

Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC (Text with EEA relevance) (repealed)

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## ANNEX I

### ESSENTIAL REQUIREMENTS REFERRED TO IN ARTICLE 5

#### 1. Protection requirements

Equipment shall be so designed and manufactured, having regard to the state of the art, as to ensure that:

- (a) the electromagnetic disturbance generated does not exceed the level above which radio and telecommunications equipment or other equipment cannot operate as intended;
- (b) it has a level of immunity to the electromagnetic disturbance to be expected in its intended use which allows it to operate without unacceptable degradation of its intended use.

#### 2. Specific requirements for fixed installations

Installation and intended use of components

A fixed installation shall be installed applying good engineering practices and respecting the information on the intended use of its components, with a view to meeting the protection requirements set out in Point 1. Those good engineering practices shall be documented and the documentation shall be held by the person(s) responsible at the disposal of the relevant national authorities for inspection purposes for as long as the fixed installation is in operation.

## ANNEX II

### CONFORMITY ASSESSMENT PROCEDURE REFERRED TO IN ARTICLE 7 (internal production control)

1. The manufacturer shall perform an electromagnetic compatibility assessment of the apparatus, on the basis of the relevant phenomena, with a view to meeting the protection requirements set out in Annex I, point 1. The correct application of all the relevant harmonised standards whose references have been published in the *Official Journal of the European Union* shall be equivalent to the carrying out of the electromagnetic compatibility assessment.
2. The electromagnetic compatibility assessment shall take into account all normal intended operating conditions. Where the apparatus is capable of taking different configurations, the electromagnetic compatibility assessment shall confirm whether the apparatus meets the protection requirements set out in Annex I, point 1, in all the possible configurations identified by the manufacturer as representative of its intended use.
3. In accordance with the provisions set out in Annex IV, the manufacturer shall draw up technical documentation providing evidence of the conformity of the apparatus with the essential requirements of this Directive.
4. The manufacturer or his authorised representative in the Community shall hold the technical documentation at the disposal of the competent authorities for at least ten years after the date on which such apparatus was last manufactured.

5. The compliance of apparatus with all relevant essential requirements shall be attested by an EC declaration of conformity issued by the manufacturer or his authorised representative in the Community.
6. The manufacturer or his authorised representative in the Community shall hold the EC declaration of conformity at the disposal of the competent authorities for a period of at least ten years after the date on which such apparatus was last manufactured.
7. If neither the manufacturer nor his authorised representative is established within the Community, the obligation to hold the EC declaration of conformity and the technical documentation at the disposal of the competent authorities shall lie with the person who places the apparatus on the Community market.
8. The manufacturer must take all measures necessary to ensure that the products are manufactured in accordance with the technical documentation referred to in point 3 and with the provisions of this Directive that apply to them.
9. The technical documentation and the EC declaration of conformity shall be drawn up in accordance with the provisions set out in Annex IV.

### ANNEX III

#### CONFORMITY ASSESSMENT PROCEDURE REFERRED TO IN ARTICLE 7

1. This procedure consists of applying Annex II, completed as follows:
2. The manufacturer or his authorised representative in the Community shall present the technical documentation to the notified body referred to in Article 12 and request the notified body for an assessment thereof. The manufacturer or his authorised representative in the Community shall specify to the notified body which aspects of the essential requirements must be assessed by the notified body.
3. The notified body shall review the technical documentation and assess whether the technical documentation properly demonstrates that the requirements of the Directive that it is to assess have been met. If the compliance of the apparatus is confirmed, the notified body shall issue a statement to the manufacturer or his authorised representative in the Community confirming the compliance of the apparatus. That statement shall be limited to those aspects of the essential requirements which have been assessed by the notified body.
4. The manufacturer shall add the statement of the notified body to the technical documentation.

### ANNEX IV

#### TECHNICAL DOCUMENTATION AND EC DECLARATION OF CONFORMITY

1. Technical documentation

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The technical documentation must enable the conformity of the apparatus with the essential requirements to be assessed. It must cover the design and manufacture of the apparatus, in particular:

- a general description of the apparatus;
- evidence of compliance with the harmonised standards, if any, applied in full or in part;
- where the manufacturer has not applied harmonised standards, or has applied them only in part, a description and explanation of the steps taken to meet the essential requirements of the Directive, including a description of the electromagnetic compatibility assessment set out in Annex II, point 1, results of design calculations made, examinations carried out, test reports, etc.;
- a statement from the notified body, when the procedure referred to in Annex III has been followed.

## 2. EC declaration of conformity

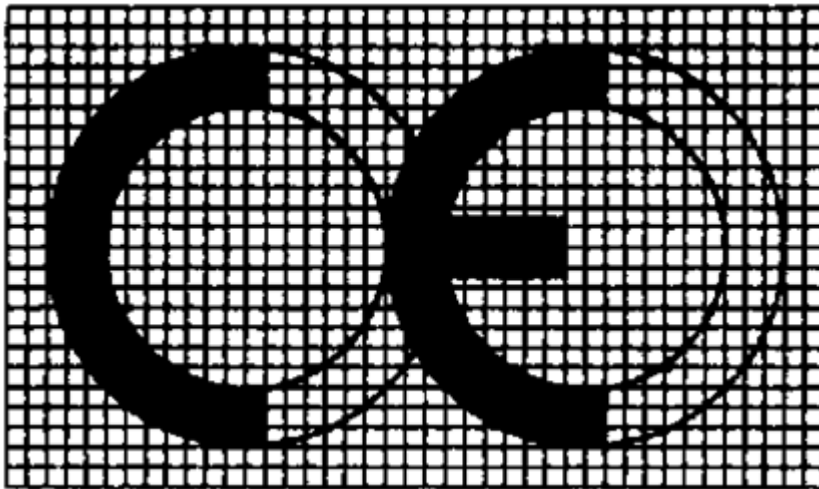
The EC declaration of conformity must contain, at least, the following:

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

## ANNEX V

### ‘CE’ MARKING REFERRED TO IN ARTICLE 8

The ‘CE’ marking shall consist in the initials ‘CE’ taking the following form:



The ‘CE’ marking must have a height of at least 5 mm. If the ‘CE’ marking is reduced or enlarged the proportions given in the above graduated drawing must be respected.

The ‘CE’ marking must be affixed to the apparatus or to its data plate. Where this is not possible or not warranted on account of the nature of the apparatus, it must be affixed to the packaging, if any, and to the accompanying documents.

Where the apparatus is the subject of other Directives covering other aspects and which also provide for the ‘CE’ marking, the latter shall indicate that the apparatus also conforms with those other Directives.

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 with the Directives applied by the manufacturer. In that case, particulars of the Directives applied, as published in the *Official Journal of the European Union*, must be given in the documents, notices or instructions required by the Directives and accompanying such apparatus.

## ANNEX VI

### CRITERIA FOR THE ASSESSMENT OF THE BODIES TO BE NOTIFIED

1. The bodies notified by the Member States shall fulfil the following minimum conditions:
  - (a) availability of personnel and of the necessary means and equipment;
  - (b) technical competence and professional integrity of personnel;
  - (c) independence in preparing the reports and performing the verification function provided for in this Directive;
  - (d) independence of staff and technical personnel in relation to all interested parties, groups or persons directly or indirectly concerned with the equipment in question;
  - (e) maintenance of professional secrecy by personnel;
  - (f) possession of civil liability insurance unless such liability is covered by the Member State under national law.
2. Fulfilment of the conditions laid down in point 1 shall be verified at intervals by the competent authorities of the Member State.

## ANNEX VII

### CORRELATION TABLE

<b>Directive 89/336/EEC</b>	<b>This Directive</b>
Article 1, point 1	Article 2(1)(a), (b) and (c)
Article 1, point 2	Article 2(1)(e)
Article 1, point 3	Article 2(1)(f)
Article 1, point 4	Article 2(1)(d)
Article 1, points 5 and 6	

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Article 2(1)	Article 1(1)
Article 2(2)	Article 1(4)
Article 2(3)	Article 1(2)
Article 3	Article 3
Article 4	Article 5 and Annex I
Article 5	Article 4(1)
Article 6	Article 4(2)
Article 7(1)(a)	Article 6(1) and (2)
Article 7(1)(b)	
Article 7(2).	
Article 7(3)	
Article 8(1)	Article 6(3) and (4)
Article 8(2)	
Article 9(1)	Article 10(1) and (2)
Article 9(2)	Article 10(3) and (4)
Article 9(3)	Article 10(5)
Article 9(4)	Article 10(3)
Article 10(1), first sub-paragraph	Article 7, Annexes II and III
Article 10(1), second sub-paragraph	Article 8
Article 10(2)	Article 7, Annexes II and III
Article 10(3)	
Article 10(4)	
Article 10(5)	Article 7, Annexes II and III
Article 10(6)	Article 12
Article 11	Article 14
Article 12	Article 16
Article 13	Article 18
Annex I, point 1	Annex IV, point 2
Annex I, point 2	Annex V
Annex II	Annex VI
Annex III, last paragraph	Article 9(5)