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(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 ⁽¹⁾,

In cooperation with the European Parliament ⁽²⁾,

Having regard to the opinion of the Economic and Social Committee ⁽³⁾,

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 ⁽⁴⁾; 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 ⁽⁵⁾, 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 ⁽⁶⁾, 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,

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

⁽²⁾ 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).

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

⁽⁴⁾ OJ No C 136, 4. 6. 1985, p. 1.

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

⁽⁶⁾ OJ No C 10, 16. 1. 1990, p. 1.

HAS ADOPTED THIS DIRECTIVE:

including the mutual recognition of their conformity ⁽¹⁰⁾;

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 ⁽¹⁾;
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 ⁽²⁾;
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 ⁽³⁾;
4. Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility ⁽⁴⁾;
5. Council Directive 89/392/EEC of 14 June 1989 on the approximation of the laws of the Member States relating to machinery ⁽⁵⁾;
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 ⁽⁶⁾;
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 ⁽⁷⁾;
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 ⁽⁸⁾;
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 ⁽⁹⁾;
10. Council Directive 91/263/EEC of 29 April 1991 on the approximation of the laws of the Member States concerning telecommunications terminal equipment,

11. Council Directive 92/42/EEC of 21 May 1992 on efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels ⁽¹¹⁾;
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 ⁽¹²⁾.

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.'

⁽¹⁾ 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).

⁽²⁾ OJ No L 187, 16. 7. 1988, p. 1.

⁽³⁾ OJ No L 40, 11. 2. 1989, p. 12.

⁽⁴⁾ 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).

⁽⁵⁾ 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).

⁽⁶⁾ OJ No L 399, 30. 12. 1989, p. 18.

⁽⁷⁾ OJ No L 189, 20. 7. 1990, p. 1.

⁽⁸⁾ OJ No L 189, 20. 7. 1990, p. 17.

⁽⁹⁾ OJ No L 196, 26. 7. 1990, p. 15.

⁽¹⁰⁾ OJ No L 128, 23. 5. 1991, p. 1.

⁽¹¹⁾ OJ No L 167, 22. 6. 1992, p. 17.

⁽¹²⁾ 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:

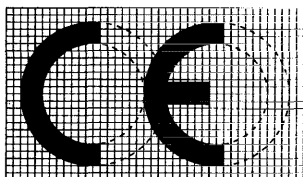
‘2. The affixing of markings on the vessels which are likely to deceive third parties as to the meaning and form of the CE marking shall be prohibited. Any other marking may be affixed to the vessels or the data plate provided that the visibility and legibility of the CE marking is not thereby reduced.’;

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;

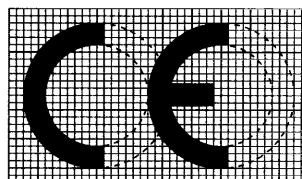
(b) where non-conformity continues, the Member State must take all appropriate measures to restrict or prohibit the placing on the market of the product in question or to ensure that it is withdrawn from the market in accordance with the procedures laid down in Article 7.'

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:

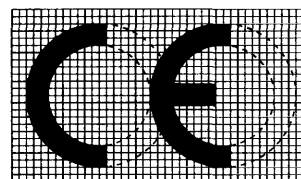
'1. Member States shall notify the Commission and the other Member States of the certification and inspection bodies and the testing laboratories which they have designated for the tasks which must be carried out for the purposes of technical approval, certificates of conformity, inspections and tests, 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

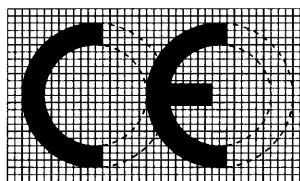
provisions concerning the CE marking and to end the infringement under conditions imposed by the Member State;

- (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:

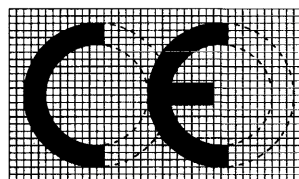
'— the year of construction';

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);

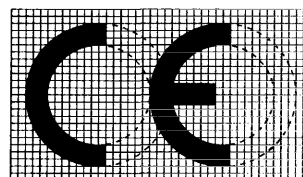
(i) the name, address and identification number of the notified body involved in the design stage of the PPE.';

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:

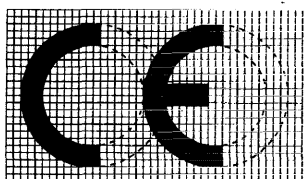
- '— the last two digits of the year in which the CE marking was affixed;';

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:

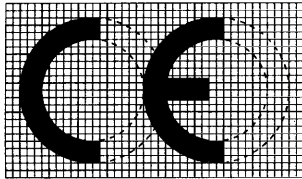
'The manufacturer or his authorized representative established within the Community shall affix the CE marking in accordance with Article 12 and draw up a written declaration of conformity. This declaration shall cover one or more identified specimens of the product and shall be kept by the manufacturer. 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.

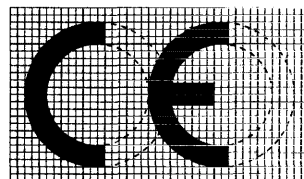
6.5. The manufacturer or his authorized representative must ensure that he is able to supply the notified body's certificates of conformity on request.

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:

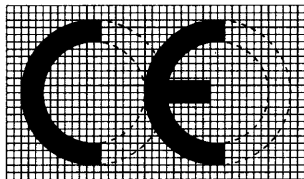
'The manufacturer or his authorized representative shall affix the markings provided for in Article 11 (1) to each product and draw up a written declaration of conformity.'

12. Annex VI is replaced by the following text:

'ANNEX VI

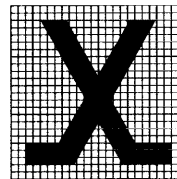
MARKING FOR THE TERMINAL EQUIPMENT REFERRED TO IN ARTICLE 11 (1)

- 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)

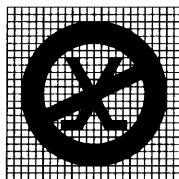
- If the CE marking is reduced or enlarged the proportions given in the above graduated drawing must be respected.
- The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm.;

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.';

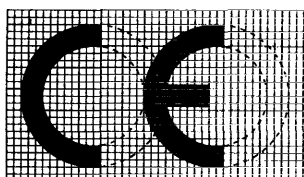
7. Annex I is replaced by the following text:

'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;

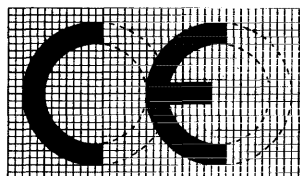
6. the following Annexes are added:

'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

COUNCIL DECISION

of 22 July 1993

concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonization directives

(93/465/EEC)

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 ⁽¹⁾,

In cooperation with the European Parliament ⁽²⁾,

Having regard to the opinion of the Economic and Social Committee ⁽³⁾,

Whereas Council Decision 90/683/EEC of 13 December 1990 concerning the modules for the various phases of the conformity assessment procedures which are intended to be used in the technical harmonization directives ⁽⁴⁾ needs to be substantially amended in various places; whereas it is necessary, in a spirit of clarity and rationality, to consolidate its provisions by means of this Decision;

Whereas the Council adopted a Resolution on 21 December 1989 concerning a global approach to conformity assessments ⁽⁵⁾;

Whereas the introduction of harmonized methods for the assessment of conformity and the adoption of a common doctrine for their implementation are likely to facilitate the adoption of future technical harmonization directives concerning the placing on the market of industrial products and thus be conducive to the implementation of the internal market;

Whereas such methods should ensure that products are in full conformity with the essential requirements laid down in the technical harmonization directives, in order to provide, in particular, for the health and safety of users and consumers;

Whereas such conformity should be assured without imposing unnecessarily onerous conditions on manufacturers, and by means of clear and comprehensible procedures;

Whereas limited flexibility should be introduced as regards use of additional modules, or variations in the modules, when the specific circumstances of a particular sector or directive so warrant, but not to such a degree as to undercut the purpose of the current Decision and only when explicitly justified;

Whereas in the abovementioned Resolution of 21 December 1989 the Council approved as a guiding principle the adoption of common rules on the use of the CE marking;

Whereas in its Decision 90/683/EEC the Council laid down that the industrial products covered by the technical harmonization directives can be placed on the market only after the manufacturer has affixed the CE marking to them;

Whereas a single CE marking should be used in order to facilitate controls on the Community market by inspectors and to clarify the obligations of economic operators in respect of marking under the various Community regulations;

Whereas the aim of the CE marking is to symbolize the conformity of a product with the levels of protection of collective interests imposed by the total harmonization directives and to indicate that the economic operator has undergone all the evaluation procedures laid down by Community law in respect of his product,

HAS DECIDED AS FOLLOWS:

Article 1

1. The procedures for conformity assessment which are to be used in the technical harmonization directives relating to the marketing of industrial products will be chosen from among the modules listed in the Annex and in accordance with the criteria set out in this Decision and in the general guidelines in the Annex.

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

⁽²⁾ 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).

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

⁽⁴⁾ OJ No L 380, 31. 12. 1990, p. 13.

⁽⁵⁾ OJ NO C 10, 16. 1. 1990, p. 1.

These procedures may only depart from the modules when the specific circumstances of a particular sector or directive so warrant. Such departures from the modules must be limited in extent and must be explicitly justified in the relevant directive.

2. This Decision lays down rules for affixing the CE conformity marking provided for in Community legislation concerning the design, manufacture, placing on the market, entry into service or use of industrial products.

3. The Commission shall report periodically on the functioning of this Decision, and on whether conformity assessment and CE marking procedures are working satisfactorily or need to be modified.

No later than the end of the transitional period in 1997, or earlier if the matter is found to be urgent, the Commission shall also report back on any special problems raised by the incorporation of Council Directive 73/23/EEC of 19 February 1973 relating to electrical

equipment designed for use within certain voltage limits ⁽¹⁾ within the scope of CE marking procedures, and, in particular, whether safety is being compromised. It shall also review any problems raised by the issue of overlapping Council directives, and whether any further Community measures are required.

Article 2

1. Decision 90/683/EEC is hereby repealed.
2. References to the Decision repealed shall be construed as references to this Decision.

Done at Brussels, 22 July 1993.

For the Council
The President

M. OFFECIERS-VAN DE WIELE

⁽¹⁾ OJ No L 77, 26. 3. 1973, p. 29.

ANNEX

CONFORMITY ASSESSMENT PROCEDURES AND CE MARKING IN THE TECHNICAL HARMONIZATION DIRECTIVES

I. GENERAL GUIDELINES

A. The principal guidelines for the use of conformity assessment procedures in technical harmonization directives are the following:

- (a) the essential objective of a conformity assessment procedure is to enable the public authorities to ensure that products placed on the market conform to the requirements as expressed in the provisions of the directives, in particular with regard to the health and safety of users and consumers;
- (b) conformity assessment can be subdivided into modules which relate to the design phase of products and to their production phase;
- (c) as a general rule a product should be subject to both phases before being able to be placed on the market if the results are positive (*);
- (d) there are a variety of modules which cover the two phases in a variety of ways. The directives must set the range of possible choices which can be considered by the Council to give the public authorities the high level of safety they seek, for a given product or product sector;
- (e) in setting the range of possible choices open to the manufacturer, the directives, will take into consideration, in particular, such issues as the appropriateness of the modules to the type of products, the nature of the risks involved, the economic infrastructures of the given sector (e.g. existence or non-existence of third parties), the types and importance of production, etc. The factors that have been taken into account must be explicitly spelled out by the Commission in these directives;
- (f) the directives will, in setting the range of possible modules for a given product or product sector, attempt to leave as wide a choice to the manufacturer as is consistent with ensuring compliance with the requirements.

The directives will set out the criteria governing the conditions in which the manufacturer chooses the most appropriate modules for his production from the modules laid down by the directives;

- (g) the directives should avoid imposing unnecessarily modules which would be too onerous relative to the objectives of the directive concerned;
- (h) notified bodies should be encouraged to apply the modules without unnecessary burden for the economic operators. The Commission, in cooperation with the Member States, must ensure that close cooperation is organized between the notified bodies in order to ensure consistent technical application of the modules;
- (i) in order to protect the manufacturers, the technical documentation provided to notified bodies has to be limited to that which is required solely for the purpose of assessment of conformity. Legal protection of confidential information is required;
- (j) whenever directives provide the manufacturer with the possibility of using modules based on quality assurance techniques, the manufacturer must also be able to have recourse to a combination of modules not using quality assurance, and *vice versa*, except where compliance with the requirements laid down by the directives requires the exclusive application of a certain procedure;
- (k) for the purposes of operating the modules, Member States must notify on their own responsibility bodies under their jurisdiction which they have chosen from the technically competent bodies complying with the requirements of the directives. This responsibility involves the obligation for the Member States to ensure that the notified bodies permanently have the technical qualifications required by the directives and that the latter keep their competent national authorities informed of the performance of their tasks. Where a Member State withdraws its notification of a body, it must take appropriate steps to ensure that the dossiers are processed by another notified body to ensure continuity;

(*) The specific directives may provide for different arrangements.

- (l) in addition, with regard to conformity assessment, the sub-contracting of work shall be subject to certain conditions guaranteeing:
 - the competence of the establishment operating as sub-contractor, on the basis of conformity with series EN 45 000 standards, and the capability of the Member State that has notified the sub-contracting body to ensure effective monitoring of such compliance,
 - the ability of the body notified to exercise effective responsibility for the work carried out under sub-contract;
- (m) notified bodies which can prove their conformity with harmonized standards (EN 45 000 series), by submitting an accreditation certificate or other documentary evidence, are presumed to conform to the requirements of the directives. Member States having notified bodies unable to prove their conformity with the harmonized standards (EN 45 000 series) may be requested to provide the Commission with the appropriate supporting documents on the basis of which notification was carried out;
- (n) a list of notified bodies must be published by the Commission in the *Official Journal of the European Communities* and constantly updated.

B. The principal guidelines for the affixing and use of the CE marking are the following:

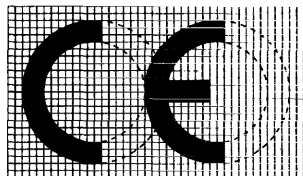
- (a) The CE marking symbolizes conformity to all the obligations incumbent on manufacturers for the product by virtue of the Community directives providing for its affixing.

Thus, such conformity is not limited to the essential requirements relating to safety, public health, consumer protection, etc., as certain directives may impose specific obligations not necessarily forming part of the essential requirements.

- (b) The CE marking affixed to industrial products symbolizes the fact that the natural or legal person having affixed or been responsible for the affixing of the said marking has verified that the product conforms to all the Community total harmonization provisions which apply to it and has been the subject of the appropriate conformity evaluation procedures.
- (c) Where the industrial products are subject to other directives concerning other aspects and which also provide for the affixing of the CE marking, the latter must indicate that the products are also presumed to conform to the provisions of 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 indicates 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 accompanying the products or, where appropriate, on the data plate.

- (d) 1. The CE conformity marking must 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.

- 2. Where the directive concerned does not impose specific dimensions, the CE marking must have a height of at least 5 mm.

3. The CE marking must be affixed to the product or to its data plate. However, where this is not possible or not warranted on account of the nature of the product, it must be affixed to the packaging, if any, and to the accompanying documents, where the directive concerned provides for such documents.

4. The CE marking must be affixed visibly, legibly and indelibly.

- (e) Any industrial product covered by the technical harmonization directives based on the principles of the global approach must bear the CE marking, save where the specific directives provide otherwise; such exceptions constitute derogations not from the marking requirement but from the administrative procedures for conformity evaluation, which may in certain cases be considered too cumbersome. Appropriate grounds must accordingly be given for any exception to or derogation from the marking requirement.

The CE marking is the only marking which certifies that the industrial products conform to the directives based on the principles of the global approach.

Member States must refrain from introducing into their national regulations any reference to a conformity marking other than the CE marking in connection with conformity to all the provisions contained in the directives on CE marking.

- (f) The CE marking must be affixed at the end of the production control phase.
- (g) The CE conformity marking must be followed by the identification number of the notified body within the meaning of paragraph I.A where the said body is involved in the production control phase within the meaning of this Decision.

Such identification numbers must be assigned by the Commission as part of the body notification procedure. The Commission must publish lists of the notified bodies in the *Official Journal of the European Communities*; such lists must be updated regularly.

A notified body must be assigned the same number when it is notified under several directives. The Commission must ensure that each notified body receives a single identification number, however many directives it is notified under.

- (h) It is necessary to lay down provisions concerning the use of certain products. In this case, the CE marking and the identification number of the notified body may be followed by a pictogram or any other mark indicating, for example, the category of use.
- (i) The affixing for any other marking liable to deceive third parties as to the meaning and form of the CE marking must be prohibited.
- (j) A product may bear different marks, for example marks indicating conformity to national or European standards or with traditional optional directives, provided such marks are not liable to cause confusion with the CE marking.

Such marks may therefore only be affixed to the product, its packaging or the documentation accompanying the product on condition that the legibility and visibility of the CE marking are not thereby reduced.

- (k) The CE marking must be affixed by the manufacturer or his agent established within the Community. In exceptional, duly warranted cases, the specific directives may provide that the CE marking can be affixed by the person responsible for placing the product on the Community market.

The identification number of the notified body must be affixed under its responsibility either by the body itself or by the manufacturer or his agent established within the Community.

- (l) Member States must take all provisions of national law necessary to exclude any possibility of confusion and to prevent abuse of the CE marking.

Without prejudice to the provisions in the directive concerned relating to the application of the safeguard clause, where a Member State establishes that the CE marking has been affixed

unduly, the manufacturer, his agent or, exceptionally, where the specific directives so provide, the person responsible for placing the product in question on the Community market is obliged to make the product comply and to end the infringement under conditions imposed by the Member State. 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 the safeguard clauses.

II. MODULES FOR CONFORMITY ASSESSMENT

Explanatory notes

Specific directives may allow the CE marking to be affixed to the packaging or the accompanying documentation, instead of to the product itself.

The declaration of conformity or the certificate of conformity (whichever of the two applies in the directive concerned) must cover either individual or several products and shall either accompany the product(s) covered or be kept by the manufacturer. The appropriate solution for the directive concerned will be specified.

References to Articles refer to the standard paragraphs of Annex II.B to the Council resolution of 7 May 1985 (OJ No C 136, 4. 6. 1985, p. 1), which have become standard Articles in the 'new approach' directives.

The development of computerized communication of certificates and other documents issued by notified bodies is envisaged within INSIS.

Specific directives may use modules A, C and H with additional provisions containing supplementary requirements which figure in the boxes in the modules.

Module C is designed to be used in combination with module B (EC type-examination). Modules D, E and F will also normally be used in combination with module B; however, in special cases (for example, when dealing with certain products of very simple design and construction) they may be used on their own.

Module A (internal production control)

1. This module describes 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 products concerned satisfy the requirements of the directive that apply to them. The manufacturer or his authorized manufacturer 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 paragraph 3 and he or his authorized representative established within the Community must keep it for a period ending at least 10 years (*) after the last product has been manufactured at the disposal of the relevant national authorities for inspection purposes.

Where neither the manufacturer nor his authorized representative is established within the Community, the obligation to keep the technical documentation available is the responsibility of the person who places the product on the Community market.

3. Technical documentation must enable the conformity of the product with the requirements of the directive to be assessed. It must, as far as relevant for such assessment, cover the design, manufacture and operation of the product (**).

(*) The specific directives may alter this period.

(**) The content of the technical documentation shall be laid down directive by directive in accordance with the products concerned.

For example, the documentation must contain so far as relevant for assessment:

- a general description of the product,
- 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 product,
- a list of the standards referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the directive where the standards referred to in Article 5 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 ensures compliance of the manufactured products with the technical documentation referred to in point 2 and with the requirements of the directive that apply to them.

Module Aa

This module consists of module A, plus the following supplementary requirements:

For each product manufactured one or more tests on one or more specific aspects of the product must be carried out by the manufacturer or on his behalf (*). The tests are carried out on the responsibility of a notified body chosen by the manufacturer.

On the responsibility of the notified body, the manufacturer must affix the former's identification number during the manufacturing process.

(*) If this option is adopted in a specific directive, the products concerned and the tests to be carried out must be specified.

or:

A notified body chosen by the manufacturer must carry out or have carried out product checks at random intervals. An adequate sample of the final products, taken on site by the notified body, must be examined and appropriate tests as set out in the relevant standard(s) referred to in Article 5, or equivalent tests, must be carried out to check the conformity of the product with the relevant requirements of the directive.

In those cases where one or more of the products checked do not conform the notified body must take appropriate measures.

The product checking must include the following aspects:

(Relevant aspects must be specified here such as for example the statistical method to be applied, the sampling plan with its operational characteristics, etc.)

On the responsibility of the notified body, the manufacturer must affix the former's identification number during the manufacturing process.

Module B (EC type-examination)

1. This module describes that part of the procedure by which a notified body ascertains and attests that a specimen, representative of the production envisaged, meets the provisions of the directive that apply to it.
2. The application for the EC type-examination must be lodged by the manufacturer or his authorized representative established within the Community with a notified body of his choice.

The application must include:

- the name and address of the manufacturer and, if the application is lodged by the authorized representative, his name and address in addition,
- a written declaration that the same application has not been lodged with any other notified body,
- the technical documentation, as described in point 3.

The applicant must place at the disposal of the notified body a specimen, representative of the production envisaged and hereinafter called 'type' (*). The notified body may request further specimens if needed for carrying out the test programme.

(*) A type may cover several versions of the product provided that the differences between the versions do not affect the level of safety and the other requirements concerning the performance of the product.

3. The technical documentation must enable the conformity of the product with the requirements of the directive to be assessed. It must, as far as relevant for such assessment, cover the design, manufacture and operation of the product (*).
4. The notified body must:
 - 4.1. examine the technical documentation, verify that the type has been manufactured in conformity with the technical documentation and identify the elements which have been designed in accordance with the relevant provisions of the standards referred to in Article 5, as well as the components which have been designed without applying the relevant provisions of those standards;
 - 4.2. perform or have performed the appropriate examinations and necessary tests to check whether, where the standards referred to in Article 5 have not been applied, the solutions adopted by the manufacturer meet the essential requirements of the directive;
 - 4.3. perform or have performed the appropriate examinations and necessary tests to check whether, where the manufacturer has chosen to apply the relevant standards, these have actually been applied;
 - 4.4. agree with the applicant the location where the examinations and necessary tests will be carried out.
5. Where the type meets the provisions of the directive, the notified body must issue an EC type-examination certificate to the applicant. The certificate must contain the name and address of the manufacturer, conclusions of the examination, conditions for its validity and the necessary data for identification of the approved type (**).

A list of the relevant of the technical documentation must be annexed to the certificate and a copy kept by the notified body.

If the manufacturer is denied a type certification, the notified body must provide detailed reasons for such denial.

Provision must be made for an appeals procedure.

6. The applicant must inform the notified body that holds the technical documentation concerning the EC type-examination certificate of all modifications to the approved product which must receive additional approval where such changes may affect the conformity with the essential requirements or the prescribed conditions for use of the product. This additional approval is given in the form of an addition to the original EC type-examination certificate.
7. Each notified body must communicate to the other notified bodies the relevant information concerning the EC type-examination certificates and additions issued and withdrawn (**).
8. The other notified bodies may receive copies of the EC type-examination certificates and/or their additions. The Annexes to the certificates must be kept at the disposal of the other notified bodies.
9. The manufacturer or his authorized representative must keep with the technical documentation copies of EC type-examination certificates and their additions 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, the obligation to keep the technical documentation available is the responsibility of the person who places the product on the Community market.

(*) The content of the technical documentation must be laid down directive by directive in accordance with the products concerned.

For example, the documentation must contain as far as is relevant for assessment:

- a general type-description,
- 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 product,
- a list of the standards referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the directive where the standards referred to in Article 5 have not been applied,
- results of design calculations made, examinations carried out, etc.,
- test reports.

(**) The specific directives may provide for the certificate to have a period of validity.

(***) The specific directives may provide for different arrangements.

(****) The specific directives may alter this period.

Module C (conformity to type)

1. This module describes that part of the procedure whereby the manufacturer or his authorized representative established within the Community ensures and declares that the products concerned are in conformity with the type as described in the EC type-examination certificate and satisfy the requirements of the directive that applies to them. 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 take all measures necessary to ensure that the manufacturing process assures compliance of the manufactured products with the type as described in the EC type-examination certificate and with the requirements of the directive that apply to them.
3. The manufacturer or his authorized representative must keep a copy of the declaration of conformity 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, the obligation to keep the technical documentation available is the responsibility of the person who places the product on the Community market.

Possible supplementary requirements:

For each product manufactured one or more tests on one or more specific aspects of the product must be carried out by the manufacturer or on his behalf (*). The tests must be carried out on the responsibility of a notified body, chosen by the manufacturer.

On the responsibility of the notified body, the manufacturer must affix the former's identification number during the manufacturing process.

(*) If this option is adopted in a specific directive, the products concerned and the tests to be carried out must be specified.

or:

A notified body chosen by the manufacturer must carry out or have carried out product checks at random intervals. An adequate sample of the final products, taken on site by the notified body, must be examined and appropriate tests as set out in the relevant standard(s) referred to in Article 5, or equivalent tests, must be carried out to check the conformity of production with the relevant requirements of the directive. In those cases where one or more of the products checked do not conform, the notified body must take appropriate measures.

The product checking must include the following aspects:

(Relevant aspects must be specified here such as for example the statistical method to be applied, the sampling plan with its operational characteristics, etc.)

On the responsibility of the notified body, the manufacturer must affix the former's identification number during the manufacturing process.

Module D (*), (production quality assurance)

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of point 2 ensures and declares that the products concerned [are in conformity with the type as described in the EC type-examination certificate and] satisfy the requirements of the directive that apply to them. 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. The CE marking must be accompanied by the identification symbol of the notified body responsible for EC monitoring as specified in point 4.
2. The manufacturer must operate an approved quality system for production, final product inspection and testing as specified in paragraph 3 and is subject to monitoring as specified in point 4.

(*) The specific directives may alter this period.

(**) Where this module is used without module B:

- points 2 and 3 of module A must be added between points 1 and 2 in order to incorporate the need for technical documentation,
- the words in square brackets must be deleted.

3. *Quality system*

- 3.1. The manufacturer must lodge an application for assessment of his quality system with a notified body of his choice, for the products concerned.

The application must include:

- all relevant information for the product category envisaged,
- the documentation concerning the quality system,
- if applicable, the technical documentation of the approved type and a copy of the EC type-examination certificate.

- 3.2. The quality system must ensure compliance of the products [with the type as described in the EC type-examination certificate and] with the requirements of the directive that apply to them.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation must permit a consistent interpretation of the quality programmes, plan, manuals and records.

It must contain in particular and adequate description of:

- the quality objectives and the organizational structure, responsibilities and powers of the management with regard to product quality,
- the manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used,
- the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,
- the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.,
- the means to monitor the achievement of the required product quality and the effective operation of the quality system.

- 3.3. The notified body must assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It presumes conformity with these requirements in respect of quality systems that implement the relevant harmonized standard (*).

The auditing team must have at least one member with experience of evaluation in the product technology concerned. The evaluation procedure must include an inspection visit to the manufacturer's premises.

The decision must be notified to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

- 3.4. The manufacturer must undertake to fulfil the obligations arising out of the quality system as approved and to uphold it so that it remains adequate and efficient.

The manufacturer or his authorized representative shall keep the notified body that has approved the quality system informed of any intended updating of the quality system.

The notified body must evaluate the modifications proposed and decide whether the amended quality system will still satisfy the requirements referred to in paragraph 3.2 or whether a re-assessment is required.

It must notify its decision to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

4. *Surveillance under the responsibility of the notified body*

- 4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

- 4.2. The manufacturer must allow the notified body entrance for inspection purposes to the locations of manufacture, inspection and testing, and storage and must provide it with all necessary information, in particular:

- the quality system documentation,
- the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

(*) This harmonized standard will be EN 29 002, supplemented, if necessary, to take into account the specific nature of the products for which it is implemented.

- 4.3. The notified body must periodically (*) carry out audits to make sure that the manufacturer maintains and applies the quality system and must provide an audit report to the manufacturer.
- 4.4. Additionally the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may carry out, or cause to be carried out, tests to verify that the quality system is functioning correctly, if necessary. The notified body must provide the manufacturer with a visit report and, if a test has taken place, with a test report.
5. The manufacturer must, for a period ending at least 10 years (**) after the last product has been manufactured, keep at the disposal of the national authorities:
 - the documentation referred to in the second indent of point 3.1,
 - the updating referred to in the second paragraph of point 3.4,
 - the decisions and reports from the notified body which are referred to in the final paragraph of point 3.4, points 4.3 and 4.4.
6. Each notified body must give the other notified bodies the relevant information concerning the quality system approvals issued and withdrawn (***).

Module E (****) (product quality assurance)

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of point 2 ensures and declares that the products concerned [are in conformity with the type as described in the EC type-examination certificate and] satisfy the requirements of the directive that apply to them. The manufacturer or his authorized representative established within the Community must affix the CE mark to each product and draw up a written declaration of conformity. The CE mark must be accompanied by the identification symbol of the notified body responsible for surveillance as specified in point 4.
2. The manufacturer must operate an approved quality system for final product inspection and testing as specified in paragraph 3 and must be subject to surveillance as specified in point 4.
3. *Quality system*

- 3.1. The manufacturer must lodge an application for assessment of his quality system for the products concerned, with a notified body of his choice.

The application must include:

- all relevant information for the product category envisaged,
- the quality system's documentation,
- if applicable, the technical documentation of the approved type and a copy of the EC type-examination certificate.

- 3.2. Under the quality system, each product must be 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 ensure its conformity with the relevant requirements of the directive. All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation must ensure a common understanding of the quality programmes, plans, manuals and records.

It must contain in particular and adequate description of:

- the quality objectives and the organizational structure, responsibilities and powers of the management with regard to product quality,
- the examinations and tests that will be carried out after manufacture,
- the means to monitor the effective operation of the quality system,
- quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

(*) In the specific directives, the frequency may be specified.

(**) The specific directives may alter this period.

(***) The specific directives may provide for different arrangements.

(****) When this module is used without module B:

- points 2 and 3 of module A must be added between points 1 and 2 in order to incorporate the need for technical documentation,
- the words in square brackets must be deleted.

- 3.3. The notified body must assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It presumes conformity with these requirements in respect of quality systems that implement the relevant harmonized standard (*).

The auditing team must have at least one member experienced as an assessor in the product technology concerned. The assessment procedure must include an assessment visit to the manufacturer's premises.

The decision must be notified to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

- 3.4. The manufacturer must undertake to discharge the obligations arising from the quality system as approved and to maintain it in an appropriate and efficient manner.

The manufacturer or his authorized representative must keep the notified body which has approved the quality system informed of any intended updating of the quality system.

The notified body must evaluate the modifications proposed and decide whether the modified quality system will still satisfy the requirements referred to in paragraph 3.2 or whether a re-assessment is required.

It must notify its decision to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

4. *Surveillance under the responsibility of the notified body*

- 4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

- 4.2. The manufacturer must allow the notified body entrance for inspection purposes to the locations of inspection, testing and storage and shall provide it with all necessary information, in particular:

- the quality system documentation,
- the technical documentation,
- the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

- 4.3. The notified body must periodically (**) carry out audits to ensure that the manufacturer maintains and applies the quality system and must provide an audit report to the manufacturer.

- 4.4. Additionally, the notified body may pay unexpected visits to the manufacturer. At the time of such visits, the notified body may carry out tests or have them carried out in order to check the proper functioning of the quality system where necessary; it must provide the manufacturer with a visit report and, if a test has been carried out, with a test report.

5. The manufacturer must, for a period ending at least 10 years (***) after the last product has been manufactured, keep at the disposal of the national authorities:

- the documentation referred to in the third indent of point 3.1,
- the updating referred to in the second paragraph of point 3.4,
- the decisions and reports from the notified body which are referred to in the final paragraph of point 3.4, points 4.3 and 4.4.

6. Each notified body must forward to the other notified bodies the relevant information concerning the quality system approvals issued and withdrawn (****).

Module F (****) (product verification)

1. This module describes the procedure whereby a manufacturer or his authorized representative established within the Community checks and attests that the products subject to the provisions of point 3 [are in conformity with the type as described in the EC-type examination certificate and] satisfy the requirements of the directive that apply to them.

(*) This harmonized standard will be EN 29 003, supplemented if necessary to allow for the specific features of the products for which it is implemented.

(**) The intervals between audits may be specified in the specific directives.

(***) The specific directives may alter this period.

(****) The specific directives may provide for different arrangements.

(*****) Where this module is used without module B:

- it must be supplemented by points 2 and 3 of module A (between points 1 and 2), so as to introduce the need for technical documentation,
- the next in square brackets must be deleted.

2. The manufacturer must take all measures necessary in order that the manufacturing process ensures conformity of the products [with the type as described in the EC type-examination certificate and] with the requirements of the directive that apply to them. He shall affix the CE marking to each product and shall draw up a declaration of conformity.
3. The notified body must carry out the appropriate examinations and tests in order to check the conformity of the product with the requirements of the directive either by examination and testing of every product as specified in point 4 or by examination and testing of products on a statistical basis, as specified in point 5, at the choice of the manufacturer (*).
- 3a. The manufacturer or his authorized representative must keep a copy of the declaration of conformity for a period ending at least 10 years (**) after the last product has been manufactured.
4. *Verification by examination and testing of every product*
 - 4.1. All products must 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 with [the type as described in the EC-type examination certificate and] the requirements of the directive that apply to them.
 - 4.2. The notified body must affix or cause to be affixed, its identification symbol to each approved product and draw up a written certificate of conformity relating to the tests carried out.
 - 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. *Statistical verification*
 - 5.1. The manufacturer must present his products in the form of homogeneous lots and shall take all measures necessary in order that the manufacturing process ensures the homogeneity of each lot produced.
 - 5.2. All products must be available for verification in the form of homogeneous lots. A random sample shall be drawn from each lot. Products in a sample 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 to ensure their conformity with the requirements of the directive which apply to them and to determine whether the lot is accepted or rejected.
 - 5.3. The statistical procedure must use the following elements:

(Relevant elements must be specified here such as, for example, the statistical method to be applied, the sampling plan with its operational characteristics, etc.)
 - 5.4. In the case of accepted lots, the notified body must affix, or cause to be affixed, its identification symbol to each product and shall draw up a written certificate of conformity relating to the tests carried out. All products in the lot may be put on the market except those products from the sample which were found not to be in conformity.

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

The manufacturer may, under the responsibility of the notified body, affix the latter's identification symbol during the manufacturing process.
 - 5.5. The manufacturer or his authorized representative must ensure that he is able to supply the notified body's certificates of conformity on request.

Module G (unit verification)

1. This module describes the procedure whereby the manufacturer ensures and declares that the product concerned, which has been issued with the certificate referred to in point 2, conforms to the requirements of the directive that apply to it. The manufacturer or his authorized representative established within the Community must affix the CE marking to the product and draw up a declaration of conformity.
2. The notified body must examine the individual product and carry out the appropriate tests as set out in the relevant standard(s) referred to in Article 5, or equivalent tests, to ensure its conformity with the relevant requirements of the directive.

(*) The manufacturer's discretion may be limited in the specific directives.

(**) The specific directives may alter this period.

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

3. The aim of the technical documentation is to enable conformity with the requirements of the directive to be assessed and the design, manufacture and operation of the product to be understood (*).

Module H (full quality assurance)

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of paragraph 2 ensures and declares that the products concerned satisfy the requirements of the directive that apply to them. 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. The CE marking must be accompanied by the identification symbol of the notified body responsible for the surveillance as specified in point 4.
2. The manufacturer must operate an approved quality system for design, manufacture and final product inspection and testing as specified in point 3 and shall be subject to surveillance as specified in point 4.

3. *Quality system*

- 3.1. The manufacturer must lodge an application for assessment of his quality system with a notified body.

The application must include:

- all relevant information for the product category envisaged,
- the quality system's documentation.

- 3.2. The quality system must ensure compliance of the products with the requirements of the directive that apply to them.

All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation shall ensure a common understanding of the quality policies and procedures such as quality programmes, plans, manuals and records.

It must contain in particular an adequate description of:

- the quality objectives and the organizational structure, responsibilities and powers of the management with regard to design and product quality,
- the technical design specifications, including standards, that will be applied and, where the standards referred to in Article 5 will not be applied in full, the means that will be used to ensure that the essential requirements of the directive that apply to the products will be met,
- the design control and design verification techniques, processes and systematic actions that will be used when designing the products pertaining to the product category covered,
- the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used,
- the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,
- the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.,
- the means to monitor the achievement of the required design and product quality and the effective operation of the quality system.

(*) The content of the technical documentation shall be laid down directive by directive in accordance with the products concerned. As an example, the documentation shall contain so far as relevant for assessment:

- a general description of the product,
- 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 product,
- a list of the standards referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the directive where the standards referred to in Article 5 have not been applied,
- results of design calculations made, examinations carried out, etc.,
- test reports.

- 3.3. The notified body must assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It shall presume compliance with these requirements in respect of quality systems that implement the relevant harmonized standard (*).

The auditing team must have at least one member experienced as an assessor in the product technology concerned. The evaluation procedure shall include an assessment visit to the manufacturer's premises.

The decision must be notified to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

- 3.4. The manufacturer must undertake to fulfil the obligations arising out of the quality system as approved and to uphold it so that it remains adequate and efficient.

The manufacturer or his authorized representative must keep the notified body that has approved the quality system informed of any intended updating of the quality system.

The notified body must evaluate the modifications proposed and decide whether the amended quality system will still satisfy the requirements referred to in paragraph 3.2 or whether a re-assessment is required.

It must notify its decision to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

4. *EC surveillance under the responsibility of the notified body*

- 4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

- 4.2. The manufacturer must allow the notified body entrance for inspection purposes to the locations of design, manufacture, inspection and testing, and storage, and shall provide it with all necessary information, in particular:

- the quality system documentation,
- the quality records as foreseen by the design part of the quality system, such as results of analyses, calculations, tests, etc.,
- the quality records as foreseen by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

- 4.3. The notified body must periodically (**) carry out audits to make sure that the manufacturer maintains and applies the quality system and shall provide an audit report to the manufacturer.

- 4.4. Additionally the notified body may pay unexpected visits to the manufacturer. At the time of such visits, the notified body may carry out tests or have them carried out in order to check the proper functioning of the quality system where necessary; it must provide the manufacturer with a visit report and, if a test has been carried out, with a test report.

5. The manufacturer must, for a period ending at least 10 years (***) after the last product has been manufactured, keep at the disposal of the national authorities:

- the documentation referred to in the second indent of the second subparagraph of point 3.1,
- the updating referred to in the second subparagraph of point 3.4,
- the decisions and reports from the notified body which are referred to in the final subparagraph of point 3.4, points 4.3 and 4.4.

6. Each notified body must forward to the other notified bodies the relevant information concerning the quality system approvals issued and withdrawn (****).

(*) This harmonized standard shall be EN 29 001, completed if necessary to take into consideration the specificity of the products for which it is implemented.

(**) In the specific directives, the frequency may be specified.

(***) The specific directives may alter this period.

(****) The specific directives may provide for different arrangements.

Possible supplementary requirements:

Design examination

1. The manufacturer must lodge an application for examination of the design with a single notified body.
2. The application must enable the design, manufacture and operation of the product to be understood, and shall enable conformity with the requirements of the directive to be assessed.

It must include:

- the technical design specifications, including standards, that have been applied,
 - the necessary supporting evidence for their adequacy, in particular where the standards referred to in Article 5 have not been applied in full. This supporting evidence must include the results of tests carried out by the appropriate laboratory of the manufacturer or on his behalf.
3. The notified body must examine the application and where the design meets the provisions of the directive that apply to it must issue an EC design examination certificate to the applicant. The certificate shall contain the conclusions of the examination, conditions for its validity, the necessary data for identification of the approved design and, if relevant, a description of the product's functioning.
 4. The applicant must keep the notified body that has issued the EC design examination certificate informed of any modification to the approved design. Modifications to the approved design must receive additional approval from the notified body that issued the EC design examination certificate where such changes may affect the conformity with the essential requirements of the directive or the prescribed conditions for use of the product. This additional approval is given in the form of an addition to the original EC design examination certificate.
 5. The notified bodies must forward to the other notified bodies the relevant information concerning:
 - the EC design examination certificates and additions issued,
 - the EC design approvals and additional approvals withdrawn (*).

(*) The specific directives may provide for different arrangements.

CONFORMITY ASSESSMENT PROCEDURES IN COMMUNITY LEGISLATION

A. (Internal control of production)	B. (type examination)	G. (unit verification)	H. (full quality assurance)
Manufacturer Keeps technical documentation at the disposal of national authorities Aa Intervention of notified body	Manufacturer submits to notified body — Technical documentation — Type Notified body — Ascertains conformity with essential requirements — Carries out tests, if necessary — Issues EC type-examination certificate	Manufacturer — Submits technical documentation	EN 29001 Manufacturer — Operates an approved quality system (QS) for design Notified body — Carries out surveillance of the QS — Verifies conformity of the design ⁽¹⁾ — Issues EC design examination certificate ⁽¹⁾
A. Manufacturer — Declares conformity with essential requirements — Affixes the CE marking	C. (conformity to type) Manufacturer — Declares conformity with approved type — Affixes the CE marking	D. (production quality assurance) EN 29002 Manufacturer — Operates an approved quality system (QS) for production and testing — Declares conformity with approved type — Affixes the CE marking	E. (product quality assurance) EN 29003 Manufacturer — Operates an approved quality system (QS) for inspection and testing — Declares conformity with approved type, or to essential requirements — Affixes the CE marking
Aa Notified body — Tests on specific aspects of the product ⁽¹⁾ — Product checks at random intervals ⁽¹⁾	F. (product verification) Manufacturer — Declares conformity with approved type, or with essential requirements — Affixes the CE marking	Manufacturer — Submits product — Declares conformity — Affixes the CE marking	Manufacturer — Operates an approved QS for production and testing — Declares conformity — Affixes the CE marking
Notified body — Tests on specific aspects of the product ⁽¹⁾ — Product checks at random intervals ⁽¹⁾	Notified body — Verifies conformity — Issues certificate at conformity	Notified body — Verifies conformity with essential requirements — Issues certificate of conformity	Notified body — Carries out surveillance of the QS

⁽¹⁾ Supplementary requirements which may be used in specific Directives.