, p. 3; and OJ No C 267, 19. 10. 1989, p. 3.

<sup>(6)</sup> OJ No C 10, 16. 1. 1990, p. 1.

HAS ADOPTED THIS DIRECTIVE:

*Article 1*

The following Directives are hereby amended:

1. Council Directive 87/404/EEC of 25 June 1987 on the harmonization of the laws of the Member States relating to simple pressure vessels <sup>(1)</sup>;
2. Council Directive 88/378/EEC of 3 May 1988 on the approximation of the laws of the Member States concerning the safety of toys <sup>(2)</sup>;
3. Council Directive 89/106/EEC of 21 December 1988 on the approximation of the laws, regulations and administrative provisions of the Member States relating to construction products <sup>(3)</sup>;
4. Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility <sup>(4)</sup>;
5. Council Directive 89/392/EEC of 14 June 1989 on the approximation of the laws of the Member States relating to machinery <sup>(5)</sup>;
6. Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment <sup>(6)</sup>;
7. Council Directive 90/384/EEC of 20 June 1990 on the harmonization of the laws of the Member States relating to non-automatic weighing instruments <sup>(7)</sup>;
8. Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices <sup>(8)</sup>;
9. Council Directive 90/396/EEC of 29 June 1990 on the approximation of the laws of the Member States relating to appliances burning gaseous fuels <sup>(9)</sup>;
10. Council Directive 91/263/EEC of 29 April 1991 on the approximation of the laws of the Member States concerning telecommunications terminal equipment,

<sup>(1)</sup> OJ No L 220, 8. 8. 1987, p. 48; Directive amended by Directive 90/488/EEC (OJ No L 270, 2. 10. 1990, p. 25).

<sup>(2)</sup> OJ No L 187, 16. 7. 1988, p. 1.

<sup>(3)</sup> OJ No L 40, 11. 2. 1989, p. 12.

<sup>(4)</sup> OJ No L 139, 23. 5. 1989, p. 19; Directive last amended by Directive 92/31/EEC (OJ No L 126, 12. 5. 1992, p. 11).

<sup>(5)</sup> OJ No L 183, 29. 6. 1989, p. 9; Directive amended by Directive 91/368/EEC (OJ No L 198, 22. 7. 1991, p. 16).

<sup>(6)</sup> OJ No L 399, 30. 12. 1989, p. 18.

<sup>(7)</sup> OJ No L 189, 20. 7. 1990, p. 1.

<sup>(8)</sup> OJ No L 189, 20. 7. 1990, p. 17.

<sup>(9)</sup> OJ No L 196, 26. 7. 1990, p. 15.

including the mutual recognition of their conformity <sup>(10)</sup>;

11. Council Directive 92/42/EEC of 21 May 1992 on efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels <sup>(11)</sup>;
12. Council Directive 73/23/EEC of 19 February 1973 on the harmonization of the laws of the Member States relating to electrical equipment designed for use within certain voltage limits <sup>(12)</sup>.

*Article 2*

Directive 87/404/EEC is hereby amended as follows:

1. throughout the text, the term 'EC mark' is replaced by 'CE marking';
2. in Article 5 the first paragraph is replaced by the following text:

'1. Member States shall presume that vessels bearing the CE marking comply with all the provisions of this Directive, including the conformity assessment procedures referred to in Chapter II.

Conformity of vessels with the national standards which transpose the harmonized standards the reference numbers of which have been published in the *Official Journal of the European Communities* shall result in a presumption of conformity to the essential safety requirements referred to in Article 3. Member States shall publish the reference numbers of such national standards.'

3. the following paragraph is added to Article 5:
  - '3. (a) Where the vessels are subject to other Directives covering other aspects and which also provide for the affixing of the CE marking, the latter shall indicate that the vessels in question are also presumed to conform to the provisions of those other Directives.

- (b) However, where one or more of those Directives allow the manufacturer, during a transitional period, to choose which arrangements to apply, the CE marking shall indicate conformity only to the Directives applied by the manufacturer. In this case, particulars of the Directives applied, as published in the *Official Journal of the European Communities*, must be given in the documents, notices or instructions required by the Directives and accompanying such vessels.'

<sup>(10)</sup> OJ No L 128, 23. 5. 1991, p. 1.

<sup>(11)</sup> OJ No L 167, 22. 6. 1992, p. 17.

<sup>(12)</sup> OJ No L 77, 26. 3. 1972, p. 29.

4. In Article 9 the first paragraph is replaced by the following text:

'1. Member States shall notify the Commission and the other Member States of the approved bodies which they have appointed to carry out the procedures referred to in Article 8 (1) and (2) together with the specific tasks which these bodies have been appointed to carry out and the identification numbers assigned to them beforehand by the Commission.

The Commission shall publish in the *Official Journal of the European Communities* a list of the notified bodies with their identification numbers and the tasks for which they have been notified. The Commission shall ensure that this list is kept up to date.'

5. Article 11 is replaced by the following text:

**'EC verification**

*Article 11*

1. EC verification is the procedure whereby a manufacturer or his authorized representative established within the Community ensures and declares that the vessels which have been checked in accordance with paragraph 3 are in conformity to the type described in the EC type-examination certificate or with the design and manufacturing schedule referred to in Annex II section 3 having received a certificate of adequacy.

2. The manufacturer shall take all the necessary measures for the manufacturing process to ensure that the vessels conform to the type described in the EC type-examination certificate or to the design and manufacturing schedule referred to in Annex II section 3. The manufacturer or his authorized representative established within the Community shall affix the CE marking to each vessel and draw up a declaration of conformity.

3. The approved body shall carry out the appropriate examinations and tests in order to check the conformity of the vessels with the requirements of this Directive by examination and testing of vessels in accordance with the following paragraphs:

3.1. The manufacturer shall present his vessels in the form of uniform batches and shall take all necessary measures in order that the manufacturing process ensures the uniformity of each batch produced.

3.2. These batches shall be accompanied by the EC type-examination certificate referred to in Article 10, or, where the vessels are not manufactured in accordance with an approved prototype, by the design and manufacturing schedule referred to in Annex II section 3. In this case the approved body shall, prior to EC verification, examine the schedule in order to certify its conformity.

- 3.3. When a batch is examined, the inspection body shall ensure that the vessels have been manufactured and checked in accordance with the design and manufacturing schedule and perform a hydrostatic test or a pneumatic test of equivalent effect on each vessel in the batch at a pressure  $P_h$  equal to 1,5 times the vessel's design pressure in order to check its soundness. The pneumatic test shall be subject to acceptance of the test safety procedures by the Member State in which the test is performed.

Moreover, the inspection body shall carry out tests on test-pieces taken from a representative production test-piece or from a vessel, as the manufacturer chooses, in order to examine the weld quality. The tests shall be carried out on longitudinal welds. However, where differing weld techniques are used for longitudinal and circular welds, the tests shall be repeated on the circular welds.

For the vessels referred to in Annex I, section 2.1.2 these tests on test-pieces shall be replaced by a hydrostatic test on five vessels taken at random from each batch in order to check that they conform to the requirements of Annex I, section 2.1.2.

- 3.4. In the case of accepted batches, the approved body shall affix, or cause to be affixed, its identification number to each recipient and draw up a written certificate of conformity relating to the tests carried out. All recipients in the batch may be placed on the market except for those which have not successfully undergone a hydrostatic test or a pneumatic test.

If a batch is rejected, the notified body or the competent authority shall take appropriate measures to prevent the putting on the market of that batch. In the event of frequent rejection of batches, the notified body may suspend the statistical verification.

The manufacturer may, under the responsibility of the notified body, affix the latter's identification number during the manufacturing process.

- 3.5. The manufacturer or his authorized representative must be able to supply on request the approved body's certificates of conformity referred to in subparagraph 3.4.;

6. in Article 12 (1) the first sentence is replaced by the following text:

'1. A manufacturer fulfilling the obligations arising out of Article 13 shall affix the CE marking provided for in Article 16 to vessels which he declares to be in conformity:

- to the design and manufacturing schedule referred to in Annex II section 3, and on which a certificate of adequacy has been drawn up, or
- an approved prototype.’;

7. Article 15 is replaced by the following text:

*‘Article 15*

Without prejudice to Article 7:

- (a) where a Member State establishes that the CE marking has been affixed unduly, the manufacturer or his authorized representative established within the Community shall be obliged to make the product conform as regards the provisions concerning the CE marking and to end the infringement under the conditions imposed by the Member State;
- (b) where non-conformity continues, the Member State must take all appropriate measures to restrict or prohibit the placing on the market of the product in question or to ensure that it is withdrawn from the market in accordance with the procedures laid down in Article 7.’;
8. in Article 16 (1) the second subparagraph is replaced by the following text:

‘The CE conformity marking shall consist of the initials “CE” in the form shown in the specimen in Annex II. The CE marking shall be followed by the distinguishing number referred to in Article 9 (1) of the approved inspection body responsible for EC verifications or EC surveillance.’;

9. in Article 16 the second paragraph is replaced by the following text:

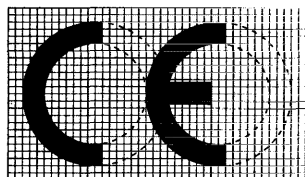
‘2. The affixing of markings on the vessels which are likely to deceive third parties as to the meaning and form of the CE marking shall be prohibited. Any other marking may be affixed to the vessels or the data plate provided that the visibility and legibility of the CE marking is not thereby reduced.’;

10. in Annex II, section 1 is replaced by the following text:

**‘1. CE MARKING AND INSCRIPTIONS**

**1. (a) CE conformity marking**

- The CE conformity marking shall consist of the initials “CE” in the following form:



- If the CE marking is reduced or enlarged the proportions given in the above graduated drawing must be respected.
- The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm.

**1. (b) Inscriptions**

The vessel or data plate must bear at least the following information:

- the maximum working pressure (PS in bar),
- the maximum working temperature ( $T_{max}$  in °C),
- the minimum working temperature ( $T_{min}$  in °C),
- the capacity of the vessel (V in l),
- the name or mark of the manufacturer,
- the type and serial or batch identification of the vessel,
- the last two digits of the year in which the CE marking was affixed.

Where the data plate is used, it must be so designed that it cannot be re-used and must include a vacant space to enable other information to be provided.’

*Article 3*

Directive 88/378/EEC is hereby amended as follows:

1. throughout the text, the term ‘EC mark’ is replaced by ‘CE marking’;
2. in Article 5 the first paragraph is replaced by the following text:

‘1. Member States shall presume that toys bearing the CE marking laid down in Article 11 comply with all the provisions of this Directive, including the conformity assessment procedures referred to in Articles 8, 9 and 10.

Conformity of toys with the national standards which transpose the harmonized standards the reference numbers of which have been published in the *Official Journal of the European Communities* shall result in a presumption of conformity to the essential safety requirements referred to in Article 3. Member States shall publish the reference numbers of such national standards.’;

3. the following paragraph is added to Article 5:

'3. (a) Where the toys are subject to other Directives covering other aspects and which also provide for the affixing of the CE marking, the latter shall indicate that the toys in question are also presumed to conform to the provisions of those other Directives.

(b) However, where one or more of these Directives allow the manufacturer, during a transitional period, to choose which arrangements to apply, the CE marking shall indicate conformity only to the Directives applied by the manufacturer. In this case, particulars of the Directives applied, as published in the *Official Journal of the European Communities*, must be given in the documents, notices or instructions required by the Directives and accompanying such toys or, failing that, on their packaging.'

4. in Article 9 the second paragraph is replaced by the following text:

'2. Member States shall notify the Commission and the other Member States of the bodies which they have appointed to carry out the EC type-examination referred to in Article 8 (2) and Article 10 together with the specific tasks which these bodies have been appointed to carry out and the identification numbers assigned to them beforehand by the Commission.

The Commission shall publish in the *Official Journal of the European Communities* a list of the notified bodies with their identification number and the tasks for which they have been notified. The Commission shall ensure that this list is kept up to date.'

5. in Article 11 the second paragraph is replaced by the following text:

'2. The CE conformity marking shall consist of the initials "CE" taking the form of the specimen given in Annex V.'

6. in Article 11 the third paragraph is replaced by the following text:

'3. The affixing of markings on the toys which are likely to deceive third parties as to the meaning and form of the CE marking shall be prohibited. Any other marking may be affixed to the toys, their packaging or a label provided that the visibility and legibility of the EC marking is not thereby reduced.'

7. the following paragraph is added to Article 12:

'1a. Without prejudice to Article 7:

(a) where a Member State establishes that the CE marking has been affixed unduly, the

manufacturer or his authorized representative established within the Community shall be obliged to make the product conform as regards the provisions concerning the CE marking and to end the infringement under the conditions imposed by the Member State;

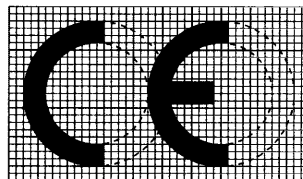
(b) where non-conformity continues, the Member State must take all appropriate measures to restrict or prohibit the placing on the market of the product in question or to ensure that it is withdrawn from the market in accordance with the procedures laid down in Article 7.'

8. the following Annex is added:

'ANNEX V

#### CE CONFORMITY MARKING

— The CE conformity marking shall consist of the initials "CE" taking the following form:



— If the CE marking is reduced or enlarged the proportions given in the above graduated drawing must be respected.

— The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm.'

#### Article 4

Directive 89/106/EEC is hereby amended as follows:

1. throughout the text, the term 'EC mark' is replaced by 'CE marking';

2. in Article 2 the second paragraph is replaced by the following text:

'2. (a) When products are subject to other Directives with regard to other aspects and which also provide for the affixing of the CE conformity marking, referred to in Article 4 (2), the latter shall indicate that the products are also presumed to conform to the provisions of those other Directives.

(b) However, where one or more of these Directives allow the manufacturer, during a transitional period, to choose which arrangements to apply, the CE marking shall

- indicate conformity only to the Directives applied by the manufacturer. In this case, particulars of the Directives applied, as published in the *Official Journal of the European Communities*, must be given in the documents, notices or instructions required by the Directives and accompany such products.';
3. in Article 4 (2) the introduction is replaced by the following text:
    - '2. Member States shall presume that products are fit for use if they enable works in which they are employed, provided the latter are properly designed and built, to satisfy the essential requirements referred to in Article 3 where such products bear the CE marking indicating that they satisfy all the provisions of this Directive, including the conformity assessment procedures laid down in Chapter V and the procedure laid down in Chapter III. The CE marking shall indicate:';
  4. in Article 4 (6) the first subparagraph is replaced by the following text:
    - '6. The CE marking signifies that products satisfy the requirements of paragraphs 2 and 4 of this Article. It is for the manufacturer or his authorized representative established within the Community to take responsibility for affixing the CE marking on the product itself, on a label attached to it, on its packaging, or on the accompanying commercial documents.';
  5. in Article 15 the second paragraph is replaced by the following text:
    - '2. Without prejudice to Article 21:
      - (a) where a Member State establishes that the CE marking has been affixed unduly, the manufacturer or his agent established within the Community shall be obliged to make the product conform as regards the provisions concerning the CE marking and to end the infringement under conditions imposed by the Member State;
      - (b) where non-conformity continues, the Member State must take all appropriate measures to restrict or prohibit the placing on the market of the product in question or to ensure that it is withdrawn from the market in accordance with the procedures laid down in Article 21.';
  6. in Article 15 the third paragraph is replaced by the following text:
    - '3. Member States shall take the measures necessary to prohibit the affixing to products or their packaging of markings which are likely to deceive third parties as to the meaning and form of the CE marking. Any other marking may be affixed to the
- construction products on a label fixed to the product packaging or on the accompanying commercial documents provided that the visibility and legibility of the CE marking is not thereby reduced.';
7. in Article 18 the first paragraph is replaced by the following text:
    - '1. Member States shall notify the Commission and the other Member States of the certification and inspection bodies and the testing laboratories which they have designated for the tasks which must be carried out for the purposes of technical approval, certificates of conformity, inspections and tests, in accordance with this Directive, together with their names and addresses and the identification numbers assigned to them beforehand by the Commission.

The Commission shall publish in the *Official Journal of the European Communities* a list of the notified bodies and laboratories with their identification numbers and the tasks and products for which they have been notified. The Commission shall ensure that this list is kept up to date.';
  8. Annex III section 4 is replaced by the following text:
    - '4.1. CE conformity marking
      - The CE conformity marking shall consist of the initials "CE" taking the following form:
      - If the CE marking is reduced or enlarged the proportions given in the above graduated drawing must be respected.
      - The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm.
      - The CE marking shall be followed by the identification number of the body involved in the production control stage.

*Additional information*

      - The CE marking shall be accompanied by the name or identifying mark of the producer, the last two digits of the year in which the marking was affixed, and where appropriate, the number of the EC certificate of conformity and, where appropriate, indications to identify the characteristics of the product on the basis of the technical specifications.'

*Article 5*

Directive 89/336/EEC is hereby amended as follows:

1. throughout the text, the term 'EC mark' is replaced by 'CE marking';
2. Article 3 is replaced by the following text:

*'Article 3*

Member States shall take all appropriate measures to ensure that the apparatus referred to in Article 2 may be placed on the market or taken into service only if it bears the CE marking provided for in Article 10 indicating its conformity to all the provisions of this Directive, including the conformity assessment procedures laid down in Article 10, when it is properly installed and maintained and when it is used for the purposes for which it is intended.;

3. the following fifth subparagraph is added to Article 10 (1):

'Member States shall take the necessary measures to prohibit the affixing to apparatus, its packaging, the instructions for use and the guarantee certificate of markings which are likely to deceive third parties as to the meaning and form of the CE marking. Any other marking may be affixed to the apparatus, its packaging, the instructions for use or the guarantee certificate provided that the visibility and legibility of the CE marking is not thereby reduced.;

4. in Article 10 (6) the first subparagraph is replaced by the following text:

'6. Member States shall notify the Commission and the other Member States of the competent authorities referred to in this Article and the bodies responsible for issuing the EC type-examination certificates referred to in paragraph 5, together with the specific tasks which these bodies have been appointed to carry out and the identification numbers assigned to them beforehand by the Commission.

The Commission shall publish in the *Official Journal of the European Communities* a list of the notified authorities and bodies with their identification numbers and the tasks for which they have been notified. The Commission shall ensure that this list is kept up to date.;

5. the following paragraph is added to Article 10:

'7. Without prejudice to Article 9:

- (a) where a Member State or a competent authority establishes that the CE marking has been affixed unduly, the manufacturer or his authorized representative established within the Community shall be obliged to make the product comply as regards the

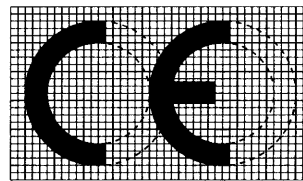
provisions concerning the CE marking and to end the infringement under conditions imposed by the Member State;

- (b) where non-compliance continues, the Member State must take all appropriate measures to restrict or prohibit the placing on the market of the product in question or to ensure that it is withdrawn from the market in accordance with the procedures laid down in Article 9.;

6. Annex I section 2 is replaced by the following text:

**2. CE conformity marking**

- The CE conformity marking shall consist of the initials "CE" taking the following form:



- If the CE marking is reduced or enlarged the proportions given in the above graduated drawing must be respected.
- Where apparatus is the subject of other Directives covering other aspects and which also provide for the CE conformity marking, the latter shall indicate that the appliances are also presumed to conform to those other Directives.
- However, where one or more of these Directives allow the manufacturer, during a transitional period, to choose which arrangements to apply, the CE marking shall indicate conformity only to the Directives applied by the manufacturer. In this case, particulars of the Directives applied, as published in the *Official Journal of the European Communities*, must be given in the documents, notices or instructions required by the Directives and accompanying such apparatus.
- The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm.'

*Article 6*

Directive 89/392/EEC is hereby amended as follows:

1. throughout the text, the term 'EC mark' is replaced by 'CE marking';

2. in Article 8 the fifth paragraph is replaced by the following text:

'5. (a) Where the machinery is subject to other Directives concerning other aspects and which also provide for the affixing of the EC marking, the latter shall indicate that the machinery is also presumed to conform to the provisions of those other Directives.

(b) However, where one or more of these Directives allow the manufacturer, during a transitional period, to choose which arrangements to apply, the CE marking shall indicate conformity only to the Directives applied by the manufacturer. In this case, particulars of the Directives applied, as published in the *Official Journal of the European Communities*, must be given in the documents, notices or instructions required by the Directives and accompanying such machinery.'

3. in Article 9 the first paragraph is replaced by the following text:

'1. Member States shall notify the Commission and the other Member States of the approved bodies which they have appointed to carry out the procedures referred to in Article 8 together with the specific tasks which these bodies have been appointed to carry out and the identification numbers assigned to them beforehand by the Commission.

The Commission shall publish in the *Official Journal of the European Communities* a list of the notified bodies and their identification numbers and the tasks for which they have been notified. The Commission shall ensure that this list is kept up to date.'

4. in Article 10 the first paragraph is replaced by the following text:

'1. The CE conformity marking shall consist of the initials "CE". The form of the marking to be used is shown in Annex III.'

5. In Article 10 the third paragraph is replaced by the following text:

'3. The affixing of markings on the machinery which are likely to deceive third parties as to the meaning and form of the CE marking shall be prohibited. Any other marking may be affixed to the machinery provided that the visibility and legibility of the CE marking is not thereby reduced.'

6. the following paragraph is added to Article 10:

'4. Without prejudice to Article 7:

(a) where a Member State establishes that the CE marking has been affixed unduly, the manufacturer or his authorized representative established within the Community shall be obliged to make the product conform as

regards the provisions concerning the CE marking and to end the infringement under the conditions imposed by the Member State;

(b) where non-conformity continues, the Member State must take all appropriate measures to restrict or prohibit the placing on the market of the product in question or to ensure that it is withdrawn from the market in accordance with the procedures laid down in Article 7.'

7. section 1.7.3 of Annex I is amended as follows:

(a) the second indent is replaced by the following text:

'— the CE marking (see Annex III)';

(b) a fifth indent is added:

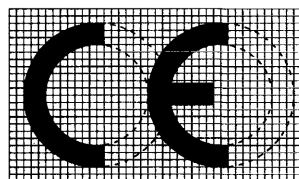
'— the year of construction';

8. Annex III is replaced by the following text:

'ANNEX III

#### CE CONFORMITY MARKING

— The CE conformity marking shall consist of the initials "CE" taking the following form:



— If the CE marking is reduced or enlarged the proportions given in the above drawing must be respected.

— The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm. This minimum dimension may be waived for small-scale machinery.'

#### Article 7

Directive 89/686/EEC is hereby amended as follows:

1. throughout the text, the term 'EC mark' is replaced by 'CE marking';

2. in Article 4 the first paragraph is replaced by the following text:

'1. Member States may not prohibit, restrict or hinder the placing on the market of PPE or PPE components which comply with the provisions of this



Directive and which bear the CE marking attesting their conformity to all the provisions of this Directive, including the certification procedures in Chapter II.;

3. the following paragraph is added to Article 5:

'6. (a) Where the PPE is subject to other Directives concerning other aspects and which also provide for the affixing of the CE marking, the latter shall indicate that the PPE is also presumed to conform to the provisions of the other Directives.

(b) However, where one or more of these Directives allow the manufacturer, during a transitional period, to choose which arrangements to apply, the CE marking shall indicate conformity to the provisions only of those Directives applied by the manufacturer. In this case, particulars of the Directives applied, as published in the *Official Journal of the European Communities*, must be given in the documents, notices or instructions required by the Directives and accompanying such PPE.;

4. in Article 9 the first paragraph is replaced by the following:

'1. Member States shall notify the Commission and the other Member States of the bodies which they have appointed to carry out the procedures referred to in Article 8 together with the specific tasks which these bodies have been appointed to carry out and the identification numbers assigned to them beforehand by the Commission.

The Commission shall publish in the *Official Journal of the European Communities* a list of the notified bodies and their identification numbers and the tasks for which they have been notified. The Commission shall ensure that this list is kept up to date.;

5. the introductory sentence of Article 12 is replaced by the following text:

'The EC declaration of conformity is the procedure whereby the manufacturer or his authorized representative established within the Community.;

6. Article 13 is replaced by the following text:

'Article 13

1. The CE conformity marking shall consist of the initials "CE" in the form shown in the specimen in Annex IV. In the event of the involvement of a

notified body in the production control phase as indicated in Article 11, its identification number shall be added.

2. The CE marking must be affixed to each piece of manufactured PPE so as to be visible, legible and indelible throughout the expected life of the PPE; however, if this is not possible in view of the characteristics of the product, the CE marking may be affixed to the packaging.

3. The affixing of markings on the PPE which are likely to deceive third parties as to the meaning and form of the CE marking shall be prohibited. Any other marking may be affixed to the PPE or its packaging provided that the visibility and legibility of the CE marking is not thereby reduced.

4. Without prejudice to Article 7:

(a) where a Member State establishes that the CE marking has been affixed unduly, the manufacturer or his authorized representative established within the Community shall be obliged to make the product conform as regards the provisions concerning the CE marking and to end the infringement under the conditions imposed by the Member State;

(b) where non-conformity continues, the Member State must take all appropriate measures to restrict or prohibit the placing on the market of the product in question or to ensure that it is withdrawn from the market in accordance with the procedures laid down in Article 7.;

7. the following text is added to section 1.4 of Annex II:

'(h) where appropriate, the references of the Directives applied in accordance with Article 5 (6) (b);

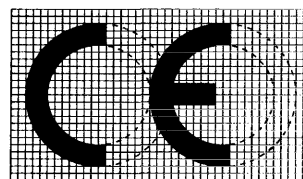
(i) the name, address and identification number of the notified body involved in the design stage of the PPE.;

8. Annex IV is replaced by the following text:

'ANNEX IV

CE CONFORMITY MARKING AND INFORMATION

— The CE conformity marking shall consist of the initials "CE" taking the following form:



— If the CE marking is reduced or enlarged the proportions given in the above graduated drawing must be respected.

- The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm. This minimum dimension may be waived for small-scale PPE.

*Additional information*

- The last two digits of the year in which the CE marking was affixed; this information is not required in the case of the PPE referred to in Article 8 (3).'

*Article 8*

Directive 90/384/EEC is hereby amended as follows:

1. throughout the text, the term 'EC mark' is replaced by 'CE marking';
2. in Article 2 the second paragraph is replaced by the following text:
 

'2. Member States shall take all steps to ensure that instruments may not be brought into service for the uses set out in Article 1 (2) (a) unless they meet the requirements of this Directive which apply to them, including the conformity assessment procedures referred to in Chapter II, and accordingly bear the CE marking provided for in Article 10.'
3. in Article 8 the third paragraph is replaced by the following text:
 

'3. (a) Where the instruments are subject to other Directives covering other aspects and which also provide for the affixing of the CE marking, the latter shall indicate that the instruments in question are also presumed to conform to the provisions of those other Directives.

(b) However, where one or more of the Directives which apply to the instruments allow the manufacturer, during a transitional period, to choose which arrangements to apply, the CE marking shall indicate conformity only to the Directives applied by the manufacturer. In this case, particulars of the Directives applied, as published in the *Official Journal of the European Communities*, must be given in the documents, notices or instructions required by the Directives and accompanying such instruments.'
4. in Article 9 the first paragraph is replaced by the following text:
 

'1. Member States shall notify the Commission and the other Member States of the bodies which they have appointed to carry out the procedures referred to in Article 8 together with the specific tasks which these bodies have been appointed to

carry out and the identification numbers assigned to them beforehand by the Commission.

The Commission shall publish in the *Official Journal of the European Communities* a list of the notified bodies and their identification numbers and the tasks for which they have been notified. The Commission shall ensure that this list is kept up to date.'

5. in Article 10 the third paragraph is replaced by the following text:

'3. The affixing of markings on the instruments which are likely to deceive third parties as to the meaning and form of the CE marking shall be prohibited. Any other marking may be affixed to the instruments provided that the visibility and legibility of the CE markings is not thereby reduced.'

6. Article 11 is replaced by the following text:

*Article 11*

Without prejudice to Article 7:

- (a) where a Member State establishes that the CE marking has been affixed unduly, the manufacturer or his authorized representative established within the Community shall be obliged to make the instrument conform as regards the provisions concerning the CE marking and to end the infringement under the conditions imposed by the Member State;
- (b) where non-conformity continues, the Member State must take all appropriate measures to restrict or prohibit the placing on the market of the instrument in question or to ensure that it is withdrawn from the market in accordance with the procedures laid down in Article 7.'

7. the following paragraphs of Annex II are amended as follows:

- (a) in paragraph 2.1 the second and third subparagraphs are replaced by the following text:

'The manufacturer or his authorized representative established within the Community shall affix the CE marking to each instrument and the inscriptions provided for in Annex IV and shall draw up a written declaration of conformity.

The CE marking shall be accompanied by the identification number of the notified body responsible for the EC surveillance referred to in paragraph 2.4.'

- (b) paragraphs 3 and 4 are replaced by the following text:

'3. EC verification

- 3.1. EC verification is the procedure whereby the manufacturer or his authorized representative established within the Community ensures and declares that the

- instruments which have been checked in accordance with paragraph 3.3 are, where applicable, in conformity to the type described in the EC type-examination certificate and satisfy the requirements of the Directive which apply to them.
- 3.2. The manufacturer shall take all necessary measures in order that the manufacturing process ensures conformity of the instruments, where applicable, with the type as described in the EC type-examination certificate and with the requirements of this Directive which apply to them. The manufacturer or his authorized representative established within the Community shall affix the CE marking to each instrument and draw up a written declaration of conformity.
- 3.3. The notified body shall carry out the appropriate examinations and tests in order to check the conformity of the product to the requirements of this Directive by examination and testing of every instrument, as specified in paragraph 3.5.
- 3.4. For instruments not subject to EC type-approval, the documents relating to the design of the instrument, as set out in Annex III, must be accessible to the notified body should the latter so request.
- 3.5. Verification by checking and testing of each instrument.
- 3.5.1. All instruments shall be individually examined and appropriate tests, as set out in the relevant standard(s) referred to in Article 5, or equivalent tests, shall be carried out in order to verify their conformity, where applicable, to the type as described in the EC type-examination certificate and the requirements of this Directive that apply to them.
- 3.5.2. The notified body shall affix, or cause to be affixed, its identification number on each instrument the conformity of which to requirements has been established and draw up a written certificate of conformity relating to the tests carried out.
- 3.5.3. The manufacturer or his authorized representative shall ensure that he is able to supply the notified body's certificates of conformity on request.
4. **EC unit verification**
- 4.1. EC unit verification is the procedure whereby the manufacturer or his authorized representative established within the Community ensures and declares that the instrument, generally designed for a specific application, which has been issued with the certificate referred to in paragraph 4.2 conforms to the requirements of this Directive that apply to it. The manufacturer or his authorized representative shall affix the CE marking to the instrument and shall draw up a written declaration of conformity.
- 4.2. The notified body shall examine the instrument and carry out the appropriate tests, as set out in the respective standard(s) referred to in Article 5, or equivalent tests, in order to ensure its conformity to the relevant requirements of this Directive.
- The notified body shall affix, or cause to be affixed, its identification number to the instrument the conformity of which to requirements has been established and shall draw up a written certificate of conformity concerning the tests carried out.
- 4.3. The aim of the technical documentation relating to the design of the instrument, as referred to in Annex III, is to enable conformity to the requirements of this Directive to be assessed and the design, manufacture and operation of the instrument to be understood. It must be accessible to the notified body.
- 4.4. The manufacturer or his authorized representative shall ensure that he is able to supply the notified body's certificates of conformity on request.;
- (c) paragraphs 5.3.1 and 5.3.2 are replaced by the following text:
- 5.3.1. Where a manufacturer has opted for execution in two stages of one of the procedures mentioned in 5.1, and where these two stages will be carried out by different parties, an instrument which has undergone the first stage of the procedure shall bear the identification number of the notified body involved in that stage.
- 5.3.2. The party which has carried out the first stage of the procedure shall issue for each of the instruments a certificate containing the necessary data for identification of the instrument and specifying the examinations and tests that have been carried out.
- The party which carries out the second stage of the procedure shall carry out those examinations and tests that have not yet been carried out.

The manufacturer or his authorized representative shall ensure that he is able to supply the notified body's certificates of conformity on request.;

(d) paragraph 5.3.4 is replaced by the following text:

'5.3.4. The CE marking shall be affixed to the instrument on completion of the second stage, along with the identification number of the notified body which took part in the second stage.;

8. in Annex IV paragraph 1.1 is amended as follows:

(a) subparagraph (a) is replaced by the following text:

- '(a) — the CE conformity marking comprising the CE symbol as described in Annex VI, followed by the last two digits of year in which it was affixed,
- the identification number(s) of the notified body/bodies that has/have carried out the EC surveillance or the EC verification.

The abovementioned marking and inscriptions shall be affixed to the instrument distinctly grouped together.;

(b) in subparagraph (2), after the sixth indent, the following indent is added:

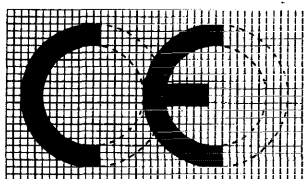
- '— the last two digits of the year in which the CE marking was affixed.;

9. Annex VI is replaced by the following text:

'ANNEX VI

#### CE CONFORMITY MARKING

— The CE conformity marking shall consist of the initials "CE" taking the following form:



- If the CE marking is reduced or enlarged the proportions given in the above graduated drawing must be respected.
- The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm.'

#### Article 9

Directive 90/385/EEC is hereby amended as follows:

1. throughout the text, the term 'EC mark' is replaced by 'CE marking';

2. in Article 4 the first paragraph is replaced by the following text:

'1. Member States shall not prevent the placing on the market or the putting into service within their territory of devices complying with the provisions of this Directive and bearing the CE marking provided for in Article 12 which indicate that they have been the subject of an evaluation of their conformity in accordance with Article 9.;

3. the following paragraph is added to Article 4:

'5. (a) Where the devices are subject to other Directives concerning other aspects and which also provide for the affixing of the CE marking, the latter shall indicate that the devices are also presumed to conform to the provisions of the other Directives.

(b) However, where one or more of these Directives allow the manufacturer, during a transitional period, to choose which arrangements to apply, the CE marking shall indicate conformity to the provisions only of those Directives applied by the manufacturer. In this case, particulars of the Directives applied, as published in the *Official Journal of the European Communities*, must be given in the documents, notices or instructions required by the Directives and accompanying such devices; these documents, notices or instructions shall be accessible without it being necessary to destroy the packaging which keeps the device sterile.;

4. in Article 11 the first paragraph is replaced by the following text:

'1. Member States shall notify the Commission and the other Member State of the bodies which they have appointed to carry out the procedures referred to in Article 9 together with the specific tasks which these bodies have been appointed to carry out and the identification numbers assigned to them beforehand by the Commission.

The Commission shall publish in the *Official Journal of the European Communities* a list of the notified bodies and their identification numbers and the tasks for which they have been notified. The Commission shall ensure that this list is kept up to date.;

5. in Article 12 (2) the second subparagraph is replaced by the following text:

'It must be followed by the identification number of the notified body responsible for implementation of the procedures set out in Annexes 2, 4 and 5.;

6. in Article 12 the third paragraph is replaced by the following text:

'3. The affixing of markings on the devices which are likely to deceive third parties as to the meaning

and form of the CE marking shall be prohibited. Any other marking may be affixed to the packaging or to the instruction leaflet accompanying the device provided that the visibility and legibility of the CE marking is not hereby reduced.';

7. Article 13 is replaced by the following text:

*'Article 13*

Without prejudice to Article 7

- (a) where a Member State establishes that the CE marking has been affixed unduly, the manufacturer or his authorized representative established within the Community shall be obliged to end the infringement under conditions imposed by the Member State;
- (b) where non-compliance continues, the Member State must take all appropriate measures to restrict or prohibit the placing on the market of the device in question or to ensure that it is withdrawn from the market in accordance with the procedures laid down in Article 7.';

8. Annex II is amended as follows:

- (a) in section 2 the second paragraph is replaced by the following text:

'The manufacturer or his authorized representative established within the Community shall affix the CE marking in accordance with Article 12 and shall draw up a written declaration of conformity.

This declaration shall cover one or more identified examples of the product and shall be kept by the manufacturer or his authorized representative established within the Community.

The CE marking shall be accompanied by the identification number of the notified body responsible.';

- (b) section 6 is replaced by the following text:

**'6. Administrative provisions**

- 6.1. For at least five years from last date of manufacture of the product, the manufacturer shall keep available for the national authorities:

- the declaration of conformity,
- the documentation referred to in the second indent of section 3.1,
- the amendments referred to in section 3.4,
- the documentation referred to in section 4.2,

— the decisions and reports of the notified body referred to in sections 3.4, 4.3, 5.3 and 5.4.

- 6.2. On request, the notified body shall make available to the other notified bodies and the competent authority all relevant information on approvals of quality systems issued, refused or withdrawn.

- 6.3. Where neither the manufacturer nor his authorized representative are established in the Community, the task of keeping available for the authorities the technical documentation referred to in Article 4 (2) shall fall to the person responsible for placing the appliance on the Community market.';

9. in Annex III sections 7 and 8 are replaced by the following text:

**'7. Administrative provisions**

- 7.1. On request, each notified body shall make available to the other notified bodies and the competent authority, all relevant information on EC type-examination certificates and addenda issued, refused or withdrawn.

- 7.2. Other notified bodies may obtain a copy of the EC type-examination certificates and/or the addenda to them. The annexes to the certificates shall be made available to the other notified bodies when a reasoned application is made and after the manufacturer has been informed.

- 7.3. The manufacturer or his authorized representative shall keep with the technical documentation a copy of the EC type-examination certificates and the supplements to them for a period of at least five years from the manufacture of the last appliance.

- 7.4. Where neither the manufacturer nor his authorized representative are established in the Community, the task of keeping the technical documentation available for the authorities shall fall to the person responsible for placing the appliance concerned on the Community market.';

10. Annex IV is replaced by the following text:

**'ANNEX IV**

**EC VERIFICATION**

- 1. EC verification is the procedure whereby the manufacturer or his authorized representative established within the Community ensures and declares that the products subject to the

- provisions of section 3 are in conformity with the type as described in the EC type-examination certification and satisfy the requirements of this Directive that apply to them.
2. The manufacturer or his authorized representative established within the Community shall take all measures necessary in order that the manufacturing process ensures conformity of the products to the type as described in the EC type-examination certification and to the requirements of this Directive that apply to them. The manufacturer or his authorized representative established within the Community shall affix the CE marking to each product and draw up a written declaration of conformity.
  3. The manufacturer shall, before the start of manufacture, prepare documents defining the manufacturing processes, in particular as regards sterilization, together with all the routine, pre-established provisions to be implemented to ensure uniformity of production and conformity of the products with the type as described in the EC type-examination certificate as well as with the relevant requirements of this Directive.
  4. The manufacturer shall undertake to institute and keep updated a post-marketing surveillance system. This undertaking shall include the obligation on the part of the manufacturer to notify the competent authorities of the following events immediately on learning of them:
    - (i) any change in the characteristics or performances and any inaccuracies in the instruction leaflet for a device which might lead to or have led to the death of a patient or deterioration in his state of health;
    - (ii) any technical or medical reason resulting in the withdrawal of a device from the market by a manufacturer.
  5. The notified body shall carry out the appropriate examinations and tests in order to check the conformity of the product to the requirements of this Directive by examination and testing of products on a statistical basis, as specified in section 6. The manufacturer must authorize the notified body to evaluate the efficiency of the measures taken pursuant to section 3, by audit where appropriate.
- 6. Statistical verification**
- 6.1. Manufacturers shall present the products manufactured in the form of uniform batches and shall take all necessary measures in order that the manufacturing process ensures the uniformity of each batch produced.
  - 6.2. A random sample shall be taken from each batch. Products in a sample shall be individually examined and appropriate tests, as set out in the standard(s) referred to in Article 5, or equivalent tests shall be carried out to verify their conformity to the type as described in the EC type-examination certificate and thereby determine whether a batch is to be accepted or rejected.
  - 6.3. Statistical control of products shall be based on attributes, entailing a sampling system with the following characteristics:
    - a level of quality corresponding to a probability of acceptance of 95 %, with a non-conformity percentage of between 0,29 and 1 %,
    - a limit quality corresponding to a probability of acceptance of 5 %, with a percentage of non-conformity of between 3 and 7 %.
  - 6.4. Where batches are accepted, the notified body shall affix, or cause to be affixed, its identification number to each product and draw up a written certificate of conformity relating to the tests carried out. All products in the batch may be placed on the market except for those products from the sample which were found not to be in conformity.
 

Where a batch is rejected, the notified body shall take appropriate measures to prevent the placing on the market of that batch. In the event of frequent rejection of batches the notified body may suspend the statistical verification.

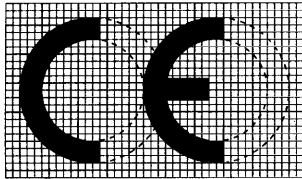
The manufacturer may, under the responsibility of the notified body, affix the latter's identification number during the manufacturing process.
  - 6.5. The manufacturer or his authorized representative shall ensure that he is able to supply the notified body's certificates of conformity on request.;
11. the second subparagraph of section 2 of Annex V is replaced by the following text:
- 'The manufacturer or his authorized representative established within the Community shall affix the CE marking in accordance with Article 12 and draw up a written declaration of conformity. This declaration shall cover one or more identified specimens of the product and shall be kept by the manufacturer. The CE marking shall be accompanied by the identification number of the notified body responsible.;

12. Annex IX is replaced by the following text:

'ANNEX IX

CE CONFORMITY MARKING

— The CE conformity marking shall consist of the initials "CE" taking the following form:



— If the CE marking is reduced or enlarged the proportions given in the above graduated drawing must be respected.

— The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm.

This minimum dimension may be waived for small-scale devices.'

Article 10

Directive 90/396/EEC is hereby amended as follows:

1. throughout the text, the term 'EC mark' is replaced by 'CE marking';

2. in Article 4 the first paragraph is replaced by the following text:

'1. Member States may not prohibit, restrict or impede the placing on the market and the putting into service of appliances which comply with all the provisions of this Directive, including the conformity assessment procedures laid down in Chapter II, and which bear the CE marking provided for in Article 10.';

3. in Article 8 the fifth paragraph is replaced by the following text:

'5. (a) Where the appliances are covered by other Directives dealing with other aspects and specifying the affixing of the CE marking, the latter shall indicate that the appliances are also presumed to conform to the provisions of those other Directives.

(b) However, where one or more of these Directives allow the manufacturer, during a transitional period, to choose which arrangements to apply, the CE marking shall indicate conformity to the provisions only of those Directives applied by the manufacturer. In this case, particulars of the Directives applied, as published in the *Official Journal of the European Communities*, must be given

in the documents, notices or instructions required by the Directives and accompanying such devices.';

4. in Article 9 the first paragraph is replaced by the following text:

'1. Member States shall notify the Commission and the other Member States of the bodies, which they have appointed to carry out the procedures referred to in Article 8 together with the specific tasks which these bodies have been appointed to carry out and the identification numbers assigned to them beforehand by the Commission.

The Commission shall, for information, publish in the *Official Journal of the European Communities*, a list of these bodies, and the identification numbers it has assigned to them and shall ensure that the list is kept up to date.';

5. in Article 10 the second paragraph is replaced by the following text:

'2. The affixing of markings on the appliances which are likely to deceive third parties as to the meaning and form of the CE marking shall be prohibited. Any other marking may be affixed to the appliance or to the data plate provided that the visibility and legibility of the CE marking is not hereby reduced.';

6. Article 11 is replaced by the following text:

'Article 11

Without prejudice to Article 7:

(a) where a Member State establishes that the CE marking has been affixed unduly, the manufacturer or his authorized representative established within the Community shall be obliged to make the product comply as regards the provisions concerning the CE marking and to end the infringement under conditions imposed by the Member State;

(b) where non-compliance continues, the Member State must take all appropriate measures to restrict or prohibit the placing on the market of the appliance in question or to ensure that it is withdrawn from the market in accordance with the procedures laid down in Article 7.';

7. Annex II is amended as follows:

(a) in point 2.1 the second sentence is replaced by the following text:

'The manufacturer or his authorized representative established within the Community shall affix the CE marking on each appliance and draw up a written certificate of conformity.';

(b) in point 2.1 the last sentence is replaced by the following text:

'The CE marking must be followed by the identification number of the notified body

responsible for the random checks set out in point 2.3.';

- (c) in point 3.1 the second sentence is replaced by the following text:

'The manufacturer or his authorized representative established within the Community must affix the CE marking to each appliance and draw up a written declaration of conformity.';

- (d) in point 3.1 the last sentence is replaced by the following text:

'The CE marking must be followed by the identification number of the notified body responsible for EC surveillance.';

- (e) in point 4.1 the second sentence is replaced by the following text:

'The manufacturer or his authorized representative established within the Community must affix the CE marking to each appliance and draw up a written declaration of conformity.';

- (f) in point 4.1 the last sentence is replaced by the following text:

'The CE marking must be followed by the identification number of the notified body responsible for EC surveillance.';

- (g) points 5 and 6 are replaced by the following text:

#### 5. EC VERIFICATION

5.1. EC verification is the procedure whereby the manufacturer or his authorized representative established within the Community ensures and declares that the appliances subject to the provisions of point 3 are in conformity to the type as described in the EC type-examination certification and satisfy the requirements of this Directive that apply to them.

5.2. The manufacturer or his authorized representative established within the Community must take all measures necessary in order that the manufacturing process ensures conformity of the appliances to the type as described in the EC type-examination certification and to the requirements of this Directive that apply to them. The manufacturer or his authorized representative established within the Community must affix the CE marking to each appliance and draw up a written declaration of conformity. The declaration of conformity may cover one or more appliances and must be kept by the manufacturer or his authorized representative established within the Community.

5.3. The notified body must carry out the appropriate examinations and tests in order

to check the conformity of the appliance to the requirements of this Directive by examination and testing of every appliance, as specified in point 5.4, or by examination and testing of appliances on a statistical basis, as specified in point 5.5, at the choice of the manufacturer.

#### 5.4. Verification by checking and testing of each appliance

5.4.1. All appliances must be individually examined and appropriate tests, as set out in the relevant standard(s) referred to in Article 5, or equivalent tests, must be carried out in order to verify their conformity with the type as described in the EC type-examination certificate and the requirements of this Directive that apply to them.

5.4.2. The notified body must affix, or cause to be affixed, its identification number on each appliance and draw up a written certificate of conformity relating to the tests carried out. The certificate of conformity may cover one or more appliances.

5.4.3. The manufacturer or his authorized representative must ensure that he is able to supply the notified body's certificates of conformity on request.

#### 5.5. Statistical verification

5.5.1. Manufacturers must present the appliances manufactured in the form of uniform batches and must take all necessary measures in order that the manufacturing process ensures the uniformity of each batch produced.

5.5.2. Statistical control is as follows:

Appliances are subject to statistical control by attributes. They should be grouped into identifiable batches consisting of units of a single model manufactured under the same conditions. A batch is examined at random intervals. The appliances constituting a sample are examined individually and appropriate tests, as laid down in the respective standard(s) referred to in Article 5, or equivalent tests are carried out to determine whether the batch is to be accepted or rejected.

A sampling system with the following characteristics is applied:

- a level of quality corresponding to a probability of acceptance of 95%, with a non-conformity percentage of between 0,5 and 1,5 %,



- a limit quality corresponding to a probability of acceptance of 5%, with a percentage of non-conformity of between 5 and 10%.

5.5.3. Where batches are accepted, the notified body must affix, or cause to be affixed, its identification number to each appliance and draw up a written certificate of conformity relating to the tests carried out. All appliances in the batch may be placed on the market except for those products from the sample which were found not to be in conformity.

Where a batch is rejected, the notified body must take appropriate measures to prevent the placing on the market of that batch. In the event of frequent rejection of batches the notified body may suspend the statistical verification.

The manufacturer may, under the responsibility of the notified body, affix the latter's identification number during the manufacturing process.

5.5.4. The manufacturer or his authorized representative must ensure that he is able to supply the notified body's certificates of conformity on request.

## 6. EC UNIT VERIFICATION

6.1. EC unit verification is the procedure whereby the manufacturer or his authorized representative established within the Community ensures and declares that the appliance concerned, which has been issued with the certificate referred to in point 2, conforms to the requirements of this Directive that apply to it. The manufacturer or his authorized representative must affix the CE marking to the appliance and draw up a written declaration of conformity which he must keep.

6.2. The notified body must examine the appliance and carry out the appropriate tests, taking account of the design documentation in order to ensure its conformity with the essential requirements of this Directive.

The notified body must affix, or cause to be affixed, its identification number to the approved appliance and must draw up a written certificate of conformity concerning the tests carried out.

6.3. The aim of the technical documentation relating to the design of the instrument, as referred to in Annex IV, is to enable conformity to the requirements of this Directive to be assessed and the design, manufacture and operation of the appliance to be understood.

The design documentation referred to in Annex IV must be made available to the notified body.

6.4. If deemed necessary by the notified body, the examinations and tests may be carried out after installation of the appliance.

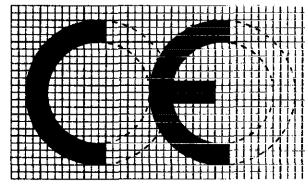
6.5. The manufacturer or his authorized representative must ensure that he is able to supply the notified body's certificates of conformity on request.

8. Annex III is replaced by the following text:

### *ANNEX III*

#### CE CONFORMITY MARKING AND INSCRIPTIONS

1. The CE conformity marking consists of the initials "CE" as shown below:



The CE marking must be followed by the identification number of the notified body involved in the production control phase.

2. The appliance or its data plate must bear the CE marking together with the following inscriptions:

- the manufacturer's name or identification symbol,
- the trade name of the appliance,
- the type of electrical supply used, if applicable,
- the appliance category,
- the last two digits of the year in which the CE marking was affixed.

Information needed for installation purposes may be added according to the nature of the appliance.

3. If the CE marking is reduced or enlarged the proportions given in the above graduated drawing must be respected.

The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm.

### *Article 11*

Directive 91/263/EEC is hereby amended as follows:

1. throughout the text, the term 'EC mark' is replaced by 'CE marking';

2. in Article 11 (4) the term 'the EC mark' is replaced by 'the initials CE as shown in Annex VI';
3. in Article 3 the first paragraph is replaced by the following text:
  - '1. Member States shall take all appropriate measures to ensure that terminal equipment may be placed on the market and put into service only if it bears the CE marking provided for in Article 11 attesting to its conformity to the requirements of this Directive, including the conformity assessment procedures laid down in Chapter II and where it is properly installed and maintained and used for its intended purpose.';
4. the following paragraph is added to Article 3:
  - '4. (a) Where the terminal equipment is subject to other Directives concerning other aspects and which also provide for the affixing of the CE marking, the latter shall indicate that the equipment is also presumed to conform to the provisions of those other Directives.
  - (b) However, where one or more of these Directives allow the manufacturer, during a transitional period, to choose which arrangements to apply, the CE marking shall indicate conformity to the provisions only of those Directives applied by the manufacturer. In this case, particulars of the Directives applied, as published in the *Official Journal of the European Communities*, must be given in the documents, notices or instructions required by the Directives and accompanying the terminal equipment.';
5. in Article 10 the first paragraph is replaced by the following text:
  - '1. Member States shall notify the Commission and the other Member States of the bodies established within the Community which they have designated for carrying out the certification, product checks and associated surveillance tasks pertaining to the procedures referred to in Article 9, together with the identification numbers assigned to them beforehand by the Commission.

Member States shall apply the minimum criteria set out in Annex V for the designation of such bodies. Bodies that satisfy the criteria fixed by the relevant harmonized standards shall be presumed to satisfy the criteria set out in Annex V.';
6. in Article 10 the third paragraph is replaced by the following text:
  - '3. The Commission shall publish in the *Official Journal of the European Communities* a list of notified bodies together with their identification numbers and a list of test laboratories together with the tasks for which they have been designated and shall ensure that these lists are kept up to date.';
7. in Article 11 the first paragraph is replaced by the following text:

'The marking of terminal equipment complying with this Directive shall consist of the CE marking consisting of the initials CE, followed by the identification number of the notified body involved in the production control stage and a symbol indicating that the equipment is intended and is suitable to be connected to the public telecommunications network. The form of CE marking to be used, together with the other information, is shown in Annex VI.';
8. in Article 11 the second paragraph is replaced by the following text:
  - '2. The affixing of markings on the equipment which are likely to deceive third parties as to the meaning and form of the CE marking specified in Annexes VI and VII shall be prohibited. Any other marking may be affixed to the equipment provided that the visibility and legibility of the CE marking is not thereby reduced.';
9. Article 12 is replaced by the following text:

'Article 12

Without prejudice to Article 8:

  - (a) where a Member State establishes that the CE marking has been affixed unduly, the manufacturer or his authorized representative established within the Community shall be obliged to make the equipment conform as regards the provisions concerning the CE marking and to end the infringement under the conditions imposed by the Member State.
  - (b) where non-conformity continues, the Member State must take all appropriate measures to restrict or prohibit the placing on the market of the equipment in question or to ensure that it is withdrawn from the market in accordance with the procedures laid down in Article 8.';
10. in Annexes II and III the last sentence of point 1 is replaced by the following text:

'The manufacturer or his authorized representative established within the Community shall affix the markings provided for in Article 11 (1) to each product and draw up a written declaration of conformity to type.';
11. in Annex IV the last sentence of point 1 is replaced by the following text:

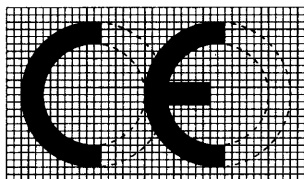
'The manufacturer or his authorized representative shall affix the markings provided for in Article 11 (1) to each product and draw up a written declaration of conformity.';

12. Annex VI is replaced by the following text:

*'ANNEX VI*

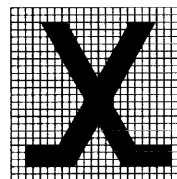
**MARKING FOR THE TERMINAL EQUIPMENT REFERRED TO IN ARTICLE 11 (1)**

— The CE conformity marking shall consist of the initials "CE" taking the following form, followed by the additional information referred to in Article 11 (1);



CE initials

Identification number of the notified body



Symbol of suitability for connection to the public telecommunications network

(See *Official Journal of the European Communities* for character font)

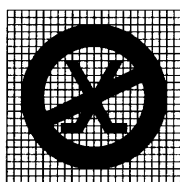
- If the CE marking is reduced or enlarged the proportions given in the above graduated drawing must be respected.
- The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm.;

service within their territories of appliances and boilers which comply with the provisions of this Directive and which bear the CE marking provided for in Article 7 attesting to the conformity to all the provisions of this Directive, including the conformity assessment procedures laid down in Articles 7 and 8, save as otherwise laid down in the Treaty or other Directives or Community provisions.;

13. Annex VII is amended as follows:

*'ANNEX VII*

**MARKING FOR THE EQUIPMENT REFERRED TO IN ARTICLE 11 (4)**



- If the CE marking is reduced or enlarged the proportions given in the above graduated drawing must be respected.
- The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm.;

*Article 12*

Directive 92/42/EEC is hereby amended as follows:

1. throughout the text, the term 'EC mark' is replaced by 'CE marking';
2. in Article 4 the first paragraph is replaced by the following text:
  - '1. Member States may not prohibit, restrict or impede the placing on the market or entry into

3. the following paragraph 5 is added to Article 4:

'5. (a) Where the boilers are subject to other Directives concerning other aspects which also provide for the affixing of the CE marking, the latter shall indicate that the boilers in question are also presumed to conform to the provisions of those other Directives.

(b) However, where one or more of these Directives allow the manufacturer, during a transitional period, to choose which arrangements to apply, the CE marking shall indicate conformity to the provisions only of those Directives applied by the manufacturer. In this case, particulars of the Directives applied, as published in the *Official Journal of the European Communities*, must be given in the documents, notices or instructions required by the Directives and accompanying the boilers.;

4. in Article 7 the fourth paragraph is replaced by the following text:

'4. The CE mark of conformity to the requirements of this Directive and to the other provisions concerning the granting of the CE marking, and also the inscriptions specified in Annex I, shall be affixed on boilers in a visible, easily legible and indelible manner. The affixing on such

products of any markings likely to deceive third parties as to the meaning and form of the CE marking shall be prohibited. Any other marking may be affixed to the boilers and appliances provided that the visibility and legibility of the CE marking is not thereby reduced.';

5. the following paragraph is added to Article 7:

'5. (a) Where a Member State or a notified body establishes that the CE marking has been affixed unduly, the manufacturer or his agent established within the Community shall be obliged to make the boiler comply as regards the provisions concerning the CE marking and to end the infringement under conditions imposed by the Member State;

(b) where non-compliance continues, the Member State must take all appropriate measures to restrict or prohibit the placing on the market of the product in question or to ensure that it is withdrawn from the market, and shall inform the Commission and the other Member States accordingly.';

6. in Article 8 the first paragraph is replaced by the following text:

'1. Member States shall inform the Commission and the other Member States of the bodies which they have appointed to carry out the procedures referred to in Article 7, together with specific tasks which these bodies have been appointed to carry out and the identification numbers assigned to them beforehand by the Commission.

The Commission shall publish in the *Official Journal of the European Communities* a list of the notified bodies with their identification numbers and the tasks for which they have been notified. The Commission shall ensure that this list is kept up to date.';

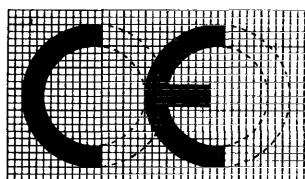
7. Annex I is replaced by the following text:

'ANNEX I

**CE CONFORMITY MARKING AND ADDITIONAL SPECIFIC MARKINGS**

**1. CE conformity marking**

The CE conformity marking shall consist of the initials "CE" taking the following form:



— If the CE marking is reduced or enlarged the proportions given in the above graduated drawing must be respected.

— The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm.

**2. Additional specific markings**

— The last two digits of the year in which the EC marking was affixed.

— The energy performance label awarded under Article 6 of this Directive consists of the following symbol:



8. Annex IV is amended as follows:

(a) the last sentence of section 1 of module C is replaced by the following text:

'The manufacturer or his authorized representative established within the Community shall affix the CE marking to each appliance and draw up a written declaration of conformity.';

(b) the last two sentences of section 1 of module D are replaced by the following text:

'The manufacturer or his authorized representative established within the Community shall affix the CE marking to each appliance and draw up a written declaration of conformity. The CE mark is accompanied by the identification number of the notified body responsible for the checks referred to in section 4.';

(c) the last two sentences of section 1 of module E are replaced by the following text:

'The manufacturer or his authorized representative established within the Community shall affix the CE marking to each boiler and appliance and draw up a written declaration of conformity. The CE marking must be accompanied by the identification number of the notified body responsible for the checks referred to in section 4.'

*Article 13*

Directive 73/23/EEC is hereby amended as follows:

1. in the preamble the following two recitals are added to the end:

'Whereas Decision 90/683/EEC (\*) establishes the modules for the various phases of the conformity

assessment procedures which are intended to be used in the technical harmonization Directives;

Whereas the choice of procedures must not lead to a lowering of safety standards of electrical equipment, which have already been established throughout the Community,

(\* ) OJ No L 380, 31. 12. 1990, p. 13.;

2. in Article 8 the first paragraph is replaced by the following text:

'1. Before being placed on the market, the electrical equipment referred to in Article 1 must have affixed to it the CE marking provided for in Article 10 attesting to its conformity to the provisions of this Directive, including the conformity assessment procedure described in Annex IV.;

3. the following paragraph 3 is added to Article 8:

'3. (a) Where electrical equipment is subject to other Directives concerning other aspects which also provide for the affixing of the CE marking, the latter shall indicate that the equipment in question is also presumed to conform to the provisions of those other Directives.

(b) However, where one or more of these Directives allow the manufacturer, during a transitional period, to choose which arrangements to apply, the CE marking shall indicate conformity to the provisions only of those Directives applied by the manufacturer. In this case, particulars of the Directives applied, as published in the *Official Journal of the European Communities*, must be given in the documents, notices or instructions required by the Directives and accompanying the electrical equipment.;

4. Article 10 is replaced by the following text:

*'Article 10*

1. The CE conformity marking referred to in Annex III shall be affixed by the manufacturer or his authorized representative established within the Community to the electrical equipment or, failing that, to the packaging, the introduction sheet or the guarantee certificate so as to be visible, easily legible and indelible.

2. The affixing on electrical equipment of any markings liable to deceive third parties as to the meaning and form of the CE marking shall be prohibited. However, any other marking may be affixed to the electrical equipment, its packaging, the instruction sheet or the guarantee certificate provided that the visibility and legibility of the CE marking is not thereby reduced.

3. Without prejudice to Article 9:

(a) where a Member State establishes that the CE marking has been affixed unduly, the manufacturer or his agent established within the Community market shall be obliged to make the electrical equipment comply as regards the provisions concerning the CE marking and to end the infringement under conditions imposed by the Member State;

(b) where non-compliance continues, the Member State must take all appropriate measures to restrict or prohibit the placing on the market of the electrical equipment in question or to ensure that it is withdrawn from the market in accordance with the procedure laid down in Article 9.;

5. in Article 11 the second indent is deleted;

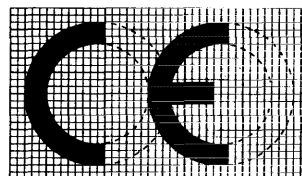
6. the following Annexes are added:

*'ANNEX III*

**CE CONFORMITY MARKING AND EC DECLARATION OF CONFORMITY**

**A. CE conformity marking**

The CE conformity marking shall consist of the initials "CE" taking the following form:



— If the CE marking is reduced or enlarged the proportions given in the above graduated drawing must be respected.

— The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm.

**B. EC declaration of conformity**

The EC declaration of conformity must contain the following elements:

— name and address of the manufacturer or his authorized representative established within the Community,

— a description of the electrical equipment,

— reference to the harmonized 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 authorized representative established within the Community,
- the last two digits of the year in which the CE marking was affixed.

## ANNEX IV

## INTERNAL PRODUCTION CONTROL

1. Internal production control is the procedure whereby the manufacturer or his authorized representative established within the Community, who carries out the obligations laid down in point 2, ensures and declares that the electrical equipment satisfies the requirements of this Directive that apply to it. The manufacturer or his authorized representative established within the Community must affix the CE marking to each product and draw up a written declaration of conformity.

2. The manufacturer must establish the technical documentation described in point 3 and he or his authorized representative established within the Community must keep it on Community territory at the disposal of the relevant national authorities for inspection purposes for a period ending at least 10 years after the last product has been manufactured.

Where neither the manufacturer nor his authorized representative is established within the Community, this obligation is the responsibility of the person who places the electrical equipment on the Community market.

3. Technical documentation must enable the conformity of the electrical equipment to the requirements of this Directive to be assessed. It must, as far as relevant for such assessment, cover the design, manufacture and operation of the electrical equipment. It must include:

- a general description of the electrical equipment,
- conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,
- descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the electrical equipment,
- a list of the standards applied in full or in part, and descriptions of the solutions adopted to satisfy the safety aspects of this Directive where standards have not been applied,

- results of design calculations made, examinations carried out, etc.
- test reports.

4. The manufacturer or his authorized representative must keep a copy of the declaration of conformity with the technical documentation.
5. The manufacturer must take all measures necessary in order that the manufacturing process shall ensure compliance of the manufactured products with the technical documentation referred to in point 2 and with the requirements of this Directive that apply to them.'

*Article 14*

1. Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive by 1 July 1994. They shall forthwith inform the Commission thereof.

They shall apply these provisions from 1 January 1995.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such a reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.

2. Until 1 January 1997 Member States shall allow the placing on the market and the bringing into service of products which comply with the marking arrangements in force before 1 January 1995.

3. Member States shall communicate to the Commission the texts of the provisions of national law which they adopt in the field covered by this Directive. The Commission shall inform the other Member States thereof.

*Article 15*

This Directive is addressed to the Member States.

Done at Brussels, 22 July 1993.

*For the Council*  
*The President*

M. OFFECIERS-VAN DE WIELE